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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		

MEMORANDUM

State of Alaska
Department of Law

To: The Honorable Kevin Meyer
Lieutenant Governor

Date: September 6, 2019

File No.: 2019200354.001

Tel. No.: 465-3600

From: Susan R. Pollard SRP
Chief Assistant Attorney General
and Regulations Attorney
Legislation and Regulations Section

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

The Department of Law has reviewed the attached regulations of the Board of Pharmacy against the statutory standards of the Administrative Procedure Act. Except as discussed below, we find no legal problems. Except for the regulations withdrawn or disapproved (discussed below), this memorandum 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 update regulations to reflect recent legislation: ch. 66, SLA 2018 (SB 37, relating to the Board of Pharmacy and drug supply chain security) and ch. 58, SLA 2018 (SB 58, relating to biological products).

Substance of regulations. Throughout changes address the need to add new licensing types authorized by AS 08.80.159 (licensing and inspection of facilities outside the state). Changes to address these new facility types are found in 12 AAC 52.610 (wholesale drug distributor license), 12 AAC 52.696 (outsourcing facilities) and 12 AAC 52.697 (third-party logistics providers).

The board, through its executive director, agrees that the amendment to 12 AAC 52.105 must be withdrawn for further work. In 12 AAC 52.105, the board addressed temporary licenses for military personnel or the spouses of active military personnel. But the regulation combines requirements for military personnel (AS 08.01.064) and spouses of military personnel (AS 08.01.063) in a confusing and inconsistent way. For example, the regulation refers to military personnel or the spouse of military personnel meeting "the requirements of AS 08.01.064(b)." But AS 08.80.064 applies to acceptance of military training as part of a licensing determination and not to a person applying as a spouse of an active duty military member (although it incorporates parts of AS 08.01.063). The board's intent to clarify how a military courtesy license is issued to a spouse of an active duty military member and how to account for military training and service is authorized, but the requirements need to be clearly defined for each license type. It is confusing and subject to misapplication to meld them into one regulation. Approaching the two statutes separately in regulation may be the better approach. *See,* 12 AAC 48.035 (military courtesy license for optometrists); 12 AAC 40.022 (postgraduate

training and active duty military service for purposes of medical board). Our department is available to assist the board in revising its approach to meet guidelines for clarity and consistency with the statutory authority.

Amendments to 12 AAC 52.070 and .095 would clarify that applications for licensure by examination and reciprocity that do not clearly meet the requirements for licensure must be sent to the board for further review. This would allow the executive administrator and staff to issue licenses where the license requirements are clearly met, but allow for board review if there is some question about whether qualifications are met. This is consistent with the broad statutory authority given to the executive administrator through AS 08.80.270.

The amendment to 12 AAC 52.240(b) on protocol for pharmacist collaborative practice authority is similar to a medical board regulation on collaborative practice (12 AAC 40.983(c)(11)). Accordingly, this amendment would prohibit dispensing some controlled substances and require acknowledgment that a pharmacist will not receive compensation for care or treatment of a patient under a written protocol (essentially, no kickbacks).

Our understanding is that 12 AAC 52.465 is a new section to provide authority to dispense "partial fills" of schedule II controlled substances as a response to public comment about the reluctance of some consumers to obtain and store more medication than they will actually need or use.

Ch. 58, SLA 2018, allows pharmacists to dispense an "interchangeable biological product" (in addition to an "equivalent drug product"). Amendments to 12 AAC 52.510(a) and (b) address this.

Two amendments were proposed to board regulations on disciplinary guidelines. First, the board adopted new 12 AAC 52.925 enumerating the crimes that affect an applicant's or licensee's ability to practice. This type of enumeration has been adopted in other licensing programs, and here, as elsewhere, the list is not exhaustive, and none of the crimes require denial. The applicable statute gives the board discretion to deny a license to an applicant based on the facts. AS 08.80.261(a). The regulation refers to "convictions," but we note that the board may wish to revisit this section to clarify whether by "conviction" the intent is to include no contest pleas and suspended impositions of sentence. *See,* AS12.62.100 (definition of conviction for registration of sex offenders include a plea of non contendere). But as written, the regulation provides adequate guidance as to the type of past acts that may affect a person's ability to practice competently and safely.

Next, the board adopted a change to add "sexual orientation [and] gender identity" to the list of forbidden types of discrimination that could result in a disciplinary action under 12 AAC 920(a). We have disapproved this regulation because Alaska law does not provide controlling direction on whether these terms identify a protected class. *See,* AS 18.80.200 (b); *see also, Rodriguez v. Alaska State Com'n for Human Rights*, 354 P. 3d 386 (Alaska 2015).[1]

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[1] In *Rodriguez,* the court considered a challenge based on the commission's dismissal of a complaint of race-based discrimination. It cited to AS 18.80.220(a) that makes it illegal for an

We have also disapproved 12 AAC 52.920(e), which would add a civil fine penalty for failure to meet continuing education requirements. While the board has broad authority to issue fines not to exceed $5,000 (AS 08.01.075(a)(8)), a fine imposed by regulation should be precise, definite and unambiguous. *See, Alaska Pub. Offices Com'n v. Stevens,* 205 P.3d 321, 326 (Alaska 2009). Here, the fine would be imposed for "missing" continuing education credits, but it is unclear whether that would include a course taken but unreported by the licensee. Further, it is unclear whether the fine is curable if the "missing" credits are accounted for. The details for imposition and possible cure are not defined enough to provide enough notice to those potentially affected by the fine. Accordingly, we are disapproving this regulation.

The board addressed emergency preparedness through 12 AAC 52.985 to allow for the board or a pharmacist to address needs to fill prescriptions during an emergency situation. We note that a governor retains authority to suspend regulations of any state agency upon finding that compliance with the regulation would "prevent, impede, or delay action necessary to cope with the disaster emergency." AS 26.23.020(b). Accordingly, the governor's authority to suspend a regulation in a declared emergency applies to all regulations, including this one. But this regulation provides some clarity for emergency situations, and in our view, is authorized under the board's stator authority (although, as noted, subject to suspension under the circumstances set out in AS 26.23.020).

Procedural steps. The April 24, 2019 public notice and the July 10, 2019 certification of adoption 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 44.62.125. The corrections are shown on the attached copy of the regulations.

SRP:srp

cc: Honorable Julie Anderson, Commissioner
Department of Commerce, Community, and Economic Development
Amy Demboski, Assistant Commissioner
Department of Commerce, Community, and Economic Development
Glenn Hoskinson, Special Assistant to the Commissioner
Department of Commerce, Community, and Economic Development
Sara Chambers, Division Director
Department of Commerce, Community, and Economic Development
Jun Maiquis, Regulations Specialist
Department of Commerce, Community, and Economic Development

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employer to discriminate based on enumerated characteristics, including sex. The court stated the "statute does not include discrimination based on a complainant's sexual orientation." *Id.* 354 P.3d at 386.

Sher Zinn, Regulations Specialist
Department of Commerce, Community, and Economic Development
Richard Holt, Chair
Board of Pharmacy
(*via e-mail through Jun Maiquis*)
Harriet Milks, Assistant Attorney General
Department of Law, Commercial & Fair Business Section

STATE OF ALASKA)
) ss.
FIRST JUDICIAL DISTRICT)

AFFIDAVIT OF BOARD ACTION

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, being duly sworn, state the following:

> The attached motion 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 was passed by the Board of Pharmacy during its June 27, 2019 teleconference meeting.

Date: 07/10/2019
Juneau, Alaska

Laura Carrillo
Laura Carrillo, Executive Administrator

SUBSCRIBED AND SWORN TO before me this 10 day of July, 2019.

Jean Bennett My Commission Expires NOTARY PUBLIC With Office State of Alaska

Jean Bennett
Notary Public in and for the
State of Alaska
My commission expires: with job

State of Alaska
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATION, BUSINESS AND PROFESSIONAL LICENSING

Alaska Board of Pharmacy
Thursday, June 27, 2019
10:30 am

By the authority of AA 08.01.070(2) and AS 08.86.030, and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Alaska Board of Pharmacy was help via video/teleconference on Thursday, June 27th, 2019.

These are DRAFT minutes prepared by the staff of the Division of Corporation, Business and Professional Licensing. These minutes have not been reviewed or approved by the Board.

Written meeting minutes reflect a brief overview of the business conducted by the board during their meeting. For a more detailed account, please request a copy of the meeting recording.

The Chair brought the meeting to order at 10:42 am

Agenda Item 1 - Roll Call

Board Members Present Constituting a Quorum:
Dr. Richard Holt – Chair
Lana Bell
Phil Sanders
Sharon Long

Board Members Absent:
Dr. Leif Holm
James Henderson
Tammy Lindemuth

Staff Members present:
Dawn K Hannasch-Records and Licensing Supervisor

Members of the Public Present:
Jessica Adams
Dan Nielson
Jessica
Victor Kao
Adel Davis
Molly Gray
Justin Chung

Agenda Item 2 - Review/Approve Agenda

The Chair, Dr. Richard Holt brought the meeting to order and requested that each member review the drafted agenda. Dr. Holt stated that there will not be a public comment period during this meeting because the public comment period for this regulations project has closed.

On a motion duly made by Lana Bell, seconded by Sharon Long, with unanimous consent it was:

resolved to approve the agenda as drafted.

Agenda Item 3 – Ethics Disclosure

Of the four board members present at the meeting, none had ethic concerns to disclose.

Agenda Item 4 – Regulations

Hearing nothing further, Dr. Holt brought the boards attention to their board packet, which contains all the written public comments that were received regarding the current regulations project affecting 12 AAC 52.010 – 12 AAC 52.995. The public comment period closed on May 24, 2019. Dr. Holt read each comment aloud for the benefit of the public.

One of the public comments offered a recommendation to the board for changes to 12 AAC 52.423(b). Mr. Sanders stated that he would prefer to complete the current regulation project and then look at other changes in the future. However, board members, Sharon Long and Lana Bell, would like to proceed with the recommended changes now. Dr. Holt requested that staff add the subject to the next meeting, and the board ultimately decided to table 12 AAC 52.470(d) for further review and discussion.

The board continued their review of each public comment.

On a motion duly made by Lana Bell, seconded by Phil Sanders, with unanimous consent it was:

resolved to approve the regulations as written and publicly noticed except for 12 AAC 52.470(d) relating to a 30-day supply.

Agenda Item 5 – Adjourn

The board adjourned the meeting following discussion of regulations.

_____

Laura Carrillo for Dawn Hannasch Date

_____

Richard Holt, Chair Date

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THIRD JUDICIAL DISTRICT

Joleesa Stepetin
being first duly sworn on oath deposes and says that he/she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

April 25, 2019

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed Joleesa Stepetin
Joleesa Stepetin

Subscribed and sworn to before me
this 29th day of April, 2019

Notary Public in and for
The State of Alaska.
Third Division
Anchorage, Alaska

MY COMMISSION EXPIRES
7/14/2020

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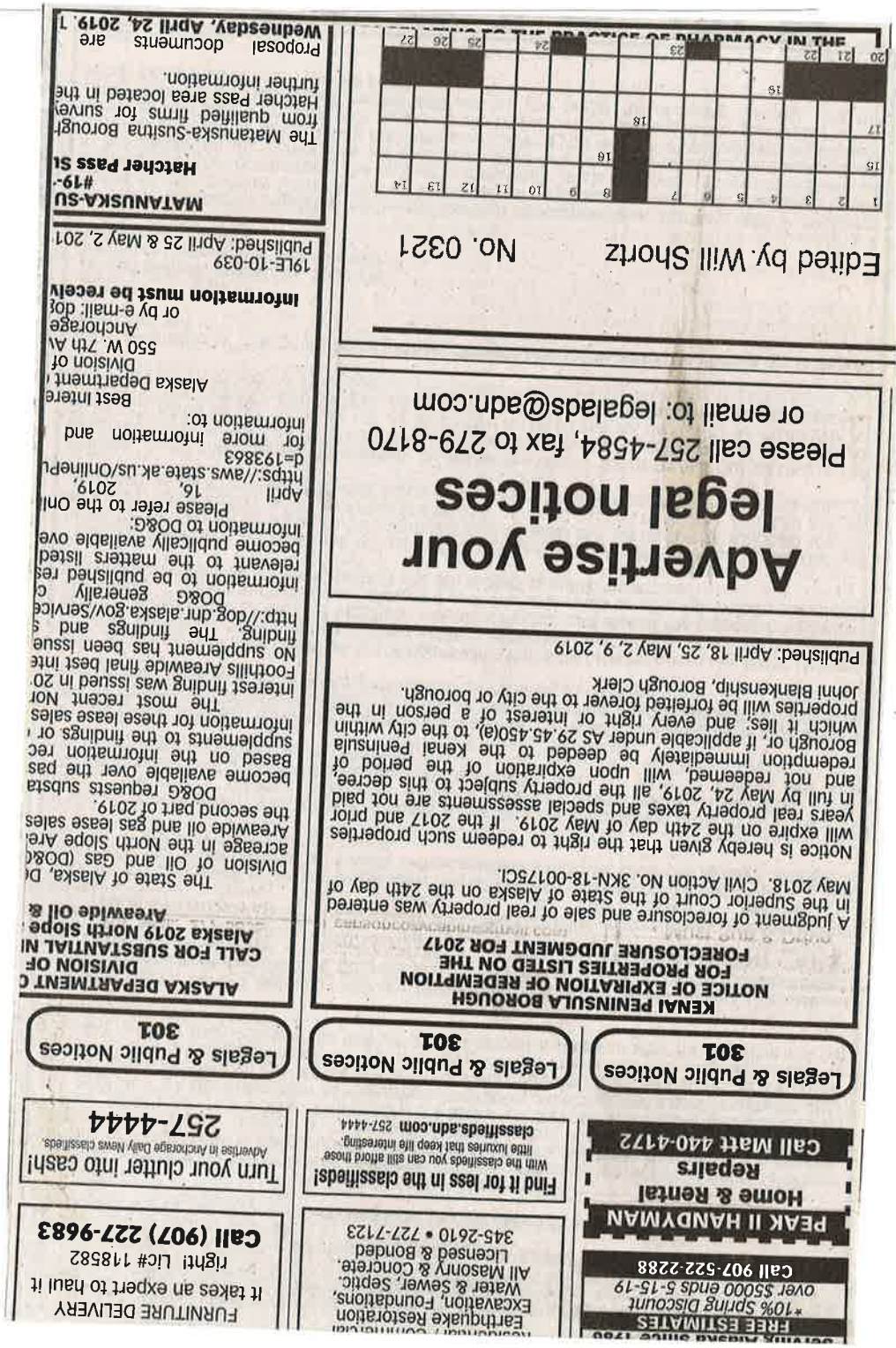
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KENAI PENINSULA BOROUGH
NOTICE OF EXPIRATION OF REDEMPTION
FOR PROPERTIES LISTED ON THE
FORECLOSURE JUDGMENT FOR 2017

A judgment of foreclosure and sale of real property was entered in the Superior Court of the State of Alaska on the 24th day of May 2018. Civil Action No. 3KN-18-00175CI.

Notice is hereby given that the right to redeem such properties will expire on the 24th day of May 2019. If the 2017 and prior years real property taxes and special assessments are not paid in full by May 24, 2019, all the property subject to this decree, and not redeemed, will upon expiration of the period of redemption immediately be deeded to the Kenai Peninsula Borough or, if applicable under AS 29.45.450(a), to the city within which it lies; and every right or interest of a person in the properties will be forfeited forever to the city or borough.

John Blankenship, Borough Clerk

Published: April 18, 25, May 2, 9, 2019

Legals & Public Notices 301

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ALASKA DEPARTMENT C
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19LE-10-039
Published: April 25 & May 2, 201

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NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update various regulations relating to the practice of pharmacy under the authority of AS 08.80 and 12 AAC 52. The proposed regulations deal with a wide range of subjects, including new licensing categories, closed pharmacies, licensure requirements, temporary license, permits, pharmacist intern license application, licensure for individual pharmacists working for tribal health program, pharmacist interns, pharmacist collaborative practice authority, approved programs, remote pharmacy license, telepharmacy system, controlled substance prescription drug orders, refills, transfer of a prescription drug order, substitution, return or exchange of drugs, wholesale drug distributor license, facilities, personnel, drug storage, disciplinary guidelines, grounds for denial or discipline for criminal history, emergency preparedness, executive administrator position, definition of terms, and to implement the statutory amendments made in AS 08.80 by Chapter 66 SLA 2018 (SB 37) and Chapter 58 SLA 2018 (SB 32).

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. **12 AAC 52.010. Classifications of licensure,** is proposed to be changed to add new licensing categories including third-party logistics providers, outsourcing facilities, and out-of-state wholesale drug distributors.

2. **12 AAC 52.050. Closed pharmacies,** is proposed to be changed to amend the requirement that when a pharmacy closes its business it must submit a form provided by the department.

3. **12 AAC 52.070. Application for pharmacist license by examination,** is proposed to be changed to amend the checklist requirements for pharmacist license by examination application.

4. **12 AAC 52.095. Application for pharmacist license by reciprocity,** is proposed to be changed to amend the checklist requirements for pharmacist license by reciprocity application.

5. **12 AAC 52.105. Temporary license for military personnel or the spouse of active duty military personnel,** is a proposed new section for temporary license application for military personnel or spouses of active duty military personnel.

6. **12 AAC 52.110. Emergency pharmacist permit,** is proposed to be changed to repeal the need to take the state jurisprudence examination.

7. **12 AAC 52.120. Review of pharmacist intern license application,** is proposed to be changed to repeal the need to obtain sponsorship and add a new regulation that intern licenses supersede pharmacy technician licenses.

8. **12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health program,** is proposed to add new regulations around out of state licensed pharmacists providing proof of licensure when working for tribal health programs in this state.

9. **12 AAC 52.220. Pharmacist interns,** is proposed to amend the regulation that a pharmacist intern may perform any duties of a pharmacy technician.

10. **12 AAC 52.240. Pharmacist collaborative practice authority,** is proposed to be changed to add that they can't result in a pharmacist dispensing or administering any schedule I, II, III, or IV controlled substance and acknowledging 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.

11. **12 AAC 52.340. Approved programs,** is proposed to be changed to clarify the type of ACPE program certificates that are approved for continuing education.

12. **12 AAC 52.423. Remote pharmacy license,** is proposed to be changed to remove the distance requirement for renewals.

13. **12 AAC 52.425. Telepharmacy system for a remote pharmacy,** is proposed to be changed to amend employment requirements, shipping drugs to a remote pharmacy from the central pharmacy or wholesale distributor, maintaining records requirements, labelling requirements, and repealing the pharmacist-in-charge of the central pharmacy maintaining compliance.

14. **12 AAC 52.465. Controlled substance prescription drug orders,** is a proposed new section to allow partial filling of schedule II controlled substances.

15. **12 AAC 52.470. Refills,** is proposed to be changed to amend the ability to dispense up to a 100-day supply and can dispense any quantity with conditions.

16. **12 AAC 52.500. Transfer of a prescription drug order,** is proposed to be amended to remove refills from what is allowed.

17. **12 AAC 52.510. Substitution,** is proposed to be changed to add interchangeable biological products and repeal the requirement to dispense a less costly equivalent drug product over the prescribed.

18. **12 AAC 52.530. Return or exchange of drugs,** is proposed to be changed to amend the ability of a patient to return medication to a pharmacy if it was filled incorrectly or was recalled by the manufacturer or FDA.

19. **12 AAC 52.610. Wholesale drug distributor license,** is proposed to be changed to amend the checklist requirements for wholesale drug distributor license application.

20. **12 AAC 52.620. Wholesale drug facilities,** is proposed to add the requirements that a wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must verify that the purchaser of the prescription drugs holds a valid license under AS 08.

21. **12 AAC 52.625. Personnel requirements; grounds for denial or other disciplinary action,** is proposed to be changed to introduce the manager position as a facility manager.

22. **12 AAC 52.630. Drug storage,** is proposed to be changed to amend temperature requirements be maintained to label requirements, and remove the reference to United States Pharmacopoeia (USP).

23. **12 AAC 52.640 – 12 AAC 52.695,** proposed changes are to amend the authority citations to include out-of-state wholesale drug distributors.

24. **12 AAC 52.696. Outsourcing facilities,** is a proposed new section that establishes requirements for an outsourcing facility license.

25. **12 AAC 52.697. Third-party logistics providers,** is a proposed new section that establishes requirements for a third-party logistics providers license.

26. **12 AAC 52.920. Disciplinary guidelines,** is proposed to be changed to add sexual orientation or gender identity discrimination as a basis for potential disciplinary action and add civil fines associated with failure to meet continuing education requirements.

27. **12 AAC 52.925. Grounds for denial or discipline for criminal history,** is a proposed new section that establishes grounds for denying or disciplining a licensee under the ability to practice competently and safely.

28. **12 AAC 52.985. Emergency preparedness,** is proposed to add new regulations regarding

emergency preparedness and what pharmacies can dispense under emergencies declared by the governor.

29. **12 AAC 52.993. Executive administrator,** is proposed to add new regulations regarding the executive administrator position.

30. **12 AAC 52.995. Definitions,** is proposed to add a new definition for "facility manager" and "moral turpitude".

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/193975, and using the comment link. **The comments must be received not later than 4:30 p.m. on May 24, 2019**. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. **The questions must be received at least 10 days before the end of the public comment period.** The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than May 17, 2019 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0419.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: 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; AS 17.30.900
Statutes Being Implemented, Interpreted, or Made Specific: 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; AS 17.30.900

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 4/24/19

Jun Maiquis, Regulations Specialist
Division of Corporations, Business and
Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Board of Pharmacy – Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Licensing 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, and definitions.

3. **Citation of regulation:** 12 AAC 52.010 – 12 AAC 52.995.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Update and clarification of current regulations; compliance with new state statutes – Chapter 66 SLA 2018 (SB 37) and Chapter 58 SLA 2018 (SB 32).

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: $100 initial application, $600 initial biennial license, and $600 biennial license renewal fees for third-party logistics provider, outsourcing facility, and non-resident wholesale drug distributor.
   Another state agency: None known.
   A municipality: None known.

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2019 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Laura Carrillo, Executive Administrator
   Alaska Board of Pharmacy
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
   Telephone: (907) 465-1073
   E-mail: laura.carrillo@alaska.gov

10. **The origin of the proposed action:** Board of Pharmacy.

11. **Date:** 4/24/19 **Prepared by:**

Jun Maiquis
Regulations Specialist
(907) 465-2537

STATE OF ALASKA)
) ss.
FIRST JUDICIAL DISTRICT)

AFFIDAVIT OF NOTICE OF PROPOSED REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to 12 AAC 52.010 through 12 AAC 52.995, 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, has been given by being

1. published in a newspaper or trade publication;
2. furnished to every person who has filed a request for notice of proposed action with the state agency;
3. furnished to appropriate state officials;
4. furnished to interested persons;
5. furnished to the Department of Law, along with a copy of the proposed regulation;
6. furnished electronically to incumbent State of Alaska legislators;
7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to persons in (2), (4), and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

DATE: 7/10/19
Juneau, Alaska

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 10 day of July, 2019.

Danielle Ames
My Commission Expires
NOTARY PUBLIC
With Office
State of Alaska

Notary Public in and for the
State of Alaska
My commission expires: w/ Office

STATE OF ALASKA)
) ss.
FIRST JUDICIAL DISTRICT)

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy 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.

DATE: 7/10/19
Juneau, Alaska

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 10 day of July, 2019.

Danielle Ames My Commission Expires NOTARY PUBLIC With Office State of Alaska

Notary Public in and for the
State of Alaska
My commission expires: W/O Afice