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OFFICE OF THE LIEUTENANT GOVERNOR
ALASKA

MEMORANDUM

TO: Victoria Caltagirone
Department of Commerce, Community and Economic Development

FROM: Kady Levale on behalf of April Simpson, Office of the Lieutenant Governor
465.4081

DATE: June 22, 2023

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy Regulations re: Licensure, registration, management and definitions (12 AAC 52.010 - .995)

Attorney General File:	2023200061
Regulation Filed:	6/15/2023
Effective Date:	7/15/2023 ← corrected date KV
Print:	247, October 2023

cc with enclosures: Colleen Bailey, Department of Law
Judy Herndon, LexisNexis
Alison Osborne, Regulations Specialist
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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June 7, 2023

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

Re: *12 AAC 52.010 - .995: Board of Pharmacy - Licensure, registration, management, definitions*

Our file: 2023200061

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 concern changes in pharmacist, pharmacist-in-charge, and pharmacist intern licensure requirements, pharmacy facilities, return or exchange of drugs, automated distribution kiosks, drug recalls, and the prescription drug monitoring program.

The regulations were adopted by the Board of Pharmacy after the close of the public comment period. The March 23, 2023 public notice and the May 24, 2023 order certifying changes 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 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. Following the completion of edits, the regulations are now 23 pages, not the 26 pages referenced in the order certifying changes.

Sincerely,

TREG TAYLOR
ATTORNEY GENERAL

By: Rebecca C. Polizzotto
Digitally signed by Rebecca C. Polizzotto
Date: 2023.06.07 11:23:42 -08'00'

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

RCP/bhp

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-six~~ twenty-three pages of regulations, dealing with classifications of licensure, registration, application, license and registration renewal, notification process for changes in name, ownership or physical address of pharmacies, pharmacist-in-charge, pharmacist interns, job shadowing, security, remote pharmacy, return or exchange of drugs, automated distribution kiosks, remodeling, designated representative, drug recalls, facilities, prescription drug monitoring program, and definitions, are certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its May 24, 2023 meeting, under the authority of 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 08.80.150, AS 08.80.155, AS 08.80.157, AS 08.80.158, AS 08.80.159, AS 08.80.160, AS 08.80.165, AS 08.80.261, AS 08.80.270, AS 08.80.315, AS 08.80.330, AS 08.80.390, AS 08.80.410, 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 July 1, 2023 after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: May 24, 2023

mph

Michael Bowles, Executive Administrator
Alaska Board of Pharmacy

April Simpson for

FILING CERTIFICATION

I, Nancy Dahlstrom, Lieutenant Governor for the State of Alaska, certify that on June 15th, 2023 at 10:57 a.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

David Sinn

Nancy Dahlstrom, Lieutenant Governor

July 15, 2023 for

Effective: ~~July 1, 2023~~.

Register: 247, October 2023

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

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:

Kady Levale, Notary Administrator

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

Chapter 52. Board of Pharmacy.

12 AAC 52.010(b) is amended by adding a new paragraph to read:

(10) manufacturer license. (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)

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158
AS 08.80.030 AS 08.80.155 AS 08.80.159
AS 08.80.116 AS 08.80.157 AS 08.80.390

(((Publisher, please move the "and" connector to the appropriate penultimate paragraph)))

12 AAC 52.020 is amended to read:

12 AAC 52.020. Pharmacy license. (a) An applicant for a pharmacy license shall submit the items required in (b) of 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.

(b) an applicant for a pharmacy 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) an attestation that **not later than** [WITHIN] 14 days after **the start** [COMMENCEMENT] of business, a self-inspection **will be completed** on a form provided by the department**; the** [WILL BE COMPLETED. THE] self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed; and

(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required under AS 08.80.390, if applicable.

(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required under AS 08.80.330 and 12 AAC 52.200.

(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.

(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is its central pharmacy.

(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** [APPLY FOR A NEW AND SEPARATE LICENSE IN ACCORDANCE WITH THIS SECTION].

(g) A pharmacy located outside of the state is not required to submit an annual information update as required under AS 08.80.158(b) to the board if the registration has been issued for not more than three months and if the information has not changed since the registration was initially issued. (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)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030 AS 08.80.270

12 AAC 52.120 is amended to read:

12 AAC 52.120. Review of pharmacist intern license application. (a) An applicant shall submit the **items required** [REQUIREMENTS IN] (b) of 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.

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

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

(2) pays the applicable fees established in 12 AAC 02.310;

(3) is

(A) presently enrolled in a college of pharmacy accredited by the ACPE and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; [OR]

(B) a graduate of an accredited professional degree program from a school or college of pharmacy within one year preceding the date of application; or

(C) a graduate of a college of pharmacy recognized by the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy; and

(4) certifies that the applicant has not been convicted of a felony or **other** [ANOTHER] crime that affects the applicant's ability to practice as a pharmacy intern competently and safely.

(c) A pharmacist intern license is valid for five years.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state.

(e) A pharmacist intern license supersedes a pharmacy technician license [AND THE PHARMACY TECHNICIAN LICENSE SHALL BE RETURNED TO THE BOARD].

(f) A pharmacist intern license may not be renewed. An applicant **who wishes** [WISHING] to continue an internship in this state after the license has expired must reapply for a new **pharmacist intern** license in accordance with this section.

(g) A pharmacy technician who obtains a pharmacist intern license under this section may submit a request to the board in writing to voluntarily expire the pharmacy technician license. A voluntary expiration of pharmacy technician licensure is considered a non-disciplinary relinquishment of the ability to practice under that license. (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)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.200(b) is amended to read:

(b) A pharmacist designated to replace the pharmacist-in-charge of a licensed or registered pharmacy shall notify the board **in writing** not later than **30** [10] days after that designation [, BY SUBMITTING A COMPLETED CHANGE OF PHARMACIST-IN CHARGE FORM PROVIDED BY THE DEPARTMENT]. **Notwithstanding 12 AAC**

52.425(a), a pharmacist may not serve as a pharmacist-in-charge unless the pharmacist is physically present in the pharmacy for a sufficient amount of time to provide supervision and control. 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.

12 AAC 52.200(c) is repealed:

(c) Repealed 7 / 15 / 2023. (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)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030 AS 08.80.160

12 AAC 52.220(d) is repealed:

(d) Repealed 7 / 15 / 2023.

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 7 / 15 / 2023, Register 247)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410
AS 08.80.030 AS 08.80.116

12 AAC 52.250 is repealed:

12 AAC 52.250. Job shadowing in pharmacy. Repealed. (Eff. 1/29/2011, Register 197; repealed 7 / 15 / 2023, Register 247)

(((Publisher, please also delete the Editor's Note that follows 12 AAC 52.250)))

12 AAC 52.300(a) is amended to read:

12 AAC 52.300. License and registration renewal. (a) Pharmacy, remote pharmacy, wholesale drug distributor, outsourcing facility, third-party logistics provider, **manufacturer,** pharmacist, pharmacy technician, and drug room licenses must be renewed biennially on or before a date set by the department.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, outsourcing facility, third-party logistics provider, **manufacturer,** or drug room license must submit on or before the license expiration date

(1) a completed renewal application on a form provided by the department;

(2) the license renewal fees required in 12 AAC 02.310; and

(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** [MUST BE RETAINED BY THE APPLICANT AND BE MADE] available to the board upon request for the duration of the licensing period in which it was completed.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application on a form provided by the department;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements

of 12 AAC 52.320 - 12 AAC 52.350 [;

(4) REPEALED 4/3/2020].

(d) Repealed 7 / 15 / 2023.

(e) Repealed 7 / 15 / 2023.

(f) Repealed 7 / 15 / 2023.

(g) All renewal applications will be administratively processed and will not require board review unless the executive administrator has reason to believe that renewing the license poses an immediate threat to public health or safety. (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)

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 52.420 is amended to read:

12 AAC 52.420. Security. (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department security requirements.

(c) **Excluding prescription drugs or devices held within an automated distribution kiosk, all** [ALL] drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) **Excluding prescription drugs or devices held within an automated distribution**

kiosk, the [THE] prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) **Excluding prescription drugs or devices held within an automated distribution kiosk, prescriptions** [PRESCRIPTIONS] shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

(g) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored. (Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

12 AAC 52.423 is amended to read:

12 AAC 52.423. Remote pharmacy license. (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 license. The central pharmacy

applying under this section **for a remote pharmacy license** must [SUBMIT TO THE DEPARTMENT]

(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 in 12 AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

[(1)] it is able to comply with the requirements of 12 AAC 52.425 [; AND

(2) THERE IS NO ACCESS TO A NON-REMOTE PHARMACY WITHIN TEN ROAD MILES OF THE PROPOSED REMOTE PHARMACY SITE UNLESS THE NON-REMOTE PHARMACY IS PREVENTED BY FEDERAL LAW FROM PROVIDING PHARMACY SERVICES TO ALL THE INDIVIDUALS WITHIN THE TEN ROAD MILES].

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

(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. (Eff. 9/17/2011, Register 199; am 10/31/2019, Register 232; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.530(b)(2) is amended to read:

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the **current** standards of the United States Pharmacopoeia **(USP)** [(1995 REVISION)] for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(Eff. 1/16/98, Register 145; am 10/31/2019, Register 232; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.030

[EDITOR'S NOTE: A COPY OF THE UNITED STATES PHARMACOPOEIA MAY BE OBTAINED FROM THE UNITED STATES PHARMACOPOEIAL CONVENTION, INC., P.O. BOX 560, WILLISTON, VT 05495.]

12 AAC 52 is amended by adding new sections to Article 5 to read:

12 AAC 52.595. Automated distribution kiosks. (a) A licensed pharmacy in this state may install and use an automated distribution kiosk that is accessible to the patient or the patient's agent while the pharmacy is open or closed for the purpose of purchasing the patient's completed prescription drug orders if

(1) the kiosk is securely installed on the same premises as the pharmacy and is properly secured to prevent removal without the use of heavy or specialized equipment;

(2) before loading the completed prescription drug order into the kiosk, the pharmacist counsels the patient in accordance with 12 AAC 52.585; and

(3) no drugs defined by state or federal law as controlled substances are placed in the kiosk, and the kiosk has a conspicuously posted sign that states "This machine does not contain controlled substances."; the sign must use a minimum of size 72 font and red color.

(b) The pharmacist on duty is responsible for loading and maintaining the automated distribution kiosk. The pharmacist on duty may delegate those tasks to a pharmacy intern or pharmacy technician.

(c) This section does not apply to a prescription drug dispensing or distribution machine used in an institutional facility. (Eff. 7 / 15 / 2023, Register 247)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.596. Remodeling. Not later than 30 days after starting the structural remodeling of a pharmacy or a prescription department within the premises of a licensed or registered pharmacy that would result in a change in layout, square footage, plumbing, or additional storage areas, the licensee or registrant shall notify the board in writing. (Eff. 7 / 10 / 2023, Register 247)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.610 is amended to read:

12 AAC 52.610. Wholesale drug distributor license. (a) An applicant for a wholesale drug distributor license shall submit the **items required** [REQUIREMENTS] in (b) of 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.

(b) A wholesale drug distributor license will be issued to an applicant who

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

(2) pays the applicable fees required in 12 AAC 02.310;

(3) provides the name of the **designated representative** [FACILITY MANAGER] who will manage the wholesale distribution 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) a Verification Accredited Wholesale Distributors (VAWD) inspection has been completed; and

(5) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, **as applicable** [IF THE APPLICANT IS A WHOLESALE DRUG DISTRIBUTOR LOCATED OUTSIDE OF THIS STATE].

(c) **A wholesale drug distributor that has changed its name,** [WITHIN 30 DAYS AFTER A CHANGE IN] physical address, **or** ownership [, OR NAME, THE WHOLESALE DRUG DISTRIBUTOR] 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** [APPLY FOR A NEW AND SEPARATE WHOLESALE DRUG DISTRIBUTOR LICENSE IN ACCORDANCE WITH THIS SECTION].

(d) When a wholesale drug distributor ceases operations, the **designated representative**

[FACILITY MANAGER] of the wholesale drug distributor shall notify the board **in writing** [ON A FORM PROVIDED BY THE DEPARTMENT] of the cessation of operations. The **written notice** [FORM] must be submitted **not later than 30** [10] days after the cessation of operations. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am 12/28/2022, Register 244; am 7/15/EV/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.625(b) is amended to read:

(b) The board will not approve an application for a wholesale drug distributor license unless the designated **representative** [FACILITY MANAGER] in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs. (Eff. 1/16/98, Register 145; am 10/31/2019, Register 232; am 7/15/EV/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159 AS 08.80.480

12 AAC 52.635 is amended to read:

12 AAC 52.635. Designated representative [FACILITY MANAGER]. (a) A **designated representative** [FACILITY MANAGER] of a wholesale drug distributor, outsourcing facility, [OR] third-party logistics provider**, or manufacturer** designated to replace

an outgoing designated representative [THE FACILITY MANAGER] of a facility shall notify the board not later than **30** [10] days after that designation, by submitting a completed change of **designated representative** [FACILITY MANAGER] notice **in writing** [ON A FORM PROVIDED BY THE DEPARTMENT]. The outgoing **designated representative** [FACILITY MANAGER] shall also notify the board **in writing** not later than **30** [10] days after departure [ON A FORM PROVIDED BY THE DEPARTMENT].

(b) A **designated representative** [FACILITY MANAGER] may be in charge of more than one location and may be designated as the **designated representative** [FACILITY MANAGER] for multiple facilities simultaneously. (Eff. 12/28/2022, Register 244; am 7 / 16/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.640 is amended to read:

12 AAC 52.640. Written policies and procedures. A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drug facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the

wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph, and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs; **and**

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary [; AND

(7) ENSURE THE PROPER HANDLING OF A DRUG RECALL AND A REPLACEMENT OF A DRUG IN ACCORDANCE WITH 12 AAC 52.670]. (Eff. 1/16/98, Register 145; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.670 is repealed:

12 AAC 52.670. Drug recalls. Repealed. (Eff. 1/16/98, Register 145; repealed 7/15/2023, Register 247)

12 AAC 52.696 is amended to read:

12 AAC 52.696. Outsourcing facilities. (a) An applicant for an outsourcing facility license shall submit the **items required** [REQUIREMENTS] in (b) of 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.

(b) An outsourcing facility 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 required in 12 AAC 02.310;

(3) provides the name of the designated **representative** [FACILITY MANAGER];

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

(5) submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years; and

(6) [(5)] submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) **An outsourcing facility that has changed its name,** [WITHIN 30 DAYS AFTER A CHANGE IN] physical address, **or** ownership [, OR NAME, THE OUTSOURCING FACILITY] must **notify the board in writing not later than 30 days after the change. The notification must include an attestation that a new self-inspection will be completed not later than 30 days after the start of business** [APPLY FOR A NEW AND SEPARATE OUTSOURCING FACILITY LICENSE IN ACCORDANCE WITH THIS SECTION].

(d) When an outsourcing facility ceases operations, the **designated representative** [FACILITY MANAGER] must submit to the board a written notice of the cessation of operations. The written notice must be submitted **not later than 30** [10] days after the cessation of operations and include

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(e) The outsourcing facility must be registered as an outsourcing facility and compliant with 21 U.S.C. 353b (sec. 503B, P.L. 113-54 (Food Drug and Cosmetic Act, Drug Quality and Security Act, Compounding Quality Act)). (Eff. 10/31/2019, Register 232; am 12/28/2022, Register 244; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52.697 is amended to read:

12 AAC 52.697. Third-party logistics providers. (a) An applicant for a third-party logistics provider license shall submit the **items required** [REQUIREMENTS] in (b) of 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.

(b) A third-party logistics provider license will be issued to an applicant who

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

(2) pays the fees required in 12 AAC 02.310;

(3) provides the name of the designated **representative** [FACILITY MANAGER]; [AND]

(4) **submits an attestation that the applicant holds a license as a third-party logistics provider in another jurisdiction and that the license is in good standing, if**

applicable; and

(5) submits an attestation that a self-inspection of the premises using the form provided by the department was completed within the last two years.

(c) **A third-party logistics provider that has changed its name,** [WITHIN 30 DAYS AFTER A CHANGE IN] physical address, **or** ownership [, OR NAME, THE THIRD-PARTY LOGISTICS PROVIDER] must **notify the board in writing not later than 30 days after the change. The notification must include an attestation that a new self-inspection will be completed not later than 30 days after the start of business** [APPLY FOR A NEW AND SEPARATE THIRD-PARTY LOGISTICS PROVIDER LICENSE IN ACCORDANCE WITH THIS SECTION].

(d) When a third-party logistics provider ceases operations, the **designated representative** [FACILITY MANAGER] must submit to the board a written notice of the cessation of operations. The written notice must be submitted **not later than 30** [10] days after the cessation of operations and include

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years. (Eff. 10/31/2019, Register 232; am 12/28/2022, Register 244; am 7/15/2023 KL, Register 247)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

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

12 AAC 52.698. Manufacturer license. (a) An applicant for a manufacturer license shall submit the items required in (b) of 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.

(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 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.

(c) A manufacturer operating as a virtual manufacturer must indicate on the application that it operates as a virtual manufacturer within the meaning given in 12 AAC 52.995.

(d) A manufacturer that has changed its name, physical address, or ownership must notify the board in writing not later than 30 days after the change. The 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.

(e) When a manufacturer ceases operations, the designated representative of the manufacturer shall notify the board in writing of the cessation of operations. The form must be submitted not later than 30 days after the cessation of operations.

(f) A manufacturer that distributes drugs and devices that it does not directly manufacture must hold a separate wholesale drug distributor license.

(g) A manufacturer that provides logistics services must hold a separate third-party logistics provider license. (Eff. 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.800 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.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

(c) A drug room that has changed its name, physical address, or ownership must notify the board on a form or in writing not later than 30 days after the change. The notification must include an attestation that a new self-inspection will be completed not

later than 30 days after the start of business.

(d) An applicant for renewal of a drug room license must comply with the requirements of 12 AAC 52.300. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 7 / 15 / 2023, Register 247)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.855(a) is amended to read:

12 AAC 52.855. Registration with the prescription drug monitoring program [CONTROLLED SUBSTANCE PRESCRIPTION DATABASE]. (a) A prescriber shall register with the **prescription** [PRESCRIPTIONS] drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

12 AAC 52.855(b) is amended to read:

(b) A licensed pharmacist 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. [IF NOT DISPENSING IN THIS STATE, A PHARMACIST SHALL SUBMIT, NOT LATER THAN 30 DAYS AFTER INITIAL LICENSURE, A PDMP DISPENSATION EXEMPTION FORM PROVIDED BY THE BOARD.] 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 [SUBMITTED A DISPENSATION EXEMPTION FORM] shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am 7/15/2023, Register 247)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

The section heading of 12 AAC 52.860 is changed to read:

12 AAC 52.860. Access to and conditions for use of the prescription drug monitoring program [DATABASE].

12 AAC 52.995(a)(20) is amended to read:

(20) "wholesale distribution"

(A) means distribution of prescription drugs to a person other than a consumer or patient**;**

(B) [, BUT] does not include

(i) an activity described in 12 AAC 52.695; **or**

(ii) a manufacturer's distribution of the manufacturer's own manufactured drugs or devices;

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

(39) "automated distribution kiosk" means a vending machine that stores and distributes prescription drugs or devices and maintains a record of transactions initiated or completed;

(40) "manufacturer" means a person or entity, including a virtual manufacturer, engaged in the manufacturing of drugs or devices;

(41) "virtual manufacturer" means a manufacturer that sells a prescription drug or device but never physically possesses the product.

12 AAC 52.995(e) is amended to read:

(e) In 12 AAC 52.610 - 12 AAC 52.697, **"designated representative"** ["FACILITY MANAGER"] means the responsible manager who serves as the supervisor or manager and is responsible for ensuring **that** the third-party logistics provider, wholesale drug distributor, [OR] outsourcing facility**, or manufacturer** is in compliance with all state and federal laws and regulations pertaining to the operations. (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)

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