

# (Public Board Packet)

## November - Alaska Board of Pharmacy Meeting - Day 2

Nov 15, 2019 9:00 AM - Nov 15, 2019 4:30 PM AKST

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**STATE OF ALASKA**

**Department of Commerce, Community, and Economic Development  
Professional Licensing**

# **ALASKA BOARD OF PHARMACY**



November 15, 2019

Teleconference/Videoconference

Robert Atwood Building Suite 1550 (Anchorage)  
State Office Building, 9<sup>th</sup> Floor, Conf. Room A (Juneau)

**Board Packet**

# 2019 STATE HOLIDAY CALENDAR

## JANUARY

S	M	T	W	R	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

## FEBRUARY

S	M	T	W	R	F	S
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3	4	5	6	7	8	9
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17	18	19	20	21	22	23
24	25	26	27	28		

## MARCH

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24	25	26	27	28	29	30
31						

## APRIL

S	M	T	W	R	F	S
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14	15	16	17	18	19	20
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28	29	30				

## MAY

S	M	T	W	R	F	S
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12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

## JUNE

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30						

## JULY

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28	29	30	31			

## AUGUST

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11	12	13	14	15	16	17
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25	26	27	28	29	30	31

## SEPTEMBER

S	M	T	W	R	F	S
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15	16	17	18	19	20	21
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29	30					

## OCTOBER

S	M	T	W	R	F	S
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20	21	22	23	24	25	26
27	28	29	30	31		

## NOVEMBER

S	M	T	W	R	F	S
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17	18	19	20	21	22	23
24	25	26	27	28	29	30

## DECEMBER

S	M	T	W	R	F	S
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8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

### State Holidays

Date	Holiday
01/01	New Year's Day
01/21	MLK Jr.'s Birthday
02/18	Presidents' Day
03/25	Seward's Day
05/27	Memorial Day
07/04	Independence Day

 Holiday

State calendar maintained by the Division of Finance, Department of Administration  
<http://doa.alaska.gov/calendars.html>

Biweekly employees please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

### State Holidays

Date	Holiday
09/02	Labor Day
10/18	Alaska Day
11/11	Veterans' Day
11/28	Thanksgiving Day
12/25	Christmas Day

Board or Commission: \_\_\_\_\_

Meeting Date: \_\_\_\_\_

Agenda Item # \_\_\_\_\_

Tab # \_\_\_\_\_

Topic: \_\_\_\_\_

### Primary Motion

**Motion:**

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

### Subsidiary Motion or Amendment

**Motion:**

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

## EXECUTIVE SESSION MOTION

### **Sec. 44.62.310. Government meetings public.**

(c) The following subject may be considered in an executive session:

- (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
- (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
- (3) matters which by law, municipal charter, or ordinance are required to be confidential;
- (4) matters involving consideration of government records that by law are not subject to public disclosure.

### **MOTION WORDING:**

**“In accordance with the provisions of Alaska Statute 44.62.310 (c), I move to go into executive session for the purpose of discussing (select the appropriate statutory citation for the situation):**

- (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity; *OR***
- (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion; *OR***
- (3) matters which by law, municipal charter, or ordinance are required to be confidential; *OR***
- (4) matters involving consideration of government records that by law are not subject to public disclosure.**

**Board staff is requested to remain during the session *OR*  
Board only to remain during session.”**

Staff will then state **“The board is off the record at \_\_\_\_\_(time).”**

## Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Richard Holt, PharmD, MBA (Chair)	03/01/2016		03/01/2020
Leif Holm, PharmD	03/01/2015	03/01/2019	03/01/2023
Lana Bell, RPh (Secretary)	05/31/2016	03/01/2018	03/01/2022
Phil Sanders, RPh (Vice Chair)	03/01/2016		03/01/2020
James Henderson, RPh	03/01/2017		03/01/2021
Tammy Lindemuth, Public Member	01/24/2018		03/01/2021
Sharon Long, Public Member	03/01/2018		03/01/2022



# ALASKA BOARD OF PHARMACY MEETING TENTATIVE AGENDA

## NOVEMBER 15, 2019 (DAY 2)

Teleconference: 1-800-315-6338  
Access Code: 52550

### Board Members:

Richard Holt,  
*PharmD, MBA*  
(Chair)

Leif Holm, *PharmD*

James Henderson,  
*RPh (Vice Chair)*

Lana Bell, *RPh*  
(Secretary)

Phil Sanders, *RPh*

Tammy Lindemuth,  
*Public Member*

Sharon Long, *Public*  
*Member*

### Upcoming Meetings:

TBD

Alternative dial-in:  
1-408-638-0968

Meeting ID:  
975 839 590

### Meeting Details

Meeting Name: June - Alaska Board of Pharmacy Meeting - Day 2

Meeting Start Time: 9:00 AM Alaskan Daylight Time

Meeting Start Date: 11/15/2019

Meeting End Time: 4:30 PM Alaskan Daylight Time

Meeting End Date: 11/15/2019

Meeting Location: Robert Atwood Building, 550 W 7th Ave, Suite 1550

### Agenda

- I. Agenda Item #1 - 9:00 a.m. Roll Call/Call to Order
- II. Agenda Item #2 - 9:05 a.m. Review/Approve Agenda
- III. Agenda Item #3 - 9:10 a.m. Implemented Regulations
  - A. Review New Regulations eff. 10/31/19
  - B. New License Type FAQs
  - C. Application Updates (Quick Stats)
    1. Third Party Logistics Provider
    2. Non-Resident Wholesale Drug Distributor
    3. Outsourcing Facilities
- IV. Agenda Item #4 - 9:15 a.m. Division Update
  - A. Right-Touch Regulations (deputy director, Sharon Walsh)

**Board Members:**

Richard Holt,  
*PharmD, MBA*  
(Chair)

Leif Holm, *PharmD*

James Henderson,  
*RPh (Vice Chair)*

Lana Bell, *RPh*  
(Secretary)

Phil Sanders, *RPh*

Tammy Lindemuth,  
*Public Member*

Sharon Long, *Public*  
*Member*

**Upcoming  
Meetings:**

TBD

B. Budget Report (administrative officer, Melissa Dumas)

1. Q3
2. Q4
3. Q3 (PDMP)
4. Q4 (PDMP)

V. Agenda Item #5 - 10:30 a.m. Review Public Comments

VI. Agenda Item #6 10:40 a.m. Public Comment

VII. Agenda Item #7 – 11:00 a.m. Regulation Projects

- A. Review/Discuss Outdated Regulations
- B. Review/Discuss Tabled Regulations
  1. Nationally Certified Pharmacy Technicians
- C. Review/Discuss New Regulations
  1. Ownership Changes
  2. Mileage Restrictions for Remote Pharmacies
  3. Opioid Overdose Training
  4. Zero Reporting to PDMP

**LUNCH – 12:30 p.m. – 1:30 p.m.**

VIII. Agenda Item #8 – 1:30 p.m. Return to Right-Touch Regulations

IX. Agenda Item #9 - 2:30 p.m. SansWrite Presentation (Matthew Milthaler)

X. Agenda Item #10 - 3:00 p.m. Board Business

- A. Review New Applications
- B. Review Tabled Applications (3:30 p.m.; may enter executive session)
- C. Review Lost/Stolen Rx
- D. Correspondence
- E. Board Dispensing Guidance
- F. USP Changes (Leif Holm)

XI. Agenda Item #11 - 4:15 p.m. CSAC Update (Tammy Lindemuth)

XII. Agenda Item #12 - 4:25 p.m. Administrative Business

- A. Task List
- B. Upcoming Travel

XIII. Agenda #13 - 4:30 p.m. Adjourn

Kevin Meyer  
Lieutenant Governor  
State Capitol  
Juneau, Alaska 99811  
907.465.3520  
WWW.LTGOV.ALASKA.GOV



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

**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

A handwritten signature in blue ink, appearing to be "AS", is written over the "FROM:" line.

**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)

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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.

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

*«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.»*

(7) third-party logistics providers license;

(8) outsourcing facility facilities 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)

<b>Authority:</b>	AS 08.80.005	AS 08.80.150	AS 08.80.158
	AS 08.80.030	AS 08.80.155	<b><u>AS 08.80.159</u></b>
	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:

~~2(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)

<b>Authority:</b>	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

Register 232, January 2019 PROFESSIONAL REGULATIONS

TO AN] applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements on the checklist <sup>set out in</sup> (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements <sup>of this section</sup> on the checklist 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, the requirements set out in (b) of this section, TO AN] applicant who meets the requirements of AS 08.80.145 and the requirements <sup>set out in</sup> on the checklist <sup>of this section</sup> 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 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 3~~ 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~~

*DC Johnson  
SPP 9/6/14*

~~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~~

*Withdrawn  
BRP 9/4/19*

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

**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 the individual's 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

*11 Publisher: To reflect the addition of 12 AAC 52.240(b)(9) and (10), please delete the "and" connector at the end of 12 AAC 52.240(b)(7).))*

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~~<sup>3</sup> 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~~ <sup>C.F.R.</sup> §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

each partial fill

(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 <sup>Term</sup>~~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~~ <sup>the United States Food and Drug Administration</sup>
- (3) ~~it is~~ segregated from the normal pharmacy inventory and may not be dispensed. <sup>if the drug is</sup>

(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 <sup>who</sup> ~~who~~ <sup>must</sup> meets the requirements ~~on the checklist~~ <sup>g</sup> set out in (b) of this section <sup>to</sup> ~~has~~ demonstrated the necessary qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements ~~on the checklist~~ <sup>of this section</sup> 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.~~ <sup>The board will issue</sup> ~~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 after ~~of~~ 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

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license under AS 08. (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~~ <sup>must</sup> meets the requirements ~~on~~ the ~~checklist~~ <sup>to</sup> set out in (b) of this section ~~has~~ <sup>to</sup> demonstrated the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements ~~on the checklist~~ <sup>of (b) of this section</sup> 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,~~ <sup>The board will issue</sup> 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 United States Food and Drug Administration (FDA).

(c) Within 10 days after 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 must ~~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 must ~~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 <sup>personnel</sup> 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 <sup>as an outsourcing facility</sup> shall be registered with the Food and Drug Administration <sup>United States</sup> as <sup>under</sup>

<sup>Sec.</sup> a 503b outsourcing facility. (Eff. 10 / 31 / 2019, Register 232)  
<sup>↑</sup>, P.L. 113-54 (Drug Supply Chain Security Act)

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 <sup>who</sup> <sup>must</sup> meets the requirements <sup>on the checklist</sup> set out in (b) of this section <sup>has</sup> 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) <sup>board will issue</sup> 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 <sup>after</sup> ~~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 a third-party logistics provider that has changed its name or physical address <sup>must</sup> ~~shall~~ 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 <sup>must</sup> ~~shall~~ 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 <sup>must</sup> ~~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 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 <sup>must</sup> ~~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. (Eff. 10 / 31 / 2019, Register 232)

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

*Disapproved  
SPP 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  
SPP 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 <sup>disaster</sup> 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 <sup>disaster</sup> 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 <sup>disaster</sup> 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' <sup>(1)</sup> 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 <sup>disaster</sup> state of emergency continues for more than 2 <sup>1</sup> 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 <sup>must</sup> ~~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

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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



November 5, 2019

## **OUTSOURCING FACILITIES, THIRD-PARTY LOGISTICS PROVIDERS, & NON-RESIDENT WHOLESALE DRUG DISTRIBUTORS**

### **FREQUENTLY ASKED QUESTIONS**

- 1. I am already registered in Alaska as an out-of-state pharmacy. Do I need to maintain my non-resident pharmacy registration in addition to obtaining an outsourcing facility, third-party logistics (3PL), or non-resident wholesale drug distributor license?** No, you do not need to maintain separate credentials if the lines of services remain the same, but please indicate the Alaska registration number in Part I of the application as the existing license number. Once the new application is processed, your old registration will expire. If you provided different lines of business, e.g.: are a 3PL and a non-resident wholesale drug distributor, separate applications are required for each.
- 2. Is there a grace period to register with any of these new license types?** The authority to regulate these new license types went into effect on July 1, 2019; however, applications were not made available until October 25, 2019, and regulations did not go into effect until October 31, 2019. The board has not issued an official grace period, but applications should be submitted as soon as possible as they are processed in the order received. Entities will not be penalized for not having an application submitted or license issued by October 31<sup>st</sup>.
- 3. What is the business license versus the professional license?** The professional license is the outsourcing facility, third-party logistics provider, or non-resident wholesale drug distributor license, which must be obtained first by the Board of Pharmacy before the business licensing section can issue a business license. After the professional license is issued, please contact the business licensing section (link below).
- 4. What is the processing time for these new license applications?** Please expect 4 – 10 weeks.
- 5. My payment was processed. Why hasn't my license been issued yet?** Our standard mail processing requires payment to be receipted before licensing staff has access to the accompanying application. It typically takes 3-7 days from the date payment and mail is initially processed to the date licensing staff has access to the documents in their electronic inbox.
- 6. How will I be notified of the status of my application?** As indicated above, licensing staff may not have access to your application for up to 7 days from the date it was received and your payment was processed. Licensing staff process applications in the order received and will send an email (if provided) to the applicant informing them of the status within 10 – 14 business days. Subsequent updates will be given as time permits.
- 7. What is the license approval process?** The board reviews applications only if there are circumstances requiring further review and discussion, such as affirmative responses to the professional fitness section of the application, which deals with adverse license actions and criminal history. The board reviews applications through their online review and voting platform, OnBoard, on a monthly basis beginning the second-to-last Friday of each month for a period of 10 – 15 days. Applications will only be uploaded for board review if they are complete. If the license is approved, it may be issued within 14 days. Applications that don't require board review may be issued administratively.



- 8. How can I check the status of my license?** Our professional license search page displays licenses that have already been issued (link below).
- 9. Am I only able to request fingerprint cards through myAlaska?** No, you can also use the standard FBI fingerprint form #FD-258 revised 09/09/2013.
- 10. How long will it take to get my fingerprint results?** Once your fingerprint cards are submitted to the department, they will be sent to the Alaska Department of Public Safety (DPS). The processing time for DPS will be 3 - 4 months.
- 11. Will the time it takes DPS to process fingerprints delay issuance of my license?** No, if a complete application is on file, the license can be issued. If the results reveal information inconsistent with what was indicated on the professional fitness section of the application, the application will be reviewed by the division's investigative unit.
- 12. Is a virtual wholesale drug distributor considered a non-resident wholesale drug distributor?** The short answer is yes, virtual wholesalers must now pursue license by the board as a wholesale drug distributor. The board acknowledges that virtual wholesalers are largely defined as entities which purchase drugs and devices from manufacturers, but do not own the new drug application (NDA) or an abbreviated new drug application (ANDA). Virtual wholesalers facilitates or brokers the transfer of drugs, devices, or cosmetics without taking ownership of these products. While the board does not currently or explicitly define *virtual* wholesalers or address ownership of NDAs or ANDAs, they do define "wholesale drug distributor" under AS 08.80.480(4) as:

"anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions."

Furthermore, 12 AAC 52.620 indicates that a wholesale drug distributor facility includes entities, "...in which, drugs are stored, repacked, or sold to persons, business, or government agencies that may legally purchase drugs." As long as the virtual wholesaler is engaged in manufacturing, repackaging, distributing, warehousing, storing, selling, or purchasing drugs, a wholesale drug distributor license is required.

- 13. Is a virtual manufacturer considered a non-resident wholesale drug distributor?** Yes, AS 08.80.480(4) includes manufacturers. The board acknowledges that virtual manufacturers own a new drug application (NDA) or abbreviated new drug application (ANDA), but do not take possession or store the drug or device. The board further acknowledges virtual manufacturers operate as entities in which act as a broker, own-label distributor, private-label manufacturer, or contract manufacturer, and contracts with other entities for the actual manufacturing of drugs or devices. By virtue of definition in AS 08.80.480(4), virtual manufacturers would be required to pursue licensure by the board.
- 14. Would a virtual manufacturer or virtual wholesaler need to designate their intention to distribute controlled substances on the wholesale drug distributor application?** There is no requirement that manufacturers or wholesale drug distributors designate their *intent* to distribute controlled substances; however, non-resident wholesale drug distributors must be registered with the DEA if distributing controlled substances and must indicate this on the Alaska license application (form #08-4812).



- 15. Is it required to have a license if we *distribute* medical devices only, without drug components? If so, what type of license should we apply for?** The board requires a wholesale drug distributor license to distribute medical devices under (AS) 08.80.030(b)(9) and AS 08.80.157(a). Although it isn't specified under AS 08.80 whether it is required to have a license to distribute prescription devices with or without drug components, an instrument, apparatus, machine, etc. is in-part defined as a "device" so long as it is required to have on the label, "Caution: Federal or state law requires dispensing by or on the order of a physician." If the device isn't required to have this indicated on the label, the board doesn't consider it a device under the definitions section of AS 08.80.480. Similarly, (9) of that section states that distribution is the delivery of a drug or device, but doesn't specify whether it is considered distributing if the device has a drug component or not.
- 16. Is it required to be licensed if assembling, packaging, or labeling a device?** No, an outsourcing facility license is not required as AS 08.80.480(20) relating to compounding only applies to sterile drugs, not devices.
- 17. We are an outsourcing facility intending on compounding patient-specific prescriptions. Is this permissible in Alaska?** Outsourcing facilities compounding patient-specific medications are 503A facilities. The board addresses compounding of medications based on a historical basis of valid prescription drug orders (within a doctor-patient-pharmacist relationship) in their *Good Compounding Practices* published in February 2008, which are appended to their statutes and regulations (link below). In this guidance, the board states that compounding drugs in an amount above what has historically been produced for the patient is considered manufacturing. Manufacturing is included in the definition of wholesale distribution under AS 08.80.480(40) and would require the entity to pursue licensure accordingly.
- 18. We are an entity that will engage in the compounding non-patient-specific medications. What type of application do we submit?** You must submit an outsourcing facility (form #08-4813) for non-patient-specific compounding. Outsourcing facilities are considered 503B facilities and are defined in AS 08.80.480(20) as, "a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location."
- 19. Can a third-party logistics provider own the drug or device product?** No, AS 08.80.480(38) indicates 3PLs cannot take ownership of the product and do not have the responsibility to direct the sale or disposition of the product.
- 20. Are there online applications available?** Not at this time. The only method to apply is by downloading the PDF version.
- 21. We are not VAWD accredited. Where can I find the Board of Pharmacy's self-inspection report for non-resident wholesale drug distributors?** The non-resident wholesale drug distributor inspection report is not available, but entities can submit the in-state inspection report (link below).

#### **Important Links**

Business Licensing: <https://www.commerce.alaska.gov/web/cbpl/BusinessLicensing/NewBLOnline.aspx>

Statutes and Regulations - <https://www.commerce.alaska.gov/web/portals/5/pub/PharmacyStatutes.pdf>

Pharmacy Homepage: <https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx>

Pharmacy ListServ: <http://list.state.ak.us/mailman/listinfo/akboardofpharmacy>

Self-Inspection Report: <https://www.commerce.alaska.gov/web/portals/5/pub/pha0098.pdf>.

myAlaska: <https://my.alaska.gov/>

Professional license search: <https://www.commerce.alaska.gov/cbp/main/>



**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

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## Instructions for Non-Resident Wholesale Distributor License Application

A wholesale drug distributor means anyone engaged in wholesale distribution of drugs, including but not limited to manufacturers; repackages; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions. A professional license must be obtained in order to engage in these services. Prior to engaging in services, a business license will be required.

### APPLICATION FOR PROFESSIONAL LICENSE REQUIREMENTS

**1. APPLICATION**

Complete, signed and notarized application form 08-4812;

**2. OWNER, DIRECTOR & STOCKHOLDER INFORMATION**

Names and resumes of all owners, directors, or primary stockholders responsible for facility;

**3. FACILITY MANAGER INFORMATION**

Name and resume of the facility manager;

**4. SELF-INSPECTION REPORT**

Completed self-inspection report on form #08-0098 **OR** a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

**5. FINGERPRINT CARD**

Complete fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety (additional instructions are included in this application packet. Login to myLicense through myAlaska to request fingerprint cards. If you don't have a myAlaska account, you must create one first. Please note when you receive your blank fingerprint cards, the client number to indicate is 1344;

**6. PROOF OF LICENSE, PERMIT, OR REGISTRATION**

Copy of a current valid facility license, permit, or registration to conduct operations in the jurisdiction in which it is located;

**7. DISTRIBUTION OF CONTROLLED SUBSTANCES**

If distributing controlled substances, an affirmative response to the Drug Enforcement Administration (DEA) section under Part IV of this application;

**8. FEES**

Fees required in accordance with 12 AAC 02.105(3) and 12 AAC 02.310, payable to the State of Alaska.

Nonrefundable Application Fee:	\$100.00
Nonresident Wholesale Drug Distributor:	\$600.00
<b>Total Required:</b>	<b>\$700.00</b>

## APPLICATION FOR CHANGE OF OWNERSHIP REQUIREMENTS

(12 AAC 52.040)

### 1. AFOREMENTIONED ITEMS

Items 1-8 as listed above;

### 2. CHANGE IN MANAGER FEE

Within 30 days of a change in manager, the \$5.00 fee required in accordance with 12 AAC 02.310, if applicable;

### 3. RETURN EXSTING LICENSE

Returned existing license (previous license will expire upon processing of new license).

---

## APPLICATION FOR CHANGE OF NAME OR LOCATION REQUIREMENTS

### 1. AFOREMENTIONED ITEMS

Items 1-7 as listed above;

### 2. CHANGE IN MANAGER FEE

Within 30 days of a change of facility manager, the new facility manager must submit the completed change of facility manager form (form #08-4064); for a change of facility manager, the \$5.00 fee required in accordance with 12 AAC 02.310.

### 3. RETURN EXSTING LICENSE

Return existing license (previous license will expire upon processing of new license);

### 4. FEES

Submit fees required in accordance with 12 AAC 02.105(3) and 12 AAC 52.02.310, payable to the State of Alaska;

Nonrefundable Application Fee: \$100.00

Duplicate License Fee: \$5.00

**Total Required: \$105.00**

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## APPLICATION FOR CHANGE OF FACILITY MANAGER

### 1. AFOREMENTIONED ITEMS

Items 3-4 listed above;

### 2. CHANGE IN MANAGER FEE

Within 30 days of a change of facility manager, the new facility manager must submit the completed change of facility manager form (form #08-4064); for a change of facility manager, the \$5.00 fee required in accordance with 12 AAC 02.310.

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## CLOSURE OPERATIONS

### 1. CESSATION OF OPERATIONS FORM

Within 10 days after business closure, a complete Cessation of Operations form (form #08-4791).

# APPLICATION INFORMATION

## Pharmacy Information

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### LICENSE TERM

There is no “inactive” status. If you choose not to renew your license, it will lapse. Licenses are issued for a two-year period and expire on December 31 of odd-numbered years, regardless of the date of issuance, except licenses issued within 90 days of the expiration date are issued to the next biennial expiration date. One renewal notice will be mailed at least 30 days before license expiration to the last known address of record.

### ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Mandatory reporting began on August 1, 2011. All the necessary information regarding the Alaska PDMP can be found on the Board of Pharmacy’s PDMP website at [pdmp.alaska.gov](http://pdmp.alaska.gov). Effective July 17, 2017, reporting is required **daily**.

### DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT (12 AAC 52.991)

A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant’s or licensee’s ability to practice competently and safely, issued against the licensee in another jurisdiction not later than 30 days after the date of the disciplinary decision or conviction.

## General Information

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### APPLICATION PROCESSING

The average time to process a paper application varies by program, but can take several weeks from the date it is received in this office, complete with all correct forms, supporting documents and appropriate fees paid. If the application is incomplete, the applicant will be notified of the incomplete and/or incorrect documents and fees. When the application is complete and correct, and all supporting documents have been received and all fees have been paid the license will be issued and sent to you. Start the process far enough in advance to allow for processing time. Applications are reviewed in order of receipt in our office, and walk-in customers should not expect immediate review.

### “YES” RESPONSES

A “Yes” response in the application does not mean your application will be denied. If you have responded “Yes” to any professional fitness questions in the application, be sure to submit a signed and dated explanation, and both charging and closing court documentation.

### DENIAL OF APPLICATION

Please be aware that the denial of an application of licensure may be reported to any person, professional licensing board, federal, state, or local governmental agency, or other entity making a relevant inquiry or as may be required by law.

### RANDOM AUDIT

If your program requires continuing education, the division will audit a percentage of the license renewals. If your license is randomly selected for audit, you will be sent a letter and required to submit copies of documentation and proof that you satisfied the continuing competency requirements as you stated on this renewal form. Please note that licensees are randomly selected by computer and may be randomly selected as often as the computer program chooses. You must save your documents for at least four years so you can respond to audits.

## **ADDRESS OR NAME CHANGE**

In accordance with 12 AAC 02.900, it is the applicant's/licensee's responsibility to notify the division, in writing, of changes of address or name. Name and address change notification forms are available on the division's website. The address of record with the division will be used to send renewals and all other official notifications and correspondence. The name appearing on the license must be your current legal name.

## **CERTIFIED TRUE COPIES**

If any of the required documents will be issued under a former name, indicate on the application and submit marriage license and/or court documents that are notarized as a "certified true copy of the original document". To obtain a certified true copy, you must present the notary with the original document along with the photocopy. You must write, "I certify this is a true copy of the original document" and sign your name. The notary will compare the original document with the copy and then notarize your signature.

## **SOCIAL SECURITY NUMBERS**

AS 08.01.060 and 08.01.100 require that a U.S. Social Security Number be on file with the division before a professional license is issued or renewed for an individual. If you do not have a U.S. Social Security Number, please complete the Request for Exemption from Social Security Number Requirement form located at *ProfessionalLicense.Alaska.gov* or contact the division for a copy of the form. This form is required with every application if you do not have a U.S. Social Security Number.

## **PUBLIC INFORMATION**

Please be aware that all information on the application form will be available to the public, unless required to be kept confidential by state or federal law. Information about current licensees, including mailing addresses, is available on the division's website at *ProfessionalLicense.Alaska.gov* under License Search.

## **ABANDONED APPLICATIONS**

Under 12 AAC 02.910, an application is considered abandoned when 12 months have elapsed since correspondence was last received from or on behalf of the applicant. An abandoned application is denied without prejudice. At the time of abandonment, the division will send notification to the last known address of the applicant, who has 30 days to submit a written request for a refund of biennial license and other fees paid. The application fee will not be refunded. If no request for refund is received within that timeframe, no refund will be issued, and all fees will be forfeited.

## **PAYMENT OF CHILD SUPPORT AND STUDENT LOANS:**

If the Alaska Child Support Enforcement Division has determined that you are in arrears on child support, you may be issued a nonrenewable temporary license valid for 150 days. Contact Child Support Services at (907) 269-6900 to resolve payment issues.

## **BUSINESS LICENSES**

The status of a professional license will directly impact the status of an associated business license. Renewal applications for business licenses are mailed separately. For more information about business licenses, (907) 465-2550 or *BusinessLicense.Alaska.gov*

## **STATUTES AND REGULATIONS**

The complete set of statutes and regulations for this program are available by written request or online at the division's website: *ProfessionalLicense.Alaska.Gov*

If you would like to receive notice of all proposed regulation changes for your program, please send a request in writing with your name, preferred contact method (mail or email), and the program you want to be updated on to the address below.

REGULATIONS SPECIALIST: Department of Commerce, Community, and Economic Development

Division of Corporations, Business and Professional Licensing

EMAIL: *RegulationsAndPublicComment@Alaska.Gov*

US MAIL: P.O. Box 110806, Juneau, Alaska 99811-0806

# Fingerprinting Requirements

This license application must be accompanied by a complete fingerprint card (may be used for the Alaska Department of Public Safety (DPS) and for the FBI national check). Fingerprint cards submitted must be those provided by the State of Alaska (printed in the pale blue ink); you may also use the standard *FBI Form FD-258*. Take the card, the instructions and photo identification to local law enforcement or other authorized agency to have the fingerprinting done. Please follow these instructions and the back of the fingerprint card.

DPS/the FBI will not accept any fingerprint cards that do not comply with the following:

1. No staples or staple holes are permitted in fingerprint cards. Also do not tape, tear or fold the cards.
2. Ensure the prints are done properly and well. Poor quality prints, smudging, non-rolled or incomplete fingerprints will cause the cards to be rejected DPS, the FBI or both.
3. All applicable sections of the top portion of the card must be legible and complete. The information/signatures must be typed, printed or signed in BLACK ink; no other color is permitted. Individual information blocks on the fingerprint cards must be filled in as follows:

**NAME:** Applicant's last name (comma), first name, then middle name if any; suffix denoting seniority (Jr., Sr., II, etc.) follow the middle or first name.

**SIGNATURE OF PERSON FINGERPRINTED:** Must be signed by the applicant.

**RESIDENCE OF PERSON FINGERPRINTED:** Enter the applicant's physical residence address.

**DATE:** Date fingerprinting was done.

**SIGNATURE OF OFFICIAL TAKING FINGERPRINTS:** Signature of the person who rolled the fingerprints.

**EMPLOYER AND ADDRESS AND REASON FINGERPRINTED:** These blocks to be completed by the State of Alaska.

**ALIASES/AKA:** List other names used by applicant that are different than that entered in NAME block; also list maiden names and all previous married names of females. Enter client number, **1344**, at bottom of block.

**CITIZENSHIP/CTZ:** Enter US if a citizen of the United States; otherwise, enter correct country abbreviation.

**YOUR NO./OCA:** Leave this space blank (Originating Agency Case Number).

**FBI NO./FBI:** Enter applicant's assigned FBI number, if known.

**ARMED FORCES NO/MNU:** Leave this space blank.

**SOCIAL SECURITY NO/SOC:** List applicant's Social Security number.

**MISC. NO/MNU:** If Alaska resident, enter applicant's Alaska driver's license or state ID # if applicable.

**ORIGINATING AGENCY IDENTIFIER (ORI):** Leave blank, will be printed with AKAST0100, DPS, ANCHORAGE, AK.

**SEX:** F (female) or M (male). Note: Indicate if applicant is a transvestite (cross-dresser) or has had a sex change operation. List any opposite sex names used in the Aliases/AKA block.

**RACE:** Race must be indicated by one of the following one-character alphabetic codes:

A= Asian, Pacific Islander, Chinese, Japanese, Polynesian, Korean, Vietnamese  
B= Black  
I= American Indian, Alaskan Native, Eskimo  
W= White, Mexican, Latin, Puerto Rican, Cuban, Central/South American and other Spanish cultures  
U= Unknown

**HEIGHT:** Must be shown in feet and inches, fractions rounded off to nearest inch (i.e., 5'11" entered as 511)

**WEIGHT:** Must be expressed in pounds, fractions rounded off to nearest pound.

**EYES:** Indicate eye color by one of the following three-character codes:

BLK = Black	GRY = Gray	MAR = Maroon
BLU = Blue	GRN = Green	PNK = Pink
BRO = Brown	HAZ = Hazel	UNK = Unknown

**HAIR:** Indicate hair color by one of the following three-character codes:

BAL = Bald	BRO = Brown	SDY = Sandy
BLK = Black	GRY = Gray	WHI = White
BLN = Blonde	RED = Red	XXX = Unknown

**PLACE OF BIRTH/POB:** List the state, territorial possession, Canadian province, or country of birth. Use the correct abbreviation for foreign countries or correctly spell the country's name. Do not use city or county name as a POB.

**DATE OF BIRTH/DOB:** Enter birth date as month, day, year. Fingerprint cards of person 80+ years of age are not processed by the FBI. Note: If DOB is blank, the card will be immediately returned unprocessed.

**FINGERPRINT IMPRESSION BLOCKS:** (Individual and Simultaneous): It is very important care be taken to prepare the fingerprint cards properly. It will save much more time and avoid rejections to assure acceptability the first time. Use black printer's ink. Fingers should be clean and dry before being inked. Use neither too much nor too little ink nor too little nor too much pressure to make the impressions. To help ensure legibility, all 10 fingers must be rolled from nail to nail, and include the first flexion crease. Detail must be sufficient on all 10 individual prints to clearly define the loop, whorl, arch or other pattern. Roll the prints in the correct sequence.

All instructions must be followed correctly. All information on the card is essential. Please double check your work before sending the card. Illegible, incomplete or incorrect cards will be rejected and returned unprocessed.



THE STATE  
of **ALASKA**

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

PHA

FOR DIVISION USE ONLY

**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

## Non-Resident Wholesale Drug Distributor Application

### PART I Payment of Fees

<b>New Application:</b>	<input type="checkbox"/> Nonrefundable Application Fee	\$100.00	} \$700.00
	<input type="checkbox"/> Non-Resident Wholesale Distributor License	\$600.00	
<b>Change Application:</b>	<input type="checkbox"/> Ownership Change	Existing License Number: -----	\$700.00
	<input type="checkbox"/> Name Change Only		\$65.00
	<input type="checkbox"/> Location Change Only		\$65.00

### PART II License Information

<b>Company/Owner Name:</b>			
<b>Wholesaler Name (DBA):</b>			
<b>Current License #:</b>		<b>Jurisdiction:</b>	
<b>Mailing Address:</b>			
<b>Physical Address:</b>			
<b>Contact Phone:</b>			

**EMAIL AGREEMENT:** By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.

<b>Email:</b>		<input type="checkbox"/> Send my Correspondence by Email <input type="checkbox"/> Send my Correspondence by US Mail
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## PART III Professional Fitness Questions

- The following questions must be answered. “Yes” answers may not automatically result in registration denial, however you must explain dates and circumstances under separate cover on a signed and dated statement. Send supporting documents, such as a copy of court records, including charging documents and judgments showing disposition of the charges, and/or all board orders pertaining to a licensing action.
- If you answered “Yes” to Question #1 or #2, include the name of the board, licensing or disciplinary authority and the date of the order, and, if applicable, the date of the termination of the condition and/or probation.
- Online print-outs are not acceptable. All disciplinary decisions or convictions must be reported to the board no later than 30 days, in accordance with 12 AAC 52.991.

### *When in doubt, disclose and explain.*

1. Has the pharmacy, owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy ever had a professional license denied, revoked, suspended, or otherwise restricted, conditioned, or limited or have you surrendered a professional license, been fined, placed on probation, reprimanded, disciplined, or entered into a settlement with a licensing authority in connection with a professional license you or the pharmacy have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending?

Yes  
 No

*\* If “Yes”, have you previously disclosed this to the Board?*

Yes  
 No

2. Have you as the owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy, ever been convicted of a crime or are you currently charged with committing a crime? For purposes of this question, “crime” includes a misdemeanor, felony, or a military offense, including but not limited to, driving under the influence (DUI) or driving while intoxicated (DWI), driving without a license, reckless driving, or driving with a suspended or revoked license. “Convicted” includes having been found guilty by verdict of a judge or jury, having entered a plea of guilty, nolo contendere or no contest, or having been given probation, a suspended imposition of sentence, or a fine.

Yes  
 No

*\* If “Yes”, have you previously disclosed this to the Board?*

Yes  
 No

3. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee furnished false or fraudulent material in an application made in connection with drug or device manufacturing or distribution?

Yes  
 No

4. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had a suspension or revocation by federal, state, or local government of a license currently or previously held for the manufacture or distribution of drugs or devices, including controlled substances?

Yes  
 No

5. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee obtained remuneration by fraud, misrepresentation, or deception?

Yes  
 No

6. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had dealings with drugs or devices that are known or should have been known to be stolen drugs or devices?

Yes  
 No



THE STATE  
of

# ALASKA

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

State Office Building, 333 Willoughby, 9th Floor  
PO Box 110806, Juneau, AK 99501  
Phone: (907) 465-2550  
Email: [License@Alaska.Gov](mailto:License@Alaska.Gov)

## Letter of Explanation for a Professional Fitness “Yes” Answer

Use this form **only** to explain and document any Professional Fitness “Yes” answers. A “Yes” answer is not necessarily disqualifying, but concealing one may be.

Each “Yes” answer requires a separate explanation and associated documentation. Do not assume that the division has documentation that you have already provided. Submit all relevant documentation with this form.

- **Explanations** include full details, dates, locations, type of action, organizations or parties involved, and specific circumstances. If the space provided is insufficient, make additional copies as needed.
- **Documentation** includes copies of court orders, charging documents, board or license actions, satisfaction of consent agreements (fines paid, community service completed, off probation, etc.), and fitness to practice letters (statement from your provider that you are safe to practice).
- **Disciplinary actions** may include but not be limited to; suspension, surrender, revocation, probation, academic probation, reprimand, censure, restricted license, limited license, conditioned license, or letters of counseling, concern, advice, warning, caution, admonishment, or reprimand.

If you have multiple “Yes” answers or multiple incidents for any Professional Fitness question, you must use a separate copy of this form and provide a full explanation and documentation for each incident.

The contents of licensing files are public records. If you believe that the additional information you are attaching to explain a “Yes” answer should be considered confidential, state that in the attachment. A request for confidentiality may or may not be granted.



*Write the professional fitness question number you are answering “Yes” to in the box.*

<b>Location of Incident:</b>		<b>Date of Incident:</b>	
<b>Explanation of Incident:</b>			
<b>When in doubt, disclose and explain.</b> <b>Make copies as necessary.</b>			

**Did you attach all applicable documents associated with this incident?**

- Court orders     
  Consent agreements     
  License actions     
  Charging documents  
 Court records     
  Fitness to practice     
  All other documentation related to this incident  
 I have additional incidents for this “Yes” answer, or “Yes” answers to other Professional Fitness questions and have attached a separate copy of this form for each incident.

<b>Full Name:</b>		<b>PL Code:</b>	
<b>Signature:</b>		<b>Date:</b>	

## PART IV Pharmacy Information

### 1. OWNERSHIP:

 Sole

 Partnership

 Corporation

 LLC

Names of Owners, Directors, and/or Primary Stakeholder	Title	Did you attach resume?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No

### 2. FACILITY MANAGER:

Full Name:		Title:	
Phone Number:			
Email:			
I have a basic understanding of federal & state wholesale distribution of drugs: <i>Note: State laws include those under AS 08 &amp; 12 AAC 52; federal laws include 21 U.S.C 353(b).</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No

### 3. REGISTERED AGENT:

An out-of-state pharmacy applying for registration is required to appoint a registered agent in Alaska to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served on the pharmacy.

Name of registered agent: \_\_\_\_\_

A registered agent cannot be named because the registered agent cannot be found at the registered office. The registered agent will default to the department.

### 4. CONTROLLED SUBSTANCES:

Will this non-resident wholesale distributor be distributing controlled substances to Alaska?	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

If **YES**, the facility must be registered with the Drug Enforcement Administration prior to distribution.

If a DEA number has already been obtained, please fill out the section below:

DEA Registration Number	Issue Date	Expiration Date

### 5. ATTACHMENT REQUIREMENTS, OTHER THAN RESUMES:

Completed self-inspection report on the form provided by the board.

– OR –

Completed verification Accredited Wholesale Distributors (VAWD) Inspection Report.

**PART V Notarized Signature**

By signature below, I attest to the following (refer to AS 08.80.158):

That this facility acknowledges it must first verify that the purchaser of the prescription drugs holds a valid license issued by the Department of Commerce, Community, and Economic Development, Division of Corporations, Business, and Professional Licensing under AS 08. (12 AAC 52.620(d))

That the facility manager has basic knowledge of federal and state laws related to the wholesale distribution of drugs, including the Drug Quality and Security Act. (12 AAC 52.625(b) and AS 08.80.159)

That this facility acknowledges it must make sure all drugs are stored at appropriate temperatures to help ensure that the identity, strength, quality, and purity of the products are not affected. (12 AAC 52.630(a))

That this facility must obtain an Alaska business license prior to engaging in any business activity.

By my signature below, I also hereby certify that the information in this application is true and correct. I understand that any false or fraudulent information may result in failure to obtain licensure as an outsourcing facility in Alaska, or subsequent revocation of license. I understand that information supplied with this application is considered public, unless required to be kept confidential pursuant to state or federal law.

Notary Stamp	Applicant's Printed Name:			
	Applicant's Signature:			
	Notary Public for State of:		Subscribed and Sworn to Before me on this Day:	
	Notary's Signature:		My Commission Expires:	

**Before mailing this license application, have you...**



- ✓ Completed all questions in the form?
- ✓ Attached your check for fees payable to the State of Alaska or credit card payment form?
- ✓ Signed and dated the form?
- ✓ Attached explanations and supporting documents for any "Yes" responses?
- ✓ Obtained necessary signatures?
- ✓ Attached required documents?



THE STATE  
of **ALASKA**  
*Department of Commerce, Community, and Economic Development*  
*Division of Corporations, Business and Professional Licensing*

FOR DIVISION USE ONLY

State of Alaska  
Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing  
PO Box 110806, Juneau, AK 99811  
Phone: (907) 465-2550

## Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: \_\_\_\_\_

Program Type: \_\_\_\_\_ License Number (if applicable): \_\_\_\_\_

I wish to make payment by credit card for the following (check all that apply):

- |  | <b>AMOUNT</b> |
|--|---------------|
| <input type="checkbox"/> Application Fee: _____  | _____         |
| <input type="checkbox"/> License or Renewal Fee: _____   | _____         |
| <input type="checkbox"/> Other (name change, wall certificate, fine, duplicate license, exam, etc.): |               |
| 1. _____   | _____         |
| 2. _____   | _____         |

**TOTAL:** \_\_\_\_\_

Name (as shown on credit card): \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Email (optional): \_\_\_\_\_

Signature of Credit Card Holder: \_\_\_\_\_

08-4438

Rev 12/26/18

Credit Card Payment Form (all major cards accepted)

<b>CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!</b>	
<p>1. Account Number: _____</p> <p>2. Expiration Date: _____</p> <p>3. Billing ZIP Code: _____</p> <p>4. Security Code: _____</p>	<p>All four fields <b>MUST</b> be completed!</p> <p>This section will be destroyed after the payment is processed.</p>



**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

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## Instructions for Outsourcing Facility License Application

An outsourcing facility means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location. A professional license must be obtained in order to engage in these services. Prior to engaging in services, a business license is required.

### APPLICATION FOR PROFESSIONAL LICENSE REQUIREMENTS

**1. APPLICATION**

Complete, signed and notarized application form 08-4813;

**2. OWNER, DIRECTOR & STOCKHOLDER INFORMATION**

Names and resumes of all owners, directors, or primary stockholders responsible for facility;

**3. FACILITY MANAGER INFORMATION**

Name and resume of the facility manager;

**4. SELF-INSPECTION REPORT**

Completed self-inspection report on form #08-0098;

**5. FINGERPRINT CARD**

Complete fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety (additional instructions are included in this application packet. Login to myLicense through myAlaska to request fingerprint cards. If you don't have a myAlaska account, you must create one first. Please note when you receive your blank fingerprint cards, the client number to indicate is 1344;

**6. GOOD MANUFACTURING PRACTICE (GMP) INSPECTION**

Results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA);

**7. REGISTRATION WITH THE FDA**

An affirmative response to the 503b section of this application relating to registration with the FDA;

**8. DISTRIBUTION OF CONTROLLED SUBSTANCES**

An affirmative response to the authorized inspection section of this application;

**9. FEES**

Fees required in accordance with 12 AAC 02.105(3) and 12 AAC 02.310, payable to the State of Alaska.

Nonrefundable Application Fee:	\$100.00
Nonresident Wholesale Drug Distributor:	\$600.00
<b>Total Required:</b>	<b>\$700.00</b>

## APPLICATION FOR CHANGE OF OWNERSHIP REQUIREMENTS

**1. AFOREMENTIONED ITEMS**

Items 1-9 as listed above;

**2. RETURN EXISTING LICENSE**

Returned existing license (previous license will expire upon processing of new license).

---

## APPLICATION FOR CHANGE OF NAME OR LOCATION REQUIREMENTS

**1. AFOREMENTIONED ITEMS**

Items 1-8 as listed above;

**2. FEES**

Submit fees required in accordance with 12 AAC 02.105(3) and 12 AAC 52.02.310, payable to the State of Alaska

Nonrefundable Application Fee:	\$100.00
Duplicate License Fee:	\$5.00
<b>Total Required:</b>	<b>\$105.00</b>

**3. RETURN EXISTING LICENSE**

Return existing license (previous license will expire upon processing of new license).

---

## APPLICATION FOR CHANGE OF FACILITY MANAGER

**1. AFOREMENTIONED ITEMS**

Items 3-4 listed above;

**2. CHANGE OF FACILITY MANAGER**

Within 10 days of a change of facility manager, the new facility manager must submit the completed change of facility manager form (form #08-4064). The outgoing facility manager must also submit a notice to our department on a separate form (form #08-4825);

**3. FEES**

The \$5.00 fee required in accordance with 12 AAC 02.105(3).

---

## CLOSURE OPERATIONS

1. Within 10 days after business closure, a complete Cessation of Operations form (form #08-4791).

# APPLICATION INFORMATION

## Pharmacy Information

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### LICENSE TERM

There is no “inactive” status. If you choose not to renew your license, it will lapse. Licenses are issued for a two-year period and expire on December 31 of odd-numbered years, regardless of the date of issuance, except licenses issued within 90 days of the expiration date are issued to the next biennial expiration date. One renewal notice will be mailed at least 30 days before license expiration to the last known address of record.

### ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Mandatory reporting began on August 1, 2011. All the necessary information regarding the Alaska PDMP can be found on the Board of Pharmacy’s PDMP website at [pdmp.alaska.gov](http://pdmp.alaska.gov). Effective July 17, 2017, reporting is required **daily**.

### DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT (12 AAC 52.991)

A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant’s or licensee’s ability to practice competently and safely, issued against the licensee in another jurisdiction not later than 30 days after the date of the disciplinary decision or conviction.

## General Information

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### APPLICATION PROCESSING

The average time to process a paper application varies by program, but can take several weeks from the date it is received in this office, complete with all correct forms, supporting documents and appropriate fees paid. If the application is incomplete, the applicant will be notified of the incomplete and/or incorrect documents and fees. When the application is complete and correct, and all supporting documents have been received and all fees have been paid the license will be issued and sent to you. Start the process far enough in advance to allow for processing time. Applications are reviewed in order of receipt in our office, and walk-in customers should not expect immediate review.

### “YES” RESPONSES

A “Yes” response in the application does not mean your application will be denied. If you have responded “Yes” to any professional fitness questions in the application, be sure to submit a signed and dated explanation, and both charging and closing court documentation.

### DENIAL OF APPLICATION

Please be aware that the denial of an application of licensure may be reported to any person, professional licensing board, federal, state, or local governmental agency, or other entity making a relevant inquiry or as may be required by law.

### RANDOM AUDIT

If your program requires continuing education, the division will audit a percentage of the license renewals. If your license is randomly selected for audit, you will be sent a letter and required to submit copies of documentation and proof that you satisfied the continuing competency requirements as you stated on this renewal form. Please note that licensees are randomly selected by computer and may be randomly selected as often as the computer program chooses. You must save your documents for at least four years so you can respond to audits.

## **ADDRESS OR NAME CHANGE**

In accordance with 12 AAC 02.900, it is the applicant's/licensee's responsibility to notify the division, in writing, of changes of address or name. Name and address change notification forms are available on the division's website. The address of record with the division will be used to send renewals and all other official notifications and correspondence. The name appearing on the license must be your current legal name.

## **CERTIFIED TRUE COPIES**

If any of the required documents will be issued under a former name, indicate on the application and submit marriage license and/or court documents that are notarized as a "certified true copy of the original document". To obtain a certified true copy, you must present the notary with the original document along with the photocopy. You must write, "I certify this is a true copy of the original document" and sign your name. The notary will compare the original document with the copy and then notarize your signature.

## **SOCIAL SECURITY NUMBERS**

AS 08.01.060 and 08.01.100 require that a U.S. Social Security Number be on file with the division before a professional license is issued or renewed for an individual. If you do not have a U.S. Social Security Number, please complete the Request for Exemption from Social Security Number Requirement form located at *ProfessionalLicense.Alaska.gov* or contact the division for a copy of the form. This form is required with every application if you do not have a U.S. Social Security Number.

## **PUBLIC INFORMATION**

Please be aware that all information on the application form will be available to the public, unless required to be kept confidential by state or federal law. Information about current licensees, including mailing addresses, is available on the division's website at *ProfessionalLicense.Alaska.gov* under License Search.

## **ABANDONED APPLICATIONS**

Under 12 AAC 02.910, an application is considered abandoned when 12 months have elapsed since correspondence was last received from or on behalf of the applicant. An abandoned application is denied without prejudice. At the time of abandonment, the division will send notification to the last known address of the applicant, who has 30 days to submit a written request for a refund of biennial license and other fees paid. The application fee will not be refunded. If no request for refund is received within that timeframe, no refund will be issued, and all fees will be forfeited.

## **PAYMENT OF CHILD SUPPORT AND STUDENT LOANS:**

If the Alaska Child Support Enforcement Division has determined that you are in arrears on child support, you may be issued a nonrenewable temporary license valid for 150 days. Contact Child Support Services at (907) 269-6900 to resolve payment issues.

## **BUSINESS LICENSES**

The status of a professional license will directly impact the status of an associated business license. Renewal applications for business licenses are mailed separately. For more information about business licenses, (907) 465-2550 or *BusinessLicense.Alaska.gov*

## **STATUTES AND REGULATIONS**

The complete set of statutes and regulations for this program are available by written request or online at the division's website: *ProfessionalLicense.Alaska.Gov*

If you would like to receive notice of all proposed regulation changes for your program, please send a request in writing with your name, preferred contact method (mail or email), and the program you want to be updated on to the address below.

REGULATIONS SPECIALIST: Department of Commerce, Community, and Economic Development

Division of Corporations, Business and Professional Licensing

EMAIL: *RegulationsAndPublicComment@Alaska.Gov*

# Fingerprinting Requirements

This license application must be accompanied by a complete fingerprint card (may be used for the Alaska Department of Public Safety (DPS) and for the FBI national check). Fingerprint cards submitted must be those provided by the State of Alaska (printed in the pale blue ink); you may also use the standard *FBI Form FD-258*. Take the card, the instructions and photo identification to local law enforcement or other authorized agency to have the fingerprinting done. Please follow these instructions and the back of the fingerprint card.

DPS/the FBI will not accept any fingerprint cards that do not comply with the following:

1. No staples or staple holes are permitted in fingerprint cards. Also do not tape, tear or fold the cards.
2. Ensure the prints are done properly and well. Poor quality prints, smudging, non-rolled or incomplete fingerprints will cause the cards to be rejected DPS, the FBI or both.
3. All applicable sections of the top portion of the card must be legible and complete. The information/signatures must be typed, printed or signed in BLACK ink; no other color is permitted. Individual information blocks on the fingerprint cards must be filled in as follows:

**NAME:** Applicant's last name (comma), first name, then middle name if any; suffix denoting seniority (Jr., Sr., II, etc.) follow the middle or first name.

**SIGNATURE OF PERSON FINGERPRINTED:** Must be signed by the applicant.

**RESIDENCE OF PERSON FINGERPRINTED:** Enter the applicant's physical residence address.

**DATE:** Date fingerprinting was done.

**SIGNATURE OF OFFICIAL TAKING FINGERPRINTS:** Signature of the person who rolled the fingerprints.

**EMPLOYER AND ADDRESS AND REASON FINGERPRINTED:** These blocks to be completed by the State of Alaska.

**ALIASES/AKA:** List other names used by applicant that are different than that entered in NAME block; also list maiden names and all previous married names of females. Enter client number, **1344**, at bottom of block.

**CITIZENSHIP/CTZ:** Enter US if a citizen of the United States; otherwise, enter correct country abbreviation.

**YOUR NO./OCA:** Leave this space blank (Originating Agency Case Number).

**FBI NO./FBI:** Enter applicant's assigned FBI number, if known.

**ARMED FORCES NO/MNU:** Leave this space blank.

**SOCIAL SECURITY NO/SOC:** List applicant's Social Security number.

**MISC. NO/MNU:** If Alaska resident, enter applicant's Alaska driver's license or state ID # if applicable.

**ORIGINATING AGENCY IDENTIFIER (ORI):** Leave blank, will be printed with AKAST0100, DPS, ANCHORAGE, AK.

**SEX:** F (female) or M (male). Note: Indicate if applicant is a transvestite (cross-dresser) or has had a sex change operation. List any opposite sex names used in the Aliases/AKA block.

**RACE:** Race must be indicated by one of the following one-character alphabetic codes:

A= Asian, Pacific Islander, Chinese, Japanese, Polynesian, Korean, Vietnamese  
B= Black  
I= American Indian, Alaskan Native, Eskimo  
W= White, Mexican, Latin, Puerto Rican, Cuban, Central/South American and other Spanish cultures  
U= Unknown

**HEIGHT:** Must be shown in feet and inches, fractions rounded off to nearest inch (i.e., 5'11" entered as 511)

**WEIGHT:** Must be expressed in pounds, fractions rounded off to nearest pound.

**EYES:** Indicate eye color by one of the following three-character codes:

BLK = Black	GRY = Gray	MAR = Maroon
BLU = Blue	GRN = Green	PNK = Pink
BRO = Brown	HAZ = Hazel	UNK = Unknown

**HAIR:** Indicate hair color by one of the following three-character codes:

BAL = Bald	BRO = Brown	SDY = Sandy
BLK = Black	GRY = Gray	WHI = White
BLN = Blonde	RED = Red	XXX = Unknown

**PLACE OF BIRTH/POB:** List the state, territorial possession, Canadian province, or country of birth. Use the correct abbreviation for foreign countries or correctly spell the country's name. Do not use city or county name as a POB.

**DATE OF BIRTH/DOB:** Enter birth date as month, day, year. Fingerprint cards of person 80+ years of age are not processed by the FBI. Note: If DOB is blank, the card will be immediately returned unprocessed.

**FINGERPRINT IMPRESSION BLOCKS:** (Individual and Simultaneous): It is very important care be taken to prepare the fingerprint cards properly. It will save much more time and avoid rejections to assure acceptability the first time. Use black printer's ink. Fingers should be clean and dry before being inked. Use neither too much nor too little ink nor too little nor too much pressure to make the impressions. To help ensure legibility, all 10 fingers must be rolled from nail to nail, and include the first flexion crease. Detail must be sufficient on all 10 individual prints to clearly define the loop, whorl, arch or other pattern. Roll the prints in the correct sequence.

All instructions must be followed correctly. All information on the card is essential. Please double check your work before sending the card. Illegible, incomplete or incorrect cards will be rejected and returned unprocessed.



THE STATE  
of **ALASKA**

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

PHA

FOR DIVISION USE ONLY

**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

## Outsourcing Facility License Application

### PART I Payment of Fees

New Application:	<input type="checkbox"/> Nonrefundable Application Fee	\$100.00	} \$700.00
	<input type="checkbox"/> Non-Resident Wholesale Distributor License	\$600.00	
Change Application:	<input type="checkbox"/> Ownership Change		\$700.00
	<input type="checkbox"/> Name Change Only		\$65.00
	<input type="checkbox"/> Location Change Only		\$65.00

Existing License Number:  
 -----

### PART II License Information

Company/Owner Name:			
Outsourcing Name (DBA):			
Current License #:		Jurisdiction:	
Mailing Address:			
Physical Address:			
Contact Phone:			

**EMAIL AGREEMENT:** By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.

Email:	<input type="checkbox"/> Send my Correspondence by Email
	<input type="checkbox"/> Send my Correspondence by US Mail

## PART III Professional Fitness Questions

- The following questions must be answered. “Yes” answers may not automatically result in registration denial, however you must explain dates and circumstances under separate cover on a signed and dated statement. Send supporting documents, such as a copy of court records, including charging documents and judgments showing disposition of the charges, and/or all board orders pertaining to a licensing action.
- If you answered “Yes” to Question #1 or #2, include the name of the board, licensing or disciplinary authority and the date of the order, and, if applicable, the date of the termination of the condition and/or probation.
- Online print-outs are not acceptable. All disciplinary decisions or convictions must be reported to the board no later than 30 days, in accordance with 12 AAC 52.991.

### *When in doubt, disclose and explain.*

1. Has the pharmacy, owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy ever had a professional license denied, revoked, suspended, or otherwise restricted, conditioned, or limited or have you surrendered a professional license, been fined, placed on probation, reprimanded, disciplined, or entered into a settlement with a licensing authority in connection with a professional license you or the pharmacy have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending?
- Yes  
 No
- \* If “Yes”, have you previously disclosed this to the Board?*
- Yes  
 No
- 
2. Have you as the owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy, ever been convicted of a crime or are you currently charged with committing a crime? For purposes of this question, “crime” includes a misdemeanor, felony, or a military offense, including but not limited to, driving under the influence (DUI) or driving while intoxicated (DWI), driving without a license, reckless driving, or driving with a suspended or revoked license. “Convicted” includes having been found guilty by verdict of a judge or jury, having entered a plea of guilty, nolo contendere or no contest, or having been given probation, a suspended imposition of sentence, or a fine.
- Yes  
 No
- \* If “Yes”, have you previously disclosed this to the Board?*
- Yes  
 No
- 
3. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee furnished false or fraudulent material in an application made in connection with drug or device manufacturing or distribution?
- Yes  
 No
- 
4. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had a suspension or revocation by federal, state, or local government of a license currently or previously held for the manufacture or distribution of drugs or devices, including controlled substances?
- Yes  
 No
- 
5. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee obtained remuneration by fraud, misrepresentation, or deception?
- Yes  
 No
- 
6. Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had dealings with drugs or devices that are known or should have been known to be stolen drugs or devices?
- Yes  
 No



THE STATE  
of

# ALASKA

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

State Office Building, 333 Willoughby, 9th Floor  
PO Box 110806, Juneau, AK 99501  
Phone: (907) 465-2550  
Email: [License@Alaska.Gov](mailto:License@Alaska.Gov)

## Letter of Explanation for a Professional Fitness “Yes” Answer

Use this form **only** to explain and document any Professional Fitness “Yes” answers. A “Yes” answer is not necessarily disqualifying, but concealing one may be.

Each “Yes” answer requires a separate explanation and associated documentation. Do not assume that the division has documentation that you have already provided. Submit all relevant documentation with this form.

- **Explanations** include full details, dates, locations, type of action, organizations or parties involved, and specific circumstances. If the space provided is insufficient, make additional copies as needed.
- **Documentation** includes copies of court orders, charging documents, board or license actions, satisfaction of consent agreements (fines paid, community service completed, off probation, etc.), and fitness to practice letters (statement from your provider that you are safe to practice).
- **Disciplinary actions** may include but not be limited to; suspension, surrender, revocation, probation, academic probation, reprimand, censure, restricted license, limited license, conditioned license, or letters of counseling, concern, advice, warning, caution, admonishment, or reprimand.

If you have multiple “Yes” answers or multiple incidents for any Professional Fitness question, you must use a separate copy of this form and provide a full explanation and documentation for each incident.

The contents of licensing files are public records. If you believe that the additional information you are attaching to explain a “Yes” answer should be considered confidential, state that in the attachment. A request for confidentiality may or may not be granted.



*Write the professional fitness question number you are answering “Yes” to in the box.*

<b>Location of Incident:</b>		<b>Date of Incident:</b>	
<b>Explanation of Incident:</b>			
<b>When in doubt, disclose and explain.</b> <b>Make copies as necessary.</b>			

**Did you attach all applicable documents associated with this incident?**

- Court orders     
  Consent agreements     
  License actions     
  Charging documents  
 Court records     
  Fitness to practice     
  All other documentation related to this incident  
 I have additional incidents for this “Yes” answer, or “Yes” answers to other Professional Fitness questions and have attached a separate copy of this form for each incident.

<b>Full Name:</b>		<b>PL Code:</b>	
<b>Signature:</b>		<b>Date:</b>	

## PART IV Pharmacy Information

### 1. OWNERSHIP:

Sole

Partnership

Corporation

LLC

Names of Owners, Directors, and/or Primary Stakeholder	Title	Did you attach resume?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No

### 2. FACILITY MANAGER:

Full Name:		Title:	
Phone Number:			
Email:			
I have a basic understanding of federal & state wholesale distribution of drugs: <i>Note: State laws include those under AS 08 &amp; 12 AAC 52; federal laws include 21 U.S.C 353(b).</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No

### 3. AUTHORIZED INSPECTIONS:

Will this outsourcing facility permit an authorized inspector/law enforcement official to enter and inspect the facility, including delivery vehicles, records, & written operation procedures?	<input type="checkbox"/> Yes <input type="checkbox"/> No
---	--

### 4. 503b REGISTRATION:

Is this outsourcing facility registered with the Food and Drug Administration as a 503b outsourcing facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Date of initial registration:	.....
Date of most recent registration:	.....

### 5. ATTACHMENT REQUIREMENTS, OTHER THAN RESUMES:

<input type="checkbox"/> Completed self-inspection report
<input type="checkbox"/> Completed results of most recent Good Manufacturing Practice (GMP) inspection

**PART V Notarized Signature**

By signature below, I attest to the following (refer to AS 08.80.158):

That this facility acknowledges it must first verify that the purchaser of the prescription drugs holds a valid license issued by the Department of Commerce, Community, and Economic Development, Division of Corporations, Business, and Professional Licensing under AS 08. (12 AAC 52.620(d))

That the facility manager has basic knowledge of federal and state laws related to the wholesale distribution of drugs, including the Drug Quality and Security Act. (12 AAC 52.625(b) and AS 08.80.159)

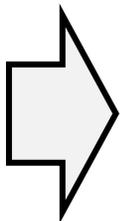
That this facility acknowledges it must make sure all drugs are stored at appropriate temperatures to help ensure that the identity, strength, quality, and purity of the products are not affected. (12 AAC 52.630(a))

That this facility must obtain an Alaska business license prior to engaging in any business activity.

By my signature below, I also hereby certify that the information in this application is true and correct. I understand that any false or fraudulent information may result in failure to obtain licensure as an outsourcing facility in Alaska, or subsequent revocation of license. I understand that information supplied with this application is considered public, unless required to be kept confidential pursuant to state or federal law.

Notary Stamp	Applicant's Printed Name:			
	Applicant's Signature:			
	Notary Public for State of:		Subscribed and Sworn to Before me on this Day:	
	Notary's Signature:		My Commission Expires:	

**Before mailing this license application, have you...**



- ✓ Completed all questions in the form?
- ✓ Attached your check for fees payable to the State of Alaska or credit card payment form?
- ✓ Signed and dated the form?
- ✓ Attached explanations and supporting documents for any "Yes" responses?
- ✓ Obtained necessary signatures?
- ✓ Attached required documents?



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PO Box 110806, Juneau, AK 99811  
Phone: (907) 465-2550

## Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: \_\_\_\_\_

Program Type: \_\_\_\_\_ License Number (if applicable): \_\_\_\_\_

I wish to make payment by credit card for the following (check all that apply):

- |  | <b>AMOUNT</b> |
|--|---------------|
| <input type="checkbox"/> Application Fee: _____  | _____         |
| <input type="checkbox"/> License or Renewal Fee: _____   | _____         |
| <input type="checkbox"/> Other (name change, wall certificate, fine, duplicate license, exam, etc.): |               |
| 1. _____   | _____         |
| 2. _____   | _____         |

**TOTAL:** \_\_\_\_\_

Name (as shown on credit card): \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Email (optional): \_\_\_\_\_

Signature of Credit Card Holder: \_\_\_\_\_

08-4438

Rev 12/26/18

Credit Card Payment Form (all major cards accepted)

<b>CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!</b>	
<p>1. Account Number: _____</p> <p>2. Expiration Date: _____</p> <p>3. Billing ZIP Code: _____</p> <p>4. Security Code: _____</p>	<p>All four fields <b>MUST</b> be completed!</p> <p>This section will be destroyed after the payment is processed.</p>



**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

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## Instructions for Third-Party Logistics Provider License Application

A third-party logistics provider means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product. A professional license must be obtained in order to engage in these services; however, prior to engaging in services, a business license will be required. Please note that a professional license must be on file first before a business license can be issued.

### APPLICATION FOR PROFESSIONAL LICENSE REQUIREMENTS

**1. APPLICATION**

Complete, signed and notarized application form 08-4814;

**2. OWNER, DIRECTOR & STOCKHOLDER INFORMATION**

Names and resumes of all owners, directors, or primary stockholders responsible for facility;

**3. FACILITY MANAGER INFORMATION**

Name and resume of the facility manager;

**4. SELF-INSPECTION REPORT**

Completed self-inspection report on form #08-0098

**5. FINGERPRINT CARD**

Complete fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety (additional instructions are included in this application packet. Login to myLicense through myAlaska to request fingerprint cards. If you don't have a myAlaska account, you must create one first. Please note when you receive your blank fingerprint cards, the client number to indicate is 1344;

**6. FEES**

Fees required in accordance with 12 AAC 02.310, payable to the State of Alaska.

Nonrefundable Application Fee:	\$100.00
Nonresident Wholesale Drug Distributor:	\$600.00
<b>Total Required:</b>	<b>\$700.00</b>

## APPLICATION FOR CHANGE OF OWNERSHIP REQUIREMENTS

### 1. AFOREMENTIONED ITEMS

Items 1-6 as listed above;

### 2. RETURN EXISTING LICENSE

Returned existing license (previous license will expire upon processing of new license).

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## APPLICATION FOR CHANGE OF NAME OR LOCATION REQUIREMENTS

### 1. AFOREMENTIONED ITEMS

Items 1-8 as listed above;

### 2. FEES

Submit fees required in accordance with 12 AAC 02.105(3) and 12 AAC 52.02.310, payable to the State of Alaska

Nonrefundable Application Fee:	\$100.00
Duplicate License Fee:	\$5.00
<b>Total Required:</b>	<b>\$105.00</b>

### 3. RETURN EXISTING LICENSE

Return existing license (previous license will expire upon processing of new license).

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## APPLICATION FOR CHANGE OF FACILITY MANAGER

### 1. AFOREMENTIONED ITEMS

Items 3-4 listed above;

### 2. CHANGE IN MANAGER FEE

Within 10 days of a change of facility manager, the new facility manager must submit the completed change of facility manager form (form #08-4064). The outgoing facility manager must also submit a notice to our department on a separate form (form #08-4825);

### 3. OTHER FEES

The \$5.00 fee required in accordance with 12 AAC 02.105(3).

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## CLOSURE OPERATIONS

### 1. CESSATION OF OPERATIONS FORM

Within 10 days after business closure, a complete Cessation of Operations form (form #08-4791)

# APPLICATION INFORMATION

## Pharmacy Information

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### LICENSE TERM

There is no “inactive” status. If you choose not to renew your license, it will lapse. Licenses are issued for a two-year period and expire on December 31 of odd-numbered years, regardless of the date of issuance, except licenses issued within 90 days of the expiration date are issued to the next biennial expiration date. One renewal notice will be mailed at least 30 days before license expiration to the last known address of record.

### ALASKA PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Mandatory reporting began on August 1, 2011. All the necessary information regarding the Alaska PDMP can be found on the Board of Pharmacy’s PDMP website at [pdmp.alaska.gov](http://pdmp.alaska.gov). Effective July 17, 2017, reporting is required **daily**.

### DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT (12 AAC 52.991)

A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant’s or licensee’s ability to practice competently and safely, issued against the licensee in another jurisdiction not later than 30 days after the date of the disciplinary decision or conviction.

## General Information

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### APPLICATION PROCESSING

The average time to process a paper application varies by program, but can take several weeks from the date it is received in this office, complete with all correct forms, supporting documents and appropriate fees paid. If the application is incomplete, the applicant will be notified of the incomplete and/or incorrect documents and fees. When the application is complete and correct, and all supporting documents have been received and all fees have been paid the license will be issued and sent to you. Start the process far enough in advance to allow for processing time. Applications are reviewed in order of receipt in our office, and walk-in customers should not expect immediate review.

### “YES” RESPONSES

A “Yes” response in the application does not mean your application will be denied. If you have responded “Yes” to any professional fitness questions in the application, be sure to submit a signed and dated explanation, and both charging and closing court documentation.

### DENIAL OF APPLICATION

Please be aware that the denial of an application of licensure may be reported to any person, professional licensing board, federal, state, or local governmental agency, or other entity making a relevant inquiry or as may be required by law.

### RANDOM AUDIT

If your program requires continuing education, the division will audit a percentage of the license renewals. If your license is randomly selected for audit, you will be sent a letter and required to submit copies of documentation and proof that you satisfied the continuing competency requirements as you stated on this renewal form. Please note that licensees are randomly selected by computer and may be randomly selected as often as the computer program chooses. You must save your documents for at least four years so you can respond to audits.

## **ADDRESS OR NAME CHANGE**

In accordance with 12 AAC 02.900, it is the applicant's/licensee's responsibility to notify the division, in writing, of changes of address or name. Name and address change notification forms are available on the division's website. The address of record with the division will be used to send renewals and all other official notifications and correspondence. The name appearing on the license must be your current legal name.

## **CERTIFIED TRUE COPIES**

If any of the required documents will be issued under a former name, indicate on the application and submit marriage license and/or court documents that are notarized as a "certified true copy of the original document". To obtain a certified true copy, you must present the notary with the original document along with the photocopy. You must write, "I certify this is a true copy of the original document" and sign your name. The notary will compare the original document with the copy and then notarize your signature.

## **SOCIAL SECURITY NUMBERS**

AS 08.01.060 and 08.01.100 require that a U.S. Social Security Number be on file with the division before a professional license is issued or renewed for an individual. If you do not have a U.S. Social Security Number, please complete the Request for Exemption from Social Security Number Requirement form located at *ProfessionalLicense.Alaska.gov* or contact the division for a copy of the form. This form is required with every application if you do not have a U.S. Social Security Number.

## **PUBLIC INFORMATION**

Please be aware that all information on the application form will be available to the public, unless required to be kept confidential by state or federal law. Information about current licensees, including mailing addresses, is available on the division's website at *ProfessionalLicense.Alaska.gov* under License Search.

## **ABANDONED APPLICATIONS**

Under 12 AAC 02.910, an application is considered abandoned when 12 months have elapsed since correspondence was last received from or on behalf of the applicant. An abandoned application is denied without prejudice. At the time of abandonment, the division will send notification to the last known address of the applicant, who has 30 days to submit a written request for a refund of biennial license and other fees paid. The application fee will not be refunded. If no request for refund is received within that timeframe, no refund will be issued, and all fees will be forfeited.

## **PAYMENT OF CHILD SUPPORT AND STUDENT LOANS:**

If the Alaska Child Support Enforcement Division has determined that you are in arrears on child support, you may be issued a nonrenewable temporary license valid for 150 days. Contact Child Support Services at (907) 269-6900 to resolve payment issues.

## **BUSINESS LICENSES**

The status of a professional license will directly impact the status of an associated business license. Renewal applications for business licenses are mailed separately. For more information about business licenses, (907) 465-2550 or *BusinessLicense.Alaska.gov*

## **STATUTES AND REGULATIONS**

The complete set of statutes and regulations for this program are available by written request or online at the division's website: *ProfessionalLicense.Alaska.Gov*

If you would like to receive notice of all proposed regulation changes for your program, please send a request in writing with your name, preferred contact method (mail or email), and the program you want to be updated on to the address below.

REGULATIONS SPECIALIST: Department of Commerce, Community, and Economic Development

Division of Corporations, Business and Professional Licensing

EMAIL: *RegulationsAndPublicComment@Alaska.Gov*

US MAIL: P.O. Box 110806, Juneau, Alaska 99811-0806

# Fingerprinting Requirements

This license application must be accompanied by a complete fingerprint card (may be used for the Alaska Department of Public Safety (DPS) and for the FBI national check). Fingerprint cards submitted must be those provided by the State of Alaska (printed in the pale blue ink); you may also use the standard *FBI Form FD-258*. Take the card, the instructions and photo identification to local law enforcement or other authorized agency to have the fingerprinting done. Please follow these instructions and the back of the fingerprint card.

DPS/the FBI will not accept any fingerprint cards that do not comply with the following:

1. No staples or staple holes are permitted in fingerprint cards. Also do not tape, tear or fold the cards.
2. Ensure the prints are done properly and well. Poor quality prints, smudging, non-rolled or incomplete fingerprints will cause the cards to be rejected DPS, the FBI or both.
3. All applicable sections of the top portion of the card must be legible and complete. The information/signatures must be typed, printed or signed in BLACK ink; no other color is permitted. Individual information blocks on the fingerprint cards must be filled in as follows:

**NAME:** Applicant's last name (comma), first name, then middle name if any; suffix denoting seniority (Jr., Sr., II, etc.) follow the middle or first name.

**SIGNATURE OF PERSON FINGERPRINTED:** Must be signed by the applicant.

**RESIDENCE OF PERSON FINGERPRINTED:** Enter the applicant's physical residence address.

**DATE:** Date fingerprinting was done.

**SIGNATURE OF OFFICIAL TAKING FINGERPRINTS:** Signature of the person who rolled the fingerprints.

**EMPLOYER AND ADDRESS AND REASON FINGERPRINTED:** These blocks to be completed by the State of Alaska.

**ALIASES/AKA:** List other names used by applicant that are different than that entered in NAME block; also list maiden names and all previous married names of females. Enter client number, **1344**, at bottom of block.

**CITIZENSHIP/CTZ:** Enter US if a citizen of the United States; otherwise, enter correct country abbreviation.

**YOUR NO./OCA:** Leave this space blank (Originating Agency Case Number).

**FBI NO./FBI:** Enter applicant's assigned FBI number, if known.

**ARMED FORCES NO/MNU:** Leave this space blank.

**SOCIAL SECURITY NO/SOC:** List applicant's Social Security number.

**MISC. NO/MNU:** If Alaska resident, enter applicant's Alaska driver's license or state ID # if applicable.

**ORIGINATING AGENCY IDENTIFIER (ORI):** Leave blank, will be printed with AKAST0100, DPS, ANCHORAGE, AK.

**SEX:** F (female) or M (male). Note: Indicate if applicant is a transvestite (cross-dresser) or has had a sex change operation. List any opposite sex names used in the Aliases/AKA block.

**RACE:** Race must be indicated by one of the following one-character alphabetic codes:

A= Asian, Pacific Islander, Chinese, Japanese, Polynesian, Korean, Vietnamese  
B= Black  
I= American Indian, Alaskan Native, Eskimo  
W= White, Mexican, Latin, Puerto Rican, Cuban, Central/South American and other Spanish cultures  
U= Unknown

**HEIGHT:** Must be shown in feet and inches, fractions rounded off to nearest inch (i.e., 5'11" entered as 511)

**WEIGHT:** Must be expressed in pounds, fractions rounded off to nearest pound.

**EYES:** Indicate eye color by one of the following three-character codes:

BLK = Black	GRY = Gray	MAR = Maroon
BLU = Blue	GRN = Green	PNK = Pink
BRO = Brown	HAZ = Hazel	UNK = Unknown

**HAIR:** Indicate hair color by one of the following three-character codes:

BAL = Bald	BRO = Brown	SDY = Sandy
BLK = Black	GRY = Gray	WHI = White
BLN = Blonde	RED = Red	XXX = Unknown

**PLACE OF BIRTH/POB:** List the state, territorial possession, Canadian province, or country of birth. Use the correct abbreviation for foreign countries or correctly spell the country's name. Do not use city or county name as a POB.

**DATE OF BIRTH/DOB:** Enter birth date as month, day, year. Fingerprint cards of person 80+ years of age are not processed by the FBI. Note: If DOB is blank, the card will be immediately returned unprocessed.

**FINGERPRINT IMPRESSION BLOCKS:** (Individual and Simultaneous): It is very important care be taken to prepare the fingerprint cards properly. It will save much more time and avoid rejections to assure acceptability the first time. Use black printer's ink. Fingers should be clean and dry before being inked. Use neither too much nor too little ink nor too little nor too much pressure to make the impressions. To help ensure legibility, all 10 fingers must be rolled from nail to nail, and include the first flexion crease. Detail must be sufficient on all 10 individual prints to clearly define the loop, whorl, arch or other pattern. Roll the prints in the correct sequence.

All instructions must be followed correctly. All information on the card is essential. Please double check your work before sending the card. Illegible, incomplete or incorrect cards will be rejected and returned unprocessed.



THE STATE  
of **ALASKA**

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

PHA

FOR DIVISION USE ONLY

**Board of Pharmacy**

PO Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2550

Email: [BoardOfPharmacy@Alaska.Gov](mailto:BoardOfPharmacy@Alaska.Gov)

Website: [ProfessionalLicense.Alaska.Gov/BoardOfPharmacy](http://ProfessionalLicense.Alaska.Gov/BoardOfPharmacy)

## Third-Party Logistics Provider License Application

PART I		Payment of Fees		
New Application:	<input type="checkbox"/> Nonrefundable Application Fee	\$100.00	} \$700.00	
	<input type="checkbox"/> Non-Resident Wholesale Distributor License	\$600.00		
Change Application:	<input type="checkbox"/> Ownership Change	<div style="border: 1px solid black; border-radius: 10px; padding: 5px; display: inline-block;">                     Existing License Number:                      -----                 </div>		
	<input type="checkbox"/> Name Change Only			\$700.00
	<input type="checkbox"/> Location Change Only			\$65.00
			\$65.00	

PART II		License Information	
Company/Owner Name:			
Third Party Logistics Provider (DBA):			
Current License #:		Jurisdiction:	
Mailing Address:			
Physical Address:			
Contact Phone:			

**EMAIL AGREEMENT:** By choosing to receive correspondence on any matter affecting my license or other business with the Alaska Division of Corporations, Business and Professional Licensing, I agree to maintain an accurate email address through the MY LICENSE web page. I understand that failure to check my email account or to keep the email address in good standing may result in an inability to receive crucial information, potentially resulting in my inability to obtain or maintain licensure.

Email:		<input type="checkbox"/> Send my Correspondence by Email <input type="checkbox"/> Send my Correspondence by US Mail
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## PART III Professional Fitness Questions

- The following questions must be answered. “Yes” answers may not automatically result in registration denial, however you must explain dates and circumstances under separate cover on a signed and dated statement. Send supporting documents, such as a copy of court records, including charging documents and judgments showing disposition of the charges, and/or all board orders pertaining to a licensing action.
- If you answered “Yes” to Question #1 or #2, include the name of the board, licensing or disciplinary authority and the date of the order, and, if applicable, the date of the termination of the condition and/or probation.
- Online print-outs are not acceptable. All disciplinary decisions or convictions must be reported to the board no later than 30 days, in accordance with 12 AAC 52.991.

### *When in doubt, disclose and explain.*

- 1.** Has the pharmacy, owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy ever had a professional license denied, revoked, suspended, or otherwise restricted, conditioned, or limited or have you surrendered a professional license, been fined, placed on probation, reprimanded, disciplined, or entered into a settlement with a licensing authority in connection with a professional license you or the pharmacy have held in any jurisdiction including Alaska and including that of any military authorities or is any such action pending?
- Yes  
 No
- \* If “Yes”, have you previously disclosed this to the Board?*
- Yes  
 No
- 
- 2.** Have you as the owner, corporation, corporate owner, or any partner, pharmacist-in-charge, or any employee of the pharmacy, ever been convicted of a crime or are you currently charged with committing a crime? For purposes of this question, “crime” includes a misdemeanor, felony, or a military offense, including but not limited to, driving under the influence (DUI) or driving while intoxicated (DWI), driving without a license, reckless driving, or driving with a suspended or revoked license. “Convicted” includes having been found guilty by verdict of a judge or jury, having entered a plea of guilty, nolo contendere or no contest, or having been given probation, a suspended imposition of sentence, or a fine.
- Yes  
 No
- \* If “Yes”, have you previously disclosed this to the Board?*
- Yes  
 No
- 
- 3.** Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee furnished false or fraudulent material in an application made in connection with drug or device manufacturing or distribution?
- Yes  
 No
- 
- 4.** Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had a suspension or revocation by federal, state, or local government of a license currently or previously held for the manufacture or distribution of drugs or devices, including controlled substances?
- Yes  
 No
- 
- 5.** Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee obtained remuneration by fraud, misrepresentation, or deception?
- Yes  
 No
- 
- 6.** Have you as the owner, or any partner, corporate officer, the pharmacist-in-charge, or any employee had dealings with drugs or devices that are known or should have been known to be stolen drugs or devices?
- Yes  
 No



THE STATE  
of

# ALASKA

Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing

State Office Building, 333 Willoughby, 9th Floor  
PO Box 110806, Juneau, AK 99501  
Phone: (907) 465-2550  
Email: [License@Alaska.Gov](mailto:License@Alaska.Gov)

## Letter of Explanation for a Professional Fitness “Yes” Answer

Use this form **only** to explain and document any Professional Fitness “Yes” answers. A “Yes” answer is not necessarily disqualifying, but concealing one may be.

Each “Yes” answer requires a separate explanation and associated documentation. Do not assume that the division has documentation that you have already provided. Submit all relevant documentation with this form.

- **Explanations** include full details, dates, locations, type of action, organizations or parties involved, and specific circumstances. If the space provided is insufficient, make additional copies as needed.
- **Documentation** includes copies of court orders, charging documents, board or license actions, satisfaction of consent agreements (fines paid, community service completed, off probation, etc.), and fitness to practice letters (statement from your provider that you are safe to practice).
- **Disciplinary actions** may include but not be limited to; suspension, surrender, revocation, probation, academic probation, reprimand, censure, restricted license, limited license, conditioned license, or letters of counseling, concern, advice, warning, caution, admonishment, or reprimand.

If you have multiple “Yes” answers or multiple incidents for any Professional Fitness question, you must use a separate copy of this form and provide a full explanation and documentation for each incident.

The contents of licensing files are public records. If you believe that the additional information you are attaching to explain a “Yes” answer should be considered confidential, state that in the attachment. A request for confidentiality may or may not be granted.



*Write the professional fitness question number you are answering “Yes” to in the box.*

<b>Location of Incident:</b>		<b>Date of Incident:</b>	
<b>Explanation of Incident:</b>			
<b>When in doubt, disclose and explain.</b> <b>Make copies as necessary.</b>			

**Did you attach all applicable documents associated with this incident?**

- Court orders     
  Consent agreements     
  License actions     
  Charging documents  
 Court records     
  Fitness to practice     
  All other documentation related to this incident  
 I have additional incidents for this “Yes” answer, or “Yes” answers to other Professional Fitness questions and have attached a separate copy of this form for each incident.

<b>Full Name:</b>		<b>PL Code:</b>	
<b>Signature:</b>		<b>Date:</b>	

## PART IV Pharmacy Information

### 1. OWNERSHIP:

 Sole

 Partnership

 Corporation

 LLC

Names of Owners, Directors, and/or Primary Stakeholder	Title	Did you attach resume?
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No
		<input type="checkbox"/> Yes <input type="checkbox"/> No

### 2. FACILITY MANAGER:

<b>Full Name:</b>		<b>Title:</b>	
<b>Phone Number:</b>			
<b>Email:</b>			
<b>I have a basic understanding of federal &amp; state wholesale distribution of drugs:</b> <i>Note: State laws include those under AS 08 &amp; 12 AAC 52; federal laws include 21 U.S.C 353(b).</i>			<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Do you acknowledge you must submit a fingerprint card request to the division as part of this application process?</b>			<input type="checkbox"/> Yes <input type="checkbox"/> No

### 3. AUTHORIZED INSPECTIONS:

<b>Will this outsourcing facility permit an authorized inspector/law enforcement official to enter and inspect the facility, including delivery vehicles, records, &amp; written operation procedures?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No
--	--

### 4. ATTACHMENT REQUIREMENTS, OTHER THAN RESUMES:

<input type="checkbox"/> Completed self-inspection report
---

**PART V Notarized Signature**

By signature below, I attest to the following (refer to AS 08.80.158):

That this facility acknowledges it must first verify that the purchaser of the prescription drugs holds a valid license issued by the Department of Commerce, Community, and Economic Development, Division of Corporations, Business, and Professional Licensing under AS 08. (12 AAC 52.620(d))

That the facility manager has basic knowledge of federal and state laws related to the wholesale distribution of drugs, including the Drug Quality and Security Act. (12 AAC 52.625(b) and AS 08.80.159)

That this facility acknowledges it must make sure all drugs are stored at appropriate temperatures to help ensure that the identity, strength, quality, and purity of the products are not affected. (12 AAC 52.630(a))

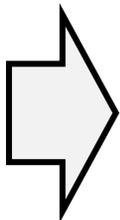
That this facility cannot dispense or distribute drugs or devices directly to patients. (AS 08.80.157(h)(7))

That this facility must obtain an Alaska business license prior to engaging in any business activity.

By my signature below, I also hereby certify that the information in this application is true and correct. I understand that any false or fraudulent information may result in failure to obtain licensure as an outsourcing facility in Alaska, or subsequent revocation of license. I understand that information supplied with this application is considered public, unless required to be kept confidential pursuant to state or federal law.

<div style="border: 1px dashed gray; padding: 10px; width: fit-content; margin: auto;">Notary Stamp</div>	Applicant's Printed Name:			
	Applicant's Signature:			
	Notary Public for State of:		Subscribed and Sworn to Before me on this Day:	
	Notary's Signature:		My Commission Expires:	

**Before mailing this license application, have you...**



- ✓ Completed all questions in the form?
- ✓ Attached your check for fees payable to the State of Alaska or credit card payment form?
- ✓ Signed and dated the form?
- ✓ Attached explanations and supporting documents for any "Yes" responses?
- ✓ Obtained necessary signatures?
- ✓ Attached required documents?



THE STATE  
of **ALASKA**  
*Department of Commerce, Community, and Economic Development*  
*Division of Corporations, Business and Professional Licensing*

FOR DIVISION USE ONLY

State of Alaska  
Department of Commerce, Community, and Economic Development  
Division of Corporations, Business and Professional Licensing  
PO Box 110806, Juneau, AK 99811  
Phone: (907) 465-2550

## Credit Card Payment Form

All major credit cards are accepted. For security purposes, do not email credit card information. Include this credit card payment form with your application.

Name of Applicant or Licensee: \_\_\_\_\_

Program Type: \_\_\_\_\_ License Number (if applicable): \_\_\_\_\_

I wish to make payment by credit card for the following (check all that apply): **AMOUNT**

Application Fee: \_\_\_\_\_

License or Renewal Fee: \_\_\_\_\_

Other (name change, wall certificate, fine, duplicate license, exam, etc.):

1. \_\_\_\_\_

2. \_\_\_\_\_

**TOTAL:** \_\_\_\_\_

Name (as shown on credit card): \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Email (optional): \_\_\_\_\_

Signature of Credit Card Holder: \_\_\_\_\_

08-4438

Rev 12/26/18

Credit Card Payment Form (all major cards accepted)

**CREDIT CARD INFO: Your payment cannot be processed unless all fields are completed!**

<p>1. Account Number: _____</p> <p>2. Expiration Date: _____</p> <p>3. Billing ZIP Code: _____</p> <p>4. Security Code: _____</p>	<p>All four fields <b>MUST</b> be completed!</p> <p>This section will be destroyed after the payment is processed.</p>
---	--

**Non-resident wholesale drug distributor / outsourcing facility / 3PL checksheet**

**FACILITY NAME (DBA):** \_\_\_\_\_ **DATE OF REVIEW:** \_\_\_/\_\_\_/\_\_\_

**JURISDICTION:** \_\_\_\_\_ **Change in owner, location, name?**  Y  N **If yes, previous #:** \_\_\_\_\_

\*If fingerprint cards have been requested through myAlaska, the license can be issued so long as other application requirements are on file. If fingerprint cards are returned indicating results inconsistent with the initial response(s) on the application, follow P&P28. The most recent version of the federal fingerprint card is from 09-09-2013 and is form #FD-258.

**NON-RESIDENT WHOLESALE DRUG DISTRIBUTOR**

(Date Received)		(Receipt #)
_____	\$100.00 non-refundable application fee	_____ (12 AAC 02.310(a)(1))
_____	\$600.00 license fee	_____ (12 AAC 2.310(b)(8))
_____	Complete, notarized application	(12 AAC 52.610(b)(1))
_____	Officers, directors, stakeholders <input type="checkbox"/> names <input type="checkbox"/> resumes	(12 AAC 52.610(b)(3))
_____	Facility manager: _____ <input type="checkbox"/> resume <input type="checkbox"/> basic knowledge	(12 AAC 52.610(b)(4))
_____	<input type="radio"/> Self-inspection <b>OR</b> <input type="radio"/> Verification Accredited Wholesale Distributor (VAWD)	(12 AAC 52.610(b)(5))
_____	Fingerprints* <input type="radio"/> requested <input type="radio"/> returned <input type="radio"/> sent to DPS	(12 AAC 52.610(b)(6))
_____	Copy of license, permit, or registration from home jurisdiction	(12 AAC 52.610(b)(7))
_____	Distributes controlled substances? <input type="radio"/> Y <input type="radio"/> N <b>If yes, is DEA-registered</b> <input type="checkbox"/>	(12 AAC 52.610(b)(7)(c)(2))

**OUTSOURCING FACILITY**

_____	\$100.00 non-refundable application fee	_____ (12 AAC 02.310(a)(1))
_____	\$600.00 license fee	_____ (12 AAC 2.310(b)(8))
_____	Complete, notarized application	(12 AAC 52.696(b)(1))
_____	Officers, directors, stakeholders <input type="checkbox"/> names <input type="checkbox"/> resumes	(12 AAC 52.696(b)(3))
_____	Facility manager: _____ <input type="checkbox"/> resume	(12 AAC 52.696(b)(4))
_____	Self-inspection report	(12 AAC 52.696(b)(5))
_____	Fingerprints* <input type="radio"/> requested <input type="radio"/> returned <input type="radio"/> sent to DPS	(12 AAC 52.696(b)(6))
_____	<input type="checkbox"/> Good Manufacturing Practice inspection from FDA <input type="checkbox"/> is FDA-registered	(12 AAC 52.696(b)(7)(h))
_____	Permits an authorized inspector or law enforcement official <input type="radio"/> Y <input type="radio"/> N	(12 AAC 52.610(g))

**THIRD-PARTY LOGISTICS PROVIDER (3PL)**

_____	\$100.00 non-refundable application fee	_____ (12 AAC 02.310(a)(1))
_____	\$600.00 license fee	_____ (12 AAC 2.310(b)(8))
_____	Complete, notarized application	(12 AAC 52.697(b)(1))
_____	Officers, directors, stakeholders <input type="checkbox"/> names <input type="checkbox"/> resumes	(12 AAC 52.697(b)(3))
_____	Facility manager: _____ <input type="checkbox"/> resume	(12 AAC 52.697(b)(4))
_____	Self-inspection report	(12 AAC 52.697(b)(5))
_____	Fingerprints* <input type="radio"/> requested <input type="radio"/> returned <input type="radio"/> sent to DPS	(12 AAC 52.697(b)(6))
_____	Permits an authorized inspector or law enforcement official <input type="radio"/> Y <input type="radio"/> N	(12 AAC 52.697(g))

**INVESTIGATIONS**  Yes  No      Question #s: \_\_\_\_\_      # of incidents: \_\_\_\_\_

Letter of Explanation (LOE): \_\_\_/\_\_\_/\_\_\_      Supporting Docs: \_\_\_/\_\_\_/\_\_\_      EA Review: \_\_\_/\_\_\_/\_\_\_  
 Further INV review?  Y  N

**License #:** \_\_\_\_\_      **Date Issued:** \_\_\_/\_\_\_/\_\_\_

# IS IT GOVERNMENT'S RESPONSIBILITY?

RETHINKING REGULATION, RISK, AND RESPONSIBILITY  
IN STATE GOVERNMENT

*The best government is that which governs least.*

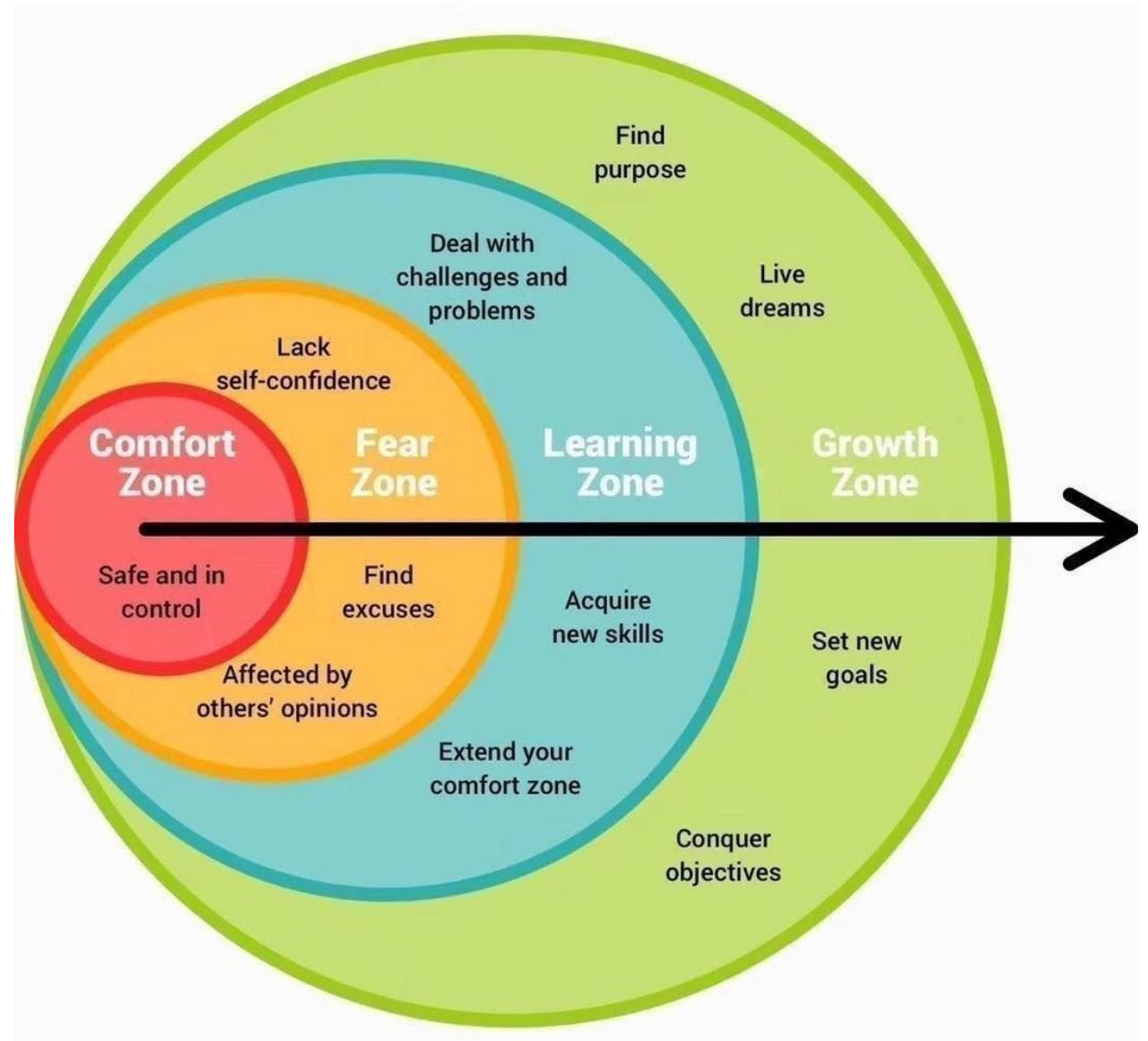
*John L. O'Sullivan, The United States Magazine and Democratic Review, Vol. 1 (1837)*

# LEARNING OBJECTIVES

- Rethink options to manage risk
- Break out of comfort zone
- Hear different perspectives
- Enable you to:
  - Evaluate current and proposed management strategies
  - Propose statute, regulation, or administrative changes to the existing regulatory landscape

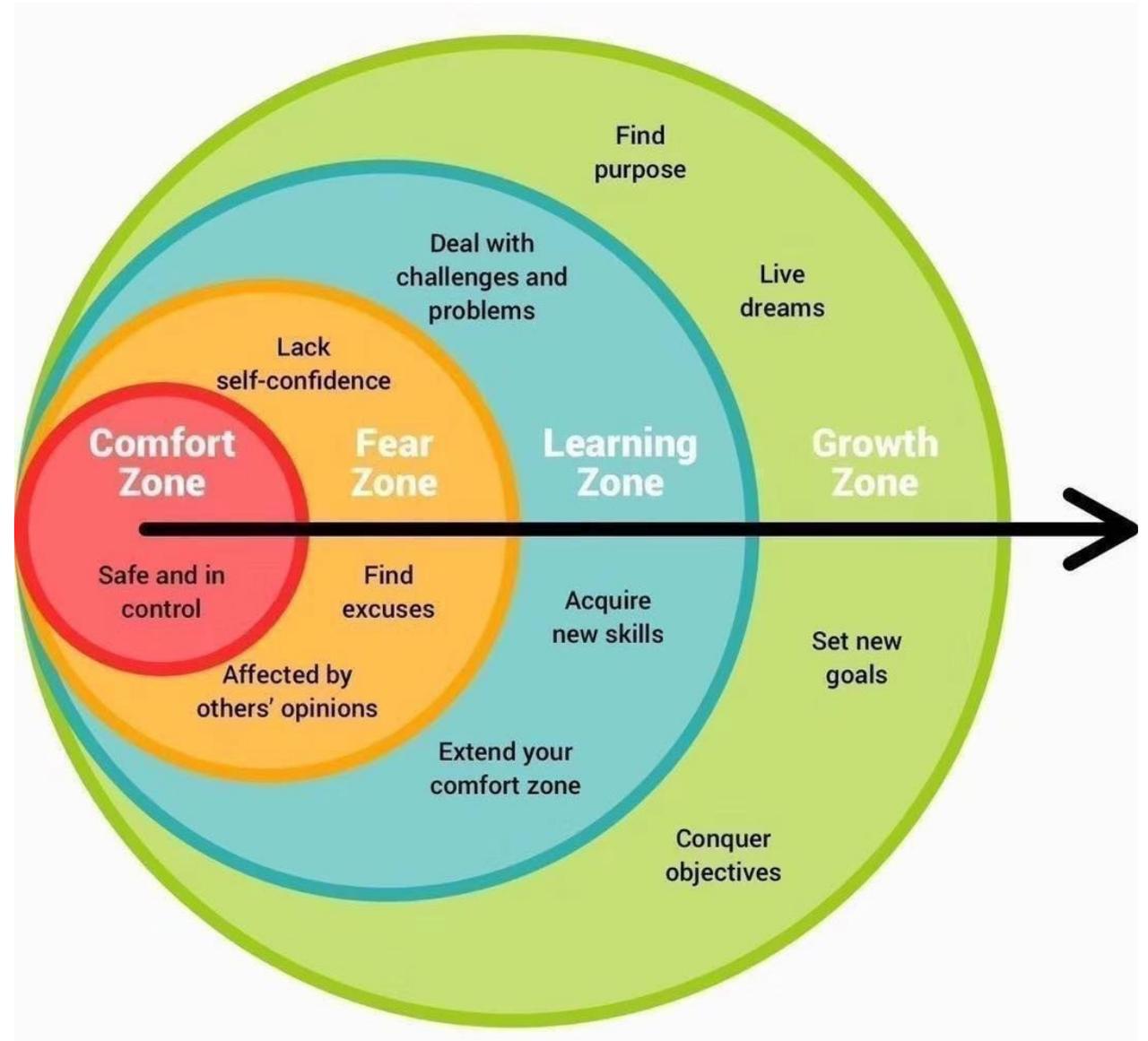
# THIS EXERCISE WILL:

- prompt you to consider new ideas to solve problems
- expose you to fresh perspectives
- encourage deep dives into alternatives to regulation
- provide a framework for further discussion
- provide justification and reinforcement of management decisions



# THIS EXERCISE WILL NOT:

- tell you how to solve the problem
- make you feel comfortable
- force you to change



# WHAT IS THE ROLE OF GOVERNMENT?

- Form a more perfect union
- Establish justice
- Insure domestic tranquility
- Provide for the common defense
- Promote the general welfare
- Secure the blessings of liberty
- Secure and transmit to succeeding generations our heritage of political, civil, and religious liberty within the union of states

# WHAT IS THE ROLE OF GOVERNMENT?

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**Preamble to the Constitution  
of the United States of  
America**

**Preamble to the Alaska  
Constitution**

# SO, WHY DO WE DO WHAT WE DO?

- Limit risk before it happens
- Provide remedy & redress of wrongs
- Gather, disseminate, and analyze data
- Ensure public process
- Create a revenue stream to pay for services
- Ensure transparency
- Provide public services
- Create stability and maintain order
- Set forth common boundaries, rights, and systems for governance
- Other reasons?

# IS IT *REALLY* GOVERNMENT'S RESPONSIBILITY?

Is it a **proper activity** of government?

Does it **duplicate work** performed in the private sector?

Does it **require a monopoly**, or can multiple entities do it?

Is it **mandated by the federal government**?

For the purpose of this exercise, include any activity performed by your agency.

# IS IT *REALLY* GOVERNMENT'S RESPONSIBILITY?

Or, do we ask government to perform our activity because:

**We have always done it that way?**

**We can't think of another way to do it?**

**We feel ownership over the activity?**

**We don't have the resources to do explore options?**

**We don't have the resources to do manage the change?**

**Statutory change is too volatile and cumbersome?**

**Stakeholders want us to do it / no alternatives?**

**The public is complacent?**

Other legitimate reasons, weak excuses, unexposed biases?

# ARE WE DOING IT WELL?

Is the way we perform our activity:

The most { **effective**  
**cost-efficient**  
**time-efficient**  
**customer-friendly**  
**inclusive** } way to do it?

# **RIGHT-TOUCH REGULATION**

**A RISK-MANAGEMENT APPROACH TO EVALUATING  
REGULATORY ACTIVITY**

*Time to use your workbook!*

# SECTION A: IDENTIFY THE PROBLEMS

The following bad things could happen when this activity is performed:

- 1.
- 2.
- 3.
- 4.
- 5.

# SECTION B: CREATE A *HAZARD PROFILE*

What are the inherent (intrinsic) hazards present when the problem occurs?

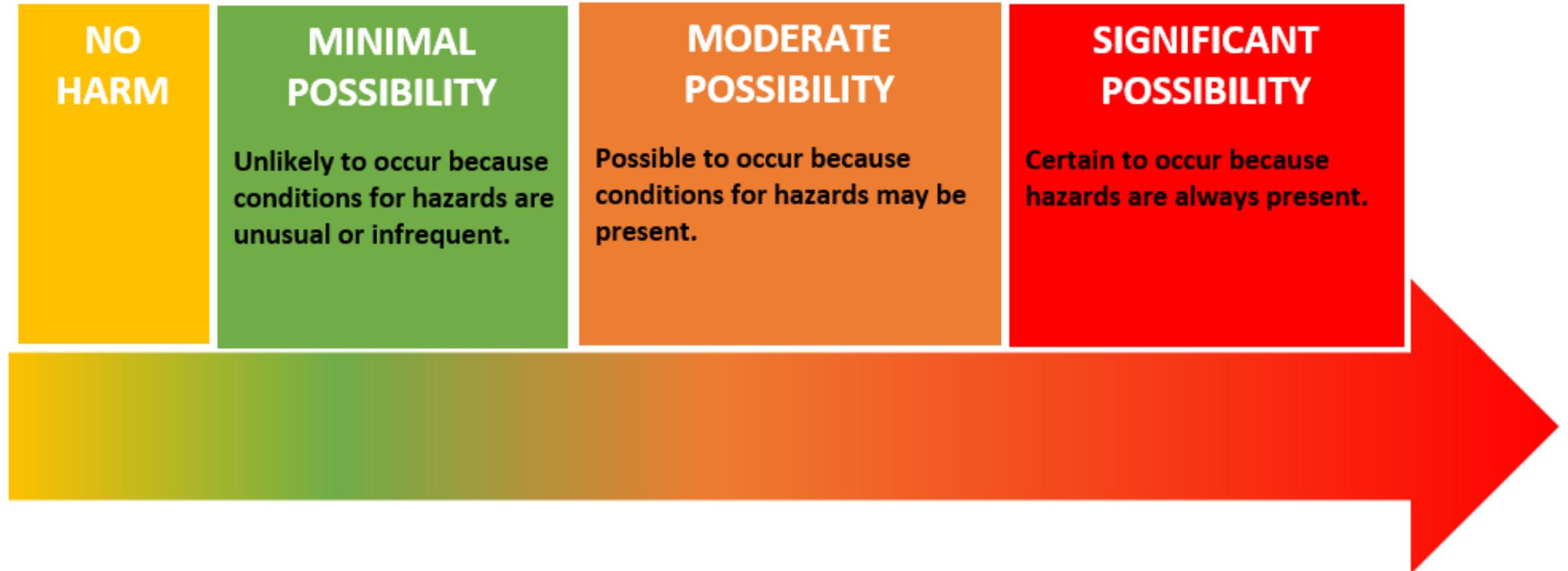
- Complexity
- Context
- Agency

What are the external (extrinsic) hazards present when the problem occurs?

- Scale
- Perception
- Impact of regulation
- Unintended consequences

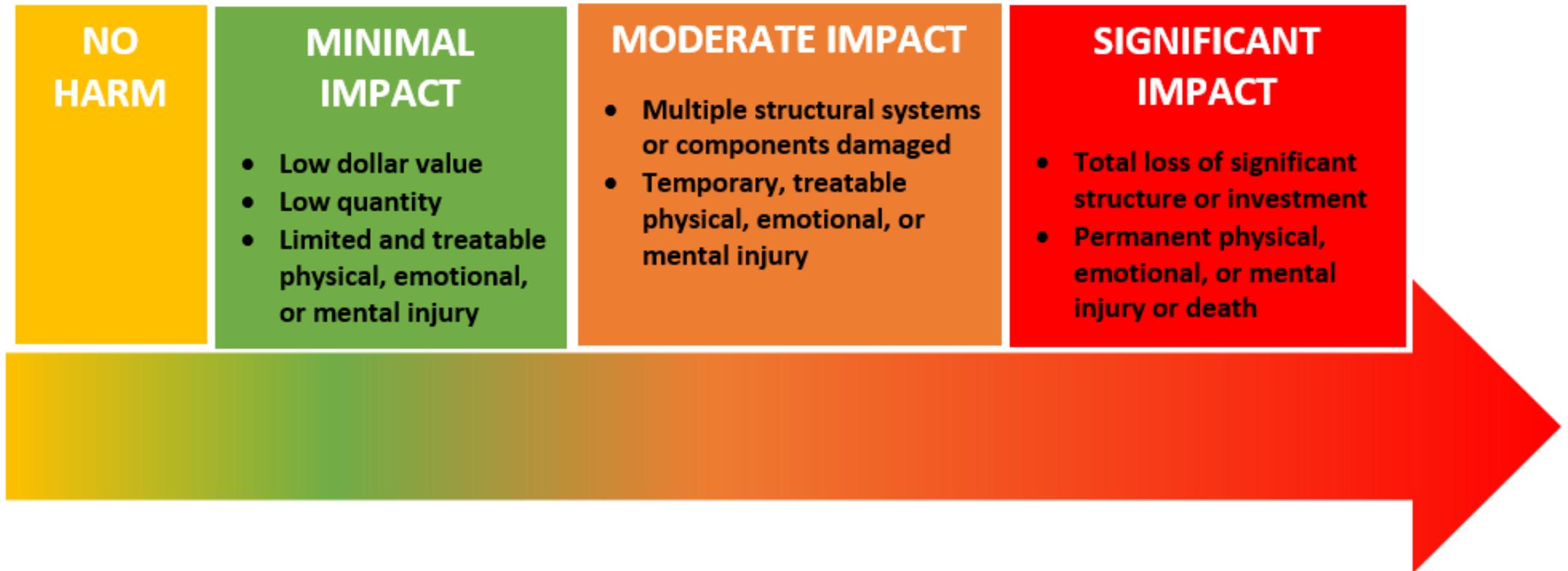
# SECTION C: HARM POSSIBILITY

What is the *possibility* for the hazard to lead to creation of a harm?



# SECTION D: HARM SIGNIFICANCE

If a harm occurs, what is its significance?



# SECTION D: HARM RATINGS

**Harm Possibility + Harm Significance = Total Harm Rating**

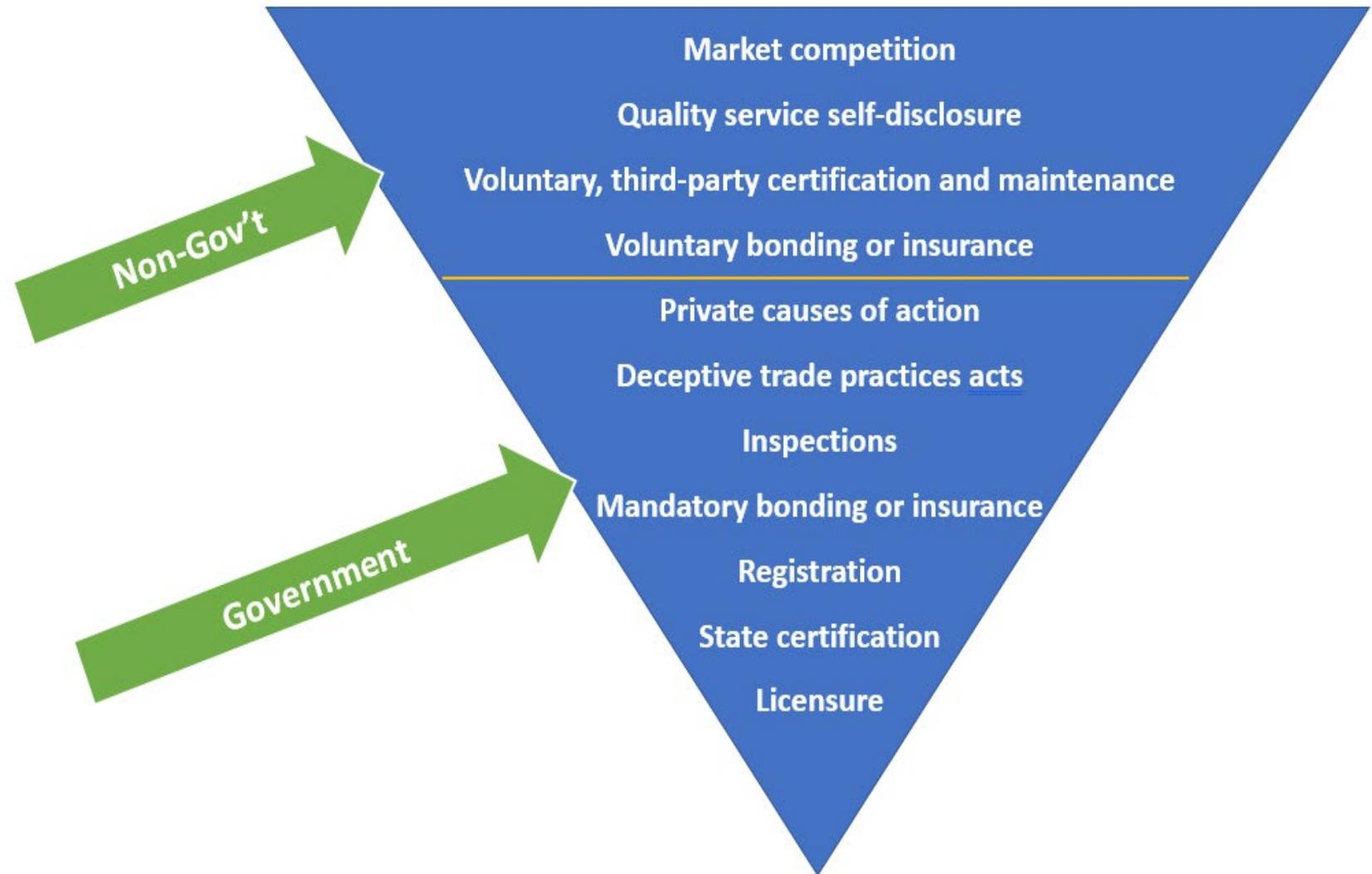
There is no scientific “high” or “low” harm rating for any particular regulated program or activity.

Compare your score with others:

- Did you have similar ratings?
- If not, what data is missing?
- What opinions or biases exist?
- Note any observations and make appropriate changes.

# SECTIONS E & F: HAZARD MANAGEMENT

Examples from the world of professional licensure



# SECTIONS E & F: HAZARD MANAGEMENT

The good, the bad, and the ugly: What is an acceptable level of risk? Oversight? Expense? Flexibility?

## MARKET

- Yelp, Angie's List, Facebook
- Written warranty or money-back guarantee
- Better Business Bureau, Good Housekeeping Seal, national accreditation
- Employer/facility oversight
- Voluntary proof of insurance or bond

## PALLIATIVE REGULATION

- Law requires proof of insurance or bonding
- Legal grounds for court action, may enjoin the state
- May be disciplined for violations

## PREVENTATIVE REGULATION

- Must appear on an approved state list
- Periodic safety or compliance reviews by state agency
- Must meet state criteria

# SECTIONS G & H: HAZARD MANAGEMENT

The good, the bad, and the ugly: What is an acceptable level of risk? Oversight? Expense? Flexibility?

Non-governmental regulation	Governmental regulation
Many options available	Fewer options available
Assumes an element of risk	Presumed safe
Less predictable, more agile	Predictable, slow to change
Less transparent, public process is optional	More transparent, public process is mandatory
Based on policy and practice	Based on statute and regulation
Accountable to the market/consumer	Accountable to state processes and agencies
Recourse through litigation, social media campaigns	Recourse through Administrative Procedures Act
May be unclear who is controlling quality, safety	Identity of the regulator is usually obvious
Cost depends on situation, funding can be fluid	Cost is set in state budget, statute, or regulation

# SECTION I: MANAGEMENT RATINGS

**Type of Management + Restrictiveness + Flexibility**  
**= Total Management Rating**

There is no scientific “high” or “low” management rating for any particular regulated program or activity.

Compare your score with others:

- Below your ratings, write down your observations and opinions.
- Are you surprised that a particular hazard has a higher number—and therefore a more regulatory management response—than others?
- Reconsider any changes.

# SECTION J: NEXT STEPS

**What are the next steps to adjust the climate of regulation of the profession you are reviewing?**

Compare your score with others:

- Review the documentation you have created in the previous exercises.
- What changes are needed to implement new management strategies?
- What are current inhibitors to improvement in management of relevant hazards?
- Reconsider any changes.
- Create a written, time-bound plan to accomplish next steps

# **THANK YOU!**

**THE REGULATORY REVIEW TEAM**  
**GOVERNOR MICHAEL J. DUNLEAVY**

*Amy Demboski, Assistant Commissioner, DCCED (Project Manager)*

*Julie Anderson, Commissioner, DCCED*

*Adam Crum, Commissioner, DHSS*

*John MacKinnon, Commissioner, DOTPF*

*Sara Chambers, Division Director, DCCED*

*Glenn Hoskinson, Special Assistant, DCCED*

# Is it government's responsibility?

## EVALUATING OCCUPATIONAL LICENSING REGULATION

Department: \_\_\_\_\_ Division \_\_\_\_\_

Rater: \_\_\_\_\_ Role: \_\_\_\_\_ Date: \_\_\_\_\_

Sector/activity/program under review: \_\_\_\_\_

This evaluation tool is based on the principles of **right-touch regulation**, which does not prescribe an outcome but leads the thoughtful regulator to explore what characteristics of oversight will properly limit or address any problems with the activity in question.

The principles state that regulation should aim to be:

<b>Proportionate</b>	Regulators should <b>only intervene when necessary</b> . Remedies should be appropriate to the risk posed, and costs identified and minimized
<b>Consistent</b>	Rules and standards must be <b>aligned and implemented fairly</b>
<b>Targeted</b>	Regulation should be <b>focused on the problem, and minimize side effects</b>
<b>Transparent</b>	Regulators should be <b>open, and keep regulations simple and user friendly</b>
<b>Accountable</b>	Regulators must be able to <b>justify decisions, and be subject to public scrutiny</b>
<b>Agile</b>	Regulation must <b>look forward</b> and be able to <b>adapt to anticipate change</b>

These principles provide the foundation for thinking on policy in all sectors of society. The concept of right-touch regulation emerges naturally from these six principles: bringing together commonly agreed-upon principles of good regulation with understanding of a sector and a quantified and qualified assessment of risk of harm. It is intended for those making decisions about the design of a regulatory framework.

### What this exercise WILL do:

- prompt you to consider new ideas to solve problems
- encourage deep dives into alternatives to regulation
- provide justification and reinforcement of management decisions
- expose you to fresh perspectives
- provide a framework for further discussion

### What this exercise WILL NOT do:

- tell you how to solve the problem
- make you feel comfortable
- force you to change

This workbook is intended to accompany an explanatory presentation with the same title. If you have received the workbook without access to the presentation or materials, please contact Sara Chambers at [sara.chambers@alaska.gov](mailto:sara.chambers@alaska.gov).

## Identify the Problems

We need to identify the problem before we can determine whether any policy is the right one. Often in policy development the need for regulatory change, as a solution, is identified before the problem is properly described and understood. This can lead to inefficiencies as resources are spent developing a regulatory solution when the problem may be better dealt with in other ways.



### *Examples from various professions:*

- An improperly built structure could collapse.
- A person could overdose on prescribed medication.
- Wildlife could be wantonly wasted.

**A. Describe the problems with this profession. List each problem on a separate line.**


## Quantify and Qualify the Risks

Once the problem has been identified, we need to understand it fully and quantify and qualify the risks associated with it. Quantifying risks means gauging the likelihood of harm occurring and its severity. Qualifying risks means looking closely at the nature of the harm, and understanding how and why it occurs. Without this two-fold evaluation, which must be based on evidence, it is impossible to judge whether regulatory action is necessary, what type of regulatory response might be needed, or whether it would be better to use other means of managing the issues. Regulation should only be chosen when it clearly provides the best solution. Simply identifying a real or potential risk is not sufficient.

### B. Create a *hazard profile* for each problem

Intrinsic Hazards		Extrinsic Hazards	
<p><b>Complexity</b></p> <p>The complexity and inherent hazards of the activity</p>	<p>Potential for harm caused by essential features of practice; for example: prescribing, surgical and psychological interventions</p>	<p><b>Scale</b></p> <ul style="list-style-type: none"> <li>• Size of service user group</li> <li>• Size of practitioner or licensee group</li> </ul>	<p>This criterion helps to ascertain the dimensions of harm. If the number of practitioners or service users is small, then this may suggest an alternative method of assurance would be appropriate. Conversely, support workers might pose a small risk volume in terms of complexity but are high in numbers.</p>
<p><b>Context</b></p> <p>The environments in which the intervention takes place</p>	<p>Environments with varying levels of oversight (hospitals, private practice, homes) may indicate greater or lesser opportunity for hazards—or the ability to proactively or reactively manage hazards.</p>	<p><b>Perception</b></p> <p>Need for:</p> <ul style="list-style-type: none"> <li>• Public confidence in the occupation</li> <li>• Assurance for employers or other stakeholders</li> </ul>	<p>This criterion enables consideration of probable effects on public confidence in the occupation or needs of employers or other agencies using the services of the occupational group.</p> <p>Take care not to allow false perceptions influence your answers.</p>
<p><b>Agency</b></p> <p>Service user vulnerability or autonomy</p>	<p>Contact with service users who may have less ability to exercise control over their care and circumstances may indicate a greater opportunity for hazards.</p>	<p><b>Impact of regulation</b></p> <ul style="list-style-type: none"> <li>• Market</li> <li>• Workforce</li> <li>• Quality</li> <li>• Cost</li> <li>• Innovation</li> </ul>	<p>This criterion considers the impact of assurance mechanisms on the cost and supply of the occupation.</p> <p>Market impact might include market size, prices, trading conditions, labor supply, employer needs, cost to licensee.</p>
		<p><b>Unintended Consequences</b></p>	<p>Any identifiable unintended consequences of the proposed forms of assurance are considered so that any implications can be addressed.</p>

Problem	Intrinsic Hazards	Extrinsic Hazards
	1.  2.  3.	1.  2.  3.

### C. What is the possibility for the hazard(s) to lead to creation of a harm?

<b>1-2</b>	<b>No harm to person or property</b> is associated with this profession.
<b>3-4</b>	<b>Minimal possibility of harm:</b> Unlikely to occur because conditions for hazards are unusual or infrequent.
<b>5-6</b>	<b>Moderate possibility of harm:</b> Possible to occur because conditions for hazards may be present.
<b>7-8</b>	<b>Significant possibility of harm:</b> Likely to occur because hazards are frequently present.
<b>9-10</b>	<b>Significant possibility of harm:</b> Certain to occur because hazards are always present.

<b>Hazard</b>	<b>Possibility Rating</b>	<b>Explanation of the possibility of harm:</b> What is the likelihood for something to go wrong? What conditions must be triggered?
1.		
2.		
3.		
4.		

5.		
6.		
7.		
8.		
9.		
10.		

## D. What is the significance of the harm?

<b>1-2</b>	<b>No harm to person or property</b> is associated with this profession.		
<b>3-4</b>	<b>Minimal harm to property:</b> Items of low dollar value or low quantity could be damaged or destroyed.		
<b>5-6</b>	<b>Moderate harm to property</b> Multiple structural systems or components or a single system/component of moderate value or investment could be damaged or destroyed.	<b>OR</b>	<b>Minimal harm to life, health, or safety</b> <ul style="list-style-type: none"> <li>Physical/emotional/mental harm to a person could be limited and minor, no treatment required</li> <li>Small number of people possibly affected</li> </ul>
<b>7-8</b>	<b>Significant harm to property</b> Total loss of significant structure or investment	<b>OR</b>	<b>Moderate harm to life, health, or safety</b> to a person <ul style="list-style-type: none"> <li>Temporary, treatable physical/emotional/mental injury could occur</li> <li>Larger number of people possibly affected</li> </ul>
<b>9-10</b>	<b>Significant harm to life, health, or safety:</b> Permanent physical/emotional/mental injury or death could occur. Wide audience of potential victims.		

Hazard	Significance Rating	Explanation of the significance of the harm
1.		
2.		
3.		
4.		
5.		
6.		
7.		

8.		
9.		
10.		

**Total your ratings regarding *harm*:**

Hazard	Harm Possibility Rating	Harm Significance Rating	<b>TOTAL</b>
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

**Write down any observations regarding your rating totals:**

## Get as Close to the Problem as Possible

Once we have identified the problem and fully understood the risks, we must look for a solution that is as close to the problem as possible. Regulation is distant and removed from the point of care and problems are best solved near to where they occur. Targeted regulation needs to understand both the range of hazards and the factors that increase or decrease the risk of them resulting in harm. This means understanding the context in which the problem arises and the different tools that may be available to tackle the issues. We may need to work with organizations and individuals that are closer to the problem to bring about change. Some problems may be best tackled by regulatory measures applying to a whole profession, while others may require more targeted regulation or a non-regulatory approach.

## Focus on the Outcome

Adopting a “right-touch” approach means staying focused on the outcome that we are looking to achieve, rather than being concerned about process, or prioritizing interests other than public safety. The outcome should be both tangible and measurable, and it must be directed towards the reduction of harm. Staying focused on the outcome helps identify the most appropriate solution. Having a clearly defined and measurable outcome also makes it easier to measure effectiveness.

## Use Regulation Only When Necessary

Once the problem has been considered, we may begin to examine whether a regulatory change is the right proposal, evaluating this against the options of doing nothing and the risks and benefits of intervening. Making changes to regulation, especially statutory regulation, can be a slow process, so regulation should only be used as a solution when other actions are unable to deliver the desired results. A right-touch regulatory solution must keep to the six principles of good regulation and should build on existing approaches where possible. This will often involve looking for solutions other than regulation and may require regulators to work with other organizations and people to bring about change.

**E. How can the hazards be managed without state regulation?** Total harm ratings under 14 *may best be managed through non-governmental strategies*. If they can't, explain why.

<b>0</b>	<b>Market competition</b>	Yelp, Angie's List, Facebook, word of mouth
<b>0</b>	<b>Quality service self-disclosure</b>	Written specific warranty or money-back guarantee
<b>0</b>	<b>Voluntary third-party certification</b>	Better Business Bureau, national accreditation
<b>1</b>	<b>Partnership with stakeholders</b>	Employer/facility oversight, such as training, qualifications, codes of conduct, supervision, and evaluation
<b>1</b>	<b>Voluntary bonding/insurance</b>	Proof of insurance or bond is available
<b>2</b>	<b>Local/municipal ordinance</b>	Regulated or managed at the local level
Assign numbers	<b>Other ideas:</b>	

<b>Hazard</b>	<b>Non-State Management Rating</b>	<b>Explanation of your suggested management <i>solution</i> in section E</b>
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

## Keep it Simple

For regulation to work, it must be clear to those who are regulated, clear to the public, clear to employers, and clear to the regulator. If each cannot explain to the other what the purpose of a regulation is and why it will work, it is not simple. This is as true in health and social care, with such a wide variety of agencies and individuals involved, as it is in other sectors. Avoiding complexity will lead to a greater impact. A regulatory response should be as simple as it can be while achieving the desired outcome.

## Check for Unintended Consequences

Assessing the probable impact of a particular solution is an essential step to help us avoid unintended consequences. In a system as interconnected and complex as health and social care, for example, it is inevitable that proposing a change in policy and practice will have consequences for other parts of the system. If regulations are not workable, people will work around them and in doing so create new risks. Regulating to remove one risk without a proper analysis of the consequences may create new risks or merely move the risk to a different place.

**F. How can the risk of hazards be managed through government regulation?** List the potential unintended consequences or new risks created by government intervention.

**Do these consequences outweigh the benefits of regulation? Why is state intervention the only solution?** Validate your answer; you may find that you change your mind.

<b>2</b>	<b>Legal recourse/consumer protection acts</b>	Legal grounds for court action, may enjoin the state
<b>3</b>	<b>Mandatory bonding/insurance</b>	Law requires proof of insurance or bonding
<b>5</b>	<b>State Inspection</b>	Periodic safety or compliance reviews by state agency
<b>6</b>	<b>State Registration</b>	Must be on an approved state list; minimal entry criteria required
<b>8</b>	<b>State Certification</b>	Must meet state criteria, no discipline is applicable
<b>10</b>	<b>State Licensure</b>	Must meet state criteria, may be disciplined for violations
Hazard	State Management Rating	Explanation of your suggested management <i>solution</i> in section F
1.		

2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

**G. Rate the level of restriction on market participants or restriction of access to services created by the management of each hazard.**

<b>1-2</b>	<b>Not restrictive:</b> No solution is necessary.
<b>3-4</b>	<b>Minimally restrictive:</b> A voluntary market solution like self-certification or bonding was selected. Most people can easily meet these criteria, and the service is widely available.
<b>5-6</b>	<b>Moderately restrictive:</b> A low-impact regulatory solution like registration, bonding, or insurance was selected. Most people seeking to enter the profession can meet these criteria, and the service is available in most markets.
<b>7-8</b>	<b>Very restrictive:</b> National certification/examination or another universal industry standard was selected. Many people seeking to enter the profession can meet these criteria, and the service is usually available in medium-to-large markets.
<b>9-10</b>	<b>Extremely restrictive:</b> Full licensure with criteria like restricted education, supervision, and examination was selected. Some people seeking to enter the profession can meet these criteria, and the service is usually only available in large markets.

Hazard	Restrictiveness Rating	Explanation of the restrictions created by your suggested <i>management</i> solutions in sections E and F.
1.		
2.		
3.		

4.		
5.		
6.		
7.		
8.		
9.		
10.		

## Review and Respond to Change

We should build flexibility into regulatory strategy to enable regulation to respond to change. All sectors evolve over time, as a result of a range of different influences. Regulators must not be left managing the crises of the past, while ignoring or being unable to react to new evidence that calls for change. This is what we mean by agility. A program of regular reviews, evaluation, and sunset audits can all help here.

### H. Rate the level of flexibility of the management strategy as determined above.

<b>1</b>	<b>Extremely flexible:</b> No solution is necessary.	
<b>3</b>	<b>Moderately flexible:</b> Solution is managed by the participant or employer.	
<b>7</b>	<b>Minimally flexible:</b> Management of the problem requires state regulation change.	
<b>10</b>	<b>Not flexible:</b> Management of the problem requires state statute change.	
Hazard	Flexibility Rating	Provide method and frequency of evaluation to determine whether the solution is relevant and effective and—if not—how changes can be made
1.		
2.		
3.		
4.		

5.		
6.		
7.		
8.		
9.		
10.		

## I. Total all your *management* ratings:

Below your ratings, write down your observations. Are you surprised that a particular hazard has a higher number—and therefore a more regulatory management response—than others? Reconsider any changes. If you are doing this exercise in a small group, discuss your ratings and answers with colleagues.

Hazard	Non-State Management Rating	State Management Rating	Restrictiveness Rating	Flexibility Rating	TOTAL
1.					
2.					
3.					
4.					
5.					

6.					
7.					
8.					
9.					
10.					

## J. Determining next steps

What must happen to adjust the climate of regulation of the profession you are reviewing? Review the documentation you have created in the previous exercises.

Hazard	Changes needed to implement new management strategies	Current inhibitors to improvement in management of relevant hazards
1.		
2.		
3.		
4.		
5.		

6.		
7.		
8.		
9.		
10.		



Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing

Board of Pharmacy  
Schedule of Revenues and Expenditures

	FY 12		FY 13		FY 14		FY 15		FY 16		FY 17		FY 18		FY19 1st - 3rd Qtr		
Licensing Revenue	\$	500,238	\$	159,341	\$	673,100	\$	269,646	\$	802,230	\$	208,755	\$	801,317	\$	153,635	
Allowable Third Party Reimbursement		-		-		1,701		-		-		3,256		\$	210	\$	73
<b>Total Revenue</b>		<b>500,238</b>		<b>159,341</b>		<b>674,801</b>		<b>269,646</b>		<b>802,230</b>		<b>212,011</b>		<b>801,527</b>		<b>153,708</b>	
<b>Direct Expenditures</b>																	
Personal Services		162,493		158,574		182,280		164,266		225,050		215,674		273,406		187,855	
Travel		15,713		18,850		24,054		24,548		16,676		11,119		13,704		7,410	
Contractual		19,799		11,798		24,633		9,149		14,812		41,331		21,960		22,834	
Supplies		1,385		365		69		90		111		519		-		26	
Equipment		-		-		-		-		-		-		-		-	
<b>Total Direct Expenditures</b>		<b>199,390</b>		<b>189,587</b>		<b>231,036</b>		<b>198,053</b>		<b>256,649</b>		<b>268,643</b>		<b>309,070</b>		<b>218,125</b>	
Indirect Expenditures*		213,722		228,785		197,912		145,863		192,296		222,916		259,680		194,760	
<b>Total Expenses</b>		<b>413,112</b>		<b>418,372</b>		<b>428,948</b>		<b>343,916</b>		<b>448,945</b>		<b>491,559</b>		<b>568,750</b>		<b>412,885</b>	
<b>Annual Surplus (Deficit)</b>		<b>87,126</b>		<b>(259,031)</b>		<b>245,853</b>		<b>(74,270)</b>		<b>353,285</b>		<b>(279,548)</b>		<b>232,777</b>		<b>(259,177)</b>	
Beginning Cumulative Surplus (Deficit)		201,801		288,927		29,896		275,749		201,479		554,764		275,216		507,993	
<b>Ending Cumulative Surplus (Deficit)</b>	<b>\$</b>	<b>288,927</b>	<b>\$</b>	<b>29,896</b>	<b>\$</b>	<b>275,749</b>	<b>\$</b>	<b>201,479</b>	<b>\$</b>	<b>554,764</b>	<b>\$</b>	<b>275,216</b>	<b>\$</b>	<b>507,993</b>	<b>\$</b>	<b>248,816</b>	

\*\* For the first three quarters, indirect costs are based on the prior fiscal year's total indirect amount on a percent of year completed basis.

The 4th quarter board reports reflect the current year's actual indirect expenses allocated to the boards.

Biennium July 1, 2018 — June 30, 2020

Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing

Appropriation	(All)
AL Sub Unit	(All)
PL Task Code	PHA1

Sum of Expenditures Object Code	Object Name	Object Type Code				Grand Total
		1000	2000	3000	4000	
1011	Regular Compensation	99,229.77				99,229.77
1014	Overtime	40.64				40.64
1023	Leave Taken	16,842.61				16,842.61
1028	Alaska Supplemental Benefit	7,133.27				7,133.27
1029	Public Employee's Retirement System Defined Benefits	9,026.66				9,026.66
1030	Public Employee's Retirement System Defined Contribution	3,940.73				3,940.73
1034	Public Employee's Retirement System Defined Cont Health Reim	2,850.94				2,850.94
1035	Public Employee's Retirement Sys Defined Cont Retiree Medical	704.35				704.35
1037	Public Employee's Retirement Sys Defined Benefit Unfnd Liab	8,985.35				8,985.35
1039	Unemployment Insurance	264.24				264.24
1040	Group Health Insurance	31,684.13				31,684.13
1041	Basic Life and Travel	48.03				48.03
1042	Worker's Compensation Insurance	1,090.69				1,090.69
1047	Leave Cash In Employer Charge	2,678.04				2,678.04
1048	Terminal Leave Employer Charge	1,530.12				1,530.12
1053	Medicare Tax	1,612.48				1,612.48
1069	SU Business Leave Bank Contributions	3.92				3.92
1077	ASEA Legal Trust	158.65				158.65
1079	ASEA Injury Leave Usage	11.33				11.33
1080	SU Legal Trst	18.84				18.84
2000	In-State Employee Airfare		1,093.53			1,093.53
2001	In-State Employee Surface Transportation		89.02			89.02
2002	In-State Employee Lodging		1,108.00			1,108.00
2003	In-State Employee Meals and Incidentals		452.00			452.00
2005	In-State Non-Employee Airfare		661.69			661.69
2007	In-State Non-Employee Lodging		2,126.00			2,126.00
2008	In-State Non-Employee Meals and Incidentals		840.00			840.00
2009	In-State Non-Employee Taxable Per Diem		240.00			240.00
2010	In-State Non-Employee Non-Taxable Reimbursement		560.27			560.27
2020	Out-State Non-Employee Meals and Incidentals		189.00			189.00
2022	Out-State Non-Employee Non-Taxable Reimbursement		48.00			48.00
2036	Cash Advance Fee		2.44			2.44
2970	Travel Cost Transfer		-			-
3001	Test Monitor/Proctor					-
3002	Memberships			250.00		250.00
3035	Long Distance			60.43		60.43
3036	Local/Equipment Charges			245.07		245.07
3045	Postage			120.59		120.59
3046	Advertising			149.70		149.70
3057	Structure, Infrastructure and Land - Rentals/Leases			60.35		60.35
3069	Commission Sales			156.50		156.50
3088	Inter-Agency Legal			14,749.55		14,749.55
4002	Business Supplies				26.00	26.00
3094	Inter-Agency Hearing/Mediation			7,041.50		7,041.50
<b>Grand Total</b>		<b>187,854.79</b>	<b>7,409.95</b>	<b>22,833.69</b>	<b>26.00</b>	<b>218,124.43</b>

Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing  
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 14	FY 15	Biennium	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium
<b>Revenue</b>									
Revenue from License Fees	\$ 673,100	\$ 269,646	\$ 942,746	\$ 802,230	\$ 208,755	\$ 1,010,985	\$ 801,317	\$ 213,770	\$ 1,015,087
Allowable Third Party Reimbursements	1,701	-	1,701	-	3,256	3,256	210	962	1,172
<b>TOTAL REVENUE</b>	<b>\$ 674,801</b>	<b>\$ 269,646</b>	<b>\$ 944,447</b>	<b>\$ 802,230</b>	<b>\$ 212,011</b>	<b>\$ 1,014,241</b>	<b>\$ 801,527</b>	<b>\$ 214,732</b>	<b>\$ 1,016,259</b>
<b>Expenditures</b>									
Non Investigation Expenditures									
1000 - Personal Services	132,988	115,222	248,210	156,115	151,947	308,062	204,727	194,745	399,472
2000 - Travel	24,054	24,548	48,602	16,676	11,119	27,795	13,704	8,299	22,003
3000 - Services	17,003	4,569	21,572	13,361	14,293	27,654	21,960	27,781	49,741
4000 - Commodities	69	90	159	111	519	630	-	26	26
5000 - Capital Outlay	-	-	-	-	-	-	-	-	-
Total Non-Investigation Expenditures	174,114	144,429	318,543	186,263	177,878	364,141	240,391	230,851	471,242
Investigation Expenditures									
1000-Personal Services	49,292	49,044	98,336	68,935	63,727	132,662	68,679	69,997	138,676
2000 - Travel	-	-	-	-	2,800	2,800	-	-	-
3023 - Expert Witness	-	-	-	-	23,355	24,806	-	3,062	3,062
3088 - Inter-Agency Legal	7,630	4,580	12,210	1,451	883	883	-	-	-
3094 - Inter-Agency Hearing/Mediation	-	-	-	-	-	-	-	-	-
3000 - Services other	-	-	-	-	-	-	-	400	400
4000 - Commodities	-	-	-	-	-	-	-	-	-
Total Investigation Expenditures	56,922	53,624	110,546	70,386	90,765	161,151	68,679	73,459	142,138
<b>Total Direct Expenditures</b>	<b>231,036</b>	<b>198,053</b>	<b>429,089</b>	<b>256,649</b>	<b>268,643</b>	<b>525,292</b>	<b>309,070</b>	<b>304,310</b>	<b>613,380</b>
Indirect Expenditures									
Internal Administrative Costs	123,716	72,555	196,271	128,025	123,008	251,033	150,986	155,128	306,114
Departmental Costs	45,898	48,021	93,919	48,707	73,682	122,389	78,139	81,374	159,513
Statewide Costs	28,298	25,287	53,585	15,564	26,226	41,790	30,555	27,069	57,624
<b>Total Indirect Expenditures</b>	<b>197,912</b>	<b>145,863</b>	<b>343,775</b>	<b>192,296</b>	<b>222,916</b>	<b>415,212</b>	<b>259,680</b>	<b>263,571</b>	<b>523,251</b>
<b>TOTAL EXPENDITURES</b>	<b>\$ 428,948</b>	<b>\$ 343,916</b>	<b>\$ 772,864</b>	<b>\$ 448,945</b>	<b>\$ 491,559</b>	<b>\$ 940,504</b>	<b>\$ 568,750</b>	<b>\$ 567,881</b>	<b>\$ 1,136,631</b>
<b>Cumulative Surplus (Deficit)</b>									
Beginning Cumulative Surplus (Deficit)	\$ 29,896	\$ 275,749		\$ 201,479	\$ 554,764		\$ 275,216	\$ 507,993	
Annual Increase/(Decrease)	245,853	(74,270)		353,285	(279,548)		232,777	(353,149)	
Ending Cumulative Surplus (Deficit)	\$ 275,749	\$ 201,479		\$ 554,764	\$ 275,216		\$ 507,993	154,844	
							* Fee analysis recommended		
<b>Statistical Information</b>									
Number of Licensees	4,134	4,756		4,649	5,068		5,680	6,203	
<b>Additional information:</b>									
<ul style="list-style-type: none"> <li>• Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses *</li> <li>• Most recent fee change: Fee reduction FY20</li> <li>• Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.</li> </ul>									

Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing  
Schedule of Revenues and Expenditures

Appropriation	(All)
AL Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures Object Name (Ex)	Object Type Name (Ex)				Grand Total
	1000 - Personal Services	2000 - Travel	3000 - Services	4000 - Commodities	
1011 - Regular Compensation	139,352.22				139,352.22
1014 - Overtime	40.64				40.64
1023 - Leave Taken	21,318.08				21,318.08
1028 - Alaska Supplemental Benefit	9,880.98				9,880.98
1029 - Public Employee's Retirement System Defined Benefits	13,710.32				13,710.32
1030 - Public Employee's Retirement System Defined Contribution	5,173.81				5,173.81
1034 - Public Employee's Retirement System Defined Cont Health Reim	3,641.88				3,641.88
1035 - Public Employee's Retirement Sys Defined Cont Retiree Medical	924.95				924.95
1037 - Public Employee's Retirement Sys Defined Benefit Unfnd Liab	11,898.30				11,898.30
1039 - Unemployment Insurance	285.51				285.51
1040 - Group Health Insurance	46,083.72				46,083.72
1041 - Basic Life and Travel	69.24				69.24
1042 - Worker's Compensation Insurance	1,347.21				1,347.21
1047 - Leave Cash In Employer Charge	3,711.66				3,711.66
1048 - Terminal Leave Employer Charge	2,245.76				2,245.76
1051 - Leave/Holiday Pool	33.51				33.51
1053 - Medicare Tax	2,236.42				2,236.42
1063 - GGU Business Leave Bank Usage	-				-
1069 - SU Business Leave Bank Contributions	3.92				3.92
1077 - ASEA Legal Trust	208.69				208.69
1079 - ASEA Injury Leave Usage	11.33				11.33
1080 - SU Legal Trst	20.76				20.76
1970 - Personal Services Transfer	2,542.97				2,542.97
2000 - In-State Employee Airfare		1,093.53			1,093.53
2001 - In-State Employee Surface Transportation		89.02			89.02
2002 - In-State Employee Lodging		1,108.00			1,108.00
2003 - In-State Employee Meals and Incidentals		452.00			452.00
2005 - In-State Non-Employee Airfare		661.69			661.69
2007 - In-State Non-Employee Lodging		2,126.00			2,126.00
2008 - In-State Non-Employee Meals and Incidentals		840.00			840.00
2009 - In-State Non-Employee Taxable Per Diem		240.00			240.00
2010 - In-State Non-Employee Non-Taxable Reimbursement		560.27			560.27
2020 - Out-State Non-Employee Meals and Incidentals		189.00			189.00
2022 - Out-State Non-Employee Non-Taxable Reimbursement		48.00			48.00
2036 - Cash Advance Fee		2.44			2.44
2970 - Travel Cost Transfer		888.91			888.91
3001 - Test Monitor/Proctor				-	-
3002 - Memberships			250.00		250.00
3035 - Long Distance			115.18		115.18
3036 - Local/Equipment Charges			450.42		450.42
3045 - Postage			344.07		344.07
3046 - Advertising			1,788.61		1,788.61
3057 - Structure, Infrastructure and Land - Rentals/Leases			80.81		80.81
3069 - Commission Sales			156.50		156.50
3088 - Inter-Agency Legal			18,245.66		18,245.66
3094 - Inter-Agency Hearing/Mediation			7,844.40		7,844.40
3970 - Contractual Transfer			1,968.00		1,968.00
4002 - Business Supplies				26.00	26.00
<b>Grand Total</b>	<b>264,741.88</b>	<b>8,298.86</b>	<b>31,243.65</b>	<b>26.00</b>	<b>304,310.39</b>

Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing

Prescription Drug Monitoring Program  
Schedule of Revenues and Expenditures

	FY 12	FY 13	FY 14	FY 15	FY16	FY17	FY18	FY19 1st - 3rd Qtr
Licensing Revenue	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 11,910	\$ 86,565
Allowable Third Party Reimbursement	-	-	-	-	-	-	\$ -	\$ -
<b>Total Revenue</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>11,910</b>	<b>86,565</b>
<b>Direct Expenditures</b>								
Personal Services	-	-	-	-	-	-	-	4
Travel	-	-	-	-	-	-	-	491
Contractual	-	-	-	-	-	-	-	12
Supplies	-	-	-	-	-	-	-	-
Equipment	-	-	-	-	-	-	-	-
<b>Total Direct Expenditures</b>	<b>-</b>	<b>507</b>						
Indirect Expenditures*	-	-	-	-	-	-	-	-
<b>Total Expenses</b>	<b>-</b>	<b>507</b>						
<b>Annual Surplus (Deficit)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>11,910</b>	<b>86,058</b>
Beginning Cumulative Surplus (Deficit)	-	-	-	-	-	-	-	11,910
<b>Ending Cumulative Surplus (Deficit)</b>	<b>\$ -</b>	<b>\$ 11,910</b>	<b>\$ 97,968</b>					

Department of Commerce Community, and Economic Development  
Corporations, Business and Professional Licensing

Appropriation	(All)
AL Sub Unit	(All)
PL Task Code	PDMP

Sum of Expenditures		Object Type Code			Grand Total
Object Code	Object Name	1000	2000	3000	
1028	Alaska Supplemental Benefit	2.76			2.76
1042	Worker's Compensation Insurance	0.39			0.39
1053	Medicare Tax	0.64			0.64
2000	In-State Employee Airfare			445.54	445.54
2003	In-State Employee Meals and Incidentals			45.00	45.00
3069	Commission Sales				12.00
<b>Grand Total</b>		<b>3.79</b>		<b>490.54</b>	<b>12.00</b>

Note: 4/22/19  
The expenses will be AJE'd to remove the TASK.

## **Maiquis, Jun C (CED)**

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**From:** Alaska Online Public Notices <noreply@state.ak.us>  
**Sent:** Friday, April 26, 2019 4:01 PM  
**To:** Maiquis, Jun C (CED)  
**Subject:** New Comment on NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY

A new comment has been submitted on the public notice **NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY.**

### **Submitted:**

4/26/2019 4:00:33 PM

Tom Wadsworth  
[wadsthom@isu.edu](mailto:wadsthom@isu.edu)

Unknown location  
Anonymous User

### **Comment:**

The intern license changes are much needed and will relieve the burden that has been placed on pharmacy interns receiving their full pharmacy education in the state. Many employers have been requiring Interns to also carry technician licenses which is redundant, costly, and abusive to Interns.

Additionally, the elimination of the sponsorship declaration form for Interns will reduce the voluminous paperwork which does not enhance patient safety or intern experience. This has been an unnecessary burden on preceptors, students, and the board for some time and I fully support these changes.

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You can review all comments on this notice by [clicking here](#).

[Alaska Online Public Notices](#)

## **Maiquis, Jun C (CED)**

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**From:** Louise Lovrich <louise@denalioutdoorcenter.com>  
**Sent:** Saturday, April 27, 2019 10:44 AM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Pharmacist licensee reduction

Hello to whom it may concern,

I am in favour of the fees being reduced.

Regards

Louise Lovrich  
RPH 1088

## Maiquis, Jun C (CED)

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**From:** Regulations and Public Comment (CED sponsored)  
**Sent:** Friday, May 03, 2019 1:46 PM  
**To:** 'lala wu'  
**Subject:** RE: Notice of Proposed Regulations (Board of Pharmacy 12 AAC 52.010 - .995)

Please review the Proposed Regulations FAQ published on the Board of Pharmacy website:  
<https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx>

Thank you,  
Jun Maiquis

**From:** lala wu <besos2lala@gmail.com>  
**Sent:** Sunday, April 28, 2019 8:45 PM  
**To:** Regulations and Public Comment (CED sponsored) <regulationsandpubliccomment@alaska.gov>  
**Subject:** Re: Notice of Proposed Regulations (Board of Pharmacy 12 AAC 52.010 - .995)

Hello ,

I received my license last year December 2019 and I only wanted it for retail pharmacy plus I haven't used because I didn't want to take a job because I will be having major surgery soon ! I've been reading trying to see what effects it would have towards me ! It's a little confusing!

On Fri, Apr 26, 2019 at 2:05 PM Regulations and Public Comment (CED sponsored) <regulationsandpubliccomment@alaska.gov> wrote:

Dear Recipient,

The Alaska 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).

Attached are copies of the public notice and draft of the proposed regulation changes.

Comments must be received not later than 4:30 p.m. on May 24, 2019.

Thank you,

Alaska Board of Pharmacy

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you know it's all good!

## Maiquis, Jun C (CED)

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**From:** Carrillo, Laura N (CED)  
**Sent:** Monday, May 06, 2019 11:27 AM  
**To:** Kristen Burns  
**Cc:** Maiquis, Jun C (CED)  
**Subject:** RE: Alaska State Regulations - Drug Establishments who Manufacture or Private Label Distribute for import to Alaska

Hi Kristen,

Please see my responses in **green**, below:

For Alaska please advise if there are the following requirements:

- 1.Registration requirement? **Yes, Alaska wholesale distributors that engage in the manufacture of drug products requiring a prescription**
2. Method of submission (online, paper, etc)? **Paper, but online will be available in the future**
3. Renewal of the registration? **Every two years**
4. Fee to register? **View proposed fees [here](#)**
5. Annual Fee? **No annual fee**

For Out of State or Foreign facilities who wish to import to Alaska-

1. Registration required? **Yes, registration will be required effective July 1, 2019**
2. Method of submission (online, paper, etc)? **Paper, but online will be available in the future**
3. Renewal of the registration? **Every two years**
4. Fee to register? **View proposed fees [here](#)**
5. Annual Fee? **No annual fee**

Please feel free to subscribe to our ListServ: <http://list.state.ak.us/mailman/listinfo/akboardofpharmacy>

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

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**From:** Kristen Burns [mailto:kburns@registrarcorp.com]  
**Sent:** Monday, May 6, 2019 10:49 AM  
**To:** Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>  
**Cc:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>; Kristen Burns <kburns@registrarcorp.com>  
**Subject:** Re: Alaska State Regulations - Drug Establishments who Manufacture or Private Label Distribute for import to Alaska

Good Day Jun -

Thank you for your prompt response and for forwarding our request.

We will await a response from Laura.

We appreciate all your time and assistance.

--

Sincerely,  
Kristen Burns, M.S.  
Regulatory Specialist  
Drug and Tobacco Division  
Registrar Corp  
144 Research Drive  
Hampton, Virginia, USA 23666  
Tel: +1-757-224-0177  
Fax: +1-757-224-0179  
Email: [kburns@registrarcorp.com](mailto:kburns@registrarcorp.com)  
Web Site: <http://www.registrarcorp.com>

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U.S. FDA Regulatory Updates: <http://fda-news.registrarcorp.com>

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On 5/6/2019 2:40 PM, Maiquis, Jun C (CED) wrote:

Hello Kristen, I will pass your questions to Laura Carrillo, Executive Administrator and the assigned staff for the Board of Pharmacy. Laura might be able to answer your questions, and I have copied her on this email.

Thanks!  
Jun Maiquis

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**From:** Kristen Burns <[kburns@registrarcorp.com](mailto:kburns@registrarcorp.com)>  
**Sent:** Monday, May 06, 2019 10:10 AM  
**To:** Maiquis, Jun C (CED) <[jun.maiquis@alaska.gov](mailto:jun.maiquis@alaska.gov)>  
**Cc:** Kristen Burns <[kburns@registrarcorp.com](mailto:kburns@registrarcorp.com)>  
**Subject:** Alaska State Regulations - Drug Establishments who Manufacture or Private Label Distribute for import to Alaska

Good Day -  
We have questions regarding the obligatory regulations for Drug Manufacturers (both Over the Counter, and Prescription), and other drug facility functions.  
Could you please advise the following information in order for us to better understand the requirements for your particular state.

It is important to note we would like to understand the role of the MFG (both in your state, and out of state or international) who will be shipping or importing drug products to your state.

For Alaska please advise if there are the following requirements:

1. Registration requirement?
2. Method of submission (online, paper, etc)?
3. Renewal of the registration?
4. Fee to register?
5. Annual Fee?

For Out of State or Foreign facilities who wish to import to Alaska-

1. Registration required?
2. Method of submission (online, paper, etc)?
3. Renewal of the registration?
4. Fee to register?
5. Annual Fee?

If you need any further clarifications of our questions please contact our office.

--

Sincerely,  
Kristen Burns, M.S.  
Regulatory Specialist  
Drug and Tobacco Division  
Registrar Corp  
144 Research Drive  
Hampton, Virginia, USA 23666  
Tel: +1-757-224-0177  
Fax: +1-757-224-0179  
Email: [kburns@registrarcorp.com](mailto:kburns@registrarcorp.com)  
Web Site: <http://www.registrarcorp.com>

24-Hour Live Online Help: <http://www.registrarcorp.com/livehelp>

U.S. FDA Regulatory Updates: <http://fda-news.registrarcorp.com>

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## **Maiquis, Jun C (CED)**

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**From:** Carrillo, Laura N (CED)  
**Sent:** Wednesday, May 08, 2019 10:48 AM  
**To:** Cory.Romzo@ge.com  
**Cc:** Maiquis, Jun C (CED)  
**Subject:** RE: Questions Regarding Proposed Changes to Board of Pharmacy Regulations

Hi Cory,

Have you checked the definitions section of our [statutes and regulations](#) (page 10)? An outsourcing facility application would be required to be submitted if your company engages in compounding of sterile drugs for a facility located elsewhere. A wholesale drug distributor mass distributes drugs, so this one sounds like it best fits the type of services your company engages in. A virtual manufacturer is more so considered a third-party logistics provider rather than a wholesale drug distributor as long as the company is not taking ownership of the actual drug products, similar to how Amazon operates. If one of the business operations of the Global Supply Chain's facility falls under the definition of "third party logistics provider" under AS 08.80.480(38), then it should apply for this license type accordingly.

The board will be reviewing public comments at their meeting on June 6<sup>th</sup> and 7<sup>th</sup> and so could provide more information to your question, if needed. The agenda is not yet available; however, please feel free to check our website periodically for updates.

You can also subscribe to our new ListServe here: <http://list.state.ak.us/mailman/listinfo/akboardofpharmacy>

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

**From:** Regulations and Public Comment (CED sponsored)  
**Sent:** Thursday, May 2, 2019 8:45 AM  
**To:** Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** FW: Questions Regarding Proposed Changes to Board of Pharmacy Regulations

Laura, here's another question, see below. Again, please cc me when you response to Mr. Romzo. Thanks! JM

**From:** Romzo, Cory (GE Healthcare) <[Cory.Romzo@ge.com](mailto:Cory.Romzo@ge.com)>  
**Sent:** Wednesday, May 01, 2019 8:49 AM  
**To:** Regulations and Public Comment (CED sponsored) <[regulationsandpubliccomment@alaska.gov](mailto:regulationsandpubliccomment@alaska.gov)>  
**Subject:** Questions Regarding Proposed Changes to Board of Pharmacy Regulations

To whom it may concern,

In reviewing the proposed regulations on your website, I was unable to confirm whether or not registration of out-of-state manufacturer's, out-of-state virtual manufacturer's or out-of-state contract manufacturers will be required to register with the Board. As my organization operates three out-of-state facilities manufacturing diagnostic imaging drugs and can fall into these three categories, I am unclear as to the expectations of this proposed regulation. As we are looking to remain compliant with the State of Alaska regulations, is it possible to receive confirmation that this can be addressed either within the new regulations or an email response?

Thank you for providing the opportunity to comment on this new regulation.

Regards,  
Cory

**Cory W. Romzo**  
Compliance Leader  
Global Supply Chain, Life Sciences  
GE Healthcare

T +1 847 385 5151 | F +1 847 818 6619 | M +1 847 226 8029  
E [cory.romzo@ge.com](mailto:cory.romzo@ge.com)  
[www.gehealthcare.com](http://www.gehealthcare.com)

## Maiquis, Jun C (CED)

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**From:** Doug Noaeill <Doug@GreatLandInfusionPharmacy.com>  
**Sent:** Wednesday, May 08, 2019 10:49 AM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Practice of Pharmacy regulations proposed changes

I have comments on three proposed changes:

12AAC 52.465 Does Federal Law allow partial fill of C-II prescriptions for a patient who is not terminally ill or residing in a long term care facility? I did not think federal law allowed this.

12 AAC 52.470 (d) PLEASE add that an insurance company and/or PBM may not take back money paid for such prescription during any audit process.

12 AAC 52.995 (a) (37) "moral turpitude" is a very ambiguous term and has been used to discriminate against people for years. Being a gay man I can easily be seen as "immoral" in certain circles/communities. I can easily see the honesty/criminal records/etc, but moral turpitude/good morals are not easily defined and should not be included anywhere within the pharmacy regulations.

Doug Noaeill RPh/Owner

Great Land Infusion Pharmacy  
2421 E. Tudor Rd #107  
Anchorage, AK 99507

(907)561-2421

## Maiquis, Jun C (CED)

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**From:** Carrillo, Laura N (CED)  
**Sent:** Thursday, May 09, 2019 1:00 PM  
**To:** Maiquis, Jun C (CED)  
**Subject:** Fwd: Remote Pharmacy License (12 AAC 52.423)  
**Attachments:** Outlook-1475781359.png; ATT00001.htm; Alaska 050119.pdf; ATT00002.htm

Public comment

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
  
Alaska Board of Pharmacy  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

Begin forwarded message:

**From:** "Chesler, Adam" <[adam.chesler@cardinalhealth.com](mailto:adam.chesler@cardinalhealth.com)>  
**Date:** May 9, 2019 at 12:51:50 PM AKDT  
**To:** "[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)" <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** **Re: Remote Pharmacy License (12 AAC 52.423)**

Laura-

Comments are attached for the proposed Remote Pharmacy License rules (12 AAC 52.423.)

Please let me know if you have any additional questions.

Thanks



CardinalHealth™

VIA EMAIL (laura.carrillo@alaska.gov)

May 1st, 2019

Laura Carrillo, Executive Administrator  
Division of Corporations, Business and Professional Licensing  
Department of Commerce, Community, and Economic Development  
P.O. Box 110806  
Juneau, AK 99811-0806

Re: Remote Pharmacy License (12 AAC 52.423)

Dear Ms. Carrillo:

On behalf of Cardinal Health, I would like to thank the Alaska Board of Pharmacy (AKBoP) for the opportunity to comment on the proposed amendments to the Remote Pharmacy License (12 AAC 52.423) chapter, which will assist in providing residents of Alaska greater access to pharmacist care. We appreciate the AKBoP's consideration of our views on this matter.

While we applaud the AKBoP for all the hard work that has gone into drafting these rules, we have identified one section which, with minor revisions, could have a much more significant impact on access to healthcare for the residents of Alaska. This includes the following:

- 12 AAC 52.423(c) is amended to remove the requirement where a Remote Pharmacy would be forced to close if another pharmacy opens within ten (10) road miles of the remote pharmacy.
- Unfortunately, the clause which only permits a remote pharmacy to open within ten (10) road miles of a non-remote pharmacy remains in place
  - Remote pharmacies are being used in urban medically underserved areas where patients may have disabilities or transportation issues. Studies have shown that even a mile can be a hardship for these patients leading to decreased medication adherence and outcomes to therapy. While Alaska is mostly considered a rural state, approximately 500,000 residents live in urban areas.
  - 340b clinics, hospitals, FQHC, mental health facilities, and many others struggle with patient's adherence to medications; access to a remote pharmacy on-site can reduce nonadherence
  - Inclement weather or treacherous terrain such as mountains or bodies of water can make even 10 road miles a hardship for patients, even those with reliable transportation
  - If a remote pharmacy is safe at 10 miles, it can be utilized safely without a mileage restriction. This has been demonstrated in many states, including Idaho, Arizona, North Dakota, and Illinois.

- Improved access to a pharmacist will improve healthcare for residents of Alaska. **Of the 96 cities with a population greater than 500 located in Alaska, 73%, or 70 cities, do not have a pharmacy.**
  
- We recommend an additional amendment to section 52.423 as follows
  - (b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that
    - ~~(1) it is able to comply with the requirements of 12 AAC 52.425; and~~
    - ~~(2) there is no access to a non-remote pharmacy within ten road miles of the proposed 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.~~

Cardinal Health thanks the Board for considering our comments on this matter. We hope that the board will reconsider their language to align with the public's best interest, and we are willing to meet with the Board at any time appropriate to discuss further. Please do not hesitate to contact me with any questions or for further assistance. I can be reached at 319-774-7725 or [adam.chesler@cardinalhealth.com](mailto:adam.chesler@cardinalhealth.com).

Respectfully,



Adam Chesler, PharmD, MBA

## Maiquis, Jun C (CED)

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**From:** Angharad Ratliff <ratlangh@isu.edu>  
**Sent:** Thursday, May 16, 2019 1:02 PM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Board of Pharmacy Proposed Regulation Changes

To Whom It May Concern,

I am writing in support of the proposed regulation changes as they relate to pharmacist interns. As a preceptor for many different students and in three different states, I believe it is appropriate to remove the requirement for sponsorship. This has not been a requirement in the previous states that I practiced in (Texas, California, Oklahoma) and I do not feel that it enhances the intern experience. Because of this requirement, our students are forced to select a faculty member as their sponsor who may or may not be supervising all of their activities. Other states have utilized a preceptor certification to focus the training of interns and I feel that this is more worthwhile. Preceptor certification would require additional training for those pharmacists who desire to train students.

In regards to the proposed regulation change such that a pharmacist intern may perform any duties of a pharmacy technician, I am also in support. There is not distinction between a pharmacist's ability to perform technician duties and as such, there should not be a distinction for interns. As the regulation stands, it has hindered the ability of our students to get additional training as interns without a technician license.

Thank you for your consideration,

Angharad Ratliff

--

Angharad Ratliff, PharmD, BCCCP, BCPS  
Clinical Assistant Professor  
UAA/ISU Doctor of Pharmacy Program  
[ratlangh@isu.edu](mailto:ratlangh@isu.edu)  
(907)786-0733

Alaska Regional Hospital  
[angharad.ratliff@hcahealthcare.com](mailto:angharad.ratliff@hcahealthcare.com)  
(907) 264-1140

## Maiquis, Jun C (CED)

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**From:** AKPhA <akpharmcy@alaska.net>  
**Sent:** Friday, May 17, 2019 2:01 PM  
**To:** Regulations and Public Comment (CED sponsored)  
**Cc:** Carrillo, Laura N (CED); adelecgarrison@gmail.com; 'Barry Christensen'  
**Subject:** Comments, AK Board of Pharmacy Regulation 12 AAC 52.240  
**Attachments:** 2019, Opposition to 12 AAC 52.240.pdf

Please accept the attached letter from the Alaska Pharmacists Association's Board of Directors opposing the addition of regulation 12 AAC 52.240 regarding the changes to the pharmacist collaborative practice authority.

We appreciate the opportunity to submit our comments. Please let us know if you have any questions.

Sincerely,

Molly Gray  
Executive Director  
Alaska Pharmacists Association  
203 W 15th Ave #100  
Anchorage, AK 99501  
Phone (907) 563-8880, FAX (907) 563-7880  
Office Hours: Monday - Friday, 10:30 am - 3:00 pm  
[www.alaskapharmacy.org](http://www.alaskapharmacy.org)



*Dedicated to Preserving, Promoting &  
Leading the Profession of Pharmacy in Alaska*

***Save the Date--September 28, 2019***  
*Academy of Health-System Pharmacy*  
*Fall CE Conference, Alyeska Hotel*



# Alaska Pharmacists Association

May 10, 2019

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Nome

*Amy Paul*  
Anchorage

*Brennon Nelson*  
Anchorage

Dear Alaska Board of Pharmacy:

On behalf of the Alaska Pharmacists Association, we thank you for the opportunity to publicly comment on the proposal to add regulation 12 AAC 52.240. We write to you today to express our opposition to adding 12 AAC 52.240 regarding the changes to the pharmacist collaborative practice authority (CPA). Restricting the ability of a pharmacist to prescribe controlled substances under a collaborative practice agreement could have detrimental effects on the opioid epidemic in Alaska.

The Centers for Disease Control and Prevention is working to empower states to implement comprehensive strategies, including Medication Assisted Therapy (MAT), for preventing prescription-drug overdoses. Expanding access to MAT is a crucial component of combating the opioid epidemic. The addition of 12 AAC 52.240 would undermine efforts to combat the opioid epidemic in Alaska by preventing pharmacists from dispensing or administering MAT, which includes controlled substances. Additionally, this regulation would hinder pharmacists from de-escalating patients on chronic or high-risk opioid regimens. Furthermore, 12 AAC 52.240 opposes the Alaska Opioid Policy Task Force (AOPTF) efforts by preventing access to detox services, preventing improvements to the opioid treatment system in Alaska, and adding regulation with collateral consequences.

In addition, the statement “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” is concerning as not allowing authorizing practitioner compensation could add unnecessary barriers to increasing access to care for Alaskans and advancing the practice of pharmacy. For example: Not allowing for compensation could hinder the quality improvement, auditing process, and sustainability of programs if a physician is unable to be compensated for their time in monitoring the said pharmacist under their CPA. Also, the question arises that if a pharmacist is employed as a provider within a physician clinic could a portion of their billing that goes back to the physician owned clinic be also seen as compensation?

We appreciate your efforts and leadership on this critical issue as we work together to combat the opioid epidemic in Alaska and increase access to quality health care for Alaskans.

Sincerely,

Adele Davis, President  
Alaska Pharmacists Association

<https://www.nejm.org/doi/full/10.1056/NEJMp1402780>

<http://dhss.alaska.gov/AKOpioidTaskForce/Pages/default.aspx>

E-mail: [akphrmcy@alaska.net](mailto:akphrmcy@alaska.net)

203 W. 15<sup>th</sup> Ave., Suite 100 • Anchorage, Alaska 99501 • (907) 563-8880 • (907) 563-7880

## Maiquis, Jun C (CED)

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**From:** Rich <dokholt@mac.com>  
**Sent:** Saturday, May 18, 2019 3:14 PM  
**To:** Regulations and Public Comment (CED sponsored)  
**Cc:** Carrillo, Laura N (CED)  
**Subject:** BOP regulation comment

Hello Board members.

After reviewing the regulations being amended, I recommend re-addressing regulation 12 AAC 52.470(d) for the following reasons:

1. It does not allow a pharmacy to change a dispensing quantity UNLESS it is specifically a 30-day supply. This actually restricts the pharmacy and patient as it doesn't account for any other days' supply product, i.e. topicals, inhalers, insulins, etc
2. It doesn't yet account for nationally certified pharmacy technicians with the tech-check-tech that has been discussed at past board meetings.

My recommendation to the board:

Amend 12 AAC 52.470 (d) to read something along the lines of:

"The pharmacist, nationally certified pharmacy technician or pharmacist intern may dispense any quantity of drug on an original or refill prescription drug order so long as the

- (1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription drug order, including refills; and
- (2) drug is not a federal or state scheduled controlled substance."

Strike (3) as everything in a pharmacy happens under a pharmacist who is exercising professional judgment and thus is not necessary to state in regulation.

Note: Nationally certified pharmacy technicians and pharmacist interns being added to this regulation is looking ahead to the technician regulations that you have discussed in the past. This could just as easily be added to those regulations when the board creates them.

Making the above changes may ultimately enhance flexibility, time and cost savings to the patient and pharmacy.

Thank you,  
Richard Holt  
Pharmacist

## Maiquis, Jun C (CED)

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**From:** NANCY FREI <frei@prodigy.net>  
**Sent:** Sunday, May 19, 2019 4:28 AM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Opposition to 12 AAC 52.240

Dear Alaska Board of Pharmacy:

On behalf of the Alaska Pharmacists Association, we thank you for the opportunity to publicly comment on the proposal to add regulation 12 AAC 52.240. We write to you today to express our opposition to adding 12 AAC 52.240 regarding the changes to the pharmacist collaborative practice authority (CPA). Restricting the ability of a pharmacist to prescribe controlled substances under a collaborative practice agreement could have detrimental effects on the opioid epidemic in Alaska. The Centers for Disease Control and Prevention is working to empower states to implement comprehensive strategies, including Medication Assisted Therapy (MAT), for preventing prescription-drug overdoses. Expanding access to MAT is a crucial component of combating the opioid epidemic. The addition of 12 AAC 52.240 would undermine efforts to combat the opioid epidemic in Alaska by preventing pharmacists from dispensing or administering MAT, which includes controlled substances. Additionally, this regulation would hinder pharmacists from deescalating patients on chronic or high-risk opioid regimens. Furthermore, 12 AAC 52.240 opposes the Alaska Opioid Policy Task Force (AOPTF) efforts by preventing access to detox services, preventing improvements to the opioid treatment system in Alaska, and adding regulation with collateral consequences. In addition, the statement "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" is concerning as not allowing authorizing practitioner compensation could add unnecessary barriers to increasing access to care for Alaskans and advancing the practice of pharmacy. For example: Not allowing for compensation could hinder the quality improvement, auditing process, and sustainability of programs if a physician is unable to be compensated for their time in monitoring the said pharmacist under their CPA. Also, the question arises that if a pharmacist is employed as a provider within a physician clinic could a portion of their billing that goes back to the physician owned clinic be also seen as compensation? We appreciate your efforts and leadership on this critical issue as we work together to combat the opioid epidemic in Alaska and increase access to quality health care for Alaskans.

Sincerely,

Nancy Frei, Pharm D  
Alaska Pharmacist Association

## Maiquis, Jun C (CED)

---

**From:** Carrillo, Laura N (CED)  
**Sent:** Monday, May 20, 2019 9:40 AM  
**To:** Maiquis, Jun C (CED)  
**Subject:** FW: Comments related to pharmacy statutes revisions

Hi Jun,

Can you please add this comment to the list?

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

**From:** Rod Gordon [mailto:rodsg123@yahoo.com]  
**Sent:** Sunday, May 19, 2019 1:20 PM  
**To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>  
**Subject:** Comments related to pharmacy statutes revisions

### [#1]

12 AAC 52.470(d) is amended to read: (d) If an original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense any quantity so long as [UP TO A 100-DAY SUPPLY ON REFILLS IF] 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.

(Eff. 1/16/98, Register 145; am 6/29/2018, Register 226; am \_\_\_\_/\_\_\_\_/\_\_\_\_\_, Register \_\_\_\_)  
Authority: AS 08.80.005 AS 08.80.030

As this is currently written, pharmacists would not be able to reduce the quantity dispensed for a prescription written for a 30 day supply of a CIII-CV drug that is either:

1. not currently stocked in sufficient quantity to meet the needs of a 30 day supply, or
2. not wanted by the patient, [some patients only want a week supply or less, to determine how they can tolerate the drug]

This wording forces the pharmacist to always adhere to exactly a 30 day supply of a controlled substance, when a 30 day quantity is prescribed. That will potentially limit access to needed medications [e.g., in cases where the full quantity prescribed is not in stock, the Rx would need to be sent elsewhere, but the original Rx can only be transferred elsewhere for the purpose of refilling the Rx, not the original fill] particularly in cases where controlled substance Rxs are received as Escripts. This would mean the provider would need to retransmit the Rx to another pharmacy, and that may not happen in a very timely manner. In the case where the patient is requesting only a partial fill, this would require getting a revised Rx from the prescriber, which again may not happen in a timely manner.

Also.. and more fundamentally, I don't understand the significance of the "30 day" supply? What if the Rx was written for a "10 day" supply. Would it be more acceptable to allow a pharmacist to dispense more or less than a 10 day supply of a controlled substances in that situation, given the originally prescribed quantity is not for 30 days? This just seems arbitrary to limit the statute to "30 day" supply Rxs.

To fix this I would suggest revising (d) as follows:

the pharmacist may dispense a quantity greater than the original quantity prescribed, so long as 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;
- (3) prescriber does not explicitly limit the days supply to be dispensed at one time or the timing of refills; and
- (4) pharmacist is exercising good professional judgment.

The reason for (3) could include a prescribers effort to solicit the pharmacist's assistance in adherence monitoring.

An example would be:

Truvada for PrEP should not be continued long term [>90 days] without follow up monitoring by the prescriber.

There may be additional instructions in the Rx to monitor timing of refills, so as to prevent them if gaps of >14 days exist in subsequent refills, based on projected refill due dates.

It would be negligent for a pharmacist to dispense more than a 90 day supply of Truvada at one time, since that may encourage continued use without proper monitoring.

Intermittent use of Truvada increases risk for HIV acquisition, and if HIV is acquired, Truvada would not be a complete regimen for treatment of active HIV infection. That would inadvertently lead to the development of infection with a resistant strain of the virus, which would increase the risk for transmission of resistant HIV infection to others with a virus no longer sensitive to Truvada for the prevention of HIV.

**[#2]**

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 \_\_\_\_/\_\_\_\_/\_\_\_\_\_, Register \_\_\_\_)  
Authority: AS 08.80.005 AS 08.80.030

As long as the Federal CSA only allows the transfer of CIII-V Rxs "for the purpose of refill dispensing", then the state statute should remain as it currently is. To remove [A REFILL OF] from the state statute would make the state rule less stringent than the Federal law, in which case the Federal law would apply. It makes no sense to make state law allow the transfer of the original CIII-CV Rx, unless Federal law changes too.

See excerpt of Federal Law below, from the Pharmacist Manual:

### **Transfer of Schedules III-V Prescription Information**

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA register the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, online datab up to the maximum refills permitted by law and the prescriber's authorization.

Transfers are subject to the following requirements:

1. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been trans added to the prescription record.
2. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transfe name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescripior
3. Record the date of the transfer and the name of the pharmacist transferring the information.

Thanks for considering these comments.

Rod Gordon, R.Ph.

#### **Rod Gordon, R.Ph. AAHIVP**

5684 Alora Loop  
Anchorage, AK 99504  
340-513-4703  
[rodsg123@yahoo.com](mailto:rodsg123@yahoo.com)

#### **Great Land Infusion Pharmacy**

2421 E. Tudor Rd. Ste 107  
Anchorage, AK 99507  
907-561-2421  
[rod@greatlandinfusionpharmacy.com](mailto:rod@greatlandinfusionpharmacy.com)

## Maiquis, Jun C (CED)

---

**From:** Janelle Solbos <solbjane@isu.edu>  
**Sent:** Tuesday, May 21, 2019 8:41 PM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Proposed Pharmacy Intern License Changes

Alaska Board of Pharmacy,

My name is Janelle Solbos, I am a fourth year pharmacy student and I am writing to the Board of Pharmacy in support of the proposed intern license changes (**12 AAC 52.120. Review of pharmacist intern license application**). Removing the intern sponsorship requirement will allow for more opportunities for pharmacy interns to gain experience during school. Removing the ability to hold dual intern and technician licenses will reduce confusion and allow expectations of student abilities during work and educational hours to be more clear for all parties involved.

Thank you for you time and consideration,  
Janelle Solbos

--

Janelle Solbos  
Doctor of Pharmacy Candidate 2020  
UAA/Idaho State University at Anchorage, Alaska  
Phone: (907) 350-3202  
Email: [solbjane@isu.edu](mailto:solbjane@isu.edu)

## **Maiquis, Jun C (CED)**

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**From:** Carrillo, Laura N (CED)  
**Sent:** Wednesday, May 22, 2019 11:02 AM  
**To:** [ksheare@costco.com](mailto:ksheare@costco.com)  
**Cc:** Maiquis, Jun C (CED); Regulations and Public Comment (CED sponsored)  
**Subject:** RE: Regarding New Non-Resident Wholesale Drug Distributors License

Hi Kristopher,

Can you please indicate specifically what you want to know regarding this new license type? This is a fairly broad question; if you could narrow it down, this may help in providing a more thorough response.

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

**From:** Maiquis, Jun C (CED)  
**Sent:** Wednesday, May 22, 2019 11:00 AM  
**To:** Regulations and Public Comment (CED sponsored) <[regulationsandpubliccomment@alaska.gov](mailto:regulationsandpubliccomment@alaska.gov)>; Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** RE: Regarding New Non-Resident Wholesale Drug Distributors License

Laura, did you get the chance to answer/reply to the question submitted by Mr. Shearer, see thread.

Thanks!  
Jun

**From:** Regulations and Public Comment (CED sponsored)  
**Sent:** Thursday, May 02, 2019 8:36 AM  
**To:** Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** FW: Regarding New Non-Resident Wholesale Drug Distributors License

Laura, see questions below from Mr. Shearer. Please cc me when you provide the answers that way I can add the Q & A to the FAQ.

Thanks!  
Jun

**From:** Kristopher Shearer <[ksheare@costco.com](mailto:ksheare@costco.com)>  
**Sent:** Tuesday, April 30, 2019 8:52 AM

To: Regulations and Public Comment (CED sponsored) <[regulationsandpubliccomment@alaska.gov](mailto:regulationsandpubliccomment@alaska.gov)>  
Subject: Regarding New Non-Resident Wholesale Drug Distributors License

Good morning,

What will the new New Non-Resident Wholesale Drug Distributors License cover for mail order pharmacies?

How is it different to the current Out of State Pharmacy license?

Thank you,

-----  
*Kristopher Shearer*

License Clerk

☎: 425-313-8219

Fax - 425-313-6922

✉:

[ksheare@costco.com](mailto:ksheare@costco.com)

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## **Maiquis, Jun C (CED)**

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**From:** Alaska Online Public Notices <noreply@state.ak.us>  
**Sent:** Wednesday, May 22, 2019 2:59 PM  
**To:** Maiquis, Jun C (CED)  
**Subject:** New Comment on NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY

A new comment has been submitted on the public notice **NOTICE OF PROPOSED CHANGES RELATING TO THE PRACTICE OF PHARMACY IN THE REGULATIONS OF THE BOARD OF PHARMACY.**

### **Submitted:**

5/22/2019 2:58:58 PM

Anchorage, AK, US  
Anonymous User

### **Comment:**

Proposal 12 AAC 52.120 and 12 AAC 52.220 are extremely important for current and future student pharmacist in the practice of pharmacy. Please consider making them part of the pharmacy regulation and statute.

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You can review all comments on this notice by [clicking here](#).

[Alaska Online Public Notices](#)

## Maiquis, Jun C (CED)

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**From:** Kim, Cj J (HSS)  
**Sent:** Thursday, May 23, 2019 3:24 PM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Board of Pharmacy - Comments on Proposed Regulation update

### Public comment for Board of Pharmacy

#### 12 ACC 52.985 Emergency Preparedness

- Replace or change the all of the wording where it mentions 'natural disaster' to either man made or natural disaster or just delete the word 'natural'. Disaster is a disaster regardless of the cause being either natural or man-made, as an example Exxon Valdez.
- C(1) states: "(1) in the pharmacist's professional **opinion** the medication is essential to the maintenance of life or to the continuation of therapy;"
  - Suggest to change opinion to "judgment"

Thank you,  
CJ

C.J. Kim  
Pharmacist  
Division of Public Health  
Section of Epidemiology  
3601 C Street, Suite 586  
Anchorage, AK 99503  
(O) 907-269-8029  
(F) 907-269-0472

<https://blogs.cdc.gov/publichealthmatters/2018/04/rxawareness/>  
<http://www2.cdc.gov/nip/adultimmsched/>

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## **Maiquis, Jun C (CED)**

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**From:** Daniel Nelson <daniel.nelson@tananachiefs.org>  
**Sent:** Friday, May 24, 2019 11:40 AM  
**To:** Regulations and Public Comment (CED sponsored)  
**Subject:** Proposed Pharmacy Regulation Change Public Comments  
**Attachments:** TCC Opposition to 12AAC 52.150.pdf

To whom it may concern,

Please see the attached public comments regarding one of the proposed Board of Pharmacy regulatory changes – specifically 12 AAC 52.150

Should you have any questions or concerns, please feel free to contact me via phone or email.

Thank you,

Dan Nelson, PharmD  
Director of Pharmacy  
Chief Andrew Isaac Health Center Pharmacy  
1717 W. Cowles Street  
Fairbanks, AK 99701  
[daniel.nelson@tananachiefs.org](mailto:daniel.nelson@tananachiefs.org)  
907-451-6682 ext. 3621



May 23, 2019

Alaska Board of Pharmacy,

Tanana Chiefs Conference submits these comments in opposition to the proposed regulation 12 AAC 52.150 Proof of Licensure for Individual Pharmacists Working in Tribal Health Programs. These proposed regulations are unduly burdensome to tribal programs and tribally employed pharmacists. Furthermore, that burden is disproportionate to any potential public benefit, as tribal providers have every incentive to ensure that all of their pharmacists are duly licensed as required under Federal Law. Tribal health pharmacies in Alaska have a strong commitment to and record of patient safety, excellent quality of pharmaceutical care and an obligation to follow the Federal Regulations that already govern their operations. Adding another unnecessary, bureaucratic, state-mandated hurdle that does not seem to positively impact the healthcare of Alaskans runs counter to Governor Dunleavy's push for a "smaller government."

These regulations also appear to unfairly single out tribal health organizations while turning a blind eye to addressing equivalently licensed/ authorized pharmacists employed in Federal Facilities in the state of Alaska, who also are not legally required to obtain an Alaska Pharmacist License. Examples include the United States Military and the United States Coast Guard.

The manner in which this proposed regulation was rolled-out is also extremely troubling. It was done completely behind closed doors and with no tribal consultation whatsoever. Not once was a draft version ever published prior to this current 30-day public comment period. It was on the agenda of multiple board meetings, but was never actually discussed. We (tribal pharmacy representatives who had called into the various meetings) were repeatedly met with frustration when this meeting agenda item was tabled or skipped over without any further discussion or explanation. The fact that nobody on the board proactively broached this proposed regulation with tribal health/ tribal pharmacy leaders, is further evidence that this particular proposed regulation, which impacts only tribal health care providers, should be scrapped and re-worked in collaboration with impacted providers.

Tanana Chiefs Conference would suggest that, instead of requiring that all tribally-employed pharmacists document their licensing exemption with the Board, the regulations be revised to provide that the Board will require such documentation only in individual cases where it has reason to suspect that a pharmacist employed by the Federal Government or a tribal health organization is not licensed in good standing in another state.

Respectfully,

Tanana Chiefs Conference

Victor Joseph,  
Chief/Chairman

Dan Nelson, PharmD  
Chief Andrew Isaac Health Center  
Director of Pharmacy

## Maiquis, Jun C (CED)

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**From:** island.pharm@juno.com  
**Sent:** Friday, May 24, 2019 12:20 PM  
**To:** Regulations and Public Comment (CED sponsored)

May 24, 2019

June Maiquis  
Alaska Board of Pharmacy  
Box 110806  
Juneau , AK 98111

RE: Proposed Regs Comments

Dear Regulations Specialist Maiquis,

Please accept this as my two comments for the proposed regulations changes now in the comment period.

1. 12 AAC.52.470. Refills. While I agree with the change to allow the dispensing of 100 day supply fills, I would encourage the board to change the regulations to reflect after an initial fill of 28 days versus the current regulation of 30 day initial fill. This would allow pharmacists to fill prescriptions for medications like oral contraceptives which are commonly written/dispensed in 28 day increments.
1. 12 AAC. 52.240 Pharmacist Collaborative Practice. I oppose the proposed change as current written. First, in the future, pharmacist may plan a valuable role in the current Opiate crisis by helping manage patients on Medication Assistant Treatment (MAT) protocols with patients. Secondly, this proposed change would not allow collaborating prescriber to be reimbursed from a pharmacists for reviewing any records required under the PCP agreement. This is not in keeping with good practice for either the practitioners nor the patients.

Thank you for allowing me to comment on this proposed changes.

Regards,

Barry Christensen, RPh

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Ketchikan, AK 99901  
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## Notice of proposed changes relating to the practice of pharmacy in the regulations of the Board of Pharmacy

### Proposed Regulations - FAQ

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*April 2019*

#### 1. What is the purpose of the proposed regulations? What will this regulation do?

**12 AAC 52.010. Classifications of licensure.** The proposed regulations will add new licensing categories to comply with SB 37. New licensing categories will include outsourcing facilities, third-party logistics providers, and out-of-state wholesale drug distributors. Licensure requirements for these out-of-state license types are proposed to mirror those of in-state requirements.

**12 AAC 52.050. Closed pharmacies.** The proposed regulations is to change the requirement that when a pharmacy closes its business it must submit a form provided by the department. The form is necessary for administrative purposes and to ensure the safety of the public in properly closing a pharmacy once operations have concluded.

**12 AAC 52.070. Application for pharmacist license by examination.** The proposed regulations is to amend the checklist requirements for pharmacist license by examination application. This change will give more clear guidance to board staff in conducting preliminary reviews of applications in meeting criteria for licensure. There are no proposed changes to amend licensure qualifications.

**12 AAC 52.095. Application for pharmacist license by reciprocity.** The proposed regulations is to amend the checklist requirements for pharmacist license by reciprocity application. This change will give more clear guidance to board staff in conducting preliminary reviews of applications in meeting criteria for licensure. There are no proposed changes to amend licensure qualifications.

**12 AAC 52.105. Temporary license for military personnel or the spouse of active military personnel.** The proposed regulations is a new section to provide for a method to apply for licensure to an active duty military member or military spouse. This new section applies to pharmacists, pharmacy intern, and pharmacy technician license types and is supported in statute by AS 08.01.063.

**12 AAC 52.110. Emergency pharmacist permit.** The proposed regulations is to repeal the need to take the multi-state jurisprudence examination (MPJE). The MPJE requirement will ensure applicants are apprised of current state pharmacy law.

**12 AAC 52.120. Review of pharmacist intern license application.** The proposed regulations is to repeal the need to obtain sponsorship and add a new regulation that intern licenses supersede pharmacy technician licenses. This clarifies pharmacy practice roles between interns and pharmacists, allowing pharmacy interns who were previously licensed as a pharmacy intern to return their pharmacy technician license to the department.

**12 AAC 52.150. Proof of licensure for individual pharmacists working for tribal health programs.** The proposed regulations is to add new regulations around out of state licensed pharmacists providing proof of licensure when working for tribal health programs in this state. The board is currently unable to determine which pharmacists are working under the purview of the Indian Health Service, which makes identifying pharmacists required to register with the prescription drug monitoring program (PDMP) difficult. Requiring active employment notifications will help support a transparent workforce in Alaska, but will not impose any regulatory oversight of dispensers working in tribal facilities.

**12 AAC 52.220. Pharmacist interns.** The proposed regulations is to change the regulation that a pharmacist intern may perform any duties of a pharmacy technician. This will add clarification to scope of practice but does not expand scope of practice.

**12 AAC 52.240. Pharmacist collaborative practice authority.** The proposed regulations is 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.

**12 AAC 52.340. Approved programs.** The proposed regulations is to clarify the type of ACPE program certificates that are approved for continuing education. Proposed changes will provide more opportunity to pharmacists and pharmacy technicians to comply with continuing education requirements.

**12 AAC 52.423. Remote pharmacy license.** The proposed regulations is to remove the distance requirement for renewals.

**12 AAC 52.425. Telepharmacy system for a remote pharmacy.** The proposed regulations is to change 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.

**12 AAC 52.465. Controlled substance prescription drug orders.** The proposed regulations is a new regulation to allow partial filling of schedule II controlled substances.

**12 AAC 52.470. Refills.** The proposed regulations is to amend the ability to dispense up to a 100-day supply and can dispense any quantity with conditions. Changes to this section will help reduce prescription waste.

**12 AAC 52.500. Transfer of a prescription drug order.** The proposed regulations is to remove refills from what is allowed. Changes will allow clear guidance to access of prescription medications for patients and will assist in eliminating prescription waste, as well as prescription duplications.

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

**12 AAC 52.530. Return or exchange of drugs.** The proposed regulations is to change the ability of a patient to return medication to a pharmacy if it was filled incorrectly or was recalled by the manufacturer or FDA.

**12 AAC 52.610. Wholesale drug distributor license.** The proposed regulations is to amend the checklist requirements for wholesale drug distributor license application.

**12 AAC 52.620. Wholesale drug facilities.** The proposed regulations is 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. This will help ensure the public's safety.

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

**12 AAC 52.630. Drug storage.** The proposed regulations is to amend temperature requirements be maintained to label requirements and remove USP that the board adopts by reference.

**12 AAC 52.640 – 12 AAC 52.695.** The proposed regulations in these sections are to amend authority citations to include AS 08.80.159, out-of-state wholesale drug distributors.

**12 AAC 52.696. Outsourcing facilities.** The proposed regulations is to establish application and requirements for outsourcing facility license.

**12 AAC 52.697. Third-party logistics providers.** The proposed regulations is to establish application and requirement for third-party logistics providers.

**12 AAC 52.920. Disciplinary guidelines.** The proposed regulations is 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.

**12 AAC 52.925. Grounds for denial or discipline for criminal history.** The proposed regulations establishes newly defined grounds for denying or disciplining a licensee under the ability to practice competently and safely.

**12 AAC 52.985. Emergency preparedness.** The proposed regulations is to establish guidelines regarding emergency preparedness and what pharmacies can dispense under emergencies declared by the governor.

**12 AAC 52.993. Executive Administrator.** The proposed regulations is to establish the executive administrator duties.

**12 AAC 52.995. Definitions.** The proposed regulations adds a new definition for “facility manager” and “moral turpitude”.

## 2. What are the costs to comply with the proposed regulations?

For three new licensing categories: third-party logistics provider, outsourcing facility, and non-resident wholesale drug distributor, there will be \$100 initial application, \$600 initial biennial license, and \$600 biennial license renewal fees.

## 3. When will the regulations be effective?

After public comment deadline, comments received are compiled and given to the Board for consideration. The Board may adopt the regulation as written/publicly noticed, may amend and adopt them, choose to take no action, or may withdraw the proposed regulations in part or in its whole. After Board action, the adopted regulations goes to Department of Law (DOL) for final review/approval. DOL either approves or disapproves regulations. Once approved by DOL, it goes to the Lt. Governor for filing. Regulation takes effect on the 30th day after they have been filed by the Lt. Governor.

Do you have a question that is not answered here? Please email [RegulationsAndPublicComment@alaska.gov](mailto:RegulationsAndPublicComment@alaska.gov) so it can be added.

## Ideas for redundant or unnecessary statutes/regulations

### **AS 08.80.158(b) – Annual report requirements**

- Requirement: requires non-resident (out-of-state) facilities to submit an report annually detailing changes in owners/PIC/certifying certain info, e.g.: complies with all laws
- Why repeal?: same information is submitted on renewals. If there is a change in owner, a new application is needed anyway; if there's a new PIC, a change in facility manager form is required anyway; all that's done administratively is filing of the forms; no data is changed or entered in the file

### **12 AAC 552.300(c)(1) – License Renewal**

- Requirement: submit documentation showing licensee has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350
- Why repeal? This is redundant to 12 AAC 02.960 (audit of compliance with continuing competency requirements)

### **12 AAC 52.540 and 12 AAC 52.060(a)(2) – DEA Form 106**

- These section requires pharmacies to submit the DEA Form 106, "Report of Theft or Loss of Controlled Substances".
- Why repeal? This is a notification required by the DEA, so it's unnecessary the board require it as well. The board does not take any action on these notices but only reviews them at each meeting. There seems to be no advantage to require this be submitted to the board when it is already being submitted to the DEA.

### **12 AAC 52.423(b)(2) – Remote Pharmacy**

- Restricts remote pharmacies from operating if there is a non-remote pharmacy within ten road-miles.
- Why repeal? Remove restriction for patient access and medication adherence improvements and also to avoid antitrust violation issues. Recommended to have a legal opinion on the antitrust concern.

### **12 AAC 52.095(c)(8)(9) – Reciprocity**

- The NABP license transfer document that is administratively accessed in the ePortal is evolving to include important information we need to assess qualifications.
- Our requirement under (8) is that we receive verification the applicant is currently licensed as a pharmacist in another jurisdiction and that it is not disciplined; (9) requires that the applicant submit a copy of the license transfer application to the NABP ePortal, which verifies the requirements in 8 (shows # of months/years of employment; the license status, whether it's expired, active, or in good standing; details date license was initial issued, and covers disciplinary actions taken on license)

### **12 AAC 52.095(c)(6)(A) – Reciprocity**

- (6)(A) is referencing applicants who have recently completed the 1,500 hours of internship requirements (typically those who actually should be applying by exam). In my experience, an individual who has just recently completed 1,500 hours of experience in the year preceding the date they applied are new graduates and should be meeting the application requirements of 12 AAC 52.070 (by exam) instead of reciprocity. Also, it's common these individuals haven't practiced for a full year in another jurisdiction. Consider repealing (A) since (B) realistically applies most accurately to the reciprocity application type.

#### **12 AAC 52.120(c) – Review of pharmacist intern license application**

- States intern license may be renewed, but this is incorrect; a new license is required per precedence. Consider amending to read, "An applicant wishing to continue an internship in this state after the license has expired must reapply for a new license".

#### **12 AAC 52.250 – Job shadowing in a pharmacy**

- Why repeal? Application isn't being used and it's likely that for high school students, job shadowing arrangements are made by the school. For post-secondary students, it's likely the person is already applying to be a tech or intern.

#### **12 AAC 52.080(d) – Internship requirements for a pharmacist license**

- This section indicates an internship program at a non-traditional site must be first approved by the board before the internship credit can be given. The board doesn't define non-traditional, and there is no record of an approval process.
- Why repeal? No criteria for determining whether a site is non-traditional as it's not defined in statute or regulation. Also no form for which to apply for approval.

#### **12 AAC 52.210 – Pharmacist duties**

- (1) of this section simply states, "receiving an oral prescription drug order" is a duty only a pharmacist can perform, however, it doesn't specify the circumstances under which receiving an oral prescription drug order is permitted, e.g.: confirm it is coming from a licensed provider?
- Receiving an oral prescription drug order might appropriately addressed under **12 AAC 52.460**, which is the section for prescription drug order information.

**Regulation Number:** 12 AAC 52.095

**Regulation Project Type:** Amendment.

**Intent:** to allow for primary source verification of licenses out of state.

**Cost:** None

**Authority:** Existing in regulations

**12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (a)**

The board will issue a pharmacist license by reciprocity to an applicant who meets the requirements of AS 08.80.145 and this section.

(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.

(c) An applicant for licensure under this section must submit to the department

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

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080; the verification must be sent directly to the department from the agency where the hours of internship or experience were completed; or

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) verification **on a form provided by the department or a primary source verification** that the applicant is currently licensed as a pharmacist in another licensing

jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy;

(10) verification of the present status of the applicant's license in each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist.

(d) An applicant for licensure under this section who has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (c)(1) – (6) and (8) – (10) of this section.

**Authority:** AS 08.80.005                      AS 08.80.030                      AS 08.80.145

**Regulation Number:** 12 AAC 52.865 REPORTING AND REVIEWING PDMP INFORMATION

**Regulation Project Type:** Amendment.

**Intent:** to ensure dispenser's understand zero reporting is required in order to monitor compliance.

**Cost:** None

**Authority:** 17.30.200

**12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION.** (a) Unless excused from reporting under AS 17.30.200(u), a pharmacist must submit information required under AS 17.30.200(b), if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(u), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information, **including zero reporting**, to the PDMP daily as of the previous submission date.

(c) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(d) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(f) Unless excused from reporting under AS 17.30.200(u), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(g) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**Regulation Number:** 12 AAC 52.423 REMOTE PHARMACY LICENSE

**Regulation Project Type:** Amendment.

**Intent:** to comply with AS 44.33.381

**Cost:** \$50

**12 AAC 52.423. REMOTE PHARMACY LICENSE.** (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

- (1) a complete, notarized application on a form provided by the department;
- (2) the applicable fees established in 12AAC 02.310; and
- (3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

- (1) it is able to comply with the requirements of 12 AAC 52.425; and
- (2) there is no access to a non-remote pharmacy within ten road miles of the proposed 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.

(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.

**(d) A central pharmacy using telepharmacy services under 12 AAC 52.425 shall register with the Telemedicine Business Registry in accordance with 12 AAC 02.600.**

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157 **AS 44.33.381**

**Regulation Number:** 12 AAC 52.140 PHARMACY TECHNICIAN LICENSE

**Regulation Project Type:** Amendment.

**Intent:** Improve quality of applicants by adding requirement for good moral character to licensure application.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician 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 pharmacy technician 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 pharmacy technician license.

(b) The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

- (1) submits a completed, **notarized application on a form for provided by the department** including (A) the applicant's name, mailing address, and telephone number; and (B) the applicant's date of birth that shows the applicant is at least 18 years old;
- (2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;
- (3) certifies that the applicant has earned a high school diploma, **GED or its equivalent a college or university degree** and provides the name of the issuing institution and the date the diploma, **GED or its equivalent degree** was issued;
- (4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; **and**
- (5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310; **and**
- (6) **submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.**

(c) A pharmacy technician license expires on June 30 of even-numbered years and may be renewed

**Authority:** AS 08.80.005 AS 08.80.030

**Regulation Number:** 12 AAC 52.230 PHARMACY TECHNICIANS

**Regulation Project Type:** Amendment.

**Intent:** Update regulation with nationally certified pharmacy technicians. Discuss de-licensing cashiers and bookkeepers.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(a) The following persons must be licensed:

(1) any individual who assists in performing manipulative, nondiscretionary functions associated with the practice of pharmacy; and

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy, including a cashier or a bookkeeper.

(b) A pharmacy technician shall work under the direct supervision of a ~~person who is~~ licensed ~~as a~~ pharmacist.

(c) ~~Except as provided in~~ [AAC 52.235](#) a pharmacy technician may not perform any of the duties listed in [AAC 52.210](#).

(d) An individual working as a pharmacy technician ~~or a nationally certified pharmacy technician~~ shall wear an identification badge that shows the individual's name and identifies the individual as a "pharmacy technician" ~~or a "nationally certified pharmacy technician", respectively~~.

(e) Before an individual may regularly perform the tasks of a pharmacy technician ~~or nationally certified pharmacy technician in accordance with 12 AAC 52.235~~ the individual shall complete training ~~required~~ by the pharmacist-in-charge. Duties performed ~~by the pharmacy technician~~ must be consistent with the training ~~the pharmacy technician has~~ received.

(f) If a pharmacy technician will assist in the preparation of sterile pharmaceuticals, including parenteral medications, the pharmacy technician must have completed a minimum of 40 hours of on-the-job training in the preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform those tasks.

(g) ~~Only a pharmacy technician holding a current, active certification from PTCB or ICPT, with a minimum of XXXX hours of pharmacy work experience, may perform board approved functions in the practice of pharmacy in accordance with 12 AAC 52.235~~

(h) ~~A nationally certified pharmacy technician shall conspicuously display, in the practice site, the licensee's active national certificate. The active national certificate of a nationally certified pharmacy technician practicing in an institutional facility may be displayed in a central location.~~

**Authority:**

AS 08.80.030

AS 08.80.480

AS 08.80.005

**Regulation Number:** 12 AAC 52.235 APPROVED NATIONALLY CERTIFIED PHARMACY TECHNICIAN FUNCTIONS

**Regulation Project Type:** New regulation under Article 2, Personnel

**Intent:** To create board approved functions for nationally certified pharmacy technicians.

**Statutory Authority:** AS 08.80.005

AS 08.080.030

AS 08.80.480

**Cost:** None.

- (a) A nationally certified pharmacy technician, working under the direct supervision of a pharmacist, may
  - (1) dispense a non-controlled substance prescription if
    - i. the prescription drug order has previously undergone prospective drug review by a pharmacist, including determination in substitution;
    - ii. the pharmacy uses technology assisted filling equipment that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label;
    - iii. the pharmacy uses dispensing software that displays the image of the correct drug being verified and if there is any deviation from the image and actual product being dispensed the nationally certified pharmacy technician or pharmacist intern may not dispense the order and a pharmacist shall review and dispense the order; and
    - iv. each prescription dispensed is electronically verified and documented in the patient record in accordance with 12 AAC 52.460 and 12AAC 52.470.
  - (2) clarify the following information on a non-control substance prescription drug order information with the practitioner or the practitioner's authorized agent
    - (a) number of refills;
    - (b) quantity of medication;
    - (c) date the prescription drug order was written; or
    - (d) medically necessary, diagnosis codes, or other similar language for insurance purposes.
  - (3) Administer an immunization or related emergency medication in accordance with 12 AAC 52.992.
  - (4) Transfer a prescription drug order to another pharmacy in accordance with 12 AAC 52.500. A nationally certified pharmacy technician may not receive a transfer from another pharmacy.
- (b) Prescription drug order information clarifications from (a)(2) shall be documented by writing the following information on the face of the prescription drug order
  - (1) the result of the clarification;
  - (2) the nationally certified technician initials;
  - (3) the name of the prescriber or authorized agent they spoke to; and

- (4) the date and time of the call; and
- (c) A nationally certified pharmacy technician may not sign or initial any document that is required to be signed or initialed by a pharmacist.
- (d) A nationally certified pharmacy technician may perform all the duties of a pharmacy technician.

**12 AAC 52.210. PHARMACIST DUTIES.** Except as provided in 12 AAC 52.220 **and 12 AAC 52.235**, the following duties may be performed only by a pharmacist:

- (1) receiving an oral prescription drug order **from a practitioner or authorized agent of a practitioner;**
- (2) consulting with a ~~prescriber regarding~~ a patient **in accordance with 12 AAC 52.585 or prescription;**
- (3) ~~interpreting~~ independent prescribing of a prescription drug order for vaccines, related emergency medications, or opioid overdose drugs in accordance with 12 AAC 52.992 and 12 AAC 52.994;
- (4) determining the product substitution required for a prescription in accordance with 12 AAC 52.510;
- (5) interpreting drug regimen review data in accordance with 12 AAC 52.570; and ~~a patient medication record system;~~
- (6) ~~making a final check on all aspects of a completed prescription and~~ assuming the responsibility for a filled prescription, **including the accuracy of the drug prescribed and of the prescribed drug's strength, labeling, and proper container; and**
- ~~(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system.~~

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.330

**Regulation Number:** 12 AAC 52.460 PRESCRIPTION DRUG ORDER INFORMATION

**Regulation Project Type:** Amendment.

**Intent:** Update regulation.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(a) Before a ~~pharmacist may fill a~~ prescription drug order **may be filled**, ~~the pharmacist shall obtain~~ the following information **must be obtained**:

- (1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;
- (2) address of the patient unless the prescription drug order is for a noncontrolled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;
- (3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;
- (4) name and strength of the drug prescribed;
- (5) quantity prescribed;
- (6) directions for use;
- (7) date of issue;
- (8) refills authorized, if any;
- (9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;
- (10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature; and
- (11) if the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, ~~a pharmacist~~ **the following information** shall **be recorded** ~~add the following information to the prescription drug order:~~

- (1) unique identification number of the prescription drug order;
- (2) initials or identification code of the dispensing pharmacist, **pharmacist intern or nationally certified pharmacy technician**:...

(c) After oral ~~consultation~~ **clarification** with the prescribing practitioner a pharmacist may add the following information to schedule II controlled substance prescriptions: ...

- (1) date of issue of the prescription;
- (2) address of the patient;
- (3) strength of the drug prescribed;
- (4) drug dosage form;
- (5) drug quantity prescribed;
- (6) directions for use;
- (7) DEA registration number.

(d) After oral ~~consultation~~ **clarification** with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any

modifications to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribed.

(e) a pharmacist may not ~~change~~ **modify** the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

(f) In accordance with 12 AAC 52.995(15), an institutional facility may use start or stop dates on prescription drug orders in place of (a)(5) or (8).

**Authority:** AS 08.80.005 AS 08.80.030



**Regulation Number:** 12 AAC 52.470 REFILLS  
**Regulation Project Type:** Amendment.  
**Intent:** Update regulation.  
**Statutory Authority:** Existing authority in regulation.  
**Cost:** None.

(a) A pharmacist, pharmacist intern or nationally certified pharmacy technician may dispense a refill of a prescription drug order only in accordance with the prescribing practitioner’s authorization as indicated on the prescription drug order. If there are no refill instructions on the prescription drug order, or if all refills authorized on the original prescription drug order have been dispensed, a pharmacist shall obtain authorization from the prescribing practitioner or practitioner’s authorized agent before dispensing a refill.

(b) A pharmacist or nationally certified pharmacy technician may not dispense a refill of a prescription drug order for a noncontrolled substance after  year from the date of issue of the original prescription drug order.

(c) Each time a prescription drug order is dispensed, the pharmacist pharmacy record shall ~~record the refill electronically or on the back of the prescription drug order by listing~~ contain the date of dispensing, the ~~written~~ initials or identification code of the dispensing pharmacist or nationally certified pharmacy technician and the amount quantity dispensed if different from the quantity on the original prescription drug order.

(d) n original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense any quantity so long as up to a 100-day supply on refills if 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;
- (3) ~~the~~ pharmacist is using professional judgment.

(e) To indicate that an increased refill 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.

**Authority:** AS 08.80.005 AS 08.80.030

**Regulation Number:** 12 AAC 52.480 LABELING

**Regulation Project Type:** Amendment.

**Intent:** Update regulation.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(a) One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

- (1) name, address, and phone number of the dispensing pharmacy;
- (2) unique identification number of the prescription drug order;
- (3) date the prescription drug order is dispensed;
- (4) initials of the dispensing pharmacist;
- (5) name of the prescribing practitioner;
- (6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;
- (7) directions for use;
- (8) quantity dispensed;
- (9) appropriate ancillary instructions or cautions;
- (10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";
- (11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner; **and**
- (12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent; **and**
- (13) an expiration date that is the lesser of
  - (a) one year from the date of dispensing;
  - (b) the manufacturer's original expiration date; or
  - (c) the appropriation expiration date for a reconstituted suspension or beyond use date for a compounded product.

**Authority:** AS 08.80.005 AS 08.80.295 AS 08.80.480  
AS 08.80.030

**Regulation Number:** 12 AAC 52.992 INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS

**Regulation Project Type:** Amendment.

**Intent:** Update regulation.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(a) Before a pharmacist may administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

- (A) basic immunology, vaccine, and immunization protection;
- (B) diseases that may be prevented by vaccination or immunization;
- (C) current CDC immunization schedules;
- (D) vaccine storage and management;
- (E) informed consent;
- (F) physiology and techniques for administration of immunizations;
- (G) pre-immunization and post-immunization assessment and counseling;
- (H) immunization reporting and records management; and
- (I) identifying, responding to, documenting, and reporting adverse responses.

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;

(3) who has not administered a vaccine during the past ten years must complete a course as described in (1) of this subsection before administering a vaccine; and

(4) must adhere to 12 AAC 52.320, including continuing education requirements under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist, [pharmacist intern](#) or [nationally certified pharmacy technician](#) administers a human vaccine or related emergency medication ~~under this section~~

(1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory, and that is carried by the pharmacist if providing off-site immunizations:

- (A) oral and injectable diphenhydramine; and
- (B) adult and pediatric auto-inject epinephrine device's, or injectable epinephrine.

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed; the manual must:

- (A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;
- (B) document that the policy and procedures manual has been reviewed and updated annually;

- (C) address how vaccine related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);
- (D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer recommended temperatures during transportation of vaccines;
- (E) address proper disposal of used or contaminated supplies;
- (F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions including the administration of related emergency medications; and
- (G) detail how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's or pharmacist intern's certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a **pharmacy pharmacist** intern must

- (1) have completed an ACPE accredited immunization course or other comparable course that meets the requirements (a)(1) of this section;
- (2) maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training, and
- (3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(d) A pharmacist, **pharmacist intern or nationally certified pharmacy technician** administering a vaccine must provide the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A **pharmacy in which pharmacist or intern administering a vaccine vaccines are administered** must comply with 7 AAC 27.650.

(f) For the purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if

- (1) the pharmacist meets the requirements of this chapter and is the prescriber and administrator of the vaccine;
- (2) or a pharmacist intern or nationally certified pharmacy technician meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern or nationally certified pharmacy technician is the prescriber.

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.

(h) In this section

- (1) “CDC” means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;
- (2) “FDA” means the United States Food and Drug Administration.

(i) Before administering an immunization or related emergency medication, a nationally certified pharmacy technician shall

- (1) have completed training on immunization administration techniques;
- (2) maintain certification of completing an adult and pediatric cardiopulmonary resuscitation (CPR) program and automated electronic defibrillator (AED) training, and
- (3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(j) a nationally certified pharmacy technician who has not administered a vaccine within the past xxx must complete a training course on immunization administration techniques prior to vaccinating.

**Authority:** AS 08.01.075                      AS 08.80.168                      AS 08.80.480  
AS 08.80.030                                  AS 08.80.261

**Regulation Number:** 12 AAC 52.220 INTERNS

**Regulation Project Type:** Amendment.

**Intent:** Update regulation IF nationally certified pharmacy technicians can dispense, discuss intern opportunity.

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

- (a) A pharmacist intern may not represent that the pharmacist intern is a pharmacist. Only a person licensed by the board as a pharmacist intern may take, use, or exhibit the title of pharmacist intern or any other similar term.
- (b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist or pharmacy technician, including nationally certified pharmacy technician functions, under the direct supervision of a pharmacist.
- (c) A pharmacist intern may not sign or initial any document that is required to be signed or initialed by a pharmacist unless the supervising pharmacist also signs or initials the document.
- (d) A pharmacist intern shall file with the board a report of work experience on a form provided by the department within 30 days of completion or termination of an internship in the practice of pharmacy required under 12 AAC 52.080.
- (e) A pharmacist supervising a pharmacist intern
- (1)  must be licensed as a pharmacist and be in good standing with the board;
  - (2) shall provide direct supervision to an intern during professional activities throughout the entire period of the internship;
  - (3)  ~~shall physically review prescription drug orders and the dispensed product before delivery of a product to the patient or the patient's agent;~~
  - (4) is responsible for the work of the pharmacist intern;
- may supervise more than one pharmacist intern; more than one pharmacist intern may not dispense simultaneously under the direct supervision of the same supervising pharmacist.

**Authority:** AS 08.80.005 AS 08.80.110 AS 08.80.410  
AS 08.80.030 AS 08.80.116

**☰ AAC 52.585. MANDATORY PATIENT COUNSELING.** (a) Before dispensing a new or refill prescription drug order if deemed necessary by the pharmacist, and following a review of the patient's record, ~~for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy,~~ the a pharmacist or pharmacy pharmacist intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

- (1) the name and description of the prescribed drug;
- (2) the dosage and the dosage form;
- (3) the method and route of administration;
- (4) the duration of the prescribed drug therapy;
- (5) any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
- (6) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;
- (7) patient techniques for self-monitoring of the drug therapy;
- (8) proper storage;
- (9) prescription refill information; and
- (10) the action to be taken in the event of a missed dose.

**☰** If a pharmacist provides counseling, they may provide the counseling by any verbal, written or electronic means; ~~shall counsel the patient or the patient's agent face to face. If face to face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist's own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopocia Drug Information or comparable information.~~

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient's caregiver refuses the counseling.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.480

**12 AAC 52.420. SECURITY.** (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department **and automated prescription dispensing machine** security requirements.

(c) **Except for automated prescription dispensing machines,** All drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) The prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) Prescriptions shall be stored in the prescription department **or in automated prescription dispensing machines** ~~and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.~~

(g) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored.

#### 12 AAC 52.421 Automated Prescription Dispensing Machines

(a) automated prescription dispensing machines which hold filled prescription drug orders waiting for patient pick-ups may be used on the premise of a licensed pharmacy and available to patients while the pharmacy is closed if

(i) prior to a filled prescription drug order being placed in the automated prescription dispensing machine the pharmacist shall offer patient counseling in accordance with 12 AAC 52.230;

(ii) a sign is posted near the automated prescription dispensing machine saying "This prescription dispensing machine does not contain control substances";

(iii) no state or federal controlled substances are placed in the dispensing machine, and

(iv) all containers of medications stored in the automated prescription dispensing machines are be packaged and labeled in accordance with federal and state laws and regulations.

(b) The Pharmacist-in-Charge shall have the responsibility to:

(i) assign, discontinue, or change access to the system;

(ii) ensure that access to the medications comply with state and federal regulations; and

(iii) ensure that the automated prescription dispensing machines are filled or stocked accurately and in accordance with established, written policies and procedures.

(e) This section does not apply to automated medication dispensing units used in institutional facilities for the purposes of holding drugs for use with in-patient dispensing.

**Authority:** AS 08.80.005      AS 08.80.157      AS 08.80.315      AS 08.80.030

**Regulation Number:** 12 AAC 52.995 DEFINITIONS

**Regulation Project Type:** Amendment.

**Intent:** Add definition of Nationally Certified Pharmacy Technicians

**Statutory Authority:** Existing authority in regulation.

**Cost:** None.

(36) “nationally certified pharmacy technician” means a pharmacy technician who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the Institute for the Certification of Pharmacy Technicians (ICPT).

(37) In 12 AAC 52.040, 12 AAC 52.610, 12 AAC 52.696, 12 AAC 52.697, “a new owner” means any new owner not already previously disclosed to the board who is now acquiring any initial ownership of the facility, regardless of percent control.

(38) “automated prescription dispensing machines” include, but are not limited to, mechanical systems that perform operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs, and which collect, control, and maintain all transaction information.

(39) In 12 AAC 52.865(b), “zero reporting” means a pharmacy that has not dispensed any control substances for the preceding reporting period.

(40) In 12 AAC 52.095(c)(8), “primary source verification” means a printout from another state board of pharmacy website which contains the required information and that the other state board website is a primary source.

12 AAC 52.460. **PRESCRIPTION DRUG ORDER INFORMATION.** (a) Before a pharmacist may fill a prescription drug order the pharmacist shall obtain the following information:

- (1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;
- (2) address of the patient unless the prescription drug order is for a non-controlled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;
- (3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;
- (4) name and strength of the drug prescribed;
- (5) quantity prescribed;
- (6) directions for use;
- (7) date of issue;
- (8) refills authorized, if any;
- (9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;
- (10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature, and
- (11) If the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, a pharmacist shall add the following information to the prescription drug order:

- (1) unique identification number of the prescription drug order;
- (2) initial or identification code of the dispensing pharmacist;
- (3) quantity dispensed, if different from the quantity prescribed;
- (4) date of dispensing, if different from the date of issue;
- (5) if the drug was prescribed by generic name or if an equivalent drug product other than the one prescribed was dispensed, for the drug product actually dispensed, at least one of the following:

- (A) the name of the manufacturer or distributor;
- (B) the national drug code number;
- (C) the short name code; or
- (D) the trade name.

(c) After oral consultations with the prescribing practitioner, a pharmacist may add the following information to ~~schedule H~~ controlled substance prescriptions;

- (1) date of issue of the prescription:

- (2) ~~address of the patient;~~
- (3) strength of the drug prescribed;
- (4) drug dosage form;
- (5) drug quantity prescribed;
- (6) directions for use;
- (7) DEA registration number.
- (8) Institutional DEA and suffix**

(d) After oral consultation with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any modification to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribe.

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

(12)

**From:** [Carrillo, Laura N \(CED\)](#)  
**To:** "Richard Holt"  
**Cc:** [Thompson, Norman H \(CED\)](#)  
**Subject:** RE: Alaska Board of Pharmacy re: Question on Change of Ownership  
**Date:** Friday, March 29, 2019 9:54:00 AM

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Thanks, Rich. I would agree that establishing regulations would benefit the process. What if the board defined "pharmacy ownership" under the definitions section, 12 AAC 52.995? That way, we could amend or add to the change of ownership section, 12 AAC 52.40 to specify that any new owner acquiring X% or more of the pharmacy shall submit a new facility license.

I'll go ahead and add this to our new regulations project.

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

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**From:** Richard Holt [mailto:dokholt@mac.com]  
**Sent:** Friday, March 29, 2019 7:54 AM  
**To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>  
**Cc:** Thompson, Norman H (CED) <norman.thompson@alaska.gov>  
**Subject:** Re: Alaska Board of Pharmacy re: Question on Change of Ownership

It's a good question I've never seen.

Setting it at 100% ownership makes sense but what if an owner decides to sell 50% of his business at once. Now there are two owners (1 of which is new and not on record with the board).

1) I think maybe we need to create a definition in regulation.

2) what about a change of ownership requirement any time there is a new person taking any percent of control. Then, so long as they have registered a change of ownership at the beginning it doesn't matter what percent of control they negotiate later in their transactions as they are still all owners. They can even layout their strategy in the application for change of ownership. However, if they introduce a new owner then they would file again. I think it's our intent to know who is owning any portion of a pharmacy.

Thoughts?

Sent from my iPhone

On Mar 20, 2019, at 12:04 PM, Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)> wrote:

Rich: would you agree that a new pharmacy application won't be necessary until the new owner has 100% ownership? See below regarding a gradual ownership change. Our regulations don't address on a granular level what constitutes a change of ownership, but to me, it wouldn't make sense to make the person submit a change of ownership each time they purchase 10% of the company—thoughts?

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
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**From:** Thompson, Norman H (CED)  
**Sent:** Wednesday, March 20, 2019 11:41 AM  
**To:** Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** FW: Alaska Board of Pharmacy re: Question on Change of Ownership

Laura,

This question is a bit complicated but I would probably approach it as follows:

- Single new out of state pharmacy application with names of current owners and change of ownership plan attached.
- Flag file to require ownership update at biennial renewals.
- New out of state pharmacy application with names of current owners when transfer is complete.
- I can't address the Power of attorney question.

**Norman Thompson**  
Occupational Licensing Examiner  
Alaska Board of Pharmacy  
State of Alaska – DCCED – CBPL  
Direct: 907-465-2589  
Fax: 907-465-2974

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**From:** Erica Beacom [<mailto:EBeacom@bf-law.com>]  
**Sent:** Wednesday, March 20, 2019 11:10 AM

**To:** Thompson, Norman H (CED) <[norman.thompson@alaska.gov](mailto:norman.thompson@alaska.gov)>

**Subject:** Alaska Board of Pharmacy re: Question on Change of Ownership

Mr. Thompson-

Per our phone call today (3/20/19) I am sending a brief outline of our pharmacy's question. Our pharmacy holds out of state licensure with Alaska, and in the near future the current pharmacist-in-charge ("PIC") will be purchasing 20% of the pharmacy's stock. After this initial sale the PIC will purchase an additional 10% of the stock every year until she holds 100% of the pharmacy's stock.

Per our understanding of the Alaska Board of Pharmacy's (the "Board") regulations, any change of ownership requires a new license and license number. Our question is at what point in the above scenario does this transaction qualify as a change of ownership? If the Board believes that every sale of stock qualifies for a new license/number, would it be possible for the PIC to operate under a Power of Attorney until the entire sale is completed? After completion the pharmacy would submit the appropriate paperwork (i.e. Out of State Pharmacy Registration with Sections 1 through 8 completed).

We would be happy to discuss this scenario or answer any additional questions you may have, please feel free to contact me at 806-345-6360 or via email at [ebeacom@bf-law.com](mailto:ebeacom@bf-law.com). Thank you.

***Erica L. Beacom***

***Brown & Fortunato, P.C.***

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<image002.jpg>

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**12 AAC 52.423. REMOTE PHARMACY LICENSE.** (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

- (1) a complete, notarized application on a form provided by the department;
- (2) the applicable fees established in 12AAC 02.310; and
- (3) comply with the requirements of 12 AAC 52.020.

-25-

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

- (1) it is able to comply with the requirements of 12 AAC 52.425; and
- (2) there is no access to a non-remote pharmacy within ten road miles of the proposed 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.

(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.

**From:** [Rich](#)  
**To:** [Carrillo, Laura N \(CED\)](#)  
**Subject:** Re: Opioid overdose training  
**Date:** Saturday, May 11, 2019 9:20:43 PM

---

Our intention was to complete 1 CE credit from any of the approved programs; it wasn't 1 per year and it could be from any of approved provider and did not specifically need to be ACPE. Ex: it could have come from the pharmacist association. Maybe we need to add 12 AAC 52.994 after the other two regulation numbers to make it more understanding?

---

**From:** "Carrillo, Laura N (CED)" <laura.carrillo@alaska.gov>  
**Date:** Thursday, May 9, 2019 at 12:27 PM  
**To:** Richard Holt <dokholt@mac.com>  
**Subject:** RE: Opioid overdose training

Sorry, I just noticed 12 AAC 52.994 (independent dispensing of opioid overdose drugs...) does state one hour of continuing education in opioid overdose training, but it's somewhat different in that the section on approved program applies to requirements for renewal, whereas the opioid training isn't a renewal requirement. Does this mean that only opioid overdose training programs accredited/provided/approved by the ACPE or APA will count? I'm sure there are other organizations offering this type of training. Let me know if I should add this to agenda.

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

---

**From:** Carrillo, Laura N (CED)  
**Sent:** Thursday, May 9, 2019 12:20 PM  
**To:** Richard Holt <dokholt@mac.com>  
**Subject:** Opioid overdose training

Hi Rich,

A pharmacist is inquiring about the independent administration of naloxone and whether there is certain documentation pharmacists need to provide. AS 08.80.030(13) requires the board to establish standards for approved programs around the topic of opioid overdose training. CBPLs licensing database has a separate feature for approved programs, and for other boards/programs specifically requiring programs to be "approved by the board", education providers must submit an application for their program to be approved. There is currently no language in its corresponding

regulation, 12 AAC 52.994, addressing what the board considers to be an approved opioid training program. Approved programs are listed under 12 AAC 52.340 but only addresses *continuing education*. Does this need to be amended?

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
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Fax: 907-465-2974

### *Naloxone Rescue Therapy for Opioid Overdose (18-213)*

**Needs:** Pharmacists need to be able to identify patients who are at highest risk of opioid overdose and those who could potentially benefit from naloxone, a life-saving reversal of opioid-induced respiratory depression. Pharmacists need to know about the use of naloxone for opioid overdose since they are accessible to patients and can serve as an important resource for patients by prescribing and dispensing, and teaching about the safe and appropriate use of naloxone.

**Target Learners:** This activity is intended for all pharmacists in any setting. There are no prerequisites for this course.

**Goals and Objectives:** The goal of this application-based activity is to help pharmacists in all settings develop the skills necessary to assist patients and caregivers in appropriately using naloxone for opioid overdose. Upon completion of this course, the learner will be able to:

1. Identify patients who may be at higher risk of opioid overdose.
2. Recommend alternatives to opioids for different types of chronic pain.
3. Incorporate opioid overdose and naloxone education into prescription opioid patient counseling.
4. Explain the risks and possible adverse effects of naloxone.
5. Demonstrate an understanding of the different naloxone formulations available and how to use them.
6. Identify situations and appropriate indications for the use of naloxone.
7. Educate patients on the steps that should be taken when an opioid overdose is suspected.

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*Pharmacist's Letter & Prescriber's Letter*  
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## Course Information, Goals and Objectives



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This knowledge-based course is accredited by ACPE; universal activity number 0422-0000-18-213-H01-P. Participants may earn two hours of CE credit (0.2 CEU) upon successful completion of this course.

### **Statement of Participation/Course Completion**

Credit will be awarded to participants who answer at least 70% of the quiz questions correctly and have provided an accurate NABP e-Profile ID and DOB. Participants that have successfully completed this course AND have provided accurate NABP e-Profile information, including month and day of birth, will have their CE credit submitted to CPE Monitor on a weekly basis.

It is the participant's responsibility to verify credit is accurately posted to CPE Monitor. Participants who do not see their credit on CPE Monitor 35 days after their participation should notify TRC via [CECredit@pletter.com](mailto:CECredit@pletter.com). Emails not received via [CECredit@pletter.com](mailto:CECredit@pletter.com) by day 45 may not receive credit. Official statements of credit should be printed from CPE Monitor.

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### **Time to Complete**

It should take participants about two hours to read the material and answer the questions.

**Date of Release**

April 1, 2018

**Date of Expiration**

March 31, 2020

**Cost**

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This course is best viewed with Internet Explorer® 8.0+, Firefox® 20+, Safari™ 5+ (Mac and iOS devices only), or Google™ Chrome™ 20+. It is required that you have "cookies" enabled in your web browser. Your connection to the Internet should at least be 800kbps+.

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Therapeutic Research Center

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**From:** [Carrillo, Laura N \(CED\)](#)  
**To:** [Rich](#)  
**Cc:** [Brewer, Elaine M \(CED\)](#)  
**Subject:** RE: Zero Reporting  
**Date:** Tuesday, May 21, 2019 3:34:00 PM  
**Attachments:** [image001.png](#)  
[image004.png](#)

---

Rich,

I believe we have authority to require zero reporting under AS 17.30.200(b) for both licensed and registered facilities, so my suggestion would be for the board to consider addressing zero reporting in regulation. I take this section as giving the board authority to require reporting when facilities distribute/dispense controlled substances as well as when they don't, otherwise, we won't be able to monitor compliance with this statute, which I know we'll be questioned on for our next legislative audit. We also already have zero reporting addressed in our [dispenser's guide](#).

**Sec. 17.30.200. Controlled substance prescription database.** (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (u) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (u) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
Direct: 907-465-1073  
PDMP: 907-269-8404  
PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

---

**From:** Rich [mailto:[dokholt@mac.com](mailto:dokholt@mac.com)]  
**Sent:** Saturday, May 11, 2019 9:25 PM  
**To:** Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Cc:** Brewer, Elaine M (CED) <[elaine.brewer@alaska.gov](mailto:elaine.brewer@alaska.gov)>  
**Subject:** Re: Zero Reporting

Since we don't have authority to require the certificate and use the survey what other options are available to us to help clarify reporting / monitoring?

Would a frequently asked question added to that portion of the website help in any way?

Thanks,



Richard Holt, BS Pharm, PharmD, MBA  
Alaska Board of Pharmacy  
Chair

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---

**From:** "Carrillo, Laura N (CED)" <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>

**Date:** Monday, May 6, 2019 at 10:55 AM

**To:** Richard Holt <[dokholt@mac.com](mailto:dokholt@mac.com)>

**Cc:** "Brewer, Elaine M (CED)" <[elaine.brewer@alaska.gov](mailto:elaine.brewer@alaska.gov)>

**Subject:** Zero Reporting

Rich,

Suggestion to add this topic under new business since we don't address zero reporting explicitly in regulation...I know Megyn Weigand said we didn't have the authority to require pharmacies to submit the Certification of No Controlled Substance Dispensed by February every year, so we developed the [data reporting survey](#) instead (which we still don't have the authority to require). It seems addressing zero reporting could help clarify the reporting process/assist us with monitoring.

Some variation across states: **KY** used to require zero reporting up until a few yrs ago when they realized they didn't have the authority to require it. In lieu of this, they have a dedicated analyst who just performs pharmacy compliance analyses and works to bring delinquent pharmacies into compliance. **CO** also used to require zero reports, but stopped, but now want to resume again to better monitor compliance. **WA** made zero reporting a requirement through a rule change in 2016. **ND** has required zero reports since 2007.

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
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PDMP email: [akpdmp@alaska.gov](mailto:akpdmp@alaska.gov)  
Fax: 907-465-2974

**From:** [Carrillo, Laura N \(CED\)](#)  
**To:** [Richard Holt](#)  
**Subject:** RE: Fees for change in ownership, name, location  
**Date:** Friday, July 5, 2019 11:51:00 AM

---

Awesome, I'll add this for discussion at our next meeting. I also noticed when going through all the fingerprinting requirements/administrative processing procedures, that our board doesn't have proposed fees for the fingerprint processing fee. I brought this to Sara's attention last week, and will let you once we get it straightened out. Likely a separate regs project down the road.

There are also some other differences in interpretation of the fees required in 12 AAC 52.030 (change in location or name) and 12 AAC 52.040 (ownership change). Here's a chart of what I think the fees say:

Type of Change	Current Cost on Application	My interpretation of regulation	What it should say/cost
Ownership	\$660	All fees required as it's considered a new application	Fine as written but could be clarified; see suggested in green, below
Name or Location	\$65	License + application + duplicate fee required (\$665)	Should remove the reference to duplicate fee; doesn't

Charging a duplicate licensee fee doesn't make sense when you're having to print a new license anyway. I talked to Sher about this when I first started, but she assured me the fees we currently charge are correct, which I am still skeptical about. This is how I think these sections should read:

**12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME.** (a) The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall

(1) submit a new, completed application for a pharmacy license; and  
~~(2) pay the duplicate license fee required in 12 AAC 02.105;~~ **pay the application and licensee fees required in 12 AAC 02.310.**

(3) repealed 1/17/2007.

(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.

**12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP.** (a) Repealed 1/17/2007. (b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020 **and must pay the application and license fees required in 12 AAC 52.310.**

Thank you,

**Laura Carrillo, MPH**  
 Executive Administrator

Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
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PDMP: 907-269-8404  
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Fax: 907-465-2974

---

**From:** Richard Holt [mailto:[dokholt@mac.com](mailto:dokholt@mac.com)]  
**Sent:** Friday, July 5, 2019 10:29 AM  
**To:** Carrillo, Laura N (CED) <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Subject:** Re: Fees for change in ownership, name, location

Thanks! I just got home last night from visiting my family in NY so trying to get caught up on emails; they sure add up quickly.

Yes – from my understanding of the regulation project, outsourcing facilities and 3PL's would require an entirely new application and corresponding fees.

I haven't paid too much attention to the fees that are charged but it may cause a problem that we charge for new application and all fees for outsourcing and 3PL's but we don't for other ownership changes. I would say we need to review each of our licensing categories for name/ownership/location and fees to make sure they are all consistent for the next board meeting. I don't recall the board wanting to make them different so it may have been our oversight that we need to correct going forward.

Great call out! Thanks.

---

**From:** "Carrillo, Laura N (CED)" <[laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov)>  
**Date:** Friday, July 5, 2019 at 8:51 AM  
**To:** "[dokholt@mac.com](mailto:dokholt@mac.com)" <[dokholt@mac.com](mailto:dokholt@mac.com)>  
**Subject:** Fees for change in ownership, name, location

Hi Rich,

Hope you had a happy 4<sup>th</sup>! Our historical interpretation of the fees required in change applications have been that all fees (application + license) are required for *ownership* changes only, but that just the application + \$5.00 duplicate license fees only are required for *name and location* changes. I'm in the process of creating our new forms, and am wanting to make sure I include the correct payment instructions and accurate fee box.

The way the regulations are written for outsourcing facilities and 3PLs, it seems like the application + license fees would be required for any type of change application. What are your thoughts?

Thank you,

**Laura Carrillo, MPH**  
Executive Administrator  
Alaska Board of Pharmacy  
Prescription Drug Monitoring Program  
State of Alaska – DCCED – CBPL  
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Fax: 907-465-2974



Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): 11UP9IAX4X5A

1. Enter your DEA Registration Number: BC2462668

Name of Registrant: CARR-GOTTSTEIN FOODS, CO.

Address: 1650 W NORTHERN LIGHTS BLVD

City: ANCHORAGE State: AK ZIP Code: 99517

Point of Contact: MARK KIM

Email Address: S1805C01@SAFEWAY.COM Phone No.: 9073390560

Date of the Theft or Loss (or first discovery of theft or loss): April 28, 2019 Number of Thefts and Losses in the past 24 months: 3

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY

3. Loss in Transit. (\*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)

Name of Common Carrier: \_\_\_\_\_

Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_

Have there been losses in transit from this same carrier in the past?  No  Yes (If yes, how many, excluding this theft or loss?): \_\_\_\_\_

Was the package received and accepted by the consignee?  No  Yes (If yes, the consignee is responsible for reporting the theft or loss.)

If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes

Name of Consignee / Supplier: \_\_\_\_\_

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: \_\_\_\_\_

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured?  No  Yes (if yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (if yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 31

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (if yes, fill out the following information):

Name of Police Department: \_\_\_\_\_ Police Report number: \_\_\_\_\_

Name of Responding Officer: \_\_\_\_\_ Phone No.: \_\_\_\_\_

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- Installed monitoring equipment (e.g. video camera).
- Increased employee monitoring (e.g. random drug tests).
- Installed metal bars or other security on doors or windows.
- Secured Controlled Substances within safe.
- Other (Please describe on last page).
- Provided security training to staff.
- Requested increased security patrols by Police.
- Hired security guards for premises.
- Terminated employee.





9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

DOUBLE COUNT AND BACK COUNT ALL CONTROLLED SUBSTANCES

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: MARK KIM

Title: PHARMACY MANAGER

Date Signed: June 11, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C. § 842 and § 843 of the Controlled Substances Act.

**NOTICE:** In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Freedom of Information:** Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

**From:** [Sarah Lindstrom](#)  
**To:** [Carrillo, Laura N \(CED\)](#)  
**Subject:** (noencrypt) DEA Form #106 4.21.2019 (date of loss 3.23.2019) Safeway Pharmacy #1813  
**Date:** Sunday, April 21, 2019 11:52:17 AM  
**Attachments:** [image002.png](#)  
[1813 03.23.2019 DEA 106.pdf](#)

---

Please see the attached DEA 106 Form filed for Safeway Pharmacy #1813.

For questions or comments do not reply to this email. Please forward the email to [pharmacy.pcat@safeway.com](mailto:pharmacy.pcat@safeway.com).

**Sarah Lindstrom**  
Pharmacy Compliance and Analytics



250 E ParkCenter Blvd  
Boise, ID 83706  
Phone: 208-395-5567  
PCAT: 208-395-3200  
Right Fax: 623-336-6099  
Fax: 208-395-4157  
[sarah.lindstrom@albertsons.com](mailto:sarah.lindstrom@albertsons.com)

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Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): N1REBTKX58A

1. Enter your DEA Registration Number: BC2462707  
 Name of Registrant: CARR-GOTTSTEIN FOODS, CO.  
 Address: 7731 E NORTHERN LIGHTS BLVD  
 City: ANCHORAGE State: AK ZIP Code: 99504  
 Point of Contact: BEAV CRAIG  
 Email Address: S1817C01@SAFEWAY.COM Phone No.: 9073391760

Date of the Theft or Loss (or first discovery of theft or loss): May 14, 2019 Number of Thefts and Losses in the past 24 months: 1

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY

3. Loss in Transit. (\*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)

Name of Common Carrier: \_\_\_\_\_

Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_

Have there been losses in transit from this same carrier in the past?  No  Yes (If yes, how many, excluding this theft or loss?): \_\_\_\_\_

Was the package received and accepted by the consignee?  No  Yes (If yes, the consignee is responsible for reporting the theft or loss.)

If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes

Name of Consignee / Supplier: \_\_\_\_\_

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: \_\_\_\_\_

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured?  No  Yes (If yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (If yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 234

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (If yes, fill out the following information):

Name of Police Department: \_\_\_\_\_ Police Report number: \_\_\_\_\_

Name of Responding Officer: \_\_\_\_\_ Phone No.: \_\_\_\_\_

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- Installed monitoring equipment (e.g. video camera).
- Increased employee monitoring (e.g. random drug tests).
- Installed metal bars or other security on doors or windows.
- Secured Controlled Substances within safe.
- Other (Please describe on last page).
- Provided security training to staff.
- Requested increased security patrols by Police.
- Hired security guards for premises.
- Terminated employee.





9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:  
DOUBLE BACK COUNT CONTROLS.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: BEAV CRAIG

Title: PHARMACIST

Date Signed: May 22, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C. § 842 and § 843 of the Controlled Substances Act.

**NOTICE:** In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Freedom of Information:** Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.



Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): 2J3F63GB6DJN

1. Enter your DEA Registration Number: BC2462822  
 Name of Registrant: CARR-GOTTSTEIN FOODS, CO.  
 Address: 10576 KENAI SPUR HIGHWAY  
 City: KENAI State: AK ZIP Code: 99611  
 Point of Contact: LAURA ANDERSON  
 Email Address: S1808C01@SAFEGWAY.COM Phone No.: 9072836360

Date of the Theft or Loss (or first discovery of theft or loss): September 08, 2019 Number of Thefts and Losses in the past 24 months: 2

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY

3. Loss in Transit. (\*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)

Name of Common Carrier: \_\_\_\_\_

Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_

Have there been losses in transit from this same carrier in the past?  No  Yes (If yes, how many, excluding this theft or loss?): \_\_\_\_\_

Was the package received and accepted by the consignee?  No  Yes (If yes, the consignee is responsible for reporting the theft or loss.)

If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes

Name of Consignee / Supplier: \_\_\_\_\_

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: \_\_\_\_\_

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured?  No  Yes (If yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (If yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 226

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (If yes, fill out the following information):

Name of Police Department: \_\_\_\_\_ Police Report number: \_\_\_\_\_

Name of Responding Officer: \_\_\_\_\_ Phone No.: \_\_\_\_\_

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- |  |  |
|--|--|
| <input type="checkbox"/> Installed monitoring equipment (e.g. video camera).         | <input type="checkbox"/> Provided security training to staff.            |
| <input type="checkbox"/> Increased employee monitoring (e.g. random drug tests).     | <input type="checkbox"/> Requested increased security patrols by Police. |
| <input type="checkbox"/> Installed metal bars or other security on doors or windows. | <input type="checkbox"/> Hired security guards for premises.             |
| <input type="checkbox"/> Secured Controlled Substances within safe.                  | <input type="checkbox"/> Terminated employee.                            |
| <input checked="" type="checkbox"/> Other (Please describe on last page).            |  |





9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

DOUBLE COUNT AND BACK COUNT CONTROLS.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DISCOVERED DURING A CYCLE COUNT OF CIII MEDICATIONS.

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: Laura Anderson

Title: PHARMACY MANAGER

Date Signed: September 19, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C. § 842 and § 843 of the Controlled Substances Act.

**NOTICE:** In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Freedom of Information:** Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

**From:** [Michael Wallace](#)  
**To:** [Board of Pharmacy \(CED sponsored\)](#)  
**Subject:** DEA Form #106 7.30.19 (date of loss 7.17.19) Safeway Pharmacy #1818 AK  
**Date:** Tuesday, July 30, 2019 12:13:56 PM  
**Attachments:** [image001.png](#)  
[1818 DEA 106 7.17.19.pdf](#)

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Please see the attached DEA 106 Form filed for Safeway Pharmacy #1818.

For questions/comments do not reply to this email. Please forward the email to [pharmacy.pcat@albertsons.com](mailto:pharmacy.pcat@albertsons.com).

Thank you.

Mike Wallace, Licensing Specialist  
**Pharmacy Professional Services**



250 E. Parkcenter Blvd. | Boise, ID 83706  
Office: 208.395.4301 | Fax: 208.395.4157  
[Michael.Wallace@albertsons.com](mailto:Michael.Wallace@albertsons.com)

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Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): 7QFRYAWSIFYL

1. Enter your DEA Registration Number: BC2462959

Name of Registrant: CARR-GOTTSTEIN FOODS, CO.

Address: 595 E PARKS HIGHWAY, #300

City: WASILLA State: AK ZIP Code: 99687

Point of Contact: HANNAH KEITH

Email Address: S1811C01@SAFEWAY.COM Phone No.: 9073521160

Date of the Theft or Loss (or first discovery of theft or loss): September 22, 2019 Number of Thefts and Losses in the past 24 months: 2

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY

3. Loss in Transit. (\*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)

Name of Common Carrier: \_\_\_\_\_

Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_

Have there been losses in transit from this same carrier in the past?  No  Yes (If yes, how many, excluding this theft or loss?): \_\_\_\_\_

Was the package received and accepted by the consignee?  No  Yes (If yes, the consignee is responsible for reporting the theft or loss.)

If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes

Name of Consignee / Supplier: \_\_\_\_\_

Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).

If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."

DEA Registration Number of Consignee / Supplier: \_\_\_\_\_

Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.

4. If this was a robbery, were any people injured?  No  Yes (If yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (If yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 2

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (If yes, fill out the following information):

Name of Police Department: \_\_\_\_\_ Police Report number: \_\_\_\_\_

Name of Responding Officer: \_\_\_\_\_ Phone No.: \_\_\_\_\_

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

- Installed monitoring equipment (e.g. video camera).
- Increased employee monitoring (e.g. random drug tests).
- Installed metal bars or other security on doors or windows.
- Secured Controlled Substances within safe.
- Other (Please describe on last page).
- Provided security training to staff.
- Requested increased security patrols by Police.
- Hired security guards for premises.
- Terminated employee.





9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

KEEP ALL EXPIRED CONTROLS IN THE C2 CABINET AND DOUBLE CHECKING ALL EXPIRED CONTROLLED MEDS SENT THROUGH MEDTURN FOR CORRECT ON HANDS.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: HANNAH KEITH

Title: PHARMACY MANAGER

Date Signed: October 01, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

- A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C. § 842 and § 843 of the Controlled Substances Act.

**NOTICE:** In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Freedom of Information:** Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.



Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): 75161BX6349D

1. Enter your DEA Registration Number: BC4343517  
 Name of Registrant: CARR-GOTTSTEIN FOODS, CO.  
 Address: 3033 VINTAGE BLVD  
 City: JUNEAU State: AK ZIP Code: 99801  
 Point of Contact: BRIGHT PATCH  
 Email Address: S1820C01@SAFEBAY.COM Phone No.: 9075232060

Date of the Theft or Loss (or first discovery of theft or loss): May 06, 2019 Number of Thefts and Losses in the past 24 months: 3

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: PACKAGING DISCREPANCY

3. Loss in Transit. (\*Fill out this section only if there was a loss in transit, or hijacking of transport vehicle.)  
 Name of Common Carrier: \_\_\_\_\_  
 Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_  
 Have there been losses in transit from this same carrier in the past?  No  Yes (if yes, how many, excluding this theft or loss?): \_\_\_\_\_  
 Was the package received and accepted by the consignee?  No  Yes (if yes, the consignee is responsible for reporting the theft or loss.)  
 If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes  
 Name of Consignee / Supplier: \_\_\_\_\_  
*Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee).  
 If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient, or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."*  
 DEA Registration Number of Consignee / Supplier: \_\_\_\_\_  
*Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier, (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.*

4. If this was a robbery, were any people injured?  No  Yes (if yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (if yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 3

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (if yes, fill out the following information):  
 Name of Police Department: \_\_\_\_\_ Police Report number: \_\_\_\_\_  
 Name of Responding Officer: \_\_\_\_\_ Phone No.: \_\_\_\_\_

8. Which corrective measure(s) have you taken to prevent a future theft or loss?  
 Installed monitoring equipment (e.g. video camera).  Provided security training to staff.  
 Increased employee monitoring (e.g. random drug tests).  Requested increased security patrols by Police.  
 Installed metal bars or other security on doors or windows.  Hired security guards for premises.  
 Secured Controlled Substances within safe.  Terminated employee.  
 Other (Please describe on last page).





9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?:

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

Describe any other corrective measure(s) you have taken to prevent a future theft or loss:

DOUBLE COUNT AL CONTROLLED SUBSTANCES AND BACK COUNT.

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary:

DUE TO THE VARIANCE DISCOVERED AND THE FREQUENCY OF DISPENSING OF THIS PRODUCT, WE HAVE NO EVIDENCE TO SUPPORT ANY OTHER EXPLANATION FOR THIS LOSS.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: BRIGHT PATCH

Title: PHARMACIST

Date Signed: May 22, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Reporting of unusual or excessive theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

- A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
- B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of Listed Chemicals may result in penalties under 21 U.S.C. § 842 and § 843 of the Controlled Substances Act.

**NOTICE:** In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**Freedom of Information:** Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

DEA FORM **106**

**Report of Theft or Loss of Controlled Substances**

OMB No 1117-0001 (Exp. Date 10/31/2020)

U.S. Department of Justice  
Drug Enforcement Administration  
Division of Control Division



RECEIVED  
Juneau  
MAY 03 2019

Type of Report: (check one box only)  New Report  Amendment Key (prior report dated): 83H944A1BYG8

1. Enter your DEA Registration Number: FW4979653

Name of Registrant: WALGREEN CO.

Address: 530 OLD STEESE HWY

City: FAIRBANKS State: AK ZIP Code: 99701 **CBPL**

Point of Contact: LAUREN WISE

Email Address: RXM.15944@STORE.WALGREENS.COM Phone No.: 9074579301

Date of the Theft or Loss (or first discovery of theft or loss): April 01, 2019 Number of Thefts and Losses in the past 24 months: 0

Principal Business of Registrant: CHAIN PHARMACY

2. Type of theft or loss: EMPLOYEE THEFT (OR SUSPECTED)

3. Loss in Transit. (Fill out this section only if there was a loss in transit, or hijacking of transport vehicle)

Name of Common Carrier: \_\_\_\_\_

Telephone Number of Common Carrier: \_\_\_\_\_ Package Tracking Number: \_\_\_\_\_

Have there been losses in transit from this same carrier in the past?  No  Yes (If yes, how many, excluding this theft or loss?) \_\_\_\_\_

Was the package received and accepted by the consignee?  No  Yes (If yes, the consignee is responsible for reporting the theft or loss)

If the package was accepted by the consignee, did it appear to be tampered with?  No  Yes

Name of Consignee / Supplier: \_\_\_\_\_  
*Enter the Name of Consignee (if reported by the supplier), or the Name of Supplier (if the package was accepted by the consignee)*  
*If the consignee does not have a DEA Registration Number, e.g. if this was a shipment to a patient or a nursing home emergency kit, enter "Patient" or "Nursing Home Kit."*

DEA Registration Number of Consignee / Supplier: \_\_\_\_\_  
*Enter the DEA Registration Number of Consignee (if reported by the supplier), or DEA Registration Number of Supplier (if the package was accepted by the consignee). If the controlled substances were shipped to a non-registrant, leave blank, unless a registered pharmacy shipped to an emergency kit held on site at a nursing home. In this case, the supplying pharmacy is required to report the theft or loss.*

4. If this was a robbery, were any people injured?  No  Yes (If yes, how many?): \_\_\_\_\_ Were any people killed?  No  Yes (If yes, how many?): \_\_\_\_\_

5. Purchase value to Registrant of controlled substances taken?: \$ 809

6. Were any pharmaceuticals or merchandise taken?  No  Yes (Est. Value): \_\_\_\_\_

7. Was theft reported to Police?  No  Yes (if yes, fill out the following information)

Name of Police Department: FAIRBANKS POLICE DEPARTMENT Police Report number: \_\_\_\_\_

Name of Responding Officer: \_\_\_\_\_ Phone No.: 9074506500

8. Which corrective measure(s) have you taken to prevent a future theft or loss?

Installed monitoring equipment (e.g. video camera)  Provided security training to staff

Increased employee monitoring (e.g. random drug tests).  Requested increased security patrols by Police.

Installed metal bars or other security on doors or windows.  Hired security guards for premises.

Secured Controlled Substances within safe.  Terminated employee

Other (Please describe on last page).



**Report of Theft or Loss of Controlled Substances**

OMB No. 1117-0001 (Exp. Date 10/31/2020)

U.S. Department of Justice  
Drug Enforcement Administration  
Diversion Control Division



9. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

N/A

RECEIVED  
Juneau  
MAY 03 2019

10. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers:

N/A

CBPL

Describe any other corrective measure(s) you have taken to prevent a future theft or loss.

- 1. EMPLOYEE TERMINATED
- 2. CHANGED DOOR LOCK COMBINATION

Enter remarks, if required. Description of how theft or loss occurred. Attach a separate sheet, if necessary.

The foregoing information is correct to the best of my knowledge and belief: By signing my full name in the space below, I hereby certify that the foregoing information furnished on this DEA Form 107 is true and correct, and understand that this constitutes an electronic signature for purposes of this reporting requirement only.

Signature: LAUREN WISE

Title: PHARMACY MANAGER

Date Signed: May 02, 2019

**Privacy Act Information**

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-53).

PURPOSE: Reporting of unusual occurrence theft or loss of a Controlled Substance.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

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**Freedom of Information:** Please prominently identify any confidential business information per 20 CFR 15.102, and exemption 3 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

**From:** [Debbie Mack](#)  
**Subject:** FW: Kiosks  
**Date:** Tuesday, April 23, 2019 2:04:55 PM  
**Attachments:** [attachment 1.pdf](#)

---

I am looking for clarity around whether or not automated will-call bins/ pick up machines, (“pick up kiosks”) are allowed in your state. The type of machine that I am talking about is one that would be at or near the pharmacy inside of a Walmart store which would serve as a secure place for holding prescriptions which have already been filled, verified, bagged, and are ready for pickup by the patient or patient’s agent. The prescriptions would be placed in the machine at the patient’s request for pickup either during or after pharmacy hours. The machine would have a phone available to call into the pharmacy or to a pharmacist at another Walmart Pharmacy (after hours) with access to the patient profile for purposes of consultation.

Walmart considered deploying this type of machine in our pharmacies back in 2007-2008 and later decided not to move forward with the project. We appeared in person before nearly every Board of Pharmacy and many approved without having regulations, many approved after writing regulations, and some approved pilot programs. A few states did not approve the machines due to conflicting statutes/regulations. Because our previous research is very old, I would like to refresh our database of states where this type of machine is allowed.

\*\*\*Please see the attachment for a sample of the type of pick up kiosk in questions.\*\*\*

It would be most helpful if you wouldn’t mind answering the questions below so that I know whether or not we can add these machines to one or more pharmacies in the state:

Does your state allow the use of “pick up kiosks” ( YES / NO )?

If YES:

Must the pick up kiosk be built into the wall of the pharmacy so that the loading of the machine occurs inside the footprint of the licensed pharmacy?

May the pick-up kiosk be free standing, but adjacent to the licensed pharmacy space?

May the pick-up kiosk be free standing, at any location within the Walmart store?

Can the pick-up kiosk be used to deliver both legend drugs AND controlled substances? (Or ONLY legend drugs?)

Can the pick-up kiosk be used to deliver both new AND refill prescriptions? (Or ONLY refills?)

Can the pick-up kiosk be used to deliver prescriptions for afterhours pickup?

Thank you in advance for taking the time to answer the above questions.

Thanks

Debbie

**Debbie Mack, RPh, CHC, CCEP, Sr. Director, U.S. Ethics & Compliance**

Office 479.277.0491 Cell 479.633.5768

[debbie.mack@walmart.com](mailto:debbie.mack@walmart.com)



U.S. Ethics & Compliance

702 SW 8<sup>th</sup> St.

Bentonville, AR 72716-0230

**Save money. Live better.**

**TO:** EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
**FROM:** Maureen Garrity, NABP Competency Assessment Director  
**DATE:** September 19, 2019  
**RE:** NABP Launches Pre-MPJE

---

The National Association of Boards of Pharmacy® (NABP®) is excited to announce the launch of the Pre-MPJE, a practice examination that helps individuals prepare for the Multistate Pharmacy Jurisprudence Examination® (MPJE®), which combines federal- and state-specific questions to test the pharmacy jurisprudence knowledge. Developed in response to feedback from graduates applying for initial licensure and pharmacists who have taken the MPJE, the Pre-MPJE features valid questions that appeared on and withdrawn from past MPJE exams. In addition, the exam covers topics specific to each jurisdiction that uses the MPJE as well as subjects common to all jurisdictions.

The Pre-MPJE is 40 questions in length and costs \$65. Schools and colleges of pharmacy will be able to purchase Pre-MPJE vouchers via NABP e-Profile Connect for distribution to students. Each voucher costs \$55 and is good for one examination. Schools orders of more than 100 vouchers would cost \$50 each. Candidates will be able to take the practice exam once a year per jurisdiction by logging into their NABP e-Profile.

The Pre-MPJE follows the model of two other NABP pre-exams: the Pre-NAPLEX®, which prepares pharmacy students for the North American Pharmacist Licensure Examination® and the Pre-FPGEE®, a practice exam for foreign pharmacists preparing to take the Foreign Pharmacy Graduate Equivalency Examination®. NABP is using a different testing delivery system for the Pre-MPJE that allows the practice exam to have the same look and features as the MPJE, giving candidates a better feel for the testing experience.

### ***Practice Exams Correlate With Improved Performance***

NABP statistics show a correlation between passing scores and the other pre-examinations offered by NABP. Statistics concerning performance on the NAPLEX demonstrate that from 2016-2018, 61% of candidates who took the Pre-NAPLEX before taking the NAPLEX for the first time earned higher overall scaled scores. During that time, the NAPLEX pass rates for candidates who took and who did not take the Pre-NAPLEX also were impacted as illustrated below:

- 83.1%, or 33,853 individuals (pre-exam taken)
- 79.1%, or 20,556 individuals (pre-exam not taken)

Also from 2016-2018, 36% of candidates took the Pre-FPGEE before taking the FPGEE for the first time performed better on the FPGEE. Performance data for examinations administered during that time, indicate that the FPGEE pass rates for candidates who completed and who did not complete the Pre-FPGEE were as follows:

- 73.4%, or 1,513 individuals (pre-exam taken)
- 66.9%, or 2,661 individuals (pre-exam not taken)

Candidate information about the Pre-MPJE is available at [www.nabp.pharmacy](http://www.nabp.pharmacy).

cc: NABP Executive Committee  
NABP Advisory Committee on Examinations  
Carmen A. Catizone, Executive Director/Secretary

**From:** [Adams, Henry \(MU-Student\)](#)  
**To:** [Board of Pharmacy \(CED sponsored\)](#)  
**Subject:** Question Concerning "Substitution" of "Therapeutically Equivalent Drugs"  
**Date:** Monday, September 16, 2019 2:50:59 AM

---

Hi,

I'm Henry Adams, and I'm a law student doing research on state's pharmaceutical practices. I've been tasked to determine how state pharmacists dispense therapeutically equivalent drugs (generics). I was hoping you could help (or point to someone who could help) clarify how pharmacists in Alaska apply the state's "substitution" regulations on a day-to-day basis.

By statute, Alaska defines an "equivalent drug product" and allows pharmacists to "substitute" prescriptions with equivalent drug products. AS 08.80.480(12); AS 08.80.295. The state's regulations then provide that the "determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist." 12 AAC 52.510.

My question is: how would a pharmacist in Alaska make the "equivalent drug product" determination? Do they review the drugs themselves and rely on their own professional judgement? Do they consult a manual or review FDA's generic drug equivalence publications ("orange book")?

Any guidance you could give would be very helpful. Thank you!

Have a great rest of your day,  
Henry.

*Henry Davidson Adams*  
*J. D. Candidate, Spring 2020*  
*University of Missouri, School of Law*  
[henryadams@mail.missouri.edu](mailto:henryadams@mail.missouri.edu)  
*(816) 872-9223*

**From:** [Kim, Cj J \(HSS\)](#)  
**To:** [Board of Pharmacy \(CED sponsored\)](#)  
**Subject:** Rabies Post Exposure Prophylaxis  
**Date:** Thursday, May 23, 2019 12:25:10 PM  
**Attachments:** [RabiesPostExposureTreatment.pdf](#)  
[image002.png](#)  
[Rabies\\_MMWR.PDF](#)

---

Hello,

Hopefully I am not too late to add this question into next board meeting's packet.

I wanted to get the Board's opinion as to the administration of rabies post exposure prophylaxis procedure to see if this would be under the scope/practice of pharmacy.

(30) "practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the administration of vaccines and related emergency medication; the independent dispensing of opioid overdose drugs; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

See attached PDF for background regarding the treatment which basically is two parts.

1. Vaccine administration x 4 doses / IM (**I do not see an issue with this part**)
2. Human Rabies Immune Globulin (HRIG) / immune globulin administration which states:
  - a. "As much as anatomically feasible of the HRIG should be infiltrated into and around the wound or bite. The remainder (if any) should be given by intramuscular injection at an anatomical site distant from vaccine administration."
  - b. The question is this procedure be considered under the scope of pharmacy?

Additional info/CDC MMWR - <https://www.cdc.gov/mmwr/PDF/rr/rr5703.pdf> - see attached.

From the website - <https://www.drugs.com/drp/imogam-rabies-ht.html>

## Dosage and Administration

Parenteral drug products should be inspected visually for particulate matter and/or discoloration prior to administration, whenever solution and container permit. If either of these conditions exist, the vaccine should not be administered.

Imogam Rabies - HT should be used in conjunction with Rabies Vaccine such as Rabies Vaccine Imovax Rabies, for intramuscular immunization, vaccine prepared from human diploid cell cultures. The recommended dose of Imogam Rabies - HT is 20 IU/kg (0.133 mL/kg) or 9 IU/lb (0.06 mL/lb) of body weight administered at time of the first vaccine dose.<sup>25,26,43</sup> The gluteal area should never be used for HDCV, RVA, or PCEC injections because administration of HDCV in this area results in lower neutralizing antibody titers.<sup>1,43,44</sup> If anatomically feasible, the full dose of Rabies Immune Globulin (Human) (RIG) should be thoroughly infiltrated in the area around and into the wounds. Any remaining volume should be injected intramuscularly at a site distant from vaccine administration.<sup>1</sup> Two injections would be given in the gluteal muscle if the volume is greater than 5 mL.

ADVERTISEMENT

*Human Rabies Immune Globulin (HRIG) should never be administered in the same syringe or into the same anatomical site as vaccine. Because HRIG may partially suppress active production of antibody, no more than the recommended dose should be given.*<sup>1,27</sup>

The administration of HRIG is more or less the part I am concerned with regarding pharmacist scope of practice. Per recommendations, HRIG is administered around/into the wound and the remaining to be administered into a large muscle group. An adult may need 10mL or more of HRIG. This portion may require additional training and consulting as to properly administer.

Thank you for taking time to assist with this question.  
CJ

C.J. Kim  
Pharmacist  
Division of Public Health  
Section of Epidemiology  
3601 C Street, Suite 586  
Anchorage, AK 99503  
(O) 907-269-8029  
(F) 907-269-0472

<https://blogs.cdc.gov/publichealthmatters/2018/04/rxawareness/>  
<http://www2.cdc.gov/nip/adultimmsched/>

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**From:** [Devin Wallace](#)  
**Subject:** Revised USP795, USP797, USP800 - Veterinary Clinic Question  
**Date:** Tuesday, June 4, 2019 8:43:46 AM

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With the recent release of the revised USP 795,797,800, veterinary compounding became a new main focus. Many states have cited or fully adopted USP standards for compounding into their rules and regulations, does your BOP intend to start inspecting veterinary clinics whom compound?

Devin Wallace CPhT CSPT RPhT PRS  
President & Consultant | Wallace Ventures  
970-689-2784

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[www.linkedin.com/in/devin-wallace](http://www.linkedin.com/in/devin-wallace)

**From:** [SLSNYSupport.com](mailto:SLSNYSupport.com)  
**To:** [Carrillo, Christianne D \(CED\)](#)  
**Cc:** [Carrillo, Laura N \(CED\)](#)  
**Subject:** Fwd: [#46413] New Regulations/License  
**Date:** Tuesday, October 29, 2019 11:24:00 AM

---

Ticket ID : 46413

Hi Christianne,

Thank you so much for your time on the phone today. As discussed, I am forwarding my questions to you via email with Laura in copy.

As the new regulations for nonresident wholesalers and third party logistics providers go into effect in a few days, is there a grace period in which facilities will be allowed to continue distributing into Alaska while their applications are pending with the board?

- What facility types will require the Nonresident Wholesale Distributor permit?
- More specifically, I would like to know if the following facility types will require this license:
  - Virtual Manufacturers (Appear on label as manufacturer but do not physically handle any product, conduct sales and record keeping)
  - Virtual Wholesalers (Do not physically handle any product, they direct the sale of their products and use a 3PL to distribute)
  - FDA registered Manufacturers distributing their own-labeled product
- Which product lines are regulated?
  - More specifically, I would like to know which of the following license types will require the Nonresident Wholesale Distributor permit:
    - Rx Human Drugs
    - Rx Human Devices
    - Rx Veterinary Drugs
    - Rx Veterinary Devices
    - OTC drugs
    - OTC devices
    - OTC devices containing Rx drugs
- Will a facility that conducts both wholesale distributor and 3PL activities require separate licenses for each activity?

I truly appreciate your assistance.

Kind Regards,

*Tiffany Reid-Perez, Esq.*

Regulatory Analyst  
State License Servicing, Inc.  
1751 State Route 17A, Ste. 3  
Florida, NY 10921  
Email: [compliance@slnysupport.com](mailto:compliance@slnysupport.com)  
Phone: 845-544-2482 ext 231



On Tue, 29 Oct at 1:58 PM , SLSNYSupport.com <[help@slnysupport.com](mailto:help@slnysupport.com)> wrote:  
Hi Laura,

I just left you a voice mail but I'll also send this email so that you have a chance to consider all of my questions.

- The regulations go into effect in two days, is there a grace period in which facilities will be allowed to continue distributing into Alaska while their applications are pending with the board?
- What facility types will require the Nonresident Wholesale Distributor permit?
- More specifically, I would like to know if the following facility types will require this license:
  - Virtual Manufacturers
  - Virtual Wholesalers
  - FDA registered Manufacturers distributing their own-labeled product
- Which product lines are regulated?
  - More specifically, I would like to know which of the following license types will require the Nonresident Wholesale Distributor permit:
    - Rx Drugs
    - Rx Devices
    - OTC drugs
    - OTC devices
    - OTC devices containing Rx drugs
- Will a facility that conducts both wholesale distributor and 3PL activities require separate licenses for each activity?

Thank you for your assistance.

Kind Regards,

*Tiffany Reid-Perez, Esq.*

Regulatory Analyst

State License Servicing, Inc.

1751 State Route 17A, Ste. 3

Florida, NY 10921

Email: [compliance@slnysupport.com](mailto:compliance@slnysupport.com)

Phone: 845-544-2482 ext 231



On Fri, 25 Oct at 2:51 PM , SLSNYSupport.com <[help@slnysupport.com](mailto:help@slnysupport.com)> wrote:

Hi Laura,

Yes, of course, I can provide examples.

- What facility types will require the Nonresident Wholesale Distributor permit?
  - More specifically, I would like to know if the following facility types will require this license:
    - Virtual Manufacturers
    - Virtual Wholesalers
    - FDA registered Manufacturers distributing their own-labeled product
- Which product lines are regulated?
  - More specifically, I would like to know which of the following license types will require the Nonresident Wholesale Distributor permit:

- Rx Drugs
- Rx Devices
- OTC drugs
- OTC devices
- OTC devices containing Rx drugs
- Will a facility that conducts both wholesale distributor and 3PL activities require separate licenses for each activity?
- Will VAWD be required for Nonresident Wholesale Distributors?

Thank you for your assistance.

Kind Regards,

*Tiffany Reid-Perez, Esq.*

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Phone: 845-544-2482 ext 231



On Tue, 15 Oct at 2:21 PM , SLSNYSupport.com  
<[help@slnysupport.com](mailto:help@slnysupport.com)> wrote:

**From: State License Servicing, Inc.**

Subject: New Regulations/License

Hello Ms. Carrillo,

In addition to my last email dated October 11, 2019, will VAWD be required for the wholesale distributor permit?

Thank you for your time, effort and prompt response.

Regards,  
*Cathy Lanzo*

Regulatory Analyst  
State License Servicing, Inc.  
1751 State Route 17A, Ste. 3  
Florida, NY 10921  
Email: [compliance@slnysupport.com](mailto:compliance@slnysupport.com)  
Phone: 845-544-2482 ext 223



On Fri, 11 Oct at 3:22 PM , SLSNYSupport.com  
<[help@slnysupport.com](mailto:help@slnysupport.com)> wrote:

Hello Ms. Carrillo,

As you are aware, the new regulations go into effect on October 31, 2019. Application forms for the new license categories are currently unavailable, however, the Board's website indicates that applications will be available before October 31, 2019. The Alaska board

of Pharmacy has amended its regulations to add license categories for third-party logistics providers (3PLs), outsourcing facilities, and out-of-state wholesale drug distributors.

Please answer the following questions :

1. What facility types will require the Nonresident Wholesale Distributor permit?
2. Which product lines are regulated?
3. Is more than one permit needed for multiple activities?

SLS will continue monitoring the Board's website for updates.

Regards,

*Cathy Lanzo*

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Phone: 845-544-2482 ext 223



**From:** [Janso, Lisa](#)  
**Subject:** "Electronic Mailbag" – Thursday, October 10, 2019  
**Date:** Thursday, October 10, 2019 1:58:52 PM  
**Attachments:** [image001.png](#)  
[Memo - EO - USP Postponement Impact on NABP Programs.pdf](#)

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

RE: "Electronic Mailbag" – Thursday, October 10, 2019

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- 1) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: USP Postponement Impact on NABP Programs  
Attachment

**From:** [Janso, Lisa](#)  
**Subject:** "Electronic Mailbag" – Thursday, October 17, 2019  
**Date:** Thursday, October 17, 2019 2:00:59 PM  
**Attachments:** [image001.png](#)  
[MEMO - EO - Request for info from Maryland.pdf](#)  
[MEMO - EO - Join.Amicus Brief.17Oct2019.pdf](#)  
[MEMO - EO - FDA 36th MedWatch Webinar.pdf](#)

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**TO:** EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

**FROM:** Carmen A. Catizone, Executive Director/Secretary

**RE:** "Electronic Mailbag" – Thursday, October 17, 2019

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- 1) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Request for Information from Maryland
  
- 2) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Amicus Brief Update - Opportunity for Boards of Pharmacy to Join Attachments
  
- 3) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Live Student and Health Care Professional Continuing Education Webinar Hosted by FDA's Division of Drug Information

**From:** [Janso, Lisa](#)  
**Subject:** "Electronic Mailbag" – Thursday, September 5, 2019  
**Date:** Thursday, September 5, 2019 1:52:52 PM  
**Attachments:** [image001.png](#)  
[MEMO - EO - Pharmacy Checker.pdf](#)  
[MEMO - EO - Request for info from Vermont.pdf](#)  
[MEMO - District 8 EO - Reminder - Open Member Position on EC.pdf](#)  
[MEMO - EO - FDA Home Study CE Webinars.pdf](#)

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TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

RE: "Electronic Mailbag" – Thursday, September 5, 2019

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- 1) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: PharmacyChecker.com – Not Recommended List Litigation
  
- 2) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Request for Information from Vermont
  
- 3) MEMO – DISTRICT 8 EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Deadline for Submission of Nominations for the Open Member Position on the NABP Executive Committee Representing District 8  
Attachment
  
- 4) MEMO – EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
RE: Free Home Study Continuing Education Webinars for Health Care Professionals Hosted by FDA's Division of Drug Information



**NABP**

National Association of  
Boards of Pharmacy

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TO: EXECUTIVE OFFICERS - STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: March 18, 2019  
RE: Federal Opioid Funding Threatens Prescription Drug Monitoring Programs

---

The attached letter was emailed to your Governor's Office late Friday afternoon after unsuccessful discussions with the Centers for Disease Control and Prevention (CDC) and the states' request for waivers from the Special Conditions provisions of the "Overdose Data to Action" Notice of Funding Opportunity (NOFO) grants. Please contact me if there is anything further NABP can do or if you have any questions/comments.

Thank you!

Attachment

cc: NABP Executive Committee



**VIA ELECTRONIC DELIVERY**

*This is a replica of the letter that was sent on 3/15/19 to Governors.*

March 18, 2019

**RE: Federal Opioid Funding Threatens Prescription Drug Monitoring Programs**

**Your state, along with 46 other states, the District of Columbia, and Puerto Rico could be at risk of losing millions of dollars in grant funding from the Centers for Disease Control and Prevention (CDC).**

In February, the CDC announced the “Overdose Data to Action” Notice of Funding Opportunity (NOFO) for nearly \$1 billion – up to \$21 million per state over 3 years – for state health departments to improve public health surveillance and prevention to combat the opioid epidemic. **However, buried in Appendix 11 of the NOFO are Special Conditions related to PDMPs that every state must meet to qualify for any of the funding, even if the funding will not be used for PDMPs.**

These Special Conditions were also included in a smaller PDMP-specific grant, the FY2018 Comprehensive Opioid Abuse Site-based Program Category 5, awarded to 23 states by the Department of Justice (DOJ) in September 2018.

The most alarming and disruptive requirement under these Special Conditions is forcing PDMPs to connect to the Department of Justice (DOJ)’s own untested system – called RxCheck. **By mandating this requirement, the Federal government has signaled a policy shift towards building an entirely new national, federally mandated and operated, interstate data sharing hub.**

The National Association of Boards of Pharmacy® (NABP®) is a 501(c)(3) organization whose mission is to support state boards of pharmacy and other state agencies to promote public health and safety. At the request of our members and *at no cost to states or taxpayers*, we created and operate the PMP InterConnect® system that allows 47 states, the District of Columbia, Puerto Rico, and the Defense Health Agency to securely share PDMP data. Every 30 days, more than 37 million requests for patient information flow through this system. Since NABP operates PMP InterConnect at a yearly loss, we must consider whether to continue spending scarce resources to maintain a system that the federal government has decided to replace.

For the past 7 months, we have attempted to work with the DOJ, and now the CDC, on behalf of states to request a waiver of these Special Conditions. Unfortunately, the agencies steadfastly refuse to consider any modification.

Absent decisive and immediate congressional intervention:

- 1. NABP may be forced to shutter the interstate data sharing system that your state currently uses, PMP InterConnect®. This will disrupt the current interstate data sharing system that your state PDMP relies on.**
- 2. Your state may be ineligible for the CDC Overdose Data to Action funding if it does not comply with the Special Conditions.**



### PDMP System Disruption Concerns

The Special Conditions in the DOJ and CDC grants require that states connect to a different interstate data sharing hub run by the DOJ, called RxCheck, which is *funded by taxpayers*. RxCheck is currently used by five states at most and is not yet used for integration with health care and pharmacy systems. Complying with the Special Conditions and connecting to a new system will require significant state resources to update contracts, evaluate compatibility and security, and train staff and stakeholders.

### Data Sharing and Privacy Concerns

Additionally, as written, it is unclear whether the CDC Special Conditions will require the sharing of your PDMP data with the federal government upon request. Currently, under the PMP InterConnect® hub, access to PDMP data is strictly governed by state law to ensure privacy and security but is generally available to law enforcement or certain regulatory agencies via limited (not global) request. Deidentified statistical and cumulative data is also available for trending, research, and policy-making purposes. Yet the DOJ Special Conditions may force states to release their PDMP data and – possibly also protected health information (PHI) data – despite state law limitations, in order to receive grant funds.

### Consequences of Special Conditions

The DOJ and CDC are mandating these unprecedented requirements for PDMPs outside congressionally appropriated authority. The outcome is contrary to our shared interests in addressing the opioid epidemic, advancing public health and safety, and efficiently using taxpayer dollars.

NABP is spending significant resources to run PMP InterConnect® and to attempt to remedy the issues outlined in this letter. If the Special Conditions stand and states must release PHI and use RxCheck, NABP may be forced to shut down the existing PMP InterConnect® hub in the immediate future.

If the Special Conditions are not waived, states which are unable to comply will lose the opportunity for up to \$21 million in CDC funding. Up to 23 states could also lose nearly \$1 million each from DOJ.

### Request for Action

If these Special Conditions are indeed problematic for your state as outlined above, we urge you to reach out to the CDC and DOJ immediately to voice your concerns and request a waiver of the Special Conditions for your state. We also urge you to contact your Congressional delegation to alert them to this imminent public health and patient safety crisis. **Congress did not authorize any of these Special Conditions.**

As you, your state Department of Health, and your state PDMP evaluate the impact of these Special Conditions on your state, the NABP stands ready to answer questions. Please don't hesitate to reach out to Carmen Catizone at [ExecOffice@nabp.pharmacy](mailto:ExecOffice@nabp.pharmacy) or (847) 391-4410. Our goal is to work with you, Congress, and the federal government to resolve these issues in a manner that achieves our mutual goals of fighting the opioid epidemic and protecting the public's health.

Sincerely,

Carmen A. Catizone, MS, RPh, DPh  
Executive Director/Secretary  
NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

cc: State Department of Health; State Board of Pharmacy

# Operation uncovers flood of painkillers reaching rural Alaska by mail

[rcinet.ca/eye-on-the-arctic/2019/09/23/alaska-opioid-drug-crisis-mail-dea/](https://rcinet.ca/eye-on-the-arctic/2019/09/23/alaska-opioid-drug-crisis-mail-dea/)

Zachariah Hughes, Alaska Public Media

September 23,  
2019



A pharmacist holds a bottle of traMADOL Hydrochloride made by Sun Pharma at a pharmacy in Provo, Utah, U.S., May 9, 2019. (George Frey/Reuters)

An operation by the Drug Enforcement Administration and other federal agencies has turned up a previously undocumented drug problem spread across Alaska. The DEA estimates that more than a million pills of Tramadol, a mild opioid, are reaching Alaska a year, arriving primarily in rural communities through the mail system. The investigation into illicit Tramadol is an outgrowth of the Justice Department's declaration this summer of a public safety emergency for Alaska.

On a recent weekday in the DEA's midtown office, a table was covered in Ziplock bags stuffed with pharmaceutical packages of Tramadol, the flat, white disks resembling breath mints. Beside them were piles of red and white flat-rate mail envelopes. Investigators can hear the pills rattle when they shake the parcels.

"Just tons of packages like this," said Special Agent in Charge Keith Weis.

For 45 days this summer, the DEA launched a "surge" across the state. It was a multi-pronged effort that included, among other things, an operation in Anchorage between the DEA and partner agencies seizing 204 packages containing almost 48,545 illicit or unlawfully

diverted pills. Almost all of those pills — 44,580 — were Tramadol.

“Our intelligence has always told us that Tramadol is a large problem for the entire state of Alaska. It’s an underlying drug that’s being shipped in at will, especially via mail,” Weis said.

### A state-wide problem

Tramadol is a Schedule IV drug, less tightly regulated than stronger opioid painkillers like oxycodone, but it works largely the same way. It has a mild narcotic high, and can help mitigate withdrawal symptoms for heavier opioid or heroin users. It’s also widely used in veterinary care. Many Alaskans heard about Tramadol for the first time in 2017 when some of Iditarod champion Dallas Seavey’s sled-dogs tested positive for it (Seavey was cleared of any wrong-doing). It is relatively easy to get a prescription and legally order Tramadol online to be shipped in the mail.

Based on DEA’s interdiction operation this year, Weis estimates around 100,000 pills are arriving in Alaska every month.

“It was dispersed over the whole state,” Weis said of where parcels were bound for. “It was widespread, which tells us it’s out there and pretty deeply seeded in all the communities.”

Taking higher doses of Tramadol can cause seizures and depressed breathing, and is especially dangerous if used in combination with other drugs.

The investigation came as a result of Attorney General William Barr’s June visit to Alaska, after which time he declared an emergency over the lack of rural law enforcement and public safety. That move has brought more money into the state for hiring, new equipment, and additional training. But it also spurred federal agencies to take a more active role in rural areas. The other pieces of DEA’s “surge” were bringing a plane up to Alaska so personnel could fly to 35 different communities: villages, hubs, cities and small towns along the Railbelt. A map on the wall was scattered with red dots marking every site where the group flew. There, they met with elders, leaders and law enforcement personnel, made presentations at schools and visited staff who handle prescribing medications in local clinics. The Agency hopes those introductions will foster longer-term relationships with rural communities to better handle drug issues.

### Increased enforcement

And the DEA isn’t the only agency doing that kind of work right now.

Federal prosecutors are trying to find ways to help local and state law enforcement build more criminal cases in rural areas.

“We’re looking for ways to do more,” said U.S. Attorney Brian Schroder. “To fill an appropriate role out there.”

That may mean using legal tools uniquely available to federal prosecutors, like felons found in possession of firearms, drug trafficking, or certain kinds of cases involving child pornography. The Justice Department is hiring three new prosecutors for Alaska, and a grant is paying for two more state assistant district attorneys, all of whom will be focused on cases in rural parts of the state.

On a recent trip to Kodiak with the DEA, Schroder was moved by a meeting with native leaders from surrounding communities.

“What struck me was how much concern there was by those leaders about drug problems in their villages,” Schroder said. “I don’t know that I was quite ready for that. There were people who were getting very emotional about the damage drugs are doing to their villages.”

The rekindled interest among federal law enforcement agencies comes as a statewide conversation is underway about the shortcomings of public safety and the criminal justice system in Alaska.

Related stories from around the North:

**Canada:** No opioid crisis in Canada’s eastern Arctic, CBC News

**Finland:** Finland’s six-year slump in alcohol sales ends, Yle News

**United States:** Alaska capital budget vetoes to hit homelessness, addiction treatment, Alaska Public Media



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**Via USPS Express Mail & Email (boardofpharmacy@alaska.gov)**

Laura Carrillo  
Executive Administrator  
Alaska Board of Pharmacy  
PO Box 110806  
Juneau, AK 99811-0806

**Re: USP GC <795> Nonsterile Compounding and Flavoring**

Dear Laura:

I am writing this letter as a legal representative of FLAVORx, a company that supplies custom-flavoring systems to pharmacies across the United States. I am also a licensed pharmacist, attorney, and father concerned about the impact USP's position will have on pediatric healthcare. I am writing to express my concern over a recent change implemented by USP regarding nonsterile compounding, and the impact it will have on the practice of pharmacy and pediatric healthcare in Alaska. USP recently indicated they intend to classify all flavoring of conventionally manufactured medications as nonsterile compounding. USP has taken this position despite the fact that flavorings are tested for potency and proven to be safe and inert when added to medications. The practice of flavoring medications has long been an integral and valuable part of the pharmacy profession, and USP's decision would effectively eliminate flavoring as an adherence boosting service for patients, which is currently utilized millions of times each year without a single reported incident. When community pharmacists need to obtain prescriber authorization and follow compounding procedural requirements to simply add a flavoring agent to conventionally manufactured medications, it is not surprising that pharmacies quickly discontinue offering the service to patients. Fourteen state boards of pharmacy already have language on their books excluding flavoring from the definition of compounding and not a single board has drafted regulations affirmatively recognizing flavoring as compounding.

As I'm sure you are aware, medication adherence is a critically important element of patient care and an essential determinant of clinical success. Studies conclusively show that the palatability of pediatric oral medications is one of the most critical factors influencing adherence to therapeutic regimens for children. Having children participate in flavoring their medications at their local pharmacy is a safe and proven mechanism for pharmacists to enhance medication palatability and is one of the best resources we have to support pediatric medication adherence.

To ensure community pharmacists and parents are able to continue utilizing this valuable service for pediatric patients in Alaska, I recommend the Board implement a regulation excepting the safe administration of flavoring from the definition of compounding. The Board can achieve this by narrowing the use of flavoring agents to conventionally manufactured and

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Laura Carrillo  
September 10, 2019  
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commercially available liquid medications and by setting conditions to ensure safe administration of flavoring (e.g. flavoring agents must be nonallergenic and inert, not exceeding five (5) percent of a drug product's total volume). I am more than happy to assist the Board in crafting language that safeguards the quality and safety of flavoring agents without sacrificing their benefit to patients and the public health.

I appreciate your consideration in this matter. I respectfully request an in-person meeting or conference call at your earliest convenience, so we can discuss a common-sense resolution to this public health issue. I will contact your office to set up a mutually convenient date and time for this discussion.

Very truly yours,

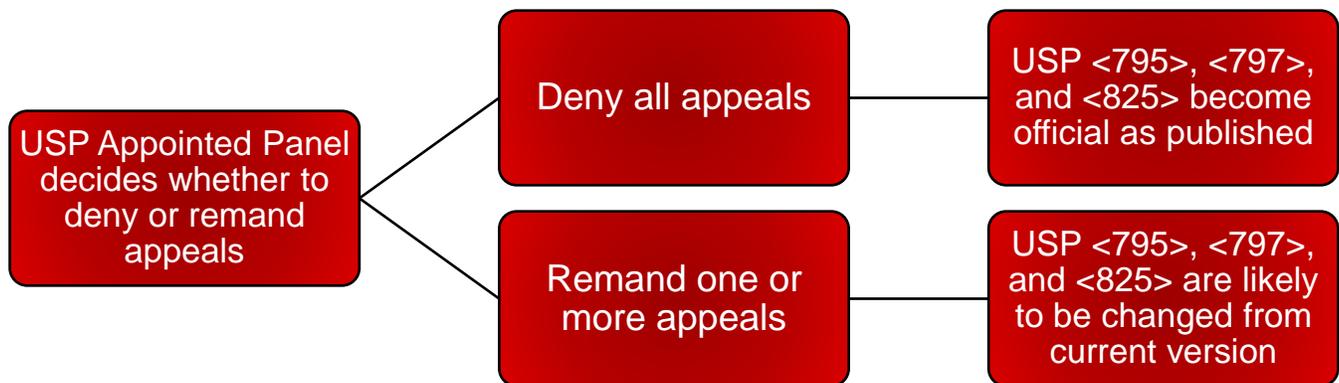
A handwritten signature in black ink, appearing to read 'Ned Milenkovich', written in a cursive style.

Ned Milenkovich, PharmD, JD

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY  
FROM: Carmen A. Catizone, Executive Director/Secretary  
DATE: September 26, 2019  
RE: USP Postpones Official Dates of USP General Chapters <795>, <797>, and <825>

United States Pharmacopeial Convention (USP) has announced that the official effective date of changes to USP General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging has been postponed.

After publication of the revised and new compounding standards, USP received appeals on certain provisions in USP <795>, <797>, and <825>. The responsible USP Expert Committees reviewed and issued decisions on the appeals to [USP <795> and <797>](#) and [USP <825>](#). However, in accordance with USP’s formal appeals process, stakeholders who submitted appeals have requested further review by an appointed panel. An infographic on the next steps in the appeals process is included below.



[USP Bylaws](#) provide that the official date of a standard under appeal must be postponed while an appeal is pending. In the interim, the currently official chapters of USP <795> (last revised in 2014) and USP <797> (last revised in 2008), including the section Radiopharmaceuticals as Compounding Sterile Preparations, will remain official.

Revisions to General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings are not subject to pending appeals and will become official on December 1, 2019.

According to General Notices Section 3.10, USP <800> will be informational upon its official date as it is not referenced in an applicable chapter. However, the 2019 revisions to USP <795> and <797> reference USP <800>, which means that if USP <795> and <797> revisions become official, USP <800> will become applicable and enforceable for the sections related to compounding. USP encourages utilization of USP <800> in the interest of advancing and protecting public health, but the

organization plays no role in enforcement. State and other regulators make their own determinations regarding the enforceability of USP <800>.

For more information on compendial applicability, please review General Notices Section 3.10 and visit the USP Identifying Official Text web page at <https://www.usp.org/frequently-asked-questions/identifying-official-text>.

NABP is monitoring this issue closely and will continue to inform its members as the Association is made aware of any updates to the process. For any questions about compounding updates and the appeals process, please contact the USP Healthcare Quality & Safety Team at [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).

cc: NABP Executive Committee



October 17, 2019

Dear Pharmacists,

As a result of the Drug Enforcement Administration's (DEA) recent actions against two prescribers and the subsequent surrendering of their Alaska professional healthcare licenses, pharmacists have been seeking guidance as to what prescriptions, if any, can be dispensed.

To expound upon our existing Frequently Asked Questions page, which addresses the validity of prescriptions following an adverse action against a prescriber's license or if the prescriber has since become deceased, we are issuing the following guidance:

- Prescriptions should still be assessed by the pharmacist to determine whether the prescription was written within the ordinary course of professional practice and for a legitimate medical reason.
- Due to the DEA registration numbers (BD1834818, previously belonging to Lavern Davidhizar and MS0819194, previously belonging to Jessica Spayd) no longer being valid, federally scheduled controlled substances issued by these providers **cannot** be dispensed.
- Non-scheduled legend drugs should continue to be dispensed.
- Remain cognizant of non-controlled substances that may have a potential for abuse when combined with other medications or illicit drugs, such as muscle relaxants.

We acknowledge the ongoing opioid crisis Alaskans are faced with and understand there is no simple answer to the nuances of the health and safety repercussions for each patient. As we continue engaging in multi-agency efforts to address and navigate the impacts of the recent prescriber indictments, please be assured there are additional resources available:

Opioid Enforcement Health Response –  
<http://dhss.alaska.gov/dph/Director/Documents/opioids/factsheet.pdf>

Patient Information/FAQ –  
[http://dhss.alaska.gov/dph/Director/Documents/opioids/Patient-Information-FAQ\\_10.15.19.pdf](http://dhss.alaska.gov/dph/Director/Documents/opioids/Patient-Information-FAQ_10.15.19.pdf)

Information for Health Care Providers, Prescribers, and Pharmacists –  
<http://dhss.alaska.gov/dph/Director/Documents/opioids/factsheet.pdf>

Prescription Drug Monitoring Program Resources –  
<https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/PrescriptionDrugMonitoringProgram/PrescribingResources.aspx>

Thank you for your continued professionalism and the support you provide to our patients. If you have additional questions, please email [laura.carrillo@alaska.gov](mailto:laura.carrillo@alaska.gov) with the Opioid Health Action Response (OHAR) team and Executive Administrator for the Board of Pharmacy.

Professionally,

A handwritten signature in blue ink that reads "Richard Holt".

Richard Holt, BS Pharm, PharmD, MBA  
Chair, Alaska Board of Pharmacy

**From:** [Shelley Tustison](#)  
**To:** [Board of Pharmacy \(CED sponsored\)](#)  
**Subject:** USP 795 & USP 800 Compliance Survey  
**Date:** Monday, September 9, 2019 7:54:06 AM

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Ms. Carrillo,

Walmart is conducting a survey to further help clarify USP 795 and USP 800. There has been some confusion on what Boards will enforce which section of each piece. With the 12/1/19 implementation date coming soon, we wanted to be able to make sure we are in compliance. Would you be able to answer the survey questions below and send this back to me? If it is easier, I have created a SurveyMonkey link below if you wish to submit online. Thank you so much for taking time out of your day to answer these questions!

**USP Survey:**

1. **Will the Board adopt the new revisions to USP 795?**
2. **If the Board will adopt the revisions to USP 795, on what date will the Board enforce?**
3. **Does the compounding area have to have a visible/well defined perimeter?**
4. **If the Board does enforce section 4.1 of USP 795, must the carpet be removed in the compounding area?**
5. **Can a large washable mat cover the floor over the carpet in the compounding area?**
6. **Does the Board consider adding flavoring to liquid medications, and/or reconstitution a form of nonsterile compounding?**
7. **Does the Board have plans to adopt USP 800?**
8. **Will the Board adopt USP 800 in full, to include the handling of finished dosage form and nonsterile compounding of hazardous drugs? Or, will the Board adopt USP 800 in part and apply only to the nonsterile compounding of hazardous drugs?**
9. **If the Board will adopt USP 800, on what date will the Board enforce?**

<https://www.surveymonkey.com/r/ZF3WNXX>

Thank you,

**Shelley Tustison, PharmD, CHC, Director, U.S. Ethics & Compliance**  
Office 479.204.8729 Cell 870.919.1873  
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**Save money. Live better.**

# NATIONAL RX ABUSE & HEROIN SUMMIT

## APRIL 2019 SUMMARY

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Laura Carrillo  
Executive Administrator  
Alaska Board of Pharmacy

### OVERVIEW OF CONFERENCE

The National Rx Abuse and Heroin Summit is the largest annual conference addressing the country's opioid crisis, and is held in Atlanta, GA every year. This summit brings together state and federal government entities, as well as researchers and clinical experts, advocacy groups, treatment facility representatives, and law enforcement officials. Thirteen tracks are available to conference attendees. The PDMP and Data Surveillance track offered 9 sessions, 8 of which are reflected in this conference summary. This year's keynote speaker was President Donald Trump.

### PDMP SESSIONS

- PDMP 3.0: investigating the future of PDMPs
- Enhancing and evaluating prescribing practices: a collaborative approach using Utah's PDMP
- Trajectories of PDMP-based patient risk indicators and likelihood of death
- Creating drug overdose surveillance and information systems: approaches by state and county
- Integrating diverse data sources: case studies from Michigan and Pennsylvania
- Making the most of PDMPs: lessons learned from Kentucky's PDMP enhancements
- Data tools and techniques to detect fraud and abuse
- Monitoring nonfatal overdose data in CDC's enhanced state opioid overdose surveillance program

### MEETING WITH APPRISS HEALTH

Discussed next steps for PDMP enhancements.

## PDMP 3.0: INVESTIGATING THE FUTURE OF PDMPs

**Study aims:** gauge support for enhanced PDMP profiles and identify barriers for implementation.

**Study:** Researchers investigated the standard version of the PDMP “PDMP 1.0” and compared its abilities and provider satisfaction against states with an enhanced PDMP “PDMP 2.0”, which Alaska has. The study conducted a focus group with PDMP administrators with versions 1.0 and 2.0. Concerns of version 1.0 included no ability to integrate into an electronic medical record (EMR), no secure sign-in from hospital, too many clicks, too many different records for the same person, provider specialty types not known, no MME measures, and no guidance for report interpretation. Concerns over the enhanced PDMP included interpretation of risk scores, liability/discipline against license, the potential for risk score visuals to inhibit or impede upon the prescriber’s clinical decision making, the availability of interpretation guidance from commercial software, and the financial and administrative costs to upgrade. One focus group participant stated that an enhanced PDMP is worth it only if the information provided is clear and concise, otherwise it may be too cumbersome to attempt to interpret.

**Conclusions:** Enhancements don’t overly drive physicians’ clinical decisions. Physicians found that regardless of whether an enhanced or standard PDMP is used, when there is an objective and verifiable medical condition, physician will use clinical judgment. With an enhanced PDMP, visual clutter should be reduced. Rating of usefulness: prescription summary (most helpful), risk factors, MED graph, pharmacy/prescriber/patient map, overdose risk score (least useful). Enhanced PDMP with advanced graphical displays and finding interpretations was associated with increased ability to determine high-risk features, does not reduce time needed to review cases and interpret PDMP, providers could determine several factors in enhanced profile compared to standard profile.

### Focus group agreements:

- Summary information should be included (# of prescribers, prescriptions, pharmacies)
- Sorting data should be enabled
- Maps showing the distance between patients, prescribers, and pharmacies should be available
- Graphical displays of a patient’s prescription use would be helpful

### → TAKE-HOME TASK FOR ALASKA

- Create new tab at [pdmp.alaska.gov](http://pdmp.alaska.gov) to highlight Alaska’s enhancement features
  - Prescriber Report Cards
  - Threshold Reports
  - Compliance Module (coming soon)
  - NarxCare (coming soon)
  - RxCheck (coming soon)

## ENHANCING AND EVALUATING PRESCRIBING PRACTICES: A COLLABORATIVE APPROACH USING UTAH'S PDMP

**Study aims:** identify barriers and challenges in developing PDMP reports and explain methods that can be used to evaluate impacts of strategies to change prescribing practices/influence opioid-related outcomes.

**Study:** Looked at rate of drug overdose deaths per 100,000 population in UT from 1999-2016. Deaths have been increasing over the last 15+ years and surpassed the US death rate in 2016 at ~16 per 100,000 versus ~14 per 100,000 population, respectively. Deaths by prescription opioids alone and deaths by heroin alone have begun to decrease; however, deaths due to concurrent use of prescription opioids and heroin began increasing after 2015. Solution is in launching the Utah Health Improvement Plan (UHIP): decrease high risk prescribing, decrease opioid overdoses, increase access to naloxone, and increase availability of treatment and recovery services. Engage practitioners, patients, healthcare officials, health educators, emergency response coordinators, epidemiologists, public information officers, and nursing directors.

### **Strategies:**

Use of four dashboard domains: 1.) patient clinical risk dashboard; 2.) prescriber dashboard; 3.) Utah public opioid dashboard; 4.) internal community assessment dashboard

Participate in academic detailing to education prescribers on use of its PDMP and to provide specialty-specific education related to safe and responsible prescribing, opioid alternatives, and tapering.

Incentivised online training course for MDs, APRNs, and DDs to educate on topics relating to opioid prescribing. All practitioners monetarily compensated.

**Conclusions:** Education about specific daily MME doses and risk of long-term addiction caused prescribers to change how they prescribe and how they talk to patients about their pain medication. Some prescribers significantly reduced the number of opioid Rx's they wrote. Some prescribers requested dialogue templates to assist in communicating with patients topics about refills and prescribing to opioid naive patients.

### → TAKE-HOME TASK FOR ALASKA

- Create Look into different dashboards. Currently, we have the OWG dashboard for the public and for interested healthcare personnel. Dashboard specific to patients?
- Dialogue template to engage in discussions with patients? Add to CBPL – CS joint statement?

## TRAJECTORIES OF PDMP-BASED PATIENT RISK INDICATORS AND LIKELIHOOD OF DEATH

**Study aims:** explain that patients who exceed thresholds for PDMP based risk indicators are typically a different group for each indicator. Distinguish patient risk trajectories over time considering Rx and illicit use.

**Study:** In three states (DE, KY, and OH), looked into what patient behavior looks like prior to meeting the threshold, and whether there are identifiers of risk visibly detected. Do patient risky behaviors reert to the mean, even without an intervention? Can proactive reporting be more targeted? Reviewed patient risk indicators: multiple provider episodes, high average daily opioid dosage (more than 90 MME), having opioid prescriptions covering 90 or more consecutive days, overlapping opioid prescriptions (7 or more days), overlapping opioid + benzos ( 7 or more days).

**Conclusions:** Exceeding risk threshold was a one-time or infrequent occurrence (patients tended to revert to the mean). Patients exceeding any risk group is at increased risk of overdose and death.

## CREATING DRUG OVERDOSE SURVEILLANCE AND INFORMATION SYSTEMS: APPROACHES BY STATE AND COUNTY

**Study aims:** identify methods for content delivery of data, such as real-time during strategic planning sessions, etrics for reports, and in response to community-wide health promotion messaging. Explain database infrastructure and data integration.

**Observations/info:** Overdoses in Rhode Island have been increasing since 2009. 2014 marked a year where RI's fatal overdose rate was among the top 6 in the country. In 2015, Governor commissioned a strategic plan on addiction and overdose, which led to a metric-based overdose prevention action plan. The action plan launched an opioid dashboard in 2016: plain-language, increased educational resources for emergening issues, increased sharing of data, published manuscripts. In 2017, RI began seeing decline in OD deaths.

County database in Massachusettes: has once centralized surveillance system, which collects timely and comprehensive data, allowing for improved efficiency in understanding scope of opioid problem and to better understand gaps in services, ie.g.: high risk times for ODs. County surveillance database consists of a case management system and administrative dashboard that houses work of its Drug Addiction and Recovery Team (DART). DART provides outreach and naloxone to business, libraries, and community groups and incorporates data from police calls, arrests, drug courts, self-referrals, behavioral health crisis responses, and emergency departments.

**Conclusions:** County surveillance provides mechanisim to follow patients through many systems. Dashboard team members can more easily communicate between one another about the patient's history. Quantitative and qualitative analyzing of the data is possible by means of aggregate and case level research.

## INTEGRATING DIVERSE DATA SOURCES: CASE STUDIES FROM MICHIGAN AND PENNSYLVANIA

**Observations/info:** Michigan OPEN is a program that was developed as a preventative approach to addressing the opioid issue, and focuses on surgery, dentistry, and emergency medicine. Studies showed that the majority of opioid prescriptions after surgery go unused (62 million), providing opportunities for abuse, misuse, addiction, and diversion. Study showed that pre-operative opioid use is actually associated with poorer outcomes after surgery, including costs for hospitalizations, increase risk of complications, and increased rate of hospital readmissions. Those most at risk for chronic opioid use are people suffering from: chronic pain conditions, anxiety, mood disorders, substance abuse history, and tobacco use. OPEN published opioid prescribing recommendations for 2019 as well as guidance to assist in counseling patients. The opioid guidelines recommend the # of tablets of oxycodone to prescribe for various procedures, including dental extractions, colectomy, knee arthroplasty, and cesarian section, to name a few: Guidelines [HERE](#). Michigan OPEN also hosts a state medication takeback event: in 2018, over 3,000 lbs of pills were collected, which was over 40,000 pills. The oldest opioid prescription collected was from 1972.

**Observations/info:** Pennsylvania's ED surveillance program for opioid overdoses collects fatal overdose data from death certificates and coroner/medical examiner's office. Non-fatal overdose data is collected by emergency medical service (EMS) and ED databases. This was originally started for threat preparedness and the ability to conduct early detection of large-scale releases of biological agents. Syndromic surveillance later expanded to include disease outbreak detection, monitoring of illness and injury trends, and identification of sentinel cases. Pennsylvania tracks any drug overdose, any opioid overdose, heroin overdose, and differentiates these based on ICD-9 and ICD-10 codes. Submits alerts to health districts weekly.

### → TAKE-HOME TASK FOR ALASKA

- Share opioid prescribing guidelines and Michigan OPEN's counseling template with prescriber licensing boards.
- Drug takeback event in Alaska, coordinate with healthcare entities.

## MAKING THE MOST OF PDMPs: LESSONS LEARNED FROM KENTUCKY'S PDMP ENHANCEMENTS

**Observations/info:** Kentucky incorporates drug conviction data “KASPER” into their state PDMP. This includes felony or Class A misdemeanor convictions for the previous 5 calendar years (launched July 1, 2018 as a result of SB 32). Kentucky became the first state to make drug conviction data available within the PDMP query.

**Study:** KY evaluating effectiveness and awareness of drug conviction data into the PDMP. Survey was sent to MDs, APRNs, DMDs, and RPhs. Participants were also presented with practice vignettes and asked to indicate what they would do in a given scenario.

**Conclusions:** prior to participating in the survey, most respondents were not aware that drug conviction data was incorporated into the PDMP. All respondents indicated they strongly agreed that having access to drug conviction data would assist in making controlled substance prescribing/dispensing decisions. APRNs had highest rate of indicating affirmative response to consider drug conviction data when prescribing (next were DMDs, then MDs). When asked when drug conviction data would be used, pharmacists had the highest rate of indicating they would use this information with every patient prescription query, whereas DMDs had the lowest. With the practice vignette relating to prescribing a schedule II opioid to an acute pain patient who had a criminal conviction within last 5 years. The majority of prescribers indicated they would prescribe a non-opioid alternative (pharmacists indicated they would call the prescriber). The second most common response was that they would speak with the patient. Some indicated they would refer the patient to a pain specialist or dismiss patient from practice.

**Other:** Kentucky also added gabapentin as a state-scheduled controlled substance, which they are currently tracking in the PDMP. Results of a study showed that 65% of pharmacists strongly agreed that abuse and diversion of gabapentin is a problem in their community, whereas 5% disagreed. 42% of pharmacists also strongly agreed that patients seek multiple prescribers (doctor shop) to obtain gabapentin, whereas 15% disagreed. 34% said that making gabapentin a controlled substance would reduce its abuse and diversion would be very effective, while 25% said somewhat effective, and 6% said not effective.

### → TAKE-HOME TASK FOR ALASKA

- Incorporate drug conviction data into PDMP via NarxCare? Relies on legislation.
- Check with the Controlled Substance Advisory Committee (CSAC) on where they are with discussion on gabapentin.
- Include practice vignettes in Awareness and Feedback Questionnaire

## DATA TOOLS AND TECHNIQUES TO DETECT FRAUD AND ABUSE

**Observations:** The US Department of Health and Human Services, Office of Inspector General reiterates that the risk of opioid dependence increases substantially for Medicare Part D patients receiving opioids continually for 3 months. In 2017, nearly 1 in 3 part D beneficiaries received at least 1 prescription opioid. 76 million opioid prescriptions were paid for by part D. 10% of beneficiaries received an opioid prescription for 3 months or more. 300 prescribers had questionable opioid prescribing for 71,000 beneficiaries who were at serious risk for misuse or overdose. In Indiana, there are 12,145 cases of fentanyl found per month and 7,460 in Kentucky.

**Strategies:** Deployed a health care fraud strike force, opioid fraud and abuse detection units, and Appalachian Regional Prescription Opioid Strike Force. These strike force locations are in Chicago, Los Angeles, Detroit, Dallas, Houston, Baton Rouge, New Orleans, Brooklyn, Newark/Philadelphia, Appalachian Region, Tampa, and Miami. Strike force partners with CDC's Opioid Rapid Response Teams; scope is on pain clinic closures, looking at spikes in opioid-related overdoses, and other relevant responses. Data-driven fraud detection requires: investigation, confirmation, then prevention. Techniques include: histograms, outlier detection, clustering, heat maps. Graph analytics include: neighborhood metrics, patterns or motifs. Predictive analytics include: regression models, decision trees, multiclass classifiers.

### Questions to ask/things to look for:

Patients – who are drug seekers? How many docs did they see? Where do they fill their Rx? How far do they travel? Harmful polypharmacy? In a MAT program?

Prescribers – medical necessity; prescribing volume? Specialty? Collusions/pill mills?

Pharmacies – all cash/cash + med? Types of compounding drugs? Most Rx from “bad” doc gateway? Out of state/mail ordered?

**Creating the tool:** F.I.A.T (Fraud Investigators' Analytic Tool). Must be actionable, web-based, dynamically generated from agnostic data model, and detailed analysis on prescriber, patient, and pharmacy, including charts and graphs. Phase 1: data analysis based on PDMP physician prescribing profile and claims data analysis. Phase 2: investigate via interviews, and Phase 3: prepare case for prosecutor.

## MONITORING NONFATAL OVERDOSE DATA IN CDC'S ENHANCED STATE OPIOID OVERDOSE SURVEILLANCE PROGRAM

**Observations/info:** The CDC's Enhanced State Opioid Overdose Surveillance (ESOOS) program funds 32 states (including Alaska) and the District of Columbia. The objective of ESOOS is to improve the timeliness of fatal and nonfatal opioid overdose data for action and response. Participating states receive support from the CDC to establish an early warning system from EDs and EMS to monitor non-fatal opioid overdoses, and to integrate data from other data sets, including the medical examiner and coronor's office. These states also have a platform to share its findings with other states and stakeholders. The CDC captures all drug, opioid, and heroin overdose data from EMS databases. In the future, fatal overdose data will be collecting information on all drug overdoses, not just those involving opioids.

### MEETING WITH APPRISS HEALTH

- Enforcing mandatory use through compliance module
- HTML data preferred with NarxCare, which is only way to transmit through integration
- With integrations, need samples of reports and screen shots from contractor to ensure confidentiality and to assess whether it aligns with spirit and language of the law
- Provider authorization as a back end check; entity must sign and agree to pass-through terms (already in place in Alaska)
- Statewide HIE vs statewide integration: in other states, found that majority of queries routed through statewide integration via Gateway
- ACE data into NarxCare