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OFFICE OF THE LIEUTENANT GOVERNOR
ALASKA

MEMORANDUM

TO: Debbie Morgan
Department of Commerce Community and Economic Development

FROM: April Simpson, Office of the Lieutenant Governor
465.4081

DATE: October 1, 2019

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy Regulation re: Board of Pharmacy: Adding New Licensing (12 AAC 52.010 - .995)

Attorney General File:	2019200354.001
Regulation Filed:	10/1/2019
Effective Date:	10/31/2019
Print:	232, January 2020

cc with enclosures: Harry Hale, Department of Law
Judy Herndon, LexisNexis

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached twenty-six pages of regulations, relating to the practice of pharmacy, including new licensing categories, licensure and registration requirements, permit, personnel, approved programs, guidelines for pharmacies and pharmacists, pharmacy practice standards, wholesale drug distributors and facilities, disciplinary guidelines, emergency preparedness, executive administrator position, and definitions, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its June 27, 2019 teleconference meeting, under the authority of AS 08.01.064, AS 08.01.075, AS 08.80.003, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.145, AS 08.80.150, AS 08.80.155, AS 08.80.157, AS 08.80.158, AS 08.80.159, AS 08.80.261, AS 08.80.270, AS 08.80.295, AS 08.80.315, AS 08.80.330, AS 08.80.345, AS 08.80.390, AS 08.80.410, 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: 07/10/2019
Juneau, Alaska

Laura Carrillo, Executive Administrator
Board of Pharmacy

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on Oct. 1, 2019 at 9:41 Am., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

Kevin Meyer, Lieutenant Governor

Effective: October 31, 2019.

Register: 232, January 2020.

Chapter 52. Board of Pharmacy.

(" Publisher: To reflect the addition of 12 AAC 52.010(b)(7) - (9), change the period at the end of 12 AAC 52.010(b)(6) to a semicolon. ")

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

(7) third-party logistics providers license;

(8) outsourcing ~~facilities~~ facility license;

(9) license of a wholesale drug distributor located outside of the state. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 10/31/2019, Register 232)

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: Existing introductory language of 12 AAC 52.050(a) is unchanged. ")

The introductory language of 12 AAC 52.050(a)(1) is amended to read:

~~(a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall~~

(1) submit **written notice** to the board [A WRITTEN NOTICE] of the cessation of pharmacy operations **on a form provided by the department**; the **form** [WRITTEN NOTICE] must be submitted within 10 days after the cessation of operations and include

. . .

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.070(a) is amended to read:

(a) **An** [THE BOARD WILL ISSUE A PHARMACIST LICENSE BY EXAMINATION

TO AN] applicant who meets the requirements of AS 08.80.110, 08.80.116, and **the requirements ~~on the checklist set out in~~ set out in (b) of** this section **has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements ~~on the checklist~~ of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by examination**.

(Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 7/1/2007, Register 182; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.095(a) is amended to read:

(a) **An** [THE BOARD WILL ISSUE A PHARMACIST LICENSE BY RECIPROCITY TO AN] applicant who meets the requirements of AS 08.80.145 (3, the requirements set out in (b) of this section,) and **the requirements ~~on the checklist set out in~~ set out in (c) of** this section **has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements ~~on the checklist~~ of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity**.

(Eff. 7/1/2007, Register 182; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

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

~~12 AAC 52.105. Temporary license for military personnel or the spouse of active~~ **duty military personnel.** (a) Military personnel or the spouse of an active duty military personnel who meets the requirements of AS 08.01.064 and (b) of this section has demonstrated the necessary qualifications for a temporary license. A military personnel applicant or the spouse of an active duty personnel who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a temporary license will not be issued a temporary license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a temporary license.

(b) The following checklist is established by the board for review of an application for a temporary license; a temporary license will be issued to a military personnel or the spouse of an active duty military personnel if the applicant

(1) submits a completed, notarized application for licensure on a form provided by the department;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) pays the application fee and temporary license fee required in 12 AAC 02.310;

(4) passes the Alaska jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substance Act) with a score of 75 or above;

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely; and

~~(6) submits a verification of a current license in good standing to practice in~~

~~another state or other jurisdiction with licensing requirements at least equivalent to those of this~~ state.

(b) An applicant whose application for permanent licensure has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 180 days. For good cause shown to the board's satisfaction, the board will extend the temporary license for an additional period not to exceed 60 days.

(d) A temporary license is not renewable.

(e) An individual may not receive more than one temporary license.

(Eff. ____/____/_____, Register _____)

Authority: AS 08.01.064 AS 08.80.030 AS 08.80.150

~~AS 08.80.005 AS 08.80.145~~

12 AAC 52.110(a)(4) is repealed:

(4) repealed 10/31/2019; and

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 8/12/2007, Register 183; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.120(b)(1) is amended to read:

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

12 AAC 52.120(b)(5) is repealed:

(5) repealed 10 / 31 / 2019;

12 AAC 52.120(c) is amended to read:

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of **(b)(1) and (2)** [(b)(1) - (2) AND (5)] of this section.

12 AAC 52.120(d) is amended to read:

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state. [THE PHARMACIST INTERN LICENSE IS VALID FOR ONLY THOSE WORK LOCATIONS FOR WHICH THE INDIVIDUAL PREVIOUSLY SUBMITTED SPONSORSHIP DECLARATIONS IN ACCORDANCE WITH (b)(5) OF THIS SECTION. BEFORE THE INDIVIDUAL MAY WORK AT AN ADDITIONAL WORK LOCATION, THE INDIVIDUAL MUST

(1) SUBMIT A SPONSORSHIP DECLARATION FOR THAT LOCATION IN ACCORDANCE WITH (b)(5) OF THIS SECTION; AND

(2) HAVE A REVISED LICENSE ISSUED TO THE INDIVIDUAL.]

12 AAC 52.120 is amended by adding a new subsection to read:

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board. (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)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116

AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 1 to read:

12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs. (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not ~~already~~ licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(A) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(B) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to non-tribal health program. In addition, an out-of-state licensed pharmacist working outside the scope of their contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80. (Eff. 10/31/2019, Register 232)

Authority: AS 08.80.003 AS 08.80.005 AS 08.80.030

12 AAC 52.220(b) is amended to read:

(b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist **or pharmacy technician** under the direct supervision of a pharmacist.

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410

AS 08.80.030 AS 08.80.116

12 AAC 52.240(b) is amended by adding new paragraphs to read:

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

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

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.340(a)(1) is amended to read:

(1) any program presented by a provider accredited by the ACPE **that results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program**;

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 5/15/2004, Register 170; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.423(c) is amended to read:

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300. [A REMOTE PHARMACY LICENSE MAY NOT BE RENEWED IF A NON-REMOTE PHARMACY OPENS FOR BUSINESS WITHIN TEN ROAD MILES OF THE 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.] (Eff. 9/17/2011, Register 199; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425(a) is amended to read:

(a) Only a **pharmacist employed by a** central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist **located in this state**. The pharmacist-in-charge of a **remote** [CENTRAL] pharmacy may supervise one or more remote

pharmacies.

The introductory language of 12 AAC 52.425(b) is amended to read:

(b) Before a **pharmacist employed by a** central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

. . .

12 AAC 52.425(e) is amended to read:

(e) Drugs may be shipped to a remote pharmacy [ONLY] from the central pharmacy **or a wholesale distributor**. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped. [ITEMIZED RECORDS OF DRUGS SHIPPED OR RECEIVED MUST BE VERIFIED BY THE SUPERVISING PHARMACIST AT BOTH THE CENTRAL PHARMACY AND THE REMOTE PHARMACY.]

12 AAC 52.425(f) is amended to read:

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must **have access to the records** [ALSO MAINTAIN A RECORD] of the prescriptions **dispensed by** [FILLED AT] the remote pharmacy. [THE RECORD MUST

DISTINGUISH PRESCRIPTIONS FILLED AT THE REMOTE PHARMACY FROM THOSE FILLED AT THE CENTRAL PHARMACY AND AT OTHER REMOTE PHARMACY LOCATIONS.]

12 AAC 52.425(g) is amended to read:

(g) The prescription label of a prescription drug **dispensed** [DISTRIBUTED] by a remote pharmacy must meet the requirements of 12 AAC 52.480.

12 AAC 52.425(h) is amended to read:

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the [CENTRAL PHARMACY AND DISTRIBUTED BY THE] remote pharmacy. A prescription drug may not be **dispensed** [DISTRIBUTED] by a remote pharmacy until a pharmacist **employed by** [AT] the central pharmacy has verified the finished prescription product through the telepharmacy system.

12 AAC 52.425(j) is repealed:

(j) Repealed 10/31/2019. (Eff. 2/15/2006, Register 177; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52 is amended by adding a new section ~~to Article 5~~ to read:

12 AAC 52.465. Controlled substance prescription drug orders. ~~(a)~~ A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for

(1) a terminally ill patient or a patient residing in a long term care facility, in

accordance with 21 CFR §1306.13; or

(2) a patient who is not terminally ill or residing in a long term care facility if

(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;

(C) each partial fill is electronically documented in the patient record;

(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(E) it only occurs at the pharmacy where the original prescription order is on file. (Eff. 10 / 31 / 2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.345

12 AAC 52.500(a) is amended to read:

(a) For the purpose of dispensing [A REFILL OF] a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 10 / 31 / 2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.510(a) is amended to read:

(a) A pharmacist may dispense an equivalent drug product **or interchangeable biological product** instead of the prescribed drug if

. . .

12 AAC 52.510(a)(3) is repealed:

(3) repealed 10 / 31 / 2019 ; and

• • •

12 AAC 52.510(b) is amended to read:

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the **terms** ~~[TERM]~~ "equivalent drug product" **or "interchangeable biological product" are** ~~[IS]~~ defined in AS 08.80.480. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am 10 / 31 / 2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.530(a) is amended to read:

(a) **A** [EXCEPT AS PROVIDED IN (b) OF THIS SECTION, A] pharmacy or pharmacist may [NOT] accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed **if**

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or

~~(2)~~ the medication was recalled by the manufacturer or ~~FDA;~~ and

~~(3) it is~~ segregated from the normal pharmacy inventory and may not be dispensed.

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

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.610 is repealed and readopted to read:

12 AAC 52.610. Wholesale drug distributor license. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The following checklist is established by the board for review of an application for a wholesale drug distributor license. A wholesale drug distributor license will be issued to an applicant who

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

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

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provides the name and the resume of the facility manager who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submits

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; or

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) submits completed fingerprint cards of the facility manager for evaluation and

investigation by the Department of Public Safety; and

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located ~~for non-resident wholesale drug distributors.~~ if the applicant is a wholesale drug distributor located outside of this state.

(c) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (b) of this section; and

(2) be registered with the DEA.

(d) Within 30 days ~~of~~ after a change in location, ownership, or facility manager, the new facility manager must

(1) submit the completed change of facility manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (b)(4) and (6) of this section.

(e) When a wholesale drug distributor ceases operations, the facility manager of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 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)

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

12 AAC 52.620 is amended by adding a new subsection to read:

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid

license under AS 08.80.(Eff. 1/16/98, Register 145; am 10/31/2019, Register 232)

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 **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)

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 52.630(a) is amended to read:

(a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements [OR OFFICIAL UNITED STATES PHARMACOPOEIA (USP), 1995 REVISION, COMPENDIUM REQUIREMENTS,] to help ensure that the identity, strength, quality, and purity of the products are not affected. [IF A TEMPERATURE REQUIREMENT IS NOT LISTED FOR A DRUG, THE DRUG MAY BE STORED AT CONTROLLED ROOM TEMPERATURE AS DEFINED IN THE USP.] (Eff. 1/16/98, Register 145; am 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

[**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.]

The authority citation of 12 AAC 52.640 is changed to read:

12 AAC 52.640. Written policies and procedures.

. . .

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

The authority citation of 12 AAC 52.645 is changed to read:

12 AAC 52.645. Examination of drug shipments.

. . .

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

The authority citation of 12 AAC 52.650 is changed to read:

12 AAC 52.650. Records and inventories.

. . .

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

The authority citation of 12 AAC 52.660 is changed to read:

12 AAC 52.660. Returned, damaged, and outdated drugs.

. . .

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

The authority citation of 12 AAC 52.670 is changed to read:

12 AAC 52.670. Drug recalls.

• • •

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

The authority citation of 12 AAC 52.680 is changed to read:

12 AAC 52.680. Inspections.

• • •

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

The authority citation of 12 AAC 52.685 is changed to read:

12 AAC 52.685. Prohibition against direct distribution.

• • •

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

The authority citation of 12 AAC 52.690 is changed to read:

12 AAC 52.690. Salvage and reprocessing.

. . .

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.695 is changed to read:

12 AAC 52.695. Provisions not applicable.

. . .

Authority: AS 08.80.005 AS 08.80.157 **AS 08.80.159**

AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 6 to read:

12 AAC 52.696. Outsourcing facilities. (a) An applicant ~~who~~ must meets the requirements ~~on the checklist~~ set out in (b) of this section ~~has~~ to demonstrated the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements ~~on the checklist~~ of (b) of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) ~~The following checklist is established by the board for review of an application for an outsourcing facility license,~~ The board will issue an outsourcing facility license ~~will be issued~~ to an applicant who

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

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

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA).

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address shall apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility shall apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager shall

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the outsourcing facility ceased operations;

(B) arrange for the records of the outsourcing facility to be retained for two years.

(g) An outsourcing facility shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility shall be registered with the Food and Drug Administration as a 503b outsourcing facility. (Eff. 10/31/2019, Register 232)

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 Article 6 to read:

12 AAC 52.697. Third-party logistics providers. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The following checklist is established by the board for review of an application for a third-party logistics provider license; a third-party logistics provider license will be issued to an applicant who

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

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

(3) provides a list of the names and résumés of officers, directors, or primary

stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(c) Within 10 days ~~of a~~ after change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of a third-party logistics provider that has changed its name or physical address ~~shall~~ must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider ~~shall~~ must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager ~~shall~~ must

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

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

(B) arrange for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider ~~shall~~ must permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility

records and written operating procedures. (Eff. 10 / 31 / 2019, Register 232)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

Disapproved SKP 9/6/19

12 AAC 52.920(a)(19) is amended to read:

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, **sexual orientation, gender identity,** or sex in the provision of a service that is part of the practice of pharmacy;

Disapproved SKP 9/6/19

12 AAC 52.920 is amended by adding a new subsection to read:

(e) Failing to meet continuing education requirements will result in a $100 civil fine per missing continuing education credit hour for pharmacists and a $25 civil fine per missing continuing education credit hour for technicians. (Eff. 1/16/98, Register 145; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

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 is amended by adding a new section to Article 10 to read:

12 AAC 52.925. Grounds for denial or discipline for criminal history. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant's or licensee's ability to practice competently and safely include

(1) murder;

(2) manslaughter;

(3) criminally negligent homicide;

(4) assault;

(5) sexual assault;

(6) sexual abuse of a minor;

(7) unlawful exploitation of a minor, including possession or distribution of child pornography;

(8) incest;

(9) indecent exposure;

(10) robbery;

(11) extortion;

(12) stalking;

(13) kidnapping;

(14) theft;

(15) burglary;

(16) forgery;

(17) endangering the welfare of a child;

(18) endangering the welfare of a vulnerable adult;

(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;

(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely. (Eff. 10/31/2019, Register 232)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.985 Emergency Preparedness. (a) If, as a consequence of a natural disaster or terrorist attack, a ~~state of~~ emergency is declared by the governor under AS 26.23.020 which results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

(b) If, as a consequence of a natural disaster or terrorist attack, a ~~state of~~ emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) When a ~~state of~~ emergency has been declared, a pharmacist in the area of the declared emergency may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication if

(1) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and

(2) the pharmacist makes a good faith effort to reduce the patients prescription drug information to a written prescription marked "emergency prescription" and then files and maintains the prescription in accordance with 12 AAC 52.450.

(d) If a declared ~~state of~~ emergency continues for more than 21 days after a pharmacist dispenses an emergency prescription under (c) of this section, the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110. (Eff. 10/31/2019, Register

232)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.993. Executive administrator. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance are to be reviewed by a board member;

(2) attend state or national meetings or conferences on behalf of the board;

(3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;

(4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;

(5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board. (Eff. 10/31/2019, Register 232)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

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

(37) "moral turpitude" includes conduct that is considered contrary to community standards of justice, honesty, or good morals.

12 AAC 52.995 is amended by adding a new subsection to read:

(e) In 12 AAC 52.610 – 12 AAC 52.697, "facility manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility 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)

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		