

Mead Treadwell  
Lieutenant Governor  
State Capitol  
Juneau, Alaska 99811  
907.465.3520 465.5400 Fax  
WWW.LTGOV.ALASKA.GOV




530 West 7<sup>th</sup> Ave, Suite 1700  
Anchorage, Alaska 99501  
907.269.7460 269.0263  
LT.GOVERNOR@ALASKA.GOV

OFFICE OF THE LIEUTENANT GOVERNOR  
ALASKA

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

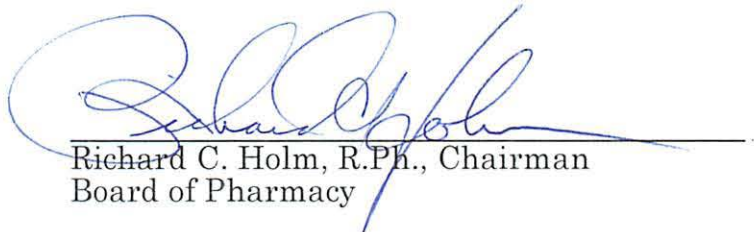
The attached five pages of regulations, dealing with facility license, review of applications for registration of pharmacies located outside of the state, inspections of pharmacies, reinstatement of an expired pharmacist or pharmacy technician license, requirement for dispensers, and definitions, are 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

# JU2013200469 (Part 1)

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

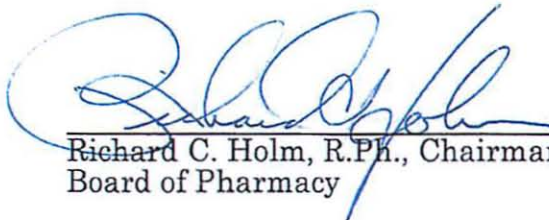
The attached five pages of regulations, dealing with facility license, review of applications for registration of pharmacies located outside of the state, inspections of pharmacies, reinstatement of an expired pharmacist or pharmacy technician license, requirement for dispensers, and definitions, are 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: 21, 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~~

XCD  
Disapproved. XCD, 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. XCD 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. XCD 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. NCR 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.  
XCT 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

12 AAC 52.865(c) is amended to read:

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

(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.  
XCH 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 <sup>under</sup> by, or pursuant to 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



**NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF  
THE BOARD OF PHARMACY**

**BRIEF DESCRIPTION**

The Board of Pharmacy proposes regulations to define certain facilities as high risk pharmacies, require physical inspections of pharmacies, update the requirements for reinstatement of an expired license, add regulations regarding persons who are authorized to access information in the controlled substance prescription database, update the definition of “dispenser”, and update the controlled substances reporting requirements for dispensers.

The Board of Pharmacy proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code, dealing with facility licensing, review of applications for registration of pharmacies, inspections of pharmacies, reinstatement of an expired license, conditions for access to controlled substance prescription database, requirement for dispensers, and definitions, including the following:

1. **12 AAC 52.020, Facility license**, is proposed to be changed to alter the requirements for facility license.
2. **12 AAC 52.130, Review of applications for registration of pharmacies located outside of the state**, is proposed to be changed to alter the requirements related to review of applications for registration of pharmacies located outside of the state.
3. **12 AAC 52.150, Inspections of pharmacies**, is a proposed new section that establishes requirements for physical inspection of a pharmacy facility, and the designation of certain facilities as “high risk pharmacies”.
4. **12 AAC 52.310, Reinstatement of an expired pharmacist or pharmacy technician license**, is proposed to be changed to alter the requirements for reinstatement of an expired pharmacist or pharmacy technician license.
5. **12 AAC 52.860, Conditions for access to and use of database**, is proposed to be changed to alter the provisions to allow for a designated individual to access or input the information in the controlled substance prescription database on behalf of the licensed practitioner or pharmacist.
6. **12 AAC 52.865, Requirement for dispensers**, is proposed to be changed to alter the controlled substance dispensing requirements.
7. **12 AAC 52.995, Definitions**, is proposed to be changed to further define terms used in AS 08.80 and 12 AAC 52.

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 by mail, fax, or e-mail to:

Jun Maiquis, Regulations Specialist  
Division of Corporations, Business and Professional Licensing  
Department of Commerce, Community, and Economic Development  
P.O. Box 110806  
Juneau, AK 99811-0806  
Fax: (907) 465-2974  
E-mail: [jun.maiquis@alaska.gov](mailto:jun.maiquis@alaska.gov)

**The written comments must be received no later than 4:30 p.m. on August 19, 2013.**

If you are a person with a disability who needs a special accommodation in order to participate in the process for written comments, please contact Jun Maiquis at (907) 465-2537 no later than August 12, 2013 to ensure that any necessary accommodations can be provided.

For a copy of the proposed regulation changes, contact Jun Maiquis at the address or phone number above, or go to <http://commerce.alaska.gov/dnn/portals/5/pub/pha-0613.pdf>

After the public comment period ends, the Board of Pharmacy will either adopt these or other provisions dealing with the same subject, without further notice, or decide to take no action on them. The language of the final regulations may be different from that of the proposed regulations. **YOU SHOULD COMMENT DURING THE TIME ALLOWED IF YOUR INTERESTS COULD BE AFFECTED.** Written comments received are public records and are subject to public inspection.

**Statutory Authority:** 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; AS 17.30.200

**Statutes Being Implemented, Interpreted, or Made Specific:** 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; AS 17.30.200

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

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, please send your request to the Division of Corporations, Business and Professional Licensing at the address above and include your name, address, and the occupational area in which you are interested.

DATE: 07/19/13

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

**ADDITIONAL REGULATIONS NOTICE INFORMATION**  
(AS 44.62.190(d))

1. **Adopting agency:** Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing – Board of Pharmacy.
2. **General subject of regulation:** Facility license, review of applications for registration of pharmacies located outside of the state, inspections of pharmacies, reinstatement of an expired license, conditions for access to and use of controlled substance prescription database, requirement for dispensers, and definitions.
3. **Citation of regulation:** 12 AAC 52.020, 12 AAC 52.130, 12 AAC 52.150, 12 AAC 52.310, 12 AAC 52.860, 12 AAC 52.865, and 12 AAC 52.995.
4. **Reason for the proposed action:** Update and clarification of current regulations, and compliance with state statute.
5. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.
6. **Cost of implementation to the state agency and available funding (in thousands of dollars):** No costs are expected in FY 2014 or in subsequent years.
7. **The name of the contact person for the regulations:**

Sher Zinn, Licensing Supervisor  
Division of Corporations, Business and Professional Licensing  
Department of Commerce, Community, and Economic Development  
(907) 465-3262  
sher.zinn@alaska.gov

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

9. **Date:** 07/19/13

**Prepared by:**   
Jun Maiquis, Regulations Specialist



# MEMORANDUM

## State of Alaska Department of Law

TO: Hon. Mead Treadwell  
Lieutenant Governor

DATE: June 5, 2014

FILE NO.: JU2013200469 (Part 1)

TELEPHONE NO.: 465-3600

FROM: Steven C. Weaver   
Sr. Assistant Attorney General  
and Assistant Regulations Attorney  
Legislation/Regulations Section--Juneau

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

We have reviewed the attached regulations from the Board of Pharmacy. I have reviewed this project under a specific delegation dated June 5, 2014 from the Regulations Attorney. A duplicate of this memorandum is being furnished to the board chair, Dirk T. White, R. Ph., along with a copy of the regulations.

The Department of Law has reviewed the attached regulations against the statutory standards of the Administrative Procedure Act. To facilitate the filing of those regulations that were ready the earliest, the Board of Pharmacy split this regulations project into two parts. Based upon our review, we find no legal problems with changes to 12 AAC 52.310 and 12 AAC 52.995(a). We have disapproved the other changes that the Board of Pharmacy proposed in Part 1 of this project. This memorandum and the attached duplicate memorandum dated June 5, 2014 constitute the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The regulation changes were adopted by the Board of Pharmacy after the close of the public comment period. The regulations update requirements for reinstatement of a lapsed pharmacist license, and make changes to the definition of "dispenser."

We have disapproved proposed 12 AAC 52.020(f), proposed 12 AAC 52.130(b)(5), and proposed 12 AAC 52.150. As a condition for an initial or renewed facility license under AS 08.80.157, these regulations proposed a mandatory physical inspection--by the Department of Commerce, Community, and Economic Development--of a pharmacy's production facility if the pharmacy were a "high risk" pharmacy or one "holding an active facility license issued by another state." *See* proposed 12 AAC 52.150(a) and (b). An out-of-state pharmacy that registers under AS 08.80.158--as required if the pharmacy regularly ships, mails, or delivers prescription drugs to consumers in the state--would also be subject to the new inspection requirement, though the state where the facility was located could perform the inspection. *See* proposed 12 AAC 52.150(f). The new inspection requirement would be more stringent than existing ones. Proposed

12 AAC 52.020(f) and proposed 12 AAC 52.130(b)(5) would make submission of a "physical inspection report" a required part of an applicant for a facility license or a registration, though 12 AAC 52.150 itself does not explicitly address reports resulting from physical inspections.

Proposed 12 AAC 52.150(h) would give the "high risk" designation to hospitals, sterile compounding facilities, home infusion facilities, and "any other facility considered high risk by the board." But the regulations do not identify the risk to be avoided, the point at which the risk is high, or why the inspection standards for high-risk pharmacies would in effect apply to all pharmacies licensed outside the state.

Furthermore, the proposed regulations do not clearly explain how the requirements would work in practice for a facility that has "an active facility license issued by another state" but that is licensed under AS 08.80.157 rather than registered under AS 08.80.158. The category proposed in 12 AAC 52.150(a) and (b) does not appear elsewhere in 12 AAC 52. If a facility had an active facility license issued by another state but was licensed under AS 08.80.157, a question would arise as to what sort of production facility would be subject to the requirement that the department do a physical inspection: a facility located outside this state, or only a facility located in this state.

In summary, the regulations proposed in 12 AAC 52.020(f), 12 AAC 52.130(b)(5), and 12 AAC 52.150 would impose a more stringent physical inspection requirement on pharmacies licensed in this state only if they were "high risk," but would impose the same requirement on pharmacies licensed outside this state regardless of risk, and would name certain classes of pharmacy as "high risk" without expressing the risk to be avoided. For these reasons, we have disapproved proposed 12 AAC 52.020(f), proposed 12 AAC 52.130(b)(5), and proposed 12 AAC 52.150.

We have also disapproved the Board of Pharmacy's proposed amendment to 12 AAC 52.865(c), in part because as formatted the proposed amendment sets up a likely error in syntax. The existing regulation is set up as two sentences: first, a requirement that a dispenser, no later than the fifth day of each month, report certain information for inclusion in the controlled substance prescription database established under AS 17.30.200; and second, a statement that the reporting requirement is subject to a regulatory requirement for time computation. The board's amendment is proposed for the second sentence, but does not make sense in context. Literally, the time computation requirement would apply except with respect to institutional facility-dispensed or practitioner-dispensed controlled substances if the quantity dispensed were only enough to treat the patient for a maximum of 72 hours. More likely, the board meant the proposed exception to apply to the first sentence, as an exception to the reporting requirement altogether.

If we assume that the proposed exception is to apply to the reporting requirement as a whole, an issue arises whether the proposed exception is consistent with existing statutory authority. Alaska Statute 17.30.200 requires that a pharmacist-in-charge or practitioner submit to the board certain information for inclusion in the board-maintained controlled substance prescription database, and requires the information submission for each controlled substance dispensed. The submission requirements are structured to apply to each prescription, and the

only exception to those requirements is also set out in statute: controlled substances "administered to a patient at a health care facility." AS 17.30.200(a) and (b). But the proposed amendment would carve out an additional exception for institutional facility-dispensed or practitioner-dispensed controlled substances if the quantity dispensed were only enough to treat the patient for a maximum of 72 hours. The statute does not explicitly authorize additional exemptions. Because a statutory amendment would be necessary in order for the board to adopt additional exceptions to the information submission requirements, we have disapproved the proposed amendment to 12 AAC 52.865(c).

The certification order for the regulations states 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 a few technical corrections to conform the regulations with the drafting manual under AS 44.62.060 and 44.62.125. The corrections are shown on the attached copy of the regulations.

SCW

cc w/enc: Dirk T. White, R.Ph., Chair  
Board of Pharmacy



# MEMORANDUM

## State of Alaska Department of Law

TO: Dirk T. White, R.Ph., Chair  
Board of Pharmacy

DATE: June 5, 2014

FILE NO.: JU2013200469 (Part 1)

TELEPHONE NO.: 465-3600

FROM: Steven C. Weaver   
Sr. Assistant Attorney General  
and Assistant Regulations Attorney  
Legislation/Regulations Section--Juneau

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

Under AS 44.62.060, we have reviewed the attached regulations changes by the Board of Pharmacy. We approve the changes to 12 AAC 52.310 and 12 AAC 52.995(a), with our corrections, for filing by the lieutenant governor. We have disapproved the other changes that the Board of Pharmacy proposed in Part 1 of this project. I have reviewed this project under a specific delegation dated June 5, 2014 from the Regulations Attorney. A duplicate original of this memorandum is being furnished to the lieutenant governor, along with the five pages of regulations and the related documents.

To facilitate the filing of those regulations that were ready the earliest, the Board of Pharmacy split this regulations project into two parts. You might wish to contact the lieutenant governor's office to confirm the filing date and effective date of the attached regulation changes.

We have disapproved proposed 12 AAC 52.020(f), proposed 12 AAC 52.130(b)(5), and proposed 12 AAC 52.150. As a condition for an initial or renewed facility license under AS 08.80.157, these regulations proposed a mandatory physical inspection--by the Department of Commerce, Community, and Economic Development--of a pharmacy's production facility if the pharmacy were a "high risk" pharmacy or one "holding an active facility license issued by another state." *See* proposed 12 AAC 52.150(a) and (b). An out-of-state pharmacy that registers under AS 08.80.158--as required if the pharmacy regularly ships, mails, or delivers prescription drugs to consumers in the state--would also be subject to the new inspection requirement, though the state where the facility was located could perform the inspection. *See* proposed 12 AAC 52.150(f). The new inspection requirement would be more stringent than existing ones. Proposed 12 AAC 52.020(f) and proposed 12 AAC 52.130(b)(5) would make submission of a "physical inspection report" a required part of an applicant for a facility license or a registration, though 12 AAC 52.150 itself does not explicitly address reports resulting from physical inspections.

Proposed 12 AAC 52.150(h) would give the "high risk" designation to hospitals, sterile compounding facilities, home infusion facilities, and "any other facility considered high risk by

the board." But the regulations do not identify the risk to be avoided, the point at which the risk is high, or why the inspection standards for high-risk pharmacies would in effect apply to all pharmacies licensed outside the state.

Furthermore, the proposed regulations do not clearly explain how the requirements would work in practice for a facility that has "an active facility license issued by another state" but that is licensed under AS 08.80.157 rather than registered under AS 08.80.158. The category proposed in 12 AAC 52.150(a) and (b) does not appear elsewhere in 12 AAC 52. If a facility had an active facility license issued by another state but was licensed under AS 08.80.157, a question would arise as to what sort of production facility would be subject to the requirement that the department do a physical inspection: a facility located outside this state, or only a facility located in this state.

In summary, the regulations proposed in 12 AAC 52.020(f), 12 AAC 52.130(b)(5), and 12 AAC 52.150 would impose a more stringent physical inspection requirement on pharmacies licensed in this state only if they were "high risk," but would impose the same requirement on pharmacies licensed outside this state regardless of risk, and would name certain classes of pharmacy as "high risk" without expressing the risk to be avoided. For these reasons, we have disapproved proposed 12 AAC 52.020(f), proposed 12 AAC 52.130(b)(5), and proposed 12 AAC 52.150.

We have also disapproved the Board of Pharmacy's proposed amendment to 12 AAC 52.865(c), in part because as formatted the proposed amendment sets up a likely error in syntax. The existing regulation is set up as two sentences: first, a requirement that a dispenser, no later than the fifth day of each month, report certain information for inclusion in the controlled substance prescription database established under AS 17.30.200; and second, a statement that the reporting requirement is subject to a regulatory requirement for time computation. The board's amendment is proposed for the second sentence, but does not make sense in context. Literally, the time computation requirement would apply except with respect to institutional facility-dispensed or practitioner-dispensed controlled substances if the quantity dispensed were only enough to treat the patient for a maximum of 72 hours. More likely, the board meant the proposed exception to apply to the first sentence, as an exception to the reporting requirement altogether.

If we assume that the proposed exception is to apply to the reporting requirement as a whole, an issue arises whether the proposed exception is consistent with existing statutory authority. Alaska Statute 17.30.200 requires that a pharmacist-in-charge or practitioner submit to the board certain information for inclusion in the board-maintained controlled substance prescription database, and requires the information submission for each controlled substance dispensed. The submission requirements are structured to apply to each prescription, and the only exception to those requirements is also set out in statute: controlled substances "administered to a patient at a health care facility." AS 17.30.200(a) and (b). But the proposed amendment would carve out an additional exception for institutional facility-dispensed or practitioner-dispensed controlled substances if the quantity dispensed were only enough to treat the patient for a maximum of 72 hours. The statute does not explicitly authorize additional

exemptions. Because a statutory amendment would be necessary in order for the board to adopt additional exceptions to the information submission requirements, we have disapproved the proposed amendment to 12 AAC 52.865(c).

If you have additional questions about those proposed regulations that are disapproved, please consult the assistant attorneys general that directly advise the professional licensing staff of the Department of Commerce, Community, and Economic Development.

The July 20, 2013 public notice and the November 21, 2013 certification order 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.

In accordance with AS 44.62.125(b)(6), some corrections have been made in the regulations, as shown on the attached copy.

SCW

cc w/enc:           Micaela Fowler, Regulations Contact  
                          Department of Commerce, Community, & Economic Development

                          Sara Chambers, Director  
                          Division of Corporations, Business, & Professional Licensing  
                          Department of Commerce, Community, & Economic Development

                          Donna M. Bellino, Licensing Examiner  
                          Division of Corporations, Business, & Professional Licensing  
                          Department of Commerce, Community, & Economic Development

                          Jun Maiquis, Regulations Specialist  
                          Division of Corporations, Business, & Professional Licensing  
                          Department of Commerce, Community, & Economic Development

                          Todd J. Araujo  
                          Assistant Attorney General  
                          Commercial & Fair Business Section--Juneau



# MEMORANDUM

## State of Alaska Department of Law

TO: Hon. Mead Treadwell  
Lieutenant Governor

DATE: June 5, 2014

FILE NO.: JU2013200469 (Part 1)

TELEPHONE NO.: 465-3600

FROM: Susan R. Pollard *SRP*  
Chief Assistant Attorney General  
& Regulations Attorney  
Legislation/Regulations Section—Juneau

SUBJECT: Specific delegation of authority  
regarding regulations review on  
Board of Pharmacy regulations  
re: reinstatement of a pharmacist  
license and definition of  
"dispenser" (12 AAC 52.310;  
12 AAC 52.995(a))

By this memorandum, I am delegating my authority as Regulations Attorney under AS 44.62 to Assistant Attorney General Steven C. Weaver for the above-referenced regulations project. Under this delegation of authority, Steven Weaver has my full authority under AS 44.62 to conduct the legal review under AS 44.62 and take necessary actions on this regulations project.

If you have questions, please let me know.

SCW

cc w/enc: Scott C. Meriwether, AAC Coordinator  
Office of the Lieutenant Governor  
  
Steven C. Weaver  
Assistant Attorney General  
Legislation/Regulations Section—Juneau

**STATE OF ALASKA**

## FIRST JUDICIAL DISTRICT

**SS.**

## AFFIDAVIT OF BOARD ACTION

I, Donna Burns, Licensing Examiner for the Board of Pharmacy, being duly sworn, state the following:

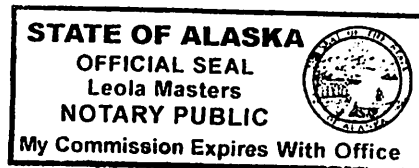
The attached motion dealing with facility licensing, review of applications for registration of pharmacies, inspections of pharmacies, reinstatement of an expired license, conditions for access to controlled substance prescription database, requirement for dispensers, and definitions was passed by the Board of Pharmacy during its August 22-23, 2013 meeting.

Date: Oct. 7, 2013  
Juneau, Alaska

Donna Burns  
Donna Burns, Licensing Examiner

SUBSCRIBED AND SWORN TO before me this 1 day of October, 2013.

Reola Masters  
Notary Public in and for the  
State of Alaska  
My commission expires: w/office



The board will review the Arizona Board of Pharmacy information that Mr. Cotter will be forwarding to the board. The information from the Arizona Board of Pharmacy is a good example on how Arizona has been successful with this issue.

The board and Mr. Howes agreed to start sending the letter out in September through the end of the year, and at the February 2014 Board of Pharmacy meeting the board will review how the response has been.

This time frame will allow for enough data to be received, and will assist in the development of what the criteria will be for discipline.

**Agenda Item 7- Proposed changes in the Regulations of The Board Of Pharmacy Continued -**

After consideration of public comment and cost to private persons, the Board of Pharmacy voted to adopt the regulation project:

**On a motion duly made by John Cotter, seconded by C.J. Kim, and approved unanimously, it was**

**RESOLVED to approve the following regulations changes as written:**

**12 AAC 52.020 Facility license**

**12 AAC 52.130 Review of applications for registration of pharmacies located outside the state**

**12 AAC 52.150 Inspections of pharmacies**

**12 AAC 52.310 Reinstatement of an expired pharmacist or pharmacy technician license**

**12 AAC 52.865 Requirement for dispensers**

**12 AAC 52.995 Definitions**

**12 AAC .860 Conditions for access and use of database – Approved pending further legal review.**

The board recessed for an early lunch -

Off the record at 11:35 p.m.

On the record at 1:02 p.m.

**Agenda item 8 - Pharmaceutical Compounding Quality and Accountability Act**



STATE OF ALASKA }  
FIRST JUDICIAL DISTRICT } ss.

**AFFIDAVIT OF NOTICE OF PROPOSED ADOPTION OF REGULATIONS  
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 52.020, 12 AAC 52.130, 12 AAC 52.150, 12 AAC 52.310, 12 AAC 52.860, 12 AAC 52.865, and 12 AAC 52.995, 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, conditions for access to and use of database, requirement for dispensers, and definitions, has been given by being:

1. published in a newspaper or trade publication;
2. furnished to interested persons;
3. furnished to appropriate state officials;
4. furnished to the Department of Law, along with a copy of the proposed regulations;
5. electronically transmitted to incumbent State of Alaska legislators;
6. furnished to the Legislative Affairs Agency, Legislative Legal and Research Services;
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);
8. furnished electronically, along with a copy of the proposed regulations, to the Legislative Affairs Agency, the chair of the Labor and Commerce Committee of the Alaska Senate and House of Representatives, the Administrative Regulation Review Committee, and the legislative council.

As required by AS 44.62.190(d), additional regulations notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (5) and (6) of the list above. The additional regulations notice information also has been posted on the Alaska Online Public Notice System.

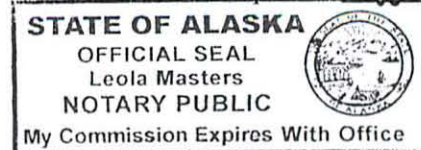
DATE: 10/14/13  
Juneau, Alaska

  
Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 14<sup>th</sup> day of Oct, 2013.

  
Notary Public in and for the  
State of Alaska

My commission expires: with office





DEPT0030  
#220968  
\$547.80

# AFFIDAVIT OF PUBLICATION

STATE OF ALASKA  
THIRD JUDICIAL DISTRICT

Joleesa Stepetin  
being first duly sworn on oath  
deposes and says that he 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

July 20, 2013

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.<sup>1</sup>

Signed

Subscribed and sworn to before

me this 14 day of OCT

20

Notary Public in and for  
The State of Alaska  
Third Division  
Anchorage, Alaska  
MY COMMISSION EXPIRES



## NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF THE BOARD OF PHARMACY

### BRIEF DESCRIPTION

The Board of Pharmacy proposes regulations to define certain facilities as high risk pharmacies, require physical inspections of pharmacies, update the requirements for reinstatement of an expired license, add regulations regarding persons who are authorized to access information in the controlled substance prescription database, update the definition of "dispenser", and update the controlled substances reporting requirements for dispensers.

The Board of Pharmacy proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code, dealing with facility licensing, review of applications for registration of pharmacies, inspections of pharmacies, reinstatement of an expired license, conditions for access to controlled substance prescription database, requirement for dispensers, and definitions, including the following:

1. **12 AAC 52.020, Facility license**, is proposed to be changed to alter the requirements for facility license.
2. **12 AAC 52.130, Review of applications for registration of pharmacies located outside of the state**, is proposed to be changed to alter the requirements related to review of applications for registration of pharmacies located outside of the state.
3. **12 AAC 52.150, Inspections of pharmacies**, is a proposed new section that establishes requirements for physical inspection of a pharmacy facility, and the designation of certain facilities as "high risk pharmacies".
4. **12 AAC 52.310, Reinstatement of an expired pharmacist or pharmacy technician license**, is proposed to be changed to alter the requirements for reinstatement of an expired pharmacist or pharmacy technician license.
5. **12 AAC 52.860, Conditions for access to and use of database**, is proposed to be changed to alter the provisions to allow for a designated individual to access or input the information in the controlled substance prescription database on behalf of the licensed practitioner or pharmacist.
6. **12 AAC 52.865, Requirement for dispensers**, is proposed to be changed to alter the controlled substance dispensing requirements.
7. **12 AAC 52.995, Definitions**, is proposed to be changed to further define terms used in AS 08.80 and 12 AAC 52.

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 by mail, fax, or e-mail to:

Jun Maiquis, Regulations Specialist  
Division of Corporations, Business and Professional Licensing  
Department of Commerce, Community, and Economic Development  
P.O. Box 110806  
Juneau, AK 99811-0806  
Fax: (907) 465-2974  
E-mail: jun.maiquis@alaska.gov

**The written comments must be received no later than 4:30 p.m. on August 19, 2013.**

If you are a person with a disability who needs a special accommodation in order to participate in the process for written comments, please contact Jun Maiquis at (907) 465-2537 no later than August 12, 2013 to ensure that any necessary accommodations can be provided.

For a copy of the proposed regulation changes, contact Jun Maiquis at the address or phone number above, or go to <http://commerce.alaska.gov/dnn/portals/5/pub/pha-0613.pdf>

After the public comment period ends, the Board of Pharmacy will either adopt these or other provisions dealing with the same subject, without further notice, or decide to take no action on them. The language of the final regulations may be different from that of the proposed regulations. **YOU SHOULD COMMENT DURING THE TIME ALLOWED IF YOUR INTERESTS COULD BE AFFECTED.** Written comments received are public records and are subject to public inspection.

**Statutory Authority:** 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; AS 17.30.200

**Statutes Being Implemented, Interpreted, or Made Specific:** 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; AS 17.30.200

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

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, please send your request to the Division of Corporations, Business and Professional Licensing at the address above and include your name, address, and the occupational area in which you are interested.

DATE: 07/19/13

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