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OFFICE OF THE LIEUTENANT GOVERNOR
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MEMORANDUM

TO: Jun Maiquis, AAC Contact
Department of Commerce, Community, & Economic Development

FROM: Scott Meriwether
Special Assistant
907.465.3509

DATE: July 4, 2014

RE: Filed Permanent Regulations: Board of Pharmacy

Regulations re: reinstatement of a pharmacist license and the definition of "dispenser": 12 AAC 52.310; 12 AAC 52.995(a)

Attorney General File:	JU2013200469 (Part 1)
Regulation Filed:	7/2/2014
Effective Date:	8/1/2014
Print:	211, October 2014

cc with enclosures: Linda Miller, Department of Law
Crystal Koeneman, Administrative Regulation Review Committee
Judy Herndon, LexisNexis

JU2013200469 (Part 1)

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached five pages of regulations, dealing with facility license, review of applications for registration of pharmacies located outside of the state, inspections of pharmacies, reinstatement of an expired pharmacist or pharmacy technician license, requirement for dispensers, and definitions, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its August 22-23, 2013 meeting, under the authority of AS 08.01.087, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.147, AS 08.80.157, AS 08.80.158, AS 08.80.165, AS 08.80.330, and AS 17.30.200 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: 11-21-13
North Pole, Alaska

Richard C. Holm, R.Ph., Chairman
Board of Pharmacy

FILING CERTIFICATION

I, Mead Treadwell, Lieutenant Governor for the State of Alaska, certify that on July 2, 2014 at 3:06 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

Mead Treadwell, Lieutenant Governor

Effective: August 1, 2014.
Register: 211, October 2014

Chapter 52. Board of Pharmacy.

12 AAC 52.020 is amended by adding a new subsection to read:

(f) In addition to the requirements of AS 08.80.157 and this section, an applicant under this section shall submit physical inspection report for a high risk pharmacy required under 12 AAC 52.150(f). (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330 AS 08.80.030

Disapproved. XCX, 6/5/2014

12 AAC 52.130(b) is amended by adding a new paragraph to read:

(5) submit physical inspection report for a high risk pharmacy required under 12 AAC 52.150(f).

(Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

Disapproved. XCX 6/5/2014

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

12 AAC 52.150. Inspections of pharmacies. (a) In order to be eligible for renewal of a facility license issued under AS 08.80.157, a high risk pharmacy or a pharmacy holding an active facility license issued by another state shall submit to a physical inspection of its production facility by the department at least once during the biennial licensing period. The board may waive this requirement if through no fault of the applicant the department was unable to

Disapproved. XCX 6/5/2014

~~complete the required investigation before the application deadline.~~

(b) An applicant for an initial facility license under AS 08.80.157 that holds an active facility license issued by another state or that intends on operating a high risk pharmacy shall pass a physical inspection by the department of its production facility prior to licensing.

(c) If a high risk pharmacy does not hold a facility license issued by another state and it holds a current accreditation by an accrediting board acceptable to the board, it may be exempt from meeting the inspection requirements of (a) and (b) of this section.

(d) All pharmacies must maintain a record of all licenses held in other state jurisdictions, the nature of pharmacy services provided out of state and shall make such information available to the department upon request.

(e) A pharmacy shall advise the board in writing within sixty days of it beginning operations as a high risk pharmacy or first receiving a pharmacy facility license issued by another state.

(f) In order to apply for a new registration under AS 08.80.158 or renew a registration, a pharmacy shall provide the board with proof that its facilities were inspected during the preceding biennial licensing period by the regulatory agency of the state where the facilities are located or that it holds a current accreditation by an accrediting body acceptable to the board.

(g) Nothing in this section limits the department authority to conduct investigations under AS 08.01.087 or prevents the board from ordering licensees to submit to additional inspections.

(h) For purposes of this section, "high risk pharmacy" includes

(1) hospitals;

(2) sterile compounding facilities;

~~(3) home infusion facilities; and~~

Disapproved. MCD 6/5/2014

~~(4) any other facility considered high-risk by the board. (Eff. __/__/__,~~

~~Register ____)~~

Authority: ~~AS 08.01.087~~ AS 08.80.030 AS 08.80.158

~~AS 08.80.005 AS 08.80.157~~

Disapproved. JCJr 6/5/2014

The introductory language of 12 AAC 52.310(c) is amended to read:

(c) The board will reinstate a pharmacist license that has been expired [AT LEAST] two years or [BUT NOT] more [THAN FIVE YEARS] if the applicant

. . .

12 AAC 52.310(c)(6) is amended to read:

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements [; OR A COPY OF THE APPLICANT'S OFFICIAL APPLICATION FOR TRANSFER OF PHARMACEUTICS LICENSURE, SENT DIRECTLY TO THE DEPARTMENT FROM THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY NOT LATER THAN 90 DAYS OF THE DATE OF ISSUE].

12 AAC 52.310(d) is repealed:

(d) Repealed 8/1/2014

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 8/21/2002, Register 163; am

2/11/2004, Register 169; am 5/26/2006, Register 178; am 9/17/2011, Register 199; am 8/1/2014, Register 211)

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005 AS 08.80.147

Publisher: Existing 12 AAC 52.865(c) is unchanged.

12 AAC 52.865(c) is amended to read:

(c) No later than the fifth day of each month, a dispenser shall report to the board the controlled substance dispensing information required under AS 17.30.200(b) concerning controlled substances dispensed during the previous month. The requirement in 12 AAC 02.920(b) for time computation applies to a report made under this section ~~except for~~

~~(1) a controlled substance dispensed by an institutional facility provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of seventy-two hours; or~~

~~(2) a controlled substance dispensed by a practitioner provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of seventy-two hours~~.

Proposed amendment disapproved. KCJ 6/5/2014

(Eff. 12/29/2011, Register 200; ~~am __/__/____, Register ____~~)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

in this paragraph, "delivers" includes

12 AAC 52.995(a)(34) is amended to read:

(34) "dispenser" **means a practitioner who delivers a controlled substance to an ultimate user or research subject** ~~by, or pursuant to~~ (under) **the lawful order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery**

[(A) MEANS A

(i) PHARMACIST WHO, UNDER A LAWFUL ORDER OF A PRACTITIONER, DELIVERS A CONTROLLED SUBSTANCE TO AN ULTIMATE USER OR RESEARCH SUBJECT;

(ii) PRACTITIONER WHO, UNDER A LAWFUL ORDER OF THAT OR ANOTHER PRACTITIONER, DELIVERS A CONTROLLED SUBSTANCE TO AN ULTIMATE USER OR RESEARCH SUBJECT;

(B) INCLUDES A

(i) PRACTITIONER WHO PRESCRIBES A CONTROLLED SUBSTANCE; AND

(ii) PHARMACIST OR PRACTITIONER WHO ADMINISTERS A CONTROLLED SUBSTANCE OR PERFORMS PACKAGING, LABELING, OR COMPOUNDING NECESSARY TO PREPARE THE SUBSTANCE FOR DELIVERY];

(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)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157