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### OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

## MEMORANDUM

TO:	Jun Maiquis Department of Commerce, Community & Economic Development
FROM:	Scott Meriwether, Office of the Lieutenant Governor
DATE:	May 30, 2018
RE:	Filed Permanent Regulations: Board of Pharmacy
	Board of Pharmacy update to regulations regarding intern license applications, out-of- state pharmacies, changes of pharmacists-in-charge, dispensing, changes of managers of wholesale drug distributors, and reporting of disciplinary actions (12 AAC 52.120(b)(8); 12 AAC 52.130(c),(d); 12 AAC 52.200(c); 12 AAC 52.470(d)-(f); 12 AAC 52.510(a)(1),(4); 12 AAC 52.610(c); 12 AAC 52.991(b))

Attorney General File:	2018200092		
Regulation Filed:	5/30/2018		
Effective Date:	6/29/2018		
Print:	226, July 2018		

cc with enclosures:

Linda Miller, Department of Law Judy Herndon, LexisNexis

#### ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached five pages of regulations, dealing with review of pharmacist intern license application, registration of pharmacies located outside of the state, pharmacist-in-charge, pharmacist collaborative practice authority, prescription drug refills, substitution, wholesale drug distributor license, and disciplinary decision or conviction reporting requirement, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its February 28 – March 1–2, 2018 meeting, under the authority of AS 08.01.075, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.157, AS 08.80.158, AS 08.80.160, AS 08.80.261, AS 08.80.295, AS 08.80.315, AS 08.80.330, AS 08.80.460, and AS 08.80.480 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: <u>05/02/2018</u> Juneau, Alaska

Leif Holm, PharmD., Chair Board of Pharmacy

regulations according to the provisions of AS 44.62.040 - 44.62.120.

Byron Mallott, Lieutenant Governor

Effective: June 29, 2018. Register: 226, July 2018.

#### FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY

I, BYRON MALLOTT, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employee to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:

Claire Richardson, Special Assistant

IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on January 7<sup>th</sup> 2015.



BYRON MALLOTT LIEUTENANT GOVERNOR

# Register 226, July 2018 PROFESSIONAL REGULATIONS

#### Chapter 52. Board of Pharmacy.

12 AAC 52.120(b) is amended by adding a new paragraph to read:

(8) submits two affidavits from reputable citizens that the applicant has known for

in Publisher: To reflect the

Addition of new 12 AAC S2. 120(6X8) glease change the forial that follows 12 AAC 52, 120(6)(7) to a semicolon, and relocate

the "and" connector from the

52.120(b)(6) to

at least one year attesting to the applicant's good moral character.

(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 6/29/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.110

charged

The section heading for 12 AAC 52.130 is amended to read:

12 AAC 52.130. Registration [REVIEW OF APPLICATIONS FOR end of 12 AAC The end of 12 AAC 52.120(2)(7). ))) **REGISTRATION**] of pharmacies located outside of the state.

12 AAC 52.130(c) is amended to read:

(c) A pharmacy located outside of the state that ships, mail, or delivers prescription drugs into the state more than twice during a 12-month period [TO INDIVIDUAL PATIENTS IN THE STATE] shall register with the board.

12 AAC 52.130 is amended by adding a new subsection to read:

(d) In AS 08.80.158(b)(4),"proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's Policies and Procedures. (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am 6/29 /2018,

DOL File#201820009

Register 226, July 2018 PROFESSIONAL REGULATIONS Register 226)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.200(c) is amended to read:

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall

92 AAC 52.240(g) is amended to read:

in Publisher: Exiting 12 AAC 52.240 (g)

2(g) Any modification to the written protocol must be approved [BY THE BOARD] as

Acquired by this section for a new written protocol.

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

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.470 is amended by adding new subsections to read:

(d) If an original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense up to a 100-day supply on refills provided that the

(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills;

(2) drug is not a federal or state scheduled controlled substance; and

(3) the pharmacist is exercising professional judgment.

(e) To indicate that an increased supply shall not be dispensed pursuant to this section, a prescriber may indicate "no change to quantity", or words of similar meaning, on the prescription drug order.

(f) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including but not limited to, a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit. (Eff. 1/16/98, Register 145; am

6/29/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.030



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12 AAC 52.510(a)(1) is amended to read:

(1) the prescribing practitioner does not **indicate** [HAND WRITE OR ELECTRONICALLY NOTE] on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording;

The introductory language of 12 AAC 52.510(a)(4) is amended to read:

(4) for the drug product actually dispensed, the **pharmacy record shall contain** [PHARMACIST NOTES ON THE PRESCRIPTION DRUG ORDER] one of the following:

. . .

(Eff. 1/16/98,	Register 145; am	10/9/2008, Register 188; am	6129 12018,	Register 226)
Authority:	AS 08.80.005	AS 08.80.030	AS 08.80.295	

12 AAC 52.610(c) is amended to read:

(c) Within 30 days of a change in facility manager, the new facility manager must submit (1) the completed change of pharmacy manager form provided by the department; (2) the applicable fees established in 12 AAC 02.310; and (3) meet the requirements of (a)(4) and (6) of this section. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am \_6 /2? / 20(?, Register 226) Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030

DOL File#2018200092

Register 226, July 2018 PROFESSIONAL REGULATIONS

12 AAC 52.991 is amended by adding a new subsection to read:

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility. (Eff. 9/17/2011, Register 199; am 4/16/2016, Register 218; am 6/29/2018, Register 226) Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315 AS 08.80.005 AS 08.80.261 AS 08.80.460

la Rublisher: To reflect the addition of new 12 AAC 52,991(b), please designate the existing test of 12 AAC 52,991 as 12 AAC 52,991(a), i.e., insert on "(a)" subsection tag for the existing test. III

