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

Alaska Board of Pharmacy

MINUTES OF THE MEETING FOR OCTOBER 12, 2018

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held at the State Office Building, 333 Willoughby Ave, 9th Floor., Conference Room B in Juneau, Alaska on October 12, 2018.

Agenda Item 1 **Call to Order/Roll Call** **Time: 1:02 p.m.**

The **October 12, 2018** meeting day was called to order by Chair, Rich Holt at 1:02 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair (Via phone)*
Leif Holm, PharmD #PHAP1606 *(Via phone)*
Lana Bell, RPh #PHAP893 *(Via phone)*
Sharon Long, Public Member *(Via phone)*
Phil Sanders, RPh #PHAP776 *(Via phone)*
James Henderson, RPh #PHAP1683 *(Via phone)*
Tammy Lindemuth, Public Member *(Via phone; on the line during executive session)*

Division staff present:

Andy Khmelev, Occupational Licensing Examiner
Laura Carrillo, Records & Licensing Supervisor/PDMP Manager
Sher Zinn, Regulations Specialist
Joe Bonnell, Records & Licensing Supervisor
Jun Maiquis, Regulations Specialist

Members from the public present:

Andy Jones, Health and Social Services – OSMAP *(Via phone)*
Heather Parker, Governor's Office
Nicole Gorle, Governor's Office
Molly Gray, Alaska Pharmacist Association *(Via phone)*
Daniel Ghaly, Pharmacy Student *(Via phone)*

Jason Vespi, Pharmacy Student *(Via phone)*
Angela Ramponi, Legislative Liaison, Commissioners Office *(Via phone)*

Agenda Item 2 **Review/Approve Agenda** **Time: 1:05 p.m.**

The board reviewed the October 12, 2018 agenda.

On a motion duly made by Lana Bell, seconded by Leif Holm, and approved unanimously, it was

RESOLVED to accept the October 12, 2018 agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Lana Bell	x			
Sharon Long	x			

The motion passed with no further discussion.

Agenda Item 3 **Ethics** **Time: 1:07 p.m.**

The board then moved on to addressing ethics, however, there were no ethics disclosures to report.

Agenda Item 4 **Legislative Proposals** **Time: 1:15 p.m.**

The board then addressed legislative proposals, which would be presented by Andy Jones with the Department of Health and Social Services. Due to the confidential nature of the discussion, the board moved to go into executive session.

Off record at 1:16 p.m.

On a motion duly made by Rich Holt and seconded by Leif Holm in accordance with AS 44.62.310(c)(2), the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

Division staff, Laura Carrillo, Program Coordinator, and Angela Ramponi, Legislative Liaison, were authorized to remain in the room. DHSS's OSMAP Director, Andy Jones and staff from

the Governor's Office, Heather Parker and Nicole Gorle were also authorized to remain in the room.

Back on record at 2:09 p.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair (Via phone)*
Leif Holm, PharmD #PHAP1606 *(Via phone)*
Lana Bell, RPh #PHAP893 *(Via phone)*
Sharon Long, Public Member *(Via phone)*
Phil Sanders, RPh #PHAP776 *(Via phone)*
James Henderson, RPh #PHAP1683 *(Via phone)*
Tammy Lindemuth, Public Member *(Via phone)*

Upon return from executive session, Chair Holt clarified for the record that no motions were made.

Agenda Item 5 Board Business Time: 2:24 p.m.

Draft Regulations for SB 37

Hearing nothing further on legislative proposals, Chair Holt moved to discussion on drafting regulations for SB 37, which provides authority for the board to regulate third-party logistics providers, wholesale drug distributors, and outsourcing facilities, and provides authority to staff an executive administrator. Included in the board packet was a regulations workflow chart, the suggested timeline, as well as regulation FAQs and a preliminary draft prepared by Chair Holt.

Draft Regulations for SB 37: Executive Administrator (12 AAC 52.993)

The board had previously discussed potential duties to be delegated to the executive administrator (EA), including reviewing and approving continuing education competency audits, but had outstanding delegation of duties to discuss for this role. Chair Holt inquired to the board as to whether any other type of license or permit approval should be delegated to the EA, for example, reviewing and approving emergency pharmacist permits. Currently those licenses require board approval. Lana Bell inquired as to how long such permits are valid for, to which Chair Holt clarified is up to 60 days or until the emergency circumstance no longer exists, whichever is shorter, according to 12 AAC 52.110.

Lana Bell commented that the board determines whether a circumstance constitutes an emergency, which inherently requires immediate deliberation by the board, adding that any cumbersome language added to the process may negate the intent of establishing an emergency. Sharon Long suggested language that an EA may authorize an emergency pharmacist license with consultation of the board chair, or the chair designee. It could be detrimental for the board to have a meeting which could extend the time past the emergency situation. An email ballot would not allow for deliberation should a board meeting have any issue or tables the

discussion. In an emergency situation it may not always be possible to get a quorum. The board also discussed the possibility of a licensee not having to take the MPJE if they are applying for an emergency license, however no motions were made.

The board further discussed delegation of duties under 12 AAC 52.110 to EA, ultimately deciding that determining the basis for an emergency could be done by the EA in consultation with two board members who are licensed pharmacists under AS 08.80.

TASK 1
Rich Holt will incorporate the board's suggested edits regarding delegation of duties to the executive administrator for 12 AAC 52.110, emergency pharmacist permits, into the SB 37 draft regulations document, then will send the draft language to regulations specialist, Jun Maiquis.

Draft Regulations for SB 37: Outsourcing Facilities (12 AAC 52.696)
Chair Holt then moved to discussing draft regulations for outsourcing facilities and went through the draft prepared and included in the board packet. Chair Holt explained that if the application is complete and clean, then it won't require a board review. An example of what would require board review would be a yes answer, much like a pharmacy technician license. Leif Holm commented that in the proposed section, (i), the language should be changed such that it's clear they should already be register with the FDA as a 503(b) rather than alluding to a directive that they must register subsequent after becoming licensed in the state, to which Chair Holt agreed. Chair Holt also explained that if the application is complete and clean, then it won't require a board review. An example of what would require board review would be a yes answer, much like a pharmacy technician license.

Draft Regulations for SB 37: Classification of Licensure (12 AAC 52.010, 12 AAC 02.310)
Chair Holt then moved to addressing 12 AAC.52.010, which adds the new license categories, third-party logistics providers, outsourcing facilities, and wholesale drug distributors. Proposed fees were also included in the draft under 12 AAC 02.310, which will need to be further assessed by Director McCullough and/or Melissa Dumas, the division's Administrative Officer.

TASK 2
Board staff will follow-up with Director McCullough and/or Melissa Dumas on the proposed fees for the new license categories.

Draft Regulations for SB 37: Wholesale Drug Distributors (12 AAC 52.610 – .695)
Chair Holt addressed the draft of wholesale drug distributors and the board discussed incorporation of the Verification-Accredited Wholesale Distributors (VAWD). The board's intent is to accept a wholesale drug distributor applicant's VAWD rather than to require it, such that it can be submitted in lieu of a self-inspection report. The board continued to discuss language to indicate that either of these reports would be acceptable.

The board also discussed the United States Pharmacopia (USP) standards. Chair Holt inquired to regulations specialist, Jun Maiquis, as to whether the board can simply refer to "the most

updated version", to which Mr. Maiquis indicated a specific [year] version should be explicitly stated in regulations. Ms. Carrillo also added that the editors note should include the most updated address to which individuals may retrieve a copy of the USP.

Chair Holt inquired to the board whether members had further comments on the draft regulations for SB 37. No further discussion was needed.

Other Regulations

The board then moved on to discussing other regulations, including drug substitutions and continuing education requirements.

Other Regulations: Substitution (SB 32 regulations; 12 AAC 42.510)

Chair Holt informed the board that AAG Megyn Greider reviewed the board's comments on her cursory review of draft language pertaining to drug substitutions (biosimilars). AAG Greider asserted in a subsequent review of the draft language that the board should use the term "interchangeable biological product" as a noun as substitution is a verb. The draft language included in the board packet reflects the language accordingly.

Phil Sanders left the room (due to connection issues) at 3:26 p.m.
Phil Sanders joined the room at 3:37 p.m.

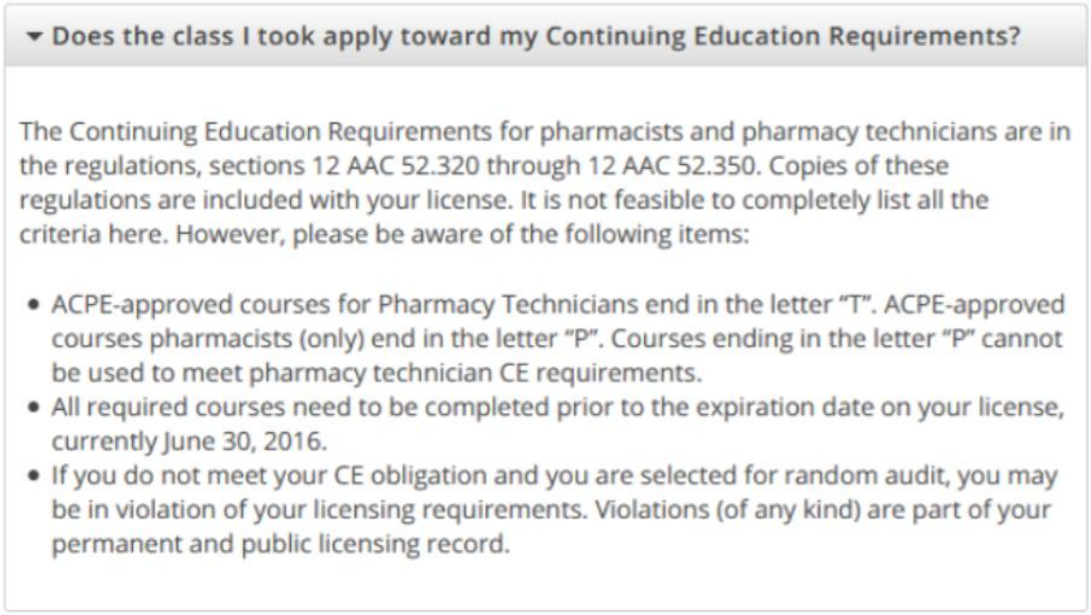
Other Regulations: Continuing Education for ACPE – P or T Courses

As a recap, during the board's August meeting, Molly Gray asked whether ACPE courses for continuing education ending in 'P' for pharmacists can be used to satisfy CE requirements for technicians. Currently, the board's FAQs pertaining to this section specifies that only those courses intended for technicians designated with a 'T' will suffice; however, regulations 12 AAC 52.340(a)(1) and (b)(1) indicate that any course is acceptable if presented or approved by the ACPE. Chair Holt stated that these are conflicting and need to be addressed. Leif Holm asked the board to consider whether allowing pharmacists to take technician courses and visa versa would provide a targeted benefit to the profession. Molly Gray with the Alaska Pharmacist Association commented that many technicians do like the opportunity to take CE meant for a pharmacist because they like the additional information. In the past, they could take a P specific CE and it would go to their state license just not to their PTCD certification, which is why some technicians were questioning that. James Henderson questioned if there was a law update, could there be a dual certification for a T and a P. Molly stated that they have dually accredited courses, and any session can be dually accredited depending on how it's presented to the ACPE. There just has to be separate learning objectives for pharmacists and technicians, as long as the objectives are submitted correctly. Molly Gray stated that technicians often feel limited if they are only able to take T specific courses. Chair Holt then concluded that the FAQ does not line up with the regulation. There is nothing in the law that states it has to be a T for a technician. If the board wants technicians to take T specific courses only, there will need to be a regulation amendment. Ms. Carrillo suggested removing the FAQ, which Chair Holt, as well as Mr. Maiquis agreed to. Board agreed to have the FAQ removed and the subject will be discussed at the following meeting.

TASK 3

Andy Khmelev will remove the FAQ pertaining to ACPE-approved courses as the language is inconsistent with existing regulations.

(Completed 10/12/18)



Does the class I took apply toward my Continuing Education Requirements?

The Continuing Education Requirements for pharmacists and pharmacy technicians are in the regulations, sections 12 AAC 52.320 through 12 AAC 52.350. Copies of these regulations are included with your license. It is not feasible to completely list all the criteria here. However, please be aware of the following items:

- ACPE-approved courses for Pharmacy Technicians end in the letter "T". ACPE-approved courses pharmacists (only) end in the letter "P". Courses ending in the letter "P" cannot be used to meet pharmacy technician CE requirements.
- All required courses need to be completed prior to the expiration date on your license, currently June 30, 2016.
- If you do not meet your CE obligation and you are selected for random audit, you may be in violation of your licensing requirements. Violations (of any kind) are part of your permanent and public licensing record.

<u>Other Regulations/Investigative Referrals for PDMP registration</u>

The board discussed a potential grace-period for pharmacist registration with the PDMP. Ms. Carrillo commented that at present, the Board of Nursing, through their Executive Administrator, sends a courtesy letter to its licensees for failing to promptly register with the database. The intent of the courtesy letter is to provide a one-time leniency so licensees can come into compliance rather than receiving disciplinary action; however, after 12/31/18, the Board of Nursing will begin issuing civil fines. Ms. Carrillo suggested that the board could issue a similar letter, to which Chair Holt agreed. The board considered establishing a 30-day limit to register with the database upon receiving licensure as a pharmacist and inquired as to whether this would need to eventually be written in regulations, to which Jun Maiquis affirmed.

TASK 4

Laura Carrillo will send Rich Holt a copy of the courtesy letter the Board of Nursing sends to its licensees for not registering with the PDMP promptly.

(Completed 10/12/2018).

On a motion duly made by Rich Holt, seconded by James Henderson, to add to the minutes to create create a new regulation 12 AAC 52.993 titled Executive Administrator outlining the job duties as provided to Laura, in addition to creating a number 6, which would allow the EA to consult with two licensed board members to approve an emergency pharmacist license. The second piece was to amend 12 AAC 52.110 by repealing (a)(4) which removes the requirement for a pharmacist to pass the MPJE and would redefine (a) to ensure that its two licensed pharmacist board members that determine if an emergency exists, and not the whole board. Third piece to amend 12 AAC 52.010 (b)(7)(8)(9) adding third party logistics providers, outsourcing facilities and wholesale drug distributors out of the state. Add 12 AAC 52.697 third party logistics, amend 12 AAC 52.995 which adds new definition of facility manager, add new regulation 12 AAC 52.696 titled outsourced facilities substitution as drafted on document stated on 10/12/18, amend regulation 12 AAC 52.510 titled substitution as drafted on document stated on 10/12/18, and to amend existing regulation 12 AAC 52.610 – 12 AAC 62.695 as documented on draft 10/12/18. Motion approved unanimously.

RESOLVED to add the new regulation 12 AAC 52.993, to amend 12 AAC 52.110 by repealing (a)(4) and redefines (a), to add 12 AAC 52.010 (b)(7)(8)(9), to add 12 AAC 52697, to amend 12 AAC 52.995, to add 12 AAC 52.696, to amend regulation 12 AAC 52.510, and to amend 52.610 – 12 AAC 62.695 under one motion.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Phil Sanders	x			
James Henderson	x			
Lana Bell	x			
Sharon Long	x			
Tammy Lindemuth	x			

The motion passed with no further discussion.

Agenda Item 6 <u>Adjourn</u> Time: 4:14 p.m.

The board had no further business to discuss.

On a motion duly made by Tammy Lindemuth, seconded by Lana Bell, and approved unanimously, it was

RESOLVED to adjourn the meeting

Regulation Project Type: Amended regulation
Statutory Authorities: SB32
Regulation Number: 12 AAC 52.510
Regulation Title: SUBSTITUTION
Intent:

1. To redefine substitution per statute to include interchangeable biological products.

Cost: No new cost to the public or existing licensees at this time.

12 AAC 52.510. SUBSTITUTION.

(a) A pharmacist may dispense an equivalent drug product **or interchangeable biological product** instead of the prescribed drug if

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

(2) the patient is notified and consents to the substitution;

(3) **repealed / /** [the equivalent drug product costs the patient less than the prescribed drug product]; and

(4) for the drug product actually dispensed, the pharmacy record contains one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(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 term**s** "equivalent drug product" **or "interchangeable biological product" are** defined in AS 08.80.480.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

Regulation Project Type: Amended regulations
Statutory Authorities: SB37
Regulation Number: 12 AAC 52.610 – 12 AAC 52.695
Regulation Title: See individual titles below
Intent:

2. To amend current wholesale drug distributor regulations to apply to both in-state and out-of-state

Cost: new licensing fee for out-of-state wholesale drug distributors; proposed: $1,000

12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE.

(a) The following checklist is established by the board for review of an application for wholesale drug distributor licenses. A wholesale drug distributor license will be issued to an applicant who

(1) submits a completed, notarized application on the form provided by the department;
(2) pay**s** the fees required in 12 AAC 02.310;
(3) provide**s** a list of the names and résumés of officers, directors, or primary stockholders responsible for the wholesale drug facility;
(4) provide**s** the name and the résumé of the facility manager who will manage the wholesale distribution of drugs and the wholesale drug facility;
(5) submit
(i) a completed self-inspection of the premises questionnaire on a form provided by the department; or
(ii) submit a completed Verification-Accredited Wholesale Distributors (VAWD) inspection report.
(6) submit**s** 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.

(b) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall
(1) meet the requirements of (a) of this section; and
(2) be registered with the DEA.

(c) Within 30 days 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 (a)(4) and (6) of this section.

(d)When a wholesale distributor ceases operations, the facility manager of the wholesale distributor shall notify the board on a form provided by the department the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

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. WHOLESALE DRUG FACILITIES.

Adding Statutory Authority AS 08.80.159

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR

OTHER DISCIPLINARY ACTION.

(a) A wholesale drug distributor shall maintain a roster of all officers, directors, and managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(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.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480 AS 08.80.030
AS 08.80.261 **AS 08.80.159**

12 AAC 52.630. DRUG STORAGE.

(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.

(b)A wholesale drug distributor shall ensure that a separate quarantine storage area is provided for drugs that are deteriorated, outdated, damaged, misbranded, adulterated, or are in a secondary container that has been opened or the seal of which has been broken.

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480 AS 08.80.030
AS 08.80.159

Editor's notes: A copy of the United States Pharmacopoeia may be obtained from the United States Pharmacopoeial Convention, Inc., P.O. Box 560, Williston, VT 05495.

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES.

Adding Statutory Authority AS 08.80.159

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS.

Adding Statutory Authority AS 08.80.159

12 AAC 52.650. RECORDS AND INVENTORIES.

Adding Statutory Authority AS 08.80.159

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS.

Adding Statutory Authority AS 08.80.159

12 AAC 52.670. DRUG RECALLS.

Adding Statutory Authority AS 08.80.159

12 AAC 52.680. INSPECTIONS.

Adding Statutory Authority AS 08.80.159

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION.

Adding Statutory Authority AS 08.80.159

12 AAC 52.690. SALVAGE AND REPROCESSING.

Adding Statutory Authority AS 08.80.159

12 AAC 52.695. PROVISIONS NOT APPLICATIONS.

Adding Statutory Authority AS 08.80.159

Regulation Project Type: Amend current regulations and add new regulation
Statutory Authorities: SB37
Regulation Number:

- Amend 12 AAC 52.010
- Amend central regulation (12 AAC 02.310)

- New regulation proposed: 12 AAC 52.697
- Amend definition to add "Facility Manager" role

New Regulation Title Proposed (12 AAC 52.697): THIRD PARTY LOGISTICS PROVIDERS.

Intent:

- To add new licensing category authorized under SB37.

Cost: proposed $1,000

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE.

(a) The board will issue the following categories of licenses or permits to a qualified individual:

(1) pharmacist license;
(2) temporary pharmacist license;
(3) emergency permit to practice pharmacy;
(4) pharmacist intern license;
(5) pharmacy technician license.

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

(1) pharmacy license;
(2) repealed 2/26/2000;
(3) wholesale drug distributor license;
(4) drug room license;
(5) registration of a pharmacy located outside of the state;
(6) remote pharmacy license.;
(7) third-party logistics providers;
(8) outsourcing facilities;
(9) license of a wholesale drug distributor located outside of the state

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158 AS 08.80.159

12 AAC 02.310. BOARD OF PHARMACY.

(a) The following fees are established for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, wholesale drug distributors, and drug dispensaries:

(1) application fee for initial license, $60
(2) repealed 10/28/2000;
(3) temporary pharmacist license fee, $60;
(4) emergency permit to practice pharmacy fee, $110;
(5) pharmacy intern license fee, $30.

(b) The following license and registration fees for all or part of the initial biennial licensing or registration period and subsequent biennial license and registration renewal fees are established for pharmacists, pharmacy technicians, remote and other pharmacies, and wholesale drug distributors:

(1) pharmacist, $240;
(2) wholesale drug distributor, $500;

(3) pharmacy, $240;
(4) drug room, $240;
(5) registered pharmacy located outside of the state, $600;
(6) pharmacy technician, $60;
(7) remote pharmacy, $240.;
(8) non-resident wholesale drug distributor, $1,000;
(9) outsourcing facility, $1,000;
(10) third-party logistics providers, $1,000.

Authority: AS 08.01.065 AS 08.80.160 AS 08.80.159

New Regulation 12 AAC 52.697 THIRD-PARTY LOGISTICS PROVIDERS

(a)An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b)The following checklist is established by the board for review of an application for a third-party logistics provider license; a third-party logistics provider license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;
(2) pays the fees required in 12 AAC 02.310;
(3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;
(4) provides the name and the résumé of the designated facility manager;
(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and
(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of a third-party logistics provider that has changed its name or physical address shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager shall
(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 2-years.

(g) A third-party logistics provider 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.

12 AAC 52.995 DEFINITIONS

(37) In 12 AAC 52.610 – 12 AAC 52.697, "Facility Manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations.

Regulation Project Type: New
Statutory Authorities: SB37
Regulation Number: 12 AAC 52.696
Regulation Title: OUTSOURCING FACILITIES
Intent:
3. To create new regulation around licensing of outsourcing facilities
Cost: proposed: $1,000

New Regulation 12 AAC 52.696 OUTSOURCING FACILITIES

(a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an outsourcing facility 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 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; 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 résumés of officers, directors, or primary stockholders responsible for the facility;
(4) provides the name and the résumé of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;
(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and
(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration.

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address shall apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility shall apply for a new and separate third-party logistics provider 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 2-years.

(g) An outsourcing facility shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) An outsourcing facility is any facility that compounds sterile drugs without a prescription and distributes the compounded drugs to Alaska.

(i) The outsourcing facility shall be registered with the Food and Drug Administration as a 503b outsourcing facility.

Regulation Project Type: New
Statutory Authorities: SB37
Regulation Number: 12 AAC 52.993
Regulation Title: EXECUTIVE ADMINISTRATOR
Intent:
4. To create regulatory job duties associated with this new position
Cost: No new cost to the public or existing licensees at this time.

The executive administrator may

1. Review and approve continuing education competency audits; audits that are not in compliance are to be reviewed by a board member;
2. Attend state or national meetings or conferences on behalf of the board;
3. Work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;
4. Work with the Chair and Vice-Chair in evaluation of questions posed to the board regarding AS 08 or 12 AAC 52; and
5. Work with regulatory specialists to draft and make regulatory amendment recommendations to 12 AAC 52. to the board.
6. In consultation with 2 licensed pharmacist board members review and approve emergency pharmacist permit applications.

Amend regulation 12 AAC 52.110

12 AAC 52.110. EMERGENCY PHARMACIST PERMIT.

(a) If **two licensed pharmacist** board **members** determine that an emergency exists, the board will issue an emergency pharmacist permit for the purpose of providing coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, to an applicant who

(1) submits a completed application for a pharmacist license;
(2) pays the emergency permit fee required in 12 AAC 02.310;
(3) submits a certified true copy of a current pharmacist license in good standing in another state;
(4) **repeal** [passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above]; and
(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit is valid for 60 days or until the emergency circumstances no longer exist, whichever is shorter.

(c) An applicant may not receive more than one emergency permit. An emergency permit is not renewable.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

Off record at 4:14 p.m.

Andy Khmelev *3/4/2019*

Andy Khmelev, Occupational Licensing Examiner (for Laura Carrillo) Date

Rich Holt, Board of Pharmacy Chair Date