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

12 AAC 52.010. Classifications of licensure.

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(b) The board will issue the following categories of licenses or registrations to a qualified facility:

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(7) third-party logistics provider license;

(8) outsourcing facility license; [AND]

(9) license of a wholesale drug distributor located outside of the state**; and**

(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 ___/___/____, Register ____)

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

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 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 ___/___/____, Register ____)

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 terminate the pharmacy technician license. A voluntary termination 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 ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.200 is amended to read:

12 AAC 52.200. Pharmacist-in-charge. (a) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) ensuring adequate policies and procedures are in place for pharmacy operations;

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals; and

(6) ensuring effective controls against theft or diversion of prescription drugs.

(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].

(c) Notwithstanding 12 AAC 52.425(a), a pharmacist may not serve as 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. (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 ____/____/_____, Register _____)

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:

12 AAC 52.220. Pharmacist interns.

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(d) **Repealed ___/___/____** [A PHARMACIST INTERN SHALL FILE WITH THE BOARD A REPORT OF WORK EXPERIENCE ON A FORM PROVIDED BY THE DEPARTMENT WITHIN 30 DAYS OF COMPLETION OR TERMINATION OF AN INTERNSHIP IN THE PRACTICE OF PHARMACY REQUIRED UNDER 12 AAC 52.080]. (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 ___/___/____, Register ____)

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 ___/___/____, Register ____)

[EDITOR'S NOTE: THE JOB SHADOWING DOCUMENTATION FORM REQUIRED BY 12 AAC 52.250 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, P.O. BOX 110806, JUNEAU, AK 99811-0806; PHONE: (907) 465-2589, OR THE DIVISION'S WEBSITE AT HTTP://WWW.DCED.STATE.AK.US/OCC/PPHA.HTM.]

12 AAC 52.300 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 self-inspection **report** must be retained**, and** [BY THE APPLICANT AND BE MADE] available **by request,** [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 / /** [A PHARMACY THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OR OWNERSHIP SINCE THE DATE IT WAS FIRST ISSUED OR LAST RENEWED IS NOT ELIGIBLE FOR RENEWAL].

(e) **Repealed / /** [A WHOLESALE DRUG DISTRIBUTOR THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY MANAGER IS NOT ELIGIBLE FOR RENEWAL IF THE CHANGE OCCURRED 30 DAYS AFTER THE DATE A RENEWAL APPLICATION IS SUBMITTED TO THE BOARD].

(f) **Repealed / /** [AN OUTSOURCING FACILITY OR THIRD-PARTY LOGISTICS PROVIDER THAT HAS CHANGED ITS NAME, PHYSICAL ADDRESS, OWNERSHIP, OR FACILITY MANAGER IS NOT ELIGIBLE FOR RENEWAL].

(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 ___/___/____, Register ____)

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 ___/___/____, Register ____)

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. **A** [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 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 ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

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

12 AAC 52.530. Return or exchange of drugs.

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(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

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(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 ___/___/____, Register ____)

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 52.230; 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. ___/___/____, Register ____)

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. ___/___/____, Register ____)

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 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 ___/___/____, Register ____)

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 ___/___/____, Register ____)

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 ___/___/____, Register ____)

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 ___/___/____, Register ____)

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 ____/____/_____, Register _____)

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 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 ___/___/____, Register ____)

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 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 ___/___/____, Register ____)

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(a).

(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 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. ____/____/____, Register ____)

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 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 ____/____/____, Register ____)

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 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.

(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.

(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 must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am _/__/___, Register _____)

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:

12 AAC 52.995. Definitions.

. . .

(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 ___/___/____, 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