PUBLIC PACKET

# May 21, 2021 - Alaska Board of Pharmacy Meeting - Day 2

May 21, 2021 9:00 AM AKDT

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**STATE OF ALASKA**

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

# ALASKA BOARD OF PHARMACY

May 20 - 21, 2021

Teleconference/Videoconference

## Board Packet

**PUBLIC PACKET**

# State of Alaska 2021 HOLIDAY CALENDAR

## State Holidays

| Date | Holiday |
|---|---|
| **01/01/2021** | New Year's Day |
| **01/18/2021** | MLK Jr.'s Birthday |
| **02/15/2021** | Presidents' Day |
| **03/29/2021** | Seward's Day |
| **05/31/2021** | Memorial Day |
| **07/04/2021** | Independence Day (observed 07/05/2021) |
| **09/06/2021** | Labor Day |
| **10/18/2021** | Alaska Day |
| **11/11/2021** | Veterans' Day |
| **11/25/2021** | Thanksgiving Day |
| **12/25/2021** | Christmas Day (observed 12/24/2021) |
| **01/01/2022** | New Year's Day (observed 12/31/2021) |

Please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

**Holiday**

### JANUARY

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State calendar maintained by the
Division of Finance, Department of Administration

http://doa.alaska.gov/calendars.html

**Revised 01/11/2**

# Alaska Board of Pharmacy Roster

| Board Member Name | Initial Appointment | Reappointed | Term End |
|---|---|---|---|
| Richard Holt, PharmD, MBA (Chair) | 03/01/2016 | 03/01/2020 | 03/01/2024 |
| Leif Holm, PharmD (Vice Chair) | 03/01/2015 | 03/01/2019 | 03/01/2023 |
| Lana Bell, RPh (Secretary) | 05/31/2016 | 03/01/2018 | 03/01/2022 |
| James Henderson, RPh | 03/01/2017 | 03/01/2017 | 03/01/2025 |
| Justin Ruffridge, PharmD | 03/01/2020 | | 03/01/2024 |
| Tammy Lindemuth (Public Member) | 01/24/2018 | 03/01/2018 | 03/01/2025 |
| Sharon Long (Public Member) | 03/01/2018 | | 03/01/2022 |

Updated 02/10/2021

# AGENDA

# ALASKA BOARD OF PHARMACY MEETING

# TENTATIVE AGENDA

## MAY 21, 2021 – DAY 2

**Call-in Number: +12532158782**
**Pin: 96520375435#, Code: 286565**

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

**Board Members:**

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh (Secretary)*

Justin Ruffridge, *(PharmD)*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

**Staff:**

Laura Carrillo, *Executive Administrator*

Lisa Sherrell, PDMP *Program Coordinator*

Heather Noe, *Occupational Licensing Examiner*

Bethany Carlile, *Occupational Licensing Examiner*

**Upcoming Zoom Meetings:**

September TBD

## Meeting Details

Meeting Name: May 21, 2021 - Alaska Board of Pharmacy Meeting - Day 2

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 05/21/2021

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 05/21/2021

Meeting Location: Videoconference via Zoom

Meeting Registration Link:

https://zoom.us/meeting/register/tJIodemrqT4uGdHXUYOfoI9pCSRSCucW1441

## Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Holt)
II. Agenda Item #2 – 9:05 a.m. Review/Approve Agenda (Chair Holt)
III. Agenda Item #3 – 9:10 a.m. Ethics Disclosures (Chair Holt)
IV. Agenda Item #4 – 9:15 a.m. Public Comment #3
V. Agenda Item #5 – 9:30 a.m. Legal Opinion Updates
    A. Expedited partner therapy (12/08/2020)
    B. Medication management/Out-of-State Pharmacies (04/14/2021)
    C. Medical examiner/coroner access to PDMP (pending)

**Board Members:**

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh (Secretary)*

Justin Ruffridge, *(PharmD)*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

**Staff:**

Laura Carrillo, *Executive Administrator*

Lisa Sherrell, PDMP *Program Coordinator*

Heather Noe, *Occupational Licensing Examiner*

Bethany Carlile, *Occupational Licensing Examiner*

**Upcoming Zoom Meetings:**

September TBD

VI. Agenda Item #6 – 9:45 a.m. Regulations Update (Chair Holt)

- A. Regulations overview
- B. Regulation projects (old)
  1. Dec. project (12 AAC 52.020 – 730)
- C. Regulation projects (new)
  1. Expedited partner therapy
  2. White/brown bagging
  3. Collaborative practice agreements (12 AAC 52.240)
     - a. Improvement plan
     - b. Proposed regulations

VII. Agenda Item #7 – 12:00 p.m. Lunch

VIII. Agenda Item #8 – 1:00 p.m. PDMP Regulations (Laura Carrillo)

- A. Registration (May 6, 2021)
- B. Renewal
- C. Notifications

IX. Agenda Item #9 – 2:00 p.m. Statute Updates

- A. HB 145
- B. Outstanding statute project

X. Agenda Item #10 – 4:00 p.m. Public Comment #4

XI. Agenda Item #11 – 4:15 p.m. Farewell Chair Holt & Upcoming Meetings

XII. Agenda Item #12 – 4:30 p.m. Adjourn

## Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

# ETHICS

**CONFIDENTIAL**

# ETHICS SUPERVISOR DETERMINATION FORM

**(Board or Commission Member)**

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does not or would not violate AS 39.52.110 - .190.

_____
Signature of Designated Ethics Supervisor (Chair)

_____
Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

**Note: Disclosure Form must be attached.** Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

# WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

## Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

## Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

## Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

## Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

## University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

## EXECUTIVE BRANCH AGENCIES

**Administration:** Dave Donley, Deputy Commissioner

**Commerce, Community & Economic Development:** Amy Demboski, Assistant Commissioner

**Corrections:** April Wilkerson, Administrative Services Director

**Education & Early Development:** Bobi Jo Grimes, HR Consultant III

**Environmental Conservation:** Theresa Zimmerman, Human Resources Manager

**Fish & Game:** Samantha Gatton, Acting Admin Services Director

**Health & Social Services:** Kimberley King, Human Resource Manager

**Labor & Workforce Development:** Cathy Muñoz, Deputy Commissioner

**Law:** Maria Bahr, Assistant Attorney General

**Military & Veterans Affairs:** Stanley A. Wright, Special Assistant to the Commissioner

**Natural Resources:** Peter Caltagirone, Special Assistant

**Public Safety:** Kelly Howell, Special Assistant to the Commissioner

**Revenue:** Brad Ewing, Administrative Services Director

**Transportation & Public Facilities:**

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

# ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

## Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

## Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

## Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.

Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.

Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

## Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

*A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

This restriction on gifts does not apply to lawful campaign contributions.

☹ The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.

☺ Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

## Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

☺ Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

☺ Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

☹ Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

## Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

☹ John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

☹ The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

## Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

☺ Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

## Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

☹ The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

☺ Andy takes the job, but specifies that he will have to work on another project.

## Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

# Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

# Disclosure Procedures

### DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

### ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

### REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

# Complaints, Hearings, and Enforcement

### COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

### CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

### HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

### PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

### PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

## DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

**Benefit** - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

**Board or Commission** - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

**Designated Ethics Supervisor** - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

**Financial Interest** - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

**Immediate Family** - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

**Official Action** - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

**Personal Interest** - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

*For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:*

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

# EXECUTIVE BRANCH ETHICS ACT

## Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

6/19

# LEGAL OPINIONS

| | |
|---|---|
| **From:** | Moses, Richard R (LAW) |
| **To:** | Carrillo, Laura N (CED) |
| **Subject:** | RE: question re: expedited partner therapy [Legal opinion request] ***confidential attorney client communication*** |
| **Date:** | Tuesday, December 8, 2020 3:08:25 PM |

Ms. Carillo:

Please see the answers to the Board of Pharmacy's four questions:

Question 1:

Yes, as long as the prescription meets all other requirements for a valid prescription in Alaska.

Question 2:

No, 12 AAC 52.460 contains the word "shall." In short, that means that pharmacists must comply with the regulation. Pharmacists are not absolved of their obligations under this regulation just because they have the lawful authority to fill prescriptions for expedited partner therapy. Pharmacists must still be able to gather all of the information required under this regulation in order to fill the prescription.

With that said, the medications at issue are not controlled substances and the Board could begin a regulations project to specifically waive 12 AAC 52.460 for expedited partner therapy.

Question 3:

Given the answer to question 2, this question is moot and need not be answered because they cannot comply. Again, the Board could begin a regulations project to make accommodations for expedited partner therapy.

Question 4:

No because "dispense" (also "dispensing") has a statutory definition under AS 08.80.480(8). It means "the preparation and delivery of a drug or device to a patient or a patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient."

The statute contemplates that non-patients will pick up prescriptions for patients by expressly allowing a patient's "agent" to pick up the prescription and administer it to the patient. This is no different than a parent picking up medication for a sick child or a spouse picking up medication for a sick spouse.

Please do not hesitate to relay any follow-up questions the Board may have to me. I am also happy to appear at their next meeting to discuss if the Board would like.

**From:** Dinegar, Harriet C (LAW)
**To:** Carrillo, Laura N (CED)
**Cc:** Walsh, Sharon J (CED); Cain, Rebecca (LAW)
**Subject:** RE: Remote order entry by out-of-state organization 05-08-2020 (003)
**Date:** Tuesday, April 6, 2021 9:47:24 AM

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Laura, I interpret your request as posing two questions. Here is what I think you have asked, with my responses to each:

1. Can a pharmacy that is registered in Alaska but located outside of Alaska provide services as a remote pharmacy directly to Alaskans? **No, not without working through a telepharmacy system that is under the direct supervision of a licensed pharmacist. 12 AAC 52.425(a), .423(a).**
2. Can a pharmacy that is registered in Alaska but located outside of Alaska provide services as a remote pharmacy to Alaskans, through an Alaska-licensed pharmacist who is located outside Alaska? **No, because 12 AAC 52.425(a) says "A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state."**

Let me know if I misunderstood the board's question or didn't answer it sufficiently.

Harriet

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**From:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
**Sent:** Monday, April 5, 2021 2:48 PM
**To:** Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
**Cc:** Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>
**Subject:** RE: Remote order entry by out-of-state organization 05-08-2020 (003)

Hello,

I apologize if I missed it, but I'm wondering if there is an update to this follow-up question, below?

Thank you,

**Laura Carrillo, MPH**
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
Fax: 907-465-2974

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**From:** Carrillo, Laura N (CED)
**Sent:** Thursday, February 25, 2021 3:14 PM
**To:** Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
**Cc:** Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Cain, Rebecca (LAW)

**From:** Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
**Sent:** Thursday, December 31, 2020 1:39 PM
**To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
**Cc:** Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>
**Subject:** Remote order entry by out-of-state organization 05-08-2020 (003)

Laura,

The short answer to the board members' question (hilited in yellow) is, as they suspected, "No." That's because with limited exceptions, a person may not practice pharmacy in Alaska without an Alaska license. AS 08.80.410; AS 08.80.475 (exception for federal facilities), and 12 AAC 52.150 (exception for tribal health programs).

There is no prohibition on partnering; out-of-state pharmacists certainly can work with or for a central pharmacy to provide services through remote pharmacies; they just all need to be licensed in Alaska:

- the central pharmacy (12 AAC 52.423(a)) and
- the pharmacist employed by the central pharmacy (AS 08.80.410 and 12 AAC 52.425).

The answer to their question hilited in turquoise is that, depending on what it is doing, an out-of-state organization may not need an Alaska license, but if it is operating a telepharmacy system in Alaska, it would have to do so through a central pharmacy located here, and that central pharmacy would have to be licensed here. 12 AAC 52.425(a), .423(a).

Reading between the lines of the members' last paragraph, I can see how these questions arise. The practice of telepharmacy envisions – and requires – direct supervision by an in-state pharmacist. So one could ask what would be wrong with having a pharmacist licensed in another state working for the central pharmacy, if she and her work are directly supervised? The answer, I think, is partly that these regulations don't really mean that the pharmacist is directly supervised. The telepharmacy regulations are more about the "telepharmacy system" and the supervising pharmacist is responsible for making sure the system itself, including the computer and video links are operating properly. Of course, before the board will license any kind of pharmacy, there must be designated a pharmacist-in-charge and that person is responsible for making sure the pharmacy complies with the regulations. AS 08.80.330; 12 AAC 52.200. But it still falls to the practicing pharmacist to receive, interpret, and respond to prescription drug orders in compliance with state and federal law. 12 AAC 52.210. And for that, the legislature requires a license. AS 08.80.410.

I hope this helps sort out these questions. The relationship among the rapidly evolving business models and modes of service delivery in this field can be hard to visualize, but I think the polestar has to be the state's obligation to protect the public through licensure within the board's jurisdiction. If there is a perceived bottleneck with out-of-state licensees getting licensed here, perhaps one area to explore is participation in a national licensure compact (if there is such a thing) or easing the requirements for licensure by reciprocity (AS 08.80.145). Just a thought.

**From:** Weigand, Megyn A (LAW)
**To:** Carrillo, Laura N (CED)
**Cc:** Walsh, Sharon J (CED)
**Subject:** Re: AS 08.80.270 & CPA
**Date:** Tuesday, December 15, 2020 6:51:04 PM
**Attachments:** image001.png

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Hi Laura (and Sharon),

As written, 12 AAC 52.240 requires a substantive evaluation of the terms of a collaborative practice agreement that cannot be delegated to the EA. Approval of licensing and permit applications is more clearly within the scope of the EA's duties because the requirements for applying are already clearly stated in statutes and regs - missing parts mean automatic disapproval.

If the PHA Board can rework 12 AAC 52.240 (especially (d) and (g)) to create a checklist which, once completed by the applicant, would automatically result in approval of the agreement *then* the Board could delegate authority to approve the agreement to the EA. Such a checklist would change the nature of the evaluation from substantive to administrative - within the purview of the EA. And 12 AAC 52.240 should be amended to specify that the EA can approve agreements.

The PHA Board will also need to amend 12 AAC 52.993 to include authority to approve collaborative practice agreements that meet the "checklist" criteria.

If the PHA Board can amend the regulations as suggested above, it will not matter whether the Medical Board changes 12 AAC 40.983(k) because an approval by the EA will count as approval by the Board.

For examples of checklist regs, check out 12 AAC 40.058 and 12 AAC 40.405. Please let me know if you'd like help with the language.

Hope this helps,
Megyn

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**From:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
**Sent:** Monday, December 14, 2020 6:05 PM
**To:** Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>
**Cc:** Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>
**Subject:** RE: AS 08.80.270 & CPA

Hi Megyn,

I don’t have any advice to attach from Harriet as the discussion was during their November board meeting, but I recall her indicating the board could delegate approval of emergency permit/courtesy

# REGULATIONS

# VI. Effective Regulations

This section is intended to provide you with a general overview of the regulations process. It is not legal guidance; the applicable statutes control. Any legal questions should be addressed to the Department of Law.

Regulations must be based on statutory authority. Within the division, regulations typically clarify the requirements of the occupational licensing program as set forth by the Alaska State Legislature in statute. As mentioned in the beginning of this manual, statutes are state laws that authorize and set out the scope of a board or commission's governance authority of a licensing program. Statutes may also authorize and direct the division's management role in all licensing programs overseen by the division. Where statutes assign to a board the responsibility of adopting regulations, that board must follow the process set forth in the Administrative Procedure Act (APA) (AS 44.62.010–44.62.305) unless the legislature has by statute directed a board or commission to follow another process. The APA's requirements are explained in detail in the *Drafting Manual for Administrative Regulations.* The Drafting Manual is at http://law.alaska.gov/doclibrary/drafting_manual.html.

State agencies subject to the APA must follow the statutory procedures in order to adopt, amend, or repeal a regulation. A significant step in the APA requires that the public receive notice of a proposed regulation and an opportunity to comment on a proposed regulatory action. This ensures that the public and interested parties—predominantly licensees and prospective licensees—are aware of the proposed changes affecting their programs and provides adequate opportunity to comment on them. By ensuring public notice and ability to comment, the APA's procedures support the public's vital role in the regulations process.

## Overview of the Regulations Process

When a board identifies the need to propose a regulation to implement, interpret or make specific a state statute, the board, it should begin organizing its collective thoughts on the matter, at a publicly noticed meeting. If the subject matter is highly technical or complex, it may be helpful for the board to form a working group from among its members. That group may engage in fact-finding outside of public meetings, for the purpose of sharing its findings with the entire board at an appropriate meeting.

The maker of the motion to propose amendment, adoption, or repeal of regulations should provide the board with a written draft of the proposal. It is the board's responsibility to be certain that the record reflects what the board intended. This means that the board should articulate what it is hoping to accomplish with the project, and it should carefully review written drafts, to ensure that the language conveys what the board intended. It is the board's job to provide at least the initial draft of language for a proposed regulation or amendment to regulation. Some boards find it helpful to request assistance from their staff, executive director, and the department's regulations specialist.

Under the APA, the public must have a minimum of 30 days to comment (either orally or in writing, or both) on proposed regulations. During the comment period, the staff must publish on the website answers to questions from the public on the proposed regulations received in writing unless the questions are received within 10 days before the close of the comment period; in that case the staff may, but is not required to, answer the questions. The board will meet either telephonically or in person after this period closes to review written comments and amend or adopt the proposal. A board may also notice a meeting at which oral testimony may be heard on the proposal.

If the board chooses to substantially amend its proposal, it must go out for another 30-day public comment period. Whether the amendments to the proposed regulations would require a new notice and comment period should be reviewed by the Department of Law. If the changes are minor and do not alter the meaning of the regulations, it may then be forwarded for review by the Department of Law.

The Department of Law will assign an agency attorney who is familiar with licensing issues to review the proposal for content. Once the agency attorney review is complete, either the regulations attorney or the assistant regulations attorney will review for legality, consistency with other provisions of law and conformance to the state's drafting style. If there are questions, the regulations attorneys will contact the agency attorney. Once the regulations have been approved by the regulations attorney in the Department of Law, the regulations are transmitted to the Office of the Lieutenant Governor for filing. Once signed by the Lieutenant Governor or the Lieutenant Governor's designee, his/her designee, the regulation will become effective in 30 days *unless* another effective date is specified in the adoption order or certification of adoption.

A typical board or commission regulations process can take 90-180 days, depending on the workload of the division Regulations Specialist, the complexity of the project, and scheduling a review with the Department of Law.

Due to Alaska's small population, Board members may be easily accessible to their licensees and public stakeholders. Board members must remember that comments on proposed regulations must be received as requested in the notice of proposed regulations. Comments may only be received on proposed regulations by -

Written comments that are received by the division Regulations Specialist during the public comment period as set out in the notice of proposed regulations, oral comments that are received by the board during the public comment period noticed on the state Online Public Notice System

Board members may not receive comments directly via email, text, in the grocery store, at the lodge, in the hair salon, or on the golf course. When well-meaning members of the public offers input, thank them for their interest but remind them that you are only one of several board members and the board can only act as one; therefore, they should submit their comment as directed in the public notice.

The Division Director may also draft and notice regulations through the same process, though there may not be a public meeting to deliberate or adopt final regulations. The same public notice provisions apply, and the Director must consider all written comments received. When setting fees for licensing programs, the Director will seek board input on proposed fees as required in AS 08.01.065. The Director may adopt regulations that pertain to all licensing programs in general (known as Centralized Regulations) and may adopt regulations that direct the licensing programs in AS 08.01 that do not have a governing board or commission.

## Where to Seek Help

The division Regulations Specialist II is trained to assist in drafting regulations and moving them through the adoption process. The Division Director, Division Operations Manager, or Executive Administrator should also be able to walk the board through the process of adopting regulations. They may also request attorney advice independently or on behalf of the board. The flow charts that follow should clarify the processes of board and division regulation adoption, though the process is ultimately administered by the Department of Law.

## Is It A Regulation Or Policy?

**REGULATIONS**

- Anything that affects the public or is used by the agency in dealing with the public;
- Have the force and effect of law;
- Licensees must follow them;
- Prospective licensees must comply with them in order to be licensed;
- Can only be created by following the process outlined in the Administrative Procedure Act – AS 44.62;
- This process can be time-consuming, taking months or years. It involves at a minimum:
    - 30-day public notice,
    - Review by Department of Law, and,
    - Can't be changed, except by formal process.

**POLICIES, ADVISORIES, AND GUIDELINES**

- Anything a regulatory boards says that:
    - Sets out the regulatory board's expectations in general, nonbinding terms,
    - Does not have the force and effect of law.

- Disciplinary Matrix is a *guideline* if it is used as a reference point, along with:

    - Careful consideration of facts and circumstances, as well as,
    - Underlying goals of the statute and purpose for the discipline.

- Disciplinary Matrix is a *regulation* if it is used:
    - As a formula: *"If licensee did X, then disciplinary response = Y."*
    - To achieve or demonstrate consistency by showing how the board will respond in every case where certain facts are present: *"All licensees who do X get Y."*

**GENERAL PRINCIPLES APPLICABLE TO BOTH REGULATIONS AND POLICIES**

- Clarity
    - If it affects licensees or the public, it should be available and understandable. *Ex.:* if the board keeps a list of activities that it will approve as uncompensated professional activities under 12 AAC 44 620((a)(2)(E), the list should be accessible on the board's website.

- Consistency
    - With other communications about similar facts;
    - With the governing statute's purpose.
    - Proportionality
        - License denials and disciplinary actions including suspension, revocations, and fines should be consistent with the statute's goals.

# Steps in the Board Regulation Adoption Process

Day 1

**1**
At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.

Day 30

**2**
Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.

**3**
Approved language is reviewed by Division attorney.

**4**
Department of Law opens file.

Day 45

**5**
Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System

**6**
Public comment period and/or hearing (if applicable).

Day 65

**7**
Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.

Day 75

**8**
Regulations Specialist compiles public comments for distribution to board.

Day 90

**9**
Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).

**10**
Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.

**11**
Agency attorney reviews regulation

**12**
Regulations attorney reviews and either approves or disapproves regulation

Day 110

**13**
Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days

Day 150

Once Regulations Are Effective

**14a**
Agency posts summary on Alaska Online Public Notice System

**14b**
Regulation published in Alaska Administrative Code

**14c**
Forms & FAQ updated on program web page

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

## 12 AAC 52.020. ~~FACILITY~~ PHARMACY LICENSE. (repeal & readopt)

(a) An applicant for a ~~**facility**~~ **pharmacy** license shall submit

(1) the **applicable** fees required in 12 AAC 02.310;

(2) a completed application on a form provided by the department;

(3) **an attestation that** within 14 days after commencement of business, a ~~**completed**~~ self-inspection ~~**of the premises questionnaire**~~ on a form provided by the department **will be completed**. **The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed;** and

(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.

(b) Repealed 1/17/2007.

(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.

(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.

(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

**(f) a pharmacy that has changed its name, ownership, or physical address shall apply for a new and separate license in accordance with this section.**

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330 AS 08.80.030

## 12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (repeal)

(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 on a form provided by the department; and**~~

~~**(2) pay the duplicate license fees required in 12 AAC 02.105;**~~

~~**(3) repealed 1/17/2007.**~~

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**Commented [RH1]:** Board reviewed and accepted 12/3/20 meeting.

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~~**(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.**~~

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330 AS 08.80.030

## 12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (repeal)

~~**(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.**~~

~~**Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 12 AAC 52.050.**~~

## 12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (amend)

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

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(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 relating 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 **from a college of pharmacy accredited by the ACPE**; ~~**and**~~ **or**

(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;

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**Commented [RH2]:** Board reviewed & approved to combine on 12/3/20

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**Deleted:** (a) An applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements of this section 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. ¶

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(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080 ~~**from the agency where the hours of internship or experience were completed**~~;

(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.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116 AS 08.80.030

## 12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (amend)

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(2) pays the ~~**application fee and the out-of-state pharmacy registration**~~ **applicable** fees established in 12 AAC 02.310;

(3) submits a ~~**certified true**~~ copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an **attestation that an** inspection report or self-inspection report **was** completed within the last two years **or since the last time the registration was initially issued. A self-inspection must be retained, and made available upon request, for the duration of the licensing period in which it was completed.**

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

## 12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (amend)

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(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 relating to the applicant's qualifications for licensure;

(4) either

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**Commented [RH3]:** Reviewed & approved by board on 12/3/20

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**Deleted:** (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070. ¶

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~~**(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 **from a college of pharmacy accredited by the ACPE**; ~~**and**~~ **or**

(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.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

**Commented [RH4]:** Reviewed & approved by board on 12/3/20

## 12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (amend)

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

**Deleted:** (a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements 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 of this section 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. ¶
(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. ¶

(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 **from a college of pharmacy accredited by the ACPE**; ~~and~~ **or**

(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;

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(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 ~~**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 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. **The license by which the applicant is seeking reciprocity from must be in good standing**;

(10) verification of the present status of the applicant's **pharmacist** license ~~**in each licensing**~~ **from the** jurisdiction where the applicant **is reciprocating.** ~~**holds, or has ever held, a license as a pharmacist.**~~

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

## 12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (repeal & re-adopt)

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

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

(2) pays the **applicable** ~~**application fee and the pharmacist intern license**~~ fee**s** established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

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**Deleted:** (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. ¶

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**Deleted:** (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license. ¶

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(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

**~~(7) submits a completed 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 Substances Act);~~** and

**~~(8) 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 pharmacist intern license is valid for **~~two~~ five** years **~~and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) and (2) of this section.~~**

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state;

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

**(f) An applicant wishing to continue an internship in this state after the license has expired must reapply for a new license in accordance with this section.**

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116 AS 08.80.030

## 12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (repeal and re-adopt)

(a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.

(c) Repealed 4/16/2016.

**~~(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.~~**

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116 AS 08.80.030

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**Commented [RH5]:** Repeal. There is no criteria in statute or regulation and there is no current form or method of board review.

## 12 AAC 52.300. LICENSE RENEWAL. (repeal and re-adopt)

(a) Pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider** and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, **outsourcing facility, third-party logistics provider** or drug room license shall submit **on or before the license expiration date**

(1) a completed renewal application **on a form provided by the department**;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) a**n attestation ~~completed~~ that a** self-inspection of the premises **using the ~~questionnaire on a~~** form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued**. **The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed**

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application **on a form provided by the department**; **and**

(2) the license renewal fees required in 12 AAC 02.310; **~~and~~**

**~~(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;~~**

(4) repealed 4/3/2020.

**(d) A pharmacy that has changed its name, physical address, or ownership since the date it was first issued or last renewed is not eligible for renewal.**

**(e) A wholesale drug distributor that has changed its name, physical address, ownership, or facility manager is not eligible for renewal if the change occurred 30-days after the date a renewal application is submitted to the board.**

**(f) An outsourcing facility or third-party logistics provider that has changed its name, physical address, ownership, or facility manager is not eligible for renewal.**

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157 AS 08.80.005 AS 08.80.147 AS 08.80.165

## 12 AAC 52.200. PHARMACIST-IN-CHARGE. (amend)

(b) The responsibilities of the pharmacist-in-charge include

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**Deleted:** (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license. ¶

(1) compliance with all laws and regulations governing the activities of the pharmacy;

(2) training of all pharmacy personnel;

(3) ~~establishing~~ ensuring adequate policies and procedures are in place for pharmacy operations~~;~~

(4) maintaining required records;

(5) storage of all materials, including drugs and chemicals;

(6) ~~establishing~~ ensuring ~~and maintaining~~ effective controls against theft or diversion of prescription drugs; and

(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department or ~~and paying the applicable fees established in 12 AAC 02.105(3).~~

**(d) A pharmacist-in-charge may practice in more than one pharmacy location and may be designated as the pharmacist-in-charge of multiple pharmacies simultaneously.**

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330 AS 08.80.030 AS 08.80.160

## 12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (repeal and re-adopt)

(b) The board will issue a wholesale drug distributor license to an applicant who

(1) submits a completed, ~~notarized~~ application on a form provided by the department;

(2) pays the **applicable** 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 **an attestation that a**

(A) **a** ~~**completed**~~ self-inspection of the premises **using the** ~~**questionnaire on a**~~ form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued. The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed**; or

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**Deleted:** (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements of this section 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. ¶

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(B) ~~a completed~~ Verification Accredited Wholesale Distributors (VAWD) inspection has been completed and a report of the inspection is available upon request;

~~(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, if the applicant is a wholesale drug distributor located outside of this state.

(d) Within 30 days after a change in physical address ~~location~~, ownership, or **name** ~~facility manager~~, the ~~new~~ facility manager must apply for a new and separate wholesale drug distributor license in accordance with this section.

~~(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.~~

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

## 12 AAC 52.696. OUTSOURCING FACILITIES. (repeal and re-adopt)

(b) The board will issue an outsourcing facility license to an applicant who

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

(2) pays the **applicable** 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**n attestation that a** completed self-inspection of the premises **using the** ~~questionnaire on a~~ form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued** and is available upon request;

~~(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.

(c) ~~Within 10 days after a change in facility manager, the new facility manager shall notify the board must meet the requirements of (b) of this section and submit the change on a form provided by~~

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**Deleted:** (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. ¶

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**Deleted:** (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. ¶
**(f) Within 10 days after a change in facility manager, the new facility manager shall notify the board by submittin** ...

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~~submitting a completed change of facility manager form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.~~

(d) Within 30-days after a change in physical address, ownership, or ~~The facility manager of an outsourcing facility that has changed its~~ name ~~or physical address~~ the facility manager must 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 apply for a new and separate outsourcing facility license in accordance with (b) of this section.~~

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480 AS 08.80.030

## 12 AAC 52.697. THIRD-PARTY LOGISTICS PROVIDERS. (repeal and re-adopt)

(b) The board will issue a third-party logistics provider license 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**n attestation that a** ~~completed~~ self-inspection of the premises **using the** ~~questionnaire on a~~ form provided by the department **was completed within the last two years or since the last time the license or registration was initially issued** and is available upon request; ~~and~~

~~(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.~~

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

(d) Within 30-days after a change in physical address, ownership, or ~~The facility manager of a third-party logistics provider that has changed its~~ name ~~or physical address~~ the facility manager must 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 must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.~~

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480 AS 08.80.030

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**Deleted:** (f) When an outsourcing facility ceases operations, the facility manager must 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 ¶
(1) the date the outsourcing facility ceased operations; and ¶
(2) arrangement for the records of the outsourcing facility to be retained for two years. ¶
(g) Outsourcing facility personnel 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 must be registered as an outsourcing facility with the United States Food and Drug Administration under Sec. 503b, P.L. 113 – 54 (Drug Supply Chain Security Act). ¶
**Deleted:** (a) An applicant must meet the requirements set out in (b) of this section to demonstrate 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 ( ...
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**Commented [RH10]:** Reviewed & approved by board ...
**Deleted:** (f) When a third-party logistics provider ceases ...

## 12 AAC 52.585. ~~MANDATORY~~ PATIENT COUNSELING. (repeal and re-adopt)

(a) ~~**Before dispensing a prescription 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**~~ **Following the review of a patient's record, if deemed necessary by the pharmacist, 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.**~~

(b) ~~**A**~~ **If a** pharmacist **or pharmacist intern** ~~**shall**~~ **provides** counseling**, they may provide the counseling by any verbal, written, or electronic means.** ~~**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 Pharmacopoeia Drug Information or comparable information.**~~

**(e) Before dispensing an opioid drug for the first time to a patient, a pharmacist or pharmacist intern must advise the patient about the potential dangers of opioid dependency,**

**(i) the pharmacist or pharmacist intern may use the PDMP to determine if the patient has previously had an opioid drug; and**

**(ii) unintentional, periodic accidental violations, or other more perceived immediate health care attention to another patient which prevents this counseling from occurring is not deemed to be a violation of this opioid counseling requirement.**

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**Deleted:** (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. ¶

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Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

## 12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION. (amend)

(a) Before a ~~**pharmacist may fill**~~ a prescription drug order **can be filled**, the ~~**pharmacist shall obtain the**~~ following information **must be obtained and recorded on the prescription drug order or in the patient medication record**:

(b) At the time of dispensing, ~~**a pharmacist shall add the following information to**~~ the **following** ~~**prescription drug order**~~ **information shall be recorded in the patient medication record**:

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner **to a scheduled II controlled substance prescription**.

**(f) An institutional facility may use start or stop dates on prescription drug orders in place of quantities or refills.**

Authority: AS 08.80.005 AS 08.80.030

## 12 AAC 52.415 AUTOMATED DISTRIBUTION KIOSKS (new)

(a) A licensed pharmacy in this state may install and use automated drug distribution kiosks which are accessible to the patient or the patient's agent, while the pharmacy is open or closed, for the purpose of purchasing their completed prescription drug orders if

(1) the kiosk is securely installed within 10-feet of the licensed pharmacy and is properly secured to prevent easy removal. The kiosk may be

(A) bolted to the floor;

(B) framed into the wall; or

(C) secured in any other physical means which prevents easy removal;

(2) prior to the completed prescription drug order being loaded into the kiosk, the pharmacist has counseled the patient in accordance with 12 AAC 52.230; and

(3) no drugs that are a controlled substance as defined by state or federal law are placed in the kiosk and there is a conspicuously posted sign on the machine which states "this machine does not contain controlled substances"

(A) the sign must use a minimum of size 72 font and red color;

(b) The pharmacist on duty is responsible for

(1) assigning, discontinuing, or modifying access to the system by pharmacy technicians or pharmacist interns; and

(2) ensuring proper maintenance of the kiosk.

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(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; ¶ ...

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**Deleted:** (2) initials or identification code of the dispensing pharmacist; ¶ ...

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**Commented [RH13]:** Same language as 12 AAC 52.420(a)

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(c) This section does not apply to

(1) prescription drug dispensing or distribution machines used in institutional facilities; or

(2) other professional practices in accordance with AS 08.80.400.

(d) In AS 08.80, "automated distribution kiosks" means a vending machine that stores and distributes prescription drugs or devices, and maintains a record of transactions initiated or completed.

## 12 AAC 52.420. SECURITY. (amend)

(c) **Excluding prescription drugs or devices held within an automated distribution kiosk,** 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) **Excluding prescription drugs or devices held within an automated distribution kiosk,** the prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(f) **Excluding prescription drugs or devices held within an automated distribution kiosk,** prescriptions shall be stored in the prescription department 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.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315 AS 08.80.030

## 12 AAC 52.230. PHARMACY TECHNICIANS. (repeal and re-adopt)

(a) ~~**The following persons must be licensed as a pharmacy technician:**~~

~~**(1)**~~ an individual who assists in performing ~~**manipulative, nondiscretionary,**~~ functions associated with the practice of pharmacy **must be licensed as a pharmacy technician**~~**; and**~~

~~**(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.**~~

(e) Before an individual may ~~**regularly**~~ perform the tasks of a pharmacy technician, **or functions 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) The following people are not required to obtain a pharmacy technician license**

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**Deleted:** (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 security requirements. ¶

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**(1) bookkeepers; or**

**(2) any person who's only function is distributing completed prescription drug orders to a patient or patient's agent.**

Authority: AS 08.80.030 AS 08.80.480

## 12 AAC 52.210. PHARMACIST DUTIES. (amend)

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) **clinical** consulting with a ~~**prescriber**~~ **practitioner or authorized agent of a practitioner** regarding a patient or prescription;

(3) interpreting a prescription drug order;

(4) determining ~~**the**~~ product **substitution** required for a prescription **in accordance with 12 AAC 52.510**;

(5) interpreting **drug regimen review** data ~~**in a patient medication record system**~~;

(6) assuming the responsibility for a filled prescription;

(7) consulting ~~**with**~~ a patient or a patient's agent **in accordance with 12 AAC 52.585** ~~**regarding a prescription or information contained in the patient medication record system**~~; and

(8) administering a prescription drug order in accordance with the practitioner's order.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

## 12 AAC 52.423. REMOTE PHARMACY LICENSE. (amend)

(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

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(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.

**(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

## 12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (amend)

(a) Before a pharmacist may independently 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 10 years must complete a course as described in (1) of this subsection before administering a vaccine; and

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(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 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 devices, 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 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 of (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

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(3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(d) A pharmacist or pharmacist intern administering a vaccine must offer 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 independently administering a**~~ vaccine**s are administered** must comply with 7 AAC 27.650.

(f) For 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; or

(2) a pharmacist intern meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern 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.

Authority: AS 08.01.075 AS 08.80.168 AS 08.80.480 AS 08.80.030 AS 08.80.261

## 12 AAC 52.990. ~~**DISPLAY**~~ AVAILABILITY OF LICENSE, CERTIFICATE, or REGISTRATION. (repeal & re-adopt)

A licensee shall **retain all licenses, certifications, or registrations,** ~~**conspicuously display,**~~ in the practice site. ~~**the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee**~~ **This documentation** shall **be made available to** ~~**display**~~ the **board, law enforcement, or inspector upon request** ~~**department's Internet web site posting confirming licensure**~~. ~~**The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.**~~

Authority: AS 08.80.005 AS 08.80.030

Drug and device expiration date on labels. Has been mentioned a couple of times.

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## 12 AAC 52.443. ~~APPROVAL~~ BOARD NOTIFICATION FOR SHARED PHARMACY SERVICES BY PHARMACY. (repeal and re-adopt)

(a) A ~~requesting~~ pharmacy in this state that ~~seeks to~~ participates in shared pharmacy services must ~~apply to~~ **notify** the board ~~for approval~~ on a form provided by the department **within 10 days of initiating shared pharmacy services. The form must include**

**(1) the name, addresses, license numbers, and phone numbers of the pharmacy locations;**

**(2) the names and license numbers of the pharmacists, pharmacist interns and pharmacy technicians participating in shared pharmacy services;**

**(3) the name and license number of the pharmacist-in-charge of each pharmacy;**

**(4) details of what services each pharmacy is providing; and**

**(5) an attestation that the pharmacies comply with the requirements of 12 AAC 52.445**

(b) The ~~board will approve an application by a requesting pharmacy to~~ **pharmacies** ~~participate~~ **participating** in shared pharmacy services ~~if the pharmacy establishes~~ **must**

(1) ~~that the pharmacy has~~ have a current in-state pharmacy license issued under AS 08.80.157 **or be registered as a pharmacy located out of state under AS 08.80.158 and 12 AAC 52.130.**~~and this chapter~~;

(2) ~~that the pharmacy is able to~~ comply with the requirements of 12 AAC 52.445;

(3) ~~that the pharmacy~~ either

(A) ~~is~~ **be** owned by the same owner ~~as the filling pharmacy with which pharmacy services are to be shared~~; or

(B) ~~has~~ **have** a written contract or agreement ~~with the filling pharmacy or filling pharmacist~~ that outlines the pharmacy services to be provided ~~and the obligation of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations~~; and

(4) ~~that the participants in shared pharmacy services~~ share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

## ~~12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. (repeal)~~

~~(a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.~~

~~(b) The board will approve an application by a requesting pharmacist to participate in shared pharmacy services if the requesting pharmacist establishes~~

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~~(1) that the pharmacist~~

~~(A) has a current in-state pharmacy license issued under AS 08.80 and this chapter;~~

~~(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligations of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and~~

~~(C) is able to comply with the requirements of 12 AAC 52.445; and~~

~~(2) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.~~

~~Authority: AS 08.80.005 AS 08.80.030~~

## 12 AAC 52.445. SHARED PHARMACY SERVICES. (repeal & re-adopt)

(a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. ~~The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.~~

~~(b) Except as provided in (c) of this section, if a filling pharmacy or filling pharmacist delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist shall provide, on the prescription container or on a separate sheet delivered with the prescription container,~~

~~(1) the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist; and~~

~~(2) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."~~

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~~(c) The requirements of (b) of this section do not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.~~

(d) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled, or dispensed, the name, initials, or identification code of each pharmacist responsible for the final verification of dispensing; ~~those records must include descriptions of actions taken in interpretation of the order, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, and refill authorization functions performed at that pharmacy or by that pharmacist;~~

~~(2) report to the board as soon as practical the results of any license disciplinary action taken by a regulatory agency in another licensing jurisdiction involving a pharmacy or pharmacist participating in shared pharmacy services;~~

~~(3) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy or by that pharmacist;~~

~~(4) provide for adequate security to protect the confidentiality and integrity of patient information;~~

~~(5) provide for inspection of any required record or information no later than 72 hours after any request by the board or its designee.~~

~~(e) Each pharmacy participating in shared pharmacy services, if a~~

~~(1) requesting pharmacy, shall have a current in-state pharmacy license issued under AS 08.80.157 and this chapter;~~

~~(2) filling pharmacy, shall either~~

~~(A) have a current in-state pharmacy license issued under AS 08.80.157 and this chapter; or~~

~~(B) be registered as an out-of-state pharmacy under AS 08.80.158 and this chapter.~~

~~(f) Each participant in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Each participant is required to maintain only those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures must~~

~~(1) outline the responsibilities of each participant;~~

~~(2) include a list that contains~~

~~(A) each pharmacy participating in shared pharmacy services, and each pharmacist acting independently of a pharmacy and participating in shared pharmacy services;~~

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~~(B) the name, address, and telephone number of each of those participants; and~~

~~(C) the license numbers for all licenses held by each of those participants; and~~

~~(3) address~~

~~(A) patient notification that meets the requirements of this section;~~

~~(B) the adequate protection of the confidentiality and integrity of patient information;~~
~~(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;~~

~~(D) the maintenance of manual or electronic records that meet the requirements of this section;~~

~~(E) compliance with federal and state laws; and~~

~~(F) the operation of a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.~~

(g) Nothing in this section prevents an individual pharmacist licensed in this state who is employed by or working under a contract with a pharmacy, or prevents a licensed ~~pharmacy~~ **pharmacist** intern or pharmacy technician working under the supervision of that licensed pharmacist, from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription order in compliance with AS 08.80 and this chapter if

(1) the pharmacy has established controls to protect the privacy and security of confidential records; and

(2) the pharmacist, ~~pharmacy~~ **pharmacist** intern, or pharmacy technician does not duplicate, download, or remove data from the pharmacy's electronic database.

(h) A pharmacist working independently outside of the state may participate in shared pharmacy services with ~~an institutional~~ **a** pharmacy in this state if the pharmacist holds

(1) a current license as a pharmacist issued under AS 08.80 and this chapter; and

(2) a current license to practice as a pharmacist issued by the licensing jurisdiction where the pharmacist is working.

(i) The pharmacist-in-charge of the ~~requesting pharmacy~~ **pharmacies** must ensure compliance with the applicable requirements of AS 08.80 and this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.158 AS 08.80.030

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## 12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY.

(a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy services without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container, the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall maintain manual or electronic records identifying, individually for each order processed, filled or dispensed,

(1) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services that distributes prescription drug orders under 12 AAC 52.235 using a pharmacy technician who holds a national certification shall maintain manual or electronic records identifying, individually for each order processed, filled, or distributed

(1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

(29) "filling pharmacist" means a pharmacist participating in shared pharmacy services that processes or fills a prescription order for a patient;

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~~(30) "filling pharmacy" means a pharmacy participating in shared pharmacy services that processes or fills a prescription order for a patient;~~

~~(31) "requesting pharmacist" means a pharmacist participating in shared pharmacy services that forwards a prescription order to another participating pharmacy or pharmacist to be processed or filled;~~

~~(32) "requesting pharmacy" means a pharmacy participating in shared pharmacy services that forwards a prescription order to another participating pharmacy to be processed or filled;~~

(33) "shared pharmacy services" means ~~a system~~ **pharmacy functions that are authorized to be shared between** ~~allowing the processing by~~ a participating pharmacist or ~~a~~ pharmacy ~~of a request from another participating pharmacist or pharmacy~~ to. **Services that may be shared include** entering, ~~or~~ reviewing, **processing, transferring, dispensing, distributing or filling** a prescription drug order ~~or process or fill a prescription drug order~~, ~~including dispensing or distributing~~, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

## FACILITY STANDARDS FOR PHARMACIES

November 2016 General Requirements.

Equipment and Supplies.

(a) All pharmacies have in their possession the equipment and supplies necessary to **engage in the practice of pharmacy relevant to the pharmacy services offered** ~~compound, dispense, label, administer and distribute drugs and devices~~. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

**NEW:** 12 AAC 52.160 INSPECTIONS

(a) Wholesale drug distributor, pharmacy, drug room, or remote pharmacy personnel shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(b) Any report from the inspection shall be sent to the board and shall be retained in the licensees' file.

(c) A licensee shall correct any discrepancies identified from the inspection within x-days. [should they send any confirmation of sort to the board documenting correction?]

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

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**REPEAL:** ~~**12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.**~~

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

**NEW:** FACILITY MANAGERS

(a) The responsibilities of the facility manager include

(1) compliance with all federal and state laws and regulations;

(2) ensuring adequate policies and procedures are in place for facility operations;

(3) maintaining required records;

(4) storage of all materials, including drugs, devices, and chemicals; and

(5) ensuring effective controls against theft or diversion of prescription drugs and devices.

(b) Within 10 days after a change in facility manager, the new facility manager shall notify the board by submitting a completed change of facility manager form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(c) A facility manager may work in more than one facility location and may be designated as the facility manager of multiple facilities simultaneously.

**NEW:** 12 AAC 52.725 INSTITUTIONAL FACILITY OUTPATIENT MEDICATIONS

A pharmacist in an institutional facility pharmacy may dispense up to a 90-day supply of a prescription drug order to a patient being discharged from the institutional facility. The prescription drug order must be recorded in the patient's record.

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL.

(a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 – **12 AAC 52.725** ~~**and 12 AAC 52.720**~~. ~~**The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.**~~

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**Commented [RH37]:** Establish or ensure?

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**Commented [RH38]:** Covered by the inspection regulation

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390 AS 08.80.030

**Commented [RH39]:** What does this have to do with drug distribution and control?

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**From:** Moses, Richard R (LAW)
**To:** Carrillo, Laura N (CED)
**Subject:** RE: question re: expedited partner therapy [Legal opinion request] ***confidential attorney client communication***
**Date:** Tuesday, December 8, 2020 3:08:25 PM

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Ms. Carillo:

Please see the answers to the Board of Pharmacy's four questions:

Question 1:

Yes, as long as the prescription meets all other requirements for a valid prescription in Alaska.

Question 2:

No, 12 AAC 52.460 contains the word "shall." In short, that means that pharmacists must comply with the regulation. Pharmacists are not absolved of their obligations under this regulation just because they have the lawful authority to fill prescriptions for expedited partner therapy. Pharmacists must still be able to gather all of the information required under this regulation in order to fill the prescription.

With that said, the medications at issue are not controlled substances and the Board could begin a regulations project to specifically waive 12 AAC 52.460 for expedited partner therapy.

Question 3:

Given the answer to question 2, this question is moot and need not be answered because they cannot comply. Again, the Board could begin a regulations project to make accommodations for expedited partner therapy.

Question 4:

No because "dispense" (also "dispensing") has a statutory definition under AS 08.80.480(8). It means "the preparation and delivery of a drug or device to a patient or a patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient."

The statute contemplates that non-patients will pick up prescriptions for patients by expressly allowing a patient's "agent" to pick up the prescription and administer it to the patient. This is no different than a parent picking up medication for a sick child or a spouse picking up medication for a sick spouse.

Please do not hesitate to relay any follow-up questions the Board may have to me. I am also happy to appear at their next meeting to discuss if the Board would like.

Sincerely,

**Richard R. Moses**
Assistant Attorney General
Commercial, Fair Business & Child Support
Alaska Department of Law
1031 W. 4th Ave., Ste. 200
Anchorage, AK 99501
907-269-5200 / 5189 (main / direct)

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**From:** Cain, Rebecca (LAW)
**Sent:** Thursday, December 3, 2020 12:03 PM
**To:** Moses, Richard R (LAW) <richard.moses@alaska.gov>
**Subject:** FW: question re: expedited partner therapy [Legal opinion request]

Hi Richard,
I have a couple of request for legal assistance from the Board of Pharmacy. I am going to assign them to you. They are a little oddball and I think we have moved a bit in our general philosophy with COVID on prescriptions. Megyn did most of the examination of prescription filling and COVID so you may want to check in with her. But other than some philosophical movement (we've moved maybe a little more liberal in our interpretation because of COVID) I don't think this or any of the other questions have been previously dealt with by anyone else.
Here you go.
Thanks!
Rebecca

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**From:** Walsh, Sharon J (CED)
**Sent:** Friday, November 20, 2020 12:32 AM
**To:** Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>
**Subject:** FW: question re: expedited partner therapy [Legal opinion request]

Hi Rebecca,
Here is another Board of Pharmacy request for interpretation on a statute and regulations.
Interesting conundrum for them.
Appreciate you being able to assign an AAG to this matter.
Thank you.
Sharon

**Sharon J. Walsh**
**Deputy Director**
**Division of Corporations, Business and Professional Licensing**
**Department of Commerce, Community, and Economic Development**
**907.269.3037**
**Sharon.walsh@alaska.gov**

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**From:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>

**Sent:** Thursday, November 19, 2020 1:52 PM
**To:** Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>
**Subject:** FW: question re: expedited partner therapy [Legal opinion request]

Hi Sharon,

From the below correspondence, Chair Holt has requested we seek an opinion from DOL as to whether prescriptions for expedited partner therapy (EPT) can be dispensed. Specifically, here are the questions:

1. Is dispensing a medication written for a patient who is positive for a sexually transmitted disease that ALSO includes a supply for the patient's partner allowable by a pharmacist/intern under AS 08 and 12 AAC 52?

2. If yes to above, how would pharmacist comply with the patient name and address requirement in 12 AAC 52.460, given the medication is intended for two separate people (one is the positive patient, and the other is the patient's partner, who arguably is also a patient by virtue of receiving a prescription medication)?

3. If the partner's information is unknown, how does a pharmacist comply with the drug regimen review in AS 08.80.480(11) if they don't know the patient?

4. If the patient is written a supply of medication including a supply for their partner, is the patient engaging in unlicensed "dispensing" if they give the supply to their partner?

**Legislation/info from other states:**
New York - https://www.health.ny.gov/diseases/communicable/std/ept/docs/faqs_for_pharmacists.pdf
Florida - https://urldefense.com/v3/__https://floridaspharmacy.gov/latest-news/update-regarding-changes-to-law-pursuant-to-hb-941/__;!!J2_8gdp6gZQ!8EfCuoNiYq0CzNL9ySEFXG--Sh2RSiTJz4M8pOTO5IEjIFtIR2JscbUC1VEFTvqR-58UFA$
Arizona - https://urldefense.com/v3/__https://www.azdhs.gov/documents/preparedness/epidemiology-disease-control/disease-integrated-services/std-control/ept-faqs-medical-professionals.pdf__;!!J2_8gdp6gZQ!4M-1DVNa3A-7R_OVnFNMK7Z6iLd2BWSf99po4WvK5pn1ALjMQsDS4n-ZENriLctbnI3F6Q$

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
Fax: 907-465-2974

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**From:** Carrillo, Laura N (CED)
**Sent:** Wednesday, November 18, 2020 4:53 PM
**To:** Starla Fox <sfox@bbahc.org>
**Subject:** RE: question re: expedited partner therapy

Hi Starla,

After polling some of the board members, it seems there isn't consensus as to whether the requirements of 12 AAC 52.460 are met if the partner is given medication and is arguably also a patient. The board may be discussing this at their December or February meeting—feel free to monitor our meeting minutes page for discussions around this topic.

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
Fax: 907-465-2974

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**From:** Carrillo, Laura N (CED)
**Sent:** Friday, November 13, 2020 4:37 PM
**To:** Starla Fox <sfox@bbahc.org>
**Subject:** RE: question re: expedited partner therapy

Hi Starla,

Thank you for your inquiry. The last question is easiest to answer, so I'll start with that. The Board of Pharmacy cannot restrict prescribers from practicing any aspect of pharmacy, including dispensing—see AS 08.80.440.

To your second point, the Board of Pharmacy statutes and regulations don't address partner therapy, and I could not find, based on review of our past meeting minutes, that this has been addressed at least in the last few years. Our prescription drug order information regulation, 12 AAC 52.460, does specify that in order to fill a prescription, specific information needs to be obtained, including the name of the patient. My question for thought would be, is the partner considered a patient since s/he is receiving a supply from their positive-patient's prescription? If the prescriber is giving a supply to the patient for later distribution and dispensing to their partner, is the patient dispensing/distributing (from our perspective, it would appear that way)?

I have asked some board members for their insight and will get back to you with more information.

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
Fax: 907-465-2974

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**From:** Starla Fox [mailto:sfox@bbahc.org]
**Sent:** Wednesday, November 11, 2020 9:39 PM
**To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
**Subject:** question re: expedited partner therapy

Hi Laura,
Marianne Murray suggested that I contact you to determine who might be able to help me. We are working on establishing a formalized Expedited Partner Therapy process at the Bristol Bay Area Health Corporation. We found statutes for Medical Providers that indicate they should prescribe treatment for partners of patients who have a diagnosis of a sexually transmitted disease. We have been unable to identify any regulations or statutes related to filling those prescriptions. Our pharmacy will not fill the prescriptions without the partners information. Many times we are unable to obtain this information from the patient who is positive. Is that issue something the state has addressed at the Board of Pharmacy? If so, where could I find the statute or regulation for pharmacists.
Our other question is related to nurses pulling the pre-pack from the pyxis for the provider to give to the patient for her sexual partner. Would this be interpreted as dispensing and is it allowed?
Thank in advance for your assistance,
Starla Fox

Starla Fox
Interim CNO
Kanakanak Hospital
Bristol Bay Area Health Corporation
6000 Kanakanak Road
Dillingham AK 99576
Tel: 907-842-9448

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# Board of Pharmacy Interest in Payer-Mandated White Bagging and Brown Bagging

April 2021 Update
ASHP Government Relations



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# ASHP Process of Evaluation

- Issue Evaluated by
  - ASHP Member White Bagged Medications Group
  - Section of Pharmacy Practice Leaders and Section of Specialty Pharmacy Executive Committees
  - Pharmacy Executive Leadership Alliance Advisory Panels
  - ASHP Board


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# ASHP Final Direction

- **Final direction:** The frequency and volume of payer-mandated white bagging of medications has become untenable and is creating a significant patient and organizational safety risk, negatively impacting continuity of care, and creating regulatory and legal compliance issues for pharmacies receiving white bagged medications
- Administering providers should have a means of rejecting payer-imposed distribution models that threaten patient safety and overall quality of care


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# ASHP Recent Actions on White Bagging

- Virtual Roundtables with health system pharmacy leaders and ASHP Section of Specialty Pharmacy Practitioners
- Letter to FDA co-signed with 61 health systems detailing concern that white bagging undermines intent of DSCSA track & trace requirements
  - Similar letter to FDA co-signed with AHA
- State Affiliate Policy Deep Dive webinar



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# ASHP Upcoming Actions on White Bagging

- Meeting with FDA to discuss DSCSA concerns
- Co-hosting a webinar with AHA for health system GR teams (mid May)
- Ongoing outreach and support to ASHP state affiliates, peer organizations and industry partners



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# ASHP Position on White Bagging and Brown Bagging

- Payer-mandated distribution models that require clinician-administered drugs to be dispensed exclusively via third-party specialty pharmacies threaten to compromise provider efforts to ensure patient safety and negatively impact pharmacists' ability to validate medication integrity and maintain oversight of storage and handling
- Payers should not require any clinician-administered drug to be dispensed directly to a patient


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# ASHP's Position Cont'd

- State legislatures and Boards of Pharmacy should enact policies to prohibit payers from unilaterally requiring methods of distribution that disrupt the patient experience and impair the provider's ability to provide optimal patient care



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# 2021 Board of Pharmacy Discussions

- Texas – February 2
- California – February 18
- Florida – April 14
- Missouri – April 15



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# Dispensing or Distributing?

- ***"Dispensing"*** *means the interpretation, evaluation, and implementation of a Prescription Drug Order, including the preparation, final Verification, and Delivery of a Drug or Device to a patient or patient's agent in a suitable container appropriately labeled for subsequent Administration to, or use by, a patient*
- ***"Distribution"*** *means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug*
- **Is a Health Care Entity the patient's agent?**



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# Redispensing

- If white and brown bagged drugs are in fact "dispensed", would the administering pharmacy be engaged in redispensing?
  - Not a defined term in most Pharmacy Practice Acts
  - Additional guidance needed to establish safe practices related to redispensing



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# Question of Ownership

- How should a receiving facility handle unadministerable medication?
  - “Dispensed” patient-specific medications are property of the patient and not the facility where they are stored prior to administration
  - Regulations commonly prohibit return to dispensing pharmacy after delivery
  - Re-mailing back to the patient also prohibited


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# Product Integrity

- How is burden of responsibility established for drugs that become adulterated as a result of mishandling?
  - Dispensing pharmacy vs. receiving pharmacy vs. carrier
- Who is responsible for replacing mishandled and adulterated product?
  - Difficult to establish burden of proof in many scenarios
- Should all white and brown bagged drugs be considered Suspect Products?


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## Section 8. Due Diligence.

(a) Supply chain Trading Partners (Manufacturers, Repackagers, Wholesale Distributors, and Dispensers) shall exercise due diligence when conducting business to expeditiously identify a Suspect Product and determine whether it is suspect (and after investigation, whether it is illegitimate).

(b) Supply chain Trading Partners (Manufacturers, Repackagers, Wholesale Distributors, and Dispensers) shall establish a system to:

(1) Quarantine and investigate Suspect Product to determine if it is illegitimate.

(2) Notify FDA, the Board, and immediate Trading Partners if Illegitimate Product is found.

(c) Manufacturers, Repackagers, Wholesale Distributors, and Dispensers shall establish processes for identifying their Trading Partners and Transactions that require heightened vigilance in preventing the receipt of Suspect Products.

(d) Heightened vigilance includes the examination of required records (invoices, shipping documents, Transaction History, and Transaction Statement) for suspicious business practices and the physical examination of Products for factors that increase the risk of a Product being suspect, such as:

(1) a Trading Partner that has been involved in business Transactions where they sold or delivered Illegitimate Product;

(2) a Trading Partner that has a history of problematic or potentially false Transaction Histories or pedigrees, such as those that contain misspelled words or incomplete information;

(3) a Trading Partner that is reluctant to provide a Transaction History associated with the Product being purchased or does not do so in a timely manner;



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# Safe Practice Procedures

- Many Boards require pharmacies under common ownership to demonstrate policies and procedures outlining safe practices for dispensing, distributing and transporting drugs from one pharmacy to another
- These requirements do not extend to dispensing of drugs between pharmacies that are not under common ownership


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# Board Questions Summary

- Is white bagging dispensing or distribution?
- Under what conditions is redispensing permissible?
- How should unadministered white bagged drug stock be handled?
- Who is responsible for replacing adulterated drug?
- Which products can be reasonably self-administered by a patient or a patient's caregiver? Which products cannot?


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# NABP Open Questions

- Who is accountable for verifying authenticity and integrity of the drug before administration?
- Who is responsible when a delay in therapy, due to a lack of coordination between patient, prescriber, and pharmacy, leads to adverse outcomes for patients?


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# Open Discussion

- What can we achieve collectively?
- What are you hearing from your member organizations?



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# Summary of Recent State Legislation to Address Payer Mandated White Bagging

April 7, 2021

# Virginia House Bill 2219

- Requires insurers and PBMs to allow non-contracted pharmacies to dispense covered drugs and be reimbursed at in-network rates
  - Stated differently: plans cannot refuse coverage for drugs filled at non-affiliated pharmacies
- Plans may not impose unequal cost sharing on patients who select out-of-network pharmacy providers


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# VA HB 2219

- Introduced January 13, 2021
- Passed both houses unanimously on February 18, 2021
- Signed into law on March 18, 2021
- Effective July 1, 2021


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# VA HB 2219 Limitations

- In order to participate, non-contracted pharmacies must execute “direct service agreements” with the plan
- Plans may continue to deny service to pharmacies without an active direct service agreement
- State regulators have no jurisdiction to adjudicate disputes between pharmacies and plans


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# Louisiana Senate Bill 191

- Requires insurers to permit enrollees to obtain clinician-administered drugs from the administering provider or a pharmacy
- Insurers may not impose unequal cost sharing on patients or unequal reimbursement to providers
- Insurance commission has authority to investigate and enforce provisions


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# Louisiana SB 191

A. A health insurance issuer shall not refuse to authorize, approve, or pay a participating provider, including any clinic, hospital outpatient department, or pharmacy under common ownership or control with the participating provider, for providing covered physician-administered drugs and related services to covered persons. A health insurance issuer shall not condition, deny, restrict, refuse to authorize or approve, or reduce payment to a participating provider for a physician-administered drug because the participating provider obtains physician-administered drugs from a pharmacy that is not a participating provider in the health insurance issuer's network. The



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# Texas House Bill 1586

- Requires health plans & PBMs to permit enrollees to obtain clinician-administered drugs from a physician's office or hospital outpatient infusion center
- Prohibits additional fees or cost sharing imposed on patients or providers
- Prohibits plans from mandating use of plan-affiliated specialty pharmacies
- Plans must provide **equal reimbursement** to providers, including out-of-network providers


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# Texas House Bill 1586

- Introduced February 2021
- Testimony heard before House Committee on Insurance on March 16, 2021
  - Link to video (testimony starts at 01:15:00)
- Left pending further review



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# Texas House Bill 1586 Fiscal Note

- "No significant fiscal implication to the State is anticipated"

https://capitol.texas.gov/tlodocs/87R/fiscalNotes/html/HB01586I.HTM



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# TX HB 1586 Testimony in Opposition

- **Myth:** "Providers will select the most expensive medication possible with maximum mark-up"
- **Reality:** Providers do not unilaterally set reimbursement rates and this bill does not effect PBM formulary requirements.



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# TX HB 1586 Testimony in Opposition

- **Myth:** "Care will be unnecessarily shifted to hospital outpatient departments that are the most expensive sites of care"
- **Reality:** Non-health system affiliated clinics are included as eligible providers.



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# TX HB 1586 Testimony in Opposition

- **Myth:** "Providers will drop out of networks so they can force plans to reimburse for billed charges"
- **Reality:** If the provider drops out of network then patients would be subjected to out-of-network cost sharing not only for the drug, but for clinic visits as well. Patient's would seek care elsewhere from an in-network facility.


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# TX HB 1586 on Out-of-Network Pharmacies

(7) not, condition, deny, restrict, or otherwise reduce payment to a hospital, pharmacy, physician's office, or hospital outpatient infusion center for a specialty drug because a hospital, physician's office, or hospital outpatient infusion center obtains a specialty drug from a pharmacy that does not participate in the health benefit plan issuer's network.

- **Translation:** Plans are banned from reimbursing out-of-network specialty pharmacies at rates *lower than* network pharmacies.



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# TX HB 1586 Testimony in Opposition

- **Myth:** "White bagging allows plans to lower costs and premiums"
- **Reality:** Ask your patients if their premiums are going down.
- PBMs are not legally required to pass savings onto beneficiaries and are not subject to Medical Loss Ratio profit ceilings.


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# Texas Senate Bill 1161

- Requires plans to allow any qualified specialty pharmacy to dispense clinician-administered drugs and be reimbursed at network rates
- Prohibits discriminatory cost-sharing for patient's using out-of-network specialty pharmacies


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# Texas Senate Bill 1161

- Introduced March 9, 2021
- Awaiting scheduling for committee hearing



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# Tennessee Senate Bill 1617

- Introduced February 2021
- Combined white bagging & 340b reimbursement parity bill
- 5 bipartisan original co-sponsors
- Committee hearing on 03/23/2021


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# TN SB 1617 (As introduced)

- Introduced version required all clinician-administered drugs to be available from the administering provider or a pharmacy
- Also required plans to provide equal access to both pathways without financial penalty to patients or providers
- **<u>The above provisions were removed by amendment</u>**



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# TN SB 1617 (as amended)

- Latest version only prohibits PBMs from charging unequal co-pays **to patients** for obtaining clinician-administered drugs **between pharmacies that are contracted with the plan**



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# Massachusetts SD 1808/HD 3407

- Requires plans that cover clinician-administered drugs under the pharmacy benefit to allow any qualified specialty pharmacy to distribute
- Only drugs supplied in a “ready-to-administer” dosage form may be white bagged
- Gives providers the option to buy-and-bill at third party specialty pharmacy rates
- Prohibits payer-mandated brown bagging
- Prohibits payer-mandated home infusion


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# MA SD 1808/HD 3407

- Introduced February 19, 2021
- Awaiting scheduling for committee hearing



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# Additional ASHP Resources

- ASHP Advocacy Podcast on White Bagging



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# Analysis and Recommendations to improve the Physician/Pharmacy Cooperative Agreement Process

Prepared by Laura Carrillo and Natalie Norberg

## Background:

Physician/Pharmacist cooperative practice agreements currently exist as an optional patient care management tool under AS 08.80 and 12 AAC 40.983 (Medical Board Regulation) and 12 AAC52.240 (Pharmacy Board Regulations). Such agreements allow pharmacists to prescribe, administer, and treat a very limited set of conditions with pharmaceutical interventions. Examples include treatment for immunizations, emergency contraception, travel medication, and hypertension.

HB 145 allows physicians/pharmacists to continue engaging in cooperative practice agreements but clarifies services pharmacists can independently provide for general wellness, disease prevention, and drug utilization services. This bill empowers the Board of Pharmacy to adopt regulations to ensure these services remain within their existing practice authority and provides for the ability for pharmacists to bill for these services.

## Analysis/Recommendations:

The existing process for reviewing, approving, and file maintenance of these agreements is duplicative and administratively burdensome. Currently the Medical Board and Board of Pharmacy have separate forms and separate, highly detailed review processes which entail each board to independently review and endorse each plan.

The following are recommendations to address these inefficiencies and streamline the Physician/Pharmacist cooperative practice agreement process:

1. Create one practice agreement form that both boards endorse
2. Adopt a reviewing protocol and procedure endorsed by both boards that ensures the Medical Board is primarily responsible for conducting the qualitative review of all practice agreement applications (based on a checklist comprised of the criteria outlined in 12 AAC 40.983) and decides whether the practice agreement may be approved or denied. Next the form is forwarded to the Board of Pharmacy administrative staff to be filed in the pharmacist's licensing file.
    - Note: to eliminate the Board of Pharmacy from having the responsibility to dually approve practice agreements the Medical Board will need to revise regulation 12 AAC 40.983 (k).

| Next Steps: | Person(s) Responsible | Date Due: |
|---|---|---|
| 1. The Medical Board and Board of Pharmacy EA's create new form and draft policy procedure for processing applications including how denied requests may appeal or be offered an opportunity for a remediation plan. | Laura & Natalie | 4/30/2021 |
| 2. Introduce draft regulation change language at the May 13-14 Medical Board Meeting for review | Natalie | 5/13/2021 |
| 3. Identify, draft and introduce any regulatory clean-up language needed by the Board of Pharmacy for example, the Medical Board would request the name of the plans be changed to "Physician/Pharmacist Cooperative Practice Agreement" instead of "Pharmacist Collaborative Practice Agreement"/ | Laura | |
| 4. Submit a work order to changes to be made to the Portal for how Cooperative Agreements are tracked. | Laura | |

**12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY.**

(a) ~~A~~To initiate or modify drug therapy in accordance with a written protocol, an authorizing pharmacist ~~planning to~~ may~~exercise~~ file a joint application with a practitioner authorized to prescribe drugs under AS 08 to engage in a ~~collaborative~~ cooperative practice ~~authority~~ agreement in the pharmacist's practice. ~~by initiating or modifying drug therapy in accordance with a written protocol~~ To engage in a cooperative practice agreement, the written protocol must first be approved by the State Medical Board under 12 AAC 40.983 and endorsed by the Board of Pharmacy before implementation of the agreement. The Board of Pharmacy will endorse a cooperative practice agreement that meets the requirements of the checklist established in this section.

~~established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.~~

~~(b) A written protocol must include~~

**Commented [CLN(1]:** Written protocol elements are duplicative of State Medical Board's regulations, 12 AAC 40.983(c); see below analysis.

~~(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;~~

~~(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;~~

~~(3) the time period during which the written protocol will be in effect, not to exceed two years;~~
~~(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including~~

~~(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and~~

~~(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;~~

~~(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;~~

~~(6) a list of the specific types of patients eligible to receive services under the written protocol;~~
~~(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months;~~

~~(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol;~~

~~(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.~~

~~(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.~~

(b) ~~(d)~~ A completed checklist must reflect receipt of

(1) a joint application to engage in a cooperative practice agreement signed by the authorizing practitioner and authorizing pharmacist;

(2) a copy of the written protocol containing the requirements in 12 AAC 40.983(c);

(3) a statement that the authorizing pharmacist and other participating personnel licensed under this chapter have met the training requirements in 12 AAC 52.992; and

(3) approval by the State Medical Board.

(c) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before ~~issuing approval of~~ endorsing the ~~protocol~~ cooperative practice agreement.

(d) ~~(e)~~ Documentation related to the written protocol and a signed copy of the approved cooperative practice application must be maintained at the pharmacist's practice for the duration of the agreement. ~~at least two years.~~

(e) ~~(f)~~ The ~~written protocol~~agreement may be terminated upon written notice by the authorizing practitioners or pharmacist~~s~~. The pharmacist~~s~~ shall notify the board ~~in writing~~ on a form provided by the department within 30 days after an ~~written protocol~~agreement is terminated.

~~(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.~~

(f) ~~(h)~~ This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(g) An approved cooperative practice agreement is valid at the authorizing pharmacist's practice and permits all qualified personnel licensed under this chapter to engage in the agreement.

~~(i) A signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times.~~

**Authority:** AS 08.80.030 AS 08.80.480

## SIMILARITIES/DIFFERENCES

| Requirement | Medical | Pharmacy |
|---|---|---|
| Requires approval | 12 AAC 40.983(b) - must be approved by the medical board, including modifications; 12 AAC 40.983(k) – must be approved by board of pharmacy | 12 AAC 52.240(a) – must be approved by the practitioner and the board of pharmacy; 12 AAC 52.240(g) – requires approval of modifications |
| Written protocol | 12 AAC 40.983(c) – similar to pharmacy regulations:<br><br>(1) physician's authorization<br>(4) duration of agreement<br><br>(5) types of decisions (drugs and procedures)<br><br>(6) documentation of decisions and feedback<br><br>(7) 3 month review<br><br>(8) patient record plan<br><br>(10) pharmacist won't receive compensation<br><br>(11) CS 1 – IV prohibited<br><br>12 AAC 40.983(c) differs in:<br><br>(2) requires license # and issue date of physician<br><br>(3) requires license details and employment information of pharmacist<br><br>(9) physician plan for overriding agreement if medically necessary | 12 AAC 52.240(b) – doesn't require license # or employment information, and no language acknowledging physician's ability to override agreement |
| Duration not to exceed two years | 12 AAC 40.983(c)(4) | 12 AAC 52.240(b)(3) |

| | | |
|---|---|---|
| Physical exam required | 12 AAC 40.983(d) | No physical exam language |
| Authorized to engage in agreement | 12 AAC 40.983(e) physician must be in active practice in state | 12 AAC 52.240(c) – says the practitioner must be in active practice, but does not specify "in the state." |
| Record keeping required | 12 AAC 40.983(f) – must be kept for at least 7 years by physician after terminated | 12 AAC 52.240(b)(3) – must be kept for at least 2 years; 12 AAC 52.240(i) requires copy of protocol to be at pharmacy location at all times |
| Can be terminated | 12 AAC 40.983(g) – either by pharmacist or physician; physician must notify medical board within 30 days | 12 AAC 52.240(f) – either by pharmacist or physician; pharmacist must notify medical board within 30 days |
| Can be renewed | 12 AAC 40.983(j) | No renewal language |
| Periodic review | 12 AAC 40.983(h) | No periodic review language |
| Exemptions | 12 AAC 40.983(i) – excludes hospital and nursing facilities | 12 AAC 52.240(h) – excludes pharmacists in institutional facilities |
| Grandfather language | 12 AAC 40.983(k) – collaborative practice approvals in effect prior to this regulation must be approved by the medical board within 6 months of being approved by the pharmacy board | No language addressing protocols prior to the effective date of 12 AAC 52.240; is obsolete anyway |
| Training requirement | No language related to training, but in 12 AAC 40.983, if the board disapproves, the board shall state the reason | 12 AAC 52.2400(d) – the board of pharmacy may require pharmacists to engage in additional training in policies and procedures before approving the protocol |

**Chapter 52. Board of Pharmacy.**

12 AAC 52.855 is repealed and readopted to read:

**12 AAC 52.855. Registration with the prescription drug monitoring program controlled substance prescription database.** (a) A prescriber shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

(b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration must be completed not later than 30 days after initial licensure if the pharmacist's practice is expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a PDMP dispensation exemption form provided by the board. A pharmacist who submitted a dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the

department.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

Kevin Meyer
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**OFFICE OF THE LIEUTENANT GOVERNOR**
**ALASKA**

# MEMORANDUM

**TO:** Amy Demboski
Department of Commerce, Community, and Economic Development

**FROM:** April Simpson, Office of the Lieutenant Governor
465.4081

**DATE:** April 6, 2021

**RE:** Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy regulations re: registration with the prescription drug monitoring program (PDMP) controlled substance prescription database (12 AAC 52.855)

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| | |
|---|---|
| Attorney General File: | 2021200007 |
| Regulation Filed: | 4/6/2021 |
| Effective Date: | 5/6/2021 |
| Print: | 238, July 2021 |

cc with enclosures: Harry Hale, Department of Law
Judy Herndon, LexisNexis
Jun Maiquis, Regulations Specialist

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached two pages of regulations, dealing with registration with the prescription drug monitoring program controlled substance prescription database, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its February 18-19, 2021 teleconference meeting, under the authority of AS 08.80.005, AS 08.80.030, and AS 17.30.200, and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: _____
Juneau, Alaska

Laura Carrillo Digitally signed by Laura Carrillo Date: 2021.02.22 15:07:36 -09'00'

Laura Carrillo, Executive Administrator
Board of Pharmacy

April Simpson, for

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on April 6, 2021 at 1:05 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

April Simpson
for Kevin Meyer, Lieutenant Governor

Effective: May 6, 2021.
Register: 238, July 2021.

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

**I, KEVIN MEYER, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employees to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:**

**Josh Applebee, Chief of Staff**
**Kady Levale, Notary Administrator**
**April Simpson, Regulations and Initiatives Specialist**

**IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on December 11th, 2018.**

.....

**KEVIN MEYER**
**LIEUTENANT GOVERNOR**

## Chapter 52. Board of Pharmacy.

repealed and readopted

12 AAC 52.855 is ~~amended~~ to read:

### 12 AAC 52.855. Registration with the prescription drug monitoring program

**controlled substance prescription database.** (a) **A prescriber shall register with the ~~PDMP~~**

not later than

**~~within~~ 30 days after the date of initial licensure or registration with the federal Drug**

the date of

**Enforcement Administration (DEA), whichever is later.**

PDMP.

**(b)** A licensed pharmacist **practicing in this state** shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP). **Registration**

(LL move)))

not later than

**must be completed ~~within~~ 30 days ~~of~~ initial licensure if the pharmacist's practice is**

after

**expected to involve** [BEFORE] dispensing a schedule II, III, or IV controlled substance under federal law. **If not dispensing in this state, a pharmacist ~~must~~ submit a PDMP dispensation**

shall

**exemption form provided by the board ~~within~~ 30 days ~~of~~ initial licensure. A pharmacist**

not later than after

(LL move, as edited)))

**who submitted a dispensation exemption form ~~must~~ register before dispensing a schedule**

shall

with the PDMP

**II, III, or IV controlled substance under federal law in this state.**

(LL bold face and underlining not necessary)))

**(c)** ~~[(b)]~~ **Except as provided in (a) of this section, before** ~~[BEFORE]~~ dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

**(d)** ~~[(c)]~~ After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

**(e)** ~~[(d)]~~ A pharmacist or practitioner required to register with the PDMP must access

information in the PDMP using the user account, login name, and password issued by the department.

(f) ~~[(e)]~~ A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**Chapter 52. Board of Pharmacy.**

12 AAC 52.855 is repealed and readopted to read:

**12 AAC 52.855. Registration with the prescription drug monitoring program controlled substance prescription database.** (a) A prescriber shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) not later than 30 days after the date of initial licensure or the date of registration with the federal Drug Enforcement Administration (DEA), whichever is later.

(b) A licensed pharmacist practicing in this state shall register with the PDMP. Registration must be completed not later than 30 days after initial licensure if the pharmacist's practice is expected to involve dispensing a schedule II, III, or IV controlled substance under federal law. If not dispensing in this state, a pharmacist shall submit, not later than 30 days after initial licensure, a PDMP dispensation exemption form provided by the board. A pharmacist who submitted a dispensation exemption form shall register with the PDMP before dispensing a schedule II, III, or IV controlled substance under federal law in this state.

(c) Except as provided in (a) of this section, before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website~~; and~~ by providing

A. a single-use secure email;

B. password;

C. user role;

D. healthcare specialty;

E. the drug enforcement administration (DEA) number issued to the prescriber, or if a pharmacist, the employer's DEA; and

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(2) pay the fee established in 12 AAC 02.107.

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a ~~user account, login name, and password by the department.~~ registration number.

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the ~~user account, login name, and password issued by the department.~~ credentials created in (c)(1)(A)(B) of this section.

(f) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.____ PDMP Registration Renewal (NEW) (a) A registration will expire on the same date as the pharmacist's or practitioner's corresponding professional license.

(b) To renew a registration, a licensee required to register must submit the fee established in 12 AAC 02.107 on or before the expiration date.

12 AAC 52.____ Change in Dispensing or Distributing of Controlled Substances (NEW) (a) a pharmacist registered with the PDMP under 12 AAC 52.855 must notify the board on a form provided by the department when the pharmacist no longer dispenses controlled substances in the state within 10 days of the change in dispensing status.

(b) a pharmacist who submitted the dispensation exemption form in 12 AAC 52.855(b) who begins dispensing controlled substances in the state must notify the board on a form provided by

the department and register with the PDMP within 10 days of the change in dispensing status.

(c) a pharmacy required to report to the PDMP that no longer dispenses or distributes controlled substances in or to the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

(d) a pharmacy that obtains a DEA registration after its license or registration is initially granted by the board and intends to dispense or distribute controlled substances in the state must notify the board on a form provided by the department within 10 days of the change in dispensing or distributing status.

# STATUTES

# CS FOR HOUSE BILL NO. 145(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - FIRST SESSION

**BY THE HOUSE HEALTH AND SOCIAL SERVICES COMMITTEE**

**Offered: 4/26/21**
**Referred: Rules**

**Sponsor(s): REPRESENTATIVES SNYDER, Tarr, McCarty, Kreiss-Tomkins, Ortiz, Schrage, Fields, Story, Spohnholz**

## A BILL

## FOR AN ACT ENTITLED

**"An Act relating to the Board of Pharmacy; relating to health care services provided by pharmacists and pharmacy technicians; and relating to the practice of pharmacy."**

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

*** Section 1.** AS 08.80.030(b) is amended to read:

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy**, including independent monitoring of drug therapy**;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent **prescribing and** administration [BY A PHARMACIST] of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent **prescribing and** dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(n);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business;

(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

*** Sec. 2.** AS 08.80.045 is amended by adding a new subsection to read:

(c) Except as otherwise provided in a regulation under (b) of this section, a pharmacist may prescribe, dispense, and administer nonprescription drugs or devices.

*** Sec. 3.** AS 08.80.155 is amended to read:

**Sec. 08.80.155. Emergency permit.** The board shall adopt regulations regarding the issuance of an emergency permit to practice **<u>under this chapter</u>** [PHARMACY].

*** Sec. 4.** AS 08.80.168(a) is amended to read:

(a) A pharmacist may independently **<u>prescribe and</u>** administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

*** Sec. 5.** AS 08.80.168(b) is amended to read:

(b) A pharmacist may independently **<u>prescribe and administer</u>** [DISPENSE] an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

*** Sec. 6.** AS 08.80.168 is amended by adding a new subsection to read:

(d) A pharmacy technician working under the immediate supervision of a pharmacist who meets the requirements of (a) of this section may administer a vaccine or related emergency medication if the pharmacy technician is authorized by the board to do so.

*** Sec. 7.** AS 08.80.297(a) is amended to read:

(a) A pharmacist **<u>or person acting at the direction of a pharmacist</u>** shall disclose the price of filling any prescription when requested by the consumer.

*** Sec. 8.** AS 08.80 is amended by adding a new section to article 3 to read:

**Sec. 08.80.337. Other patient care services.** (a) A pharmacist may, under a collaborative practice agreement with a written protocol approved by a practitioner,

provide patient care services.

(b) A pharmacist may independently provide patient care services for

(1) general health and wellness;

(2) disease prevention; or

(3) a condition that

(A) is minor and generally self limiting;

(B) has a test that is used to guide diagnosis or clinical decision-making and the test is waived under 42 U.S.C. 263a (Clinical Laboratory Improvement Amendments of 1988); or

(C) falls under a statewide standing order from the chief medical officer in the Department of Health and Social Services.

(c) This section does not authorize a pharmacist to prescribe a prescription drug that the pharmacist is not otherwise authorized to prescribe.

(d) In this section, "patient care services" means medical care services given in exchange for compensation intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.

*** Sec. 9.** AS 08.80.480(12) is amended to read:

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, [DOSAGE FORM,] and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

*** Sec. 10.** AS 08.80.480(30) is amended to read:

(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 **independent prescribing,**

**dispensing, and** administration of [VACCINES AND RELATED EMERGENCY MEDICATION; THE INDEPENDENT DISPENSING OF OPIOID OVERDOSE] drugs **in accordance with AS 08.80.168**; 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;

*** Sec. 11.** AS 21.36.090(d) is amended to read:

(d) Except to the extent necessary to comply with AS 21.42.365 and AS 21.56, a person may not practice or permit unfair discrimination against a person who provides a service covered under a group health insurance policy that extends coverage on an expense incurred basis, or under a group service or indemnity type contract issued by a health maintenance organization or a nonprofit corporation, if the service is within the scope of the provider's occupational license. In this subsection, "provider" means a state licensed physician, physician assistant, dentist, osteopath, optometrist, chiropractor, advanced practice registered nurse, **pharmacist,** naturopath, physical therapist, occupational therapist, marital and family therapist, psychologist, psychological associate, licensed clinical social worker, licensed professional counselor, or certified direct-entry midwife.

*** Sec. 12.** AS 21.42 is amended by adding a new section to read:

**Sec. 21.42.440. Coverage for costs of services provided by pharmacists.** A policy, contract, or prepaid plan for individual or group health insurance issued or delivered in the state that provides coverage for services within the scope of practice of a pharmacist licensed under AS 08.80 must provide for coverage of and reimbursement for the services if performed by a pharmacist for a person covered under the policy, contract, or plan.

**Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION.** An applicant for licensure as a pharmacist shall
(1) be fluent in the reading, writing, and speaking of the English language;
~~(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;~~
(3) be a graduate of a college in a degree program approved by the board;
(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

**Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER.** If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person
(1) submits a written application to the board on a form required by the board;
(2) is at least 18 years of age;
~~(3) is of good moral character;~~
(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
(5) has engaged in the practice of pharmacy for at least one year ~~or has met the internship requirements of this state~~ within the one-year period immediately before applying for a license under this section;
(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;
(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and (8) pays all required fees.

**Sec. 08.80.158 REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE.** REPEAL

**Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE.** (a) Before shipping, mailing, or delivering prescription drugs or devices to a
(A) licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall
(1) obtain a license under AS 08.80.157;
(2) appoint an agent on whom process can be served in the state; and
(3) authorize inspection of the facility by a designee of the board under (c) of this section or
(B) consumer in this state, a pharmacy located outside of the state shall
(1) obtain a license under AS 08.80.157; and
(2) appoint an agent on whom process can be served in the state.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall
(1) register as an outsourcing facility with the United States Food and Drug Administration; and (2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may
(1) require an inspection of the applicant's facility located outside the state; and
(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

**Sec. 08.80.160. FEES.** The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:
(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer; (4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) ~~registration or~~ licensure of a facility classified under AS 08.80.157(b).

**Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF~~ DRUGS ~~VACCINES AND RELATED EMERGENCY MEDICATIONS.~~**
(a) A pharmacist may independently prescribe
- (1) and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
- (2) and dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
- (3) and dispense dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
- (4) and dispense epinephrine auto-injectors;
- (5) and dispense drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:
  - (A) do not require a new diagnosis;
  - (B) are minor and generally self-limiting;
  - (C) have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
  - (D) in the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
- (6) In this section,
  (1) "opioid overdose drug" has the meaning given in AS 17.20.085;
  (2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

(b) The board shall not adopt any regulations authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.

**Commented [RH1]:** We are already allowed to do this: 12 AAC 52.992 and 12 AAC 52.994

**Commented [RH2]:** This is taken from Idaho laws: https://legislature.idaho.gov/statutesrules/idstat/Title54/T54CH17/SECT54-1704/

**Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES.** (a) A pharmacist or person acting at the direction of a pharmacist shall disclose the price of filling any prescription when requested by the consumer.
(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.
(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;
(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);
(C) a plan offered under AS 39.30.090 or 39.30.091;
(D) a federal governmental plan as defined under AS 21.54.500;
(E) the Medicaid or Medicare program; or
(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

**Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED.** (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.
(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.
(c) In this section, "regularly" means to dispense more than a 3-day supply to a patient.

**Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED.** (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," "apothecary", or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

**Sec. 08.80.480. DEFINITIONS.** In this chapter, unless the context otherwise requires,
(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, ~~dosage form,~~ and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(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 independent prescribing, dispensing and administration of ~~vaccines and related emergency medication; the independent dispensing of opioid overdose~~ drugs and devices in accordance with AS 08.80.168; 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;

THANK YOU

Dr. Holt:

While your absence will be felt, your presence in new endeavors will continue to benefit those who have the privilege of working with you. Your expertise, leadership, and contributions to the pharmacy profession is greatly valued and will be missed!

# STATUTES/ REGULATIONS

# *Statutes and Regulations*
# Pharmacy

***February 2021***

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

***DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING***

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Rev. 2/12/2021

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# CHAPTER 80. PHARMACISTS AND PHARMACIES

**Article**
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## ARTICLE 1. THE BOARD OF PHARMACY

**Section**
03. **Practice of pharmacy as a profession**
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10. **Creation and membership of board; officers**
30. **Powers and duties of the board**
45. **Nonprescription drugs**
50. **Applicability of Administrative Procedure Act**
60. **Meetings of the board**
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80. **Expenses of members**
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**Sec. 08.80.003. PRACTICE OF PHARMACY AS A PROFESSION.** The practice of pharmacy is declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest that only qualified persons be permitted to engage in the practice of pharmacy, and to ensure the quality of drugs and related devices distributed in the state.

**Sec. 08.80.005. STATEMENT OF PURPOSE.** It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

**Sec. 08.80.010. CREATION AND MEMBERSHIP OF BOARD; OFFICERS.** (a) There is created the Board of Pharmacy, composed of seven members, five of whom shall be pharmacists licensed in the state who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. Two shall be persons with no direct financial interest in the health care industry. Whenever possible, the board shall include at least one member from each judicial district.

(b) An officer elected by the board serves a term of one year and may not serve more than four consecutive full terms in a specific office.

**Sec. 08.80.020. Term of office**. *[Repealed, Sec. 20 ch 80 SLA 1996.]*

**Sec. 08.80.030. POWERS AND DUTIES OF THE BOARD.** (a) The board is responsible for the control and regulation of the practice of pharmacy.

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business;

(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

(c) The board shall post and maintain a link to the United States Food and Drug Administration's list of all currently approved interchangeable biological products on the board's Internet website.

(d) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

**Sec. 08.80.040. Duties of the board.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.045. NONPRESCRIPTION DRUGS.** (a) Except as provided in (b) of this section the board may not regulate the sale of patent or nonprescription drugs that are prepackaged for use by the consumer, are in their original, unbroken packaging, and are labeled in accordance with requirements of the federal government.

(b) The board may regulate the sale and distribution of patent or nonprescription drugs under AS 44.62.250 when the regulation is required by an emergency to protect the public health and safety.

**Sec. 08.80.050. APPLICABILITY OF ADMINISTRATIVE PROCEDURE ACT.** The board shall comply with AS 44.62 (Administrative Procedure Act).

**Sec. 08.80.060. MEETINGS OF THE BOARD.** The board shall meet at least three times each year at the call of the president for the transaction of business properly before it. The president shall also call the board into session when requested in writing by at least two members. Meetings may be held telephonically.

**Sec. 08.80.070. QUORUM.** Four members constitute a quorum for the transaction of business. However, when the board meets for the purpose of examining applications for licensure, three members of the board constitute a quorum.

**Sec. 08.80.080. EXPENSES OF MEMBERS.** Members of the board are entitled to reimbursement for actual travel expenses incidental to the discharge of their duties and, while in the performance of their duties, are entitled to the per diem expenses allowed by law.

**Sec. 08.80.090. Disposition of fees.** *[Repealed, Sec. 54 ch 37 SLA 1985.]*

**Sec. 08.80.100. Board secretary as certifying officer.** *[Repealed, Sec. 3 ch 59 SLA 1966.]*

**Sec. 08.80.105. REMOVAL OF BOARD MEMBERS.** A member of the board may be removed from office by the governor for cause.

## ARTICLE 2. LICENSING AND REGISTRATION

**Section**

**110. Qualifications for licensure by examination**
**116. Internship and other training programs**
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**Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION.** An applicant for licensure as a pharmacist shall

(1) be fluent in the reading, writing, and speaking of the English language;

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

(3) be a graduate of a college in a degree program approved by the board;

(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;

(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

**Sec. 08.80.115. Registration of pregraduate and postgraduate intern pharmacist.** *[Repealed, Sec. 40 ch 177 SLA 1978.]*

**Sec. 08.80.116. INTERNSHIP AND OTHER TRAINING PROGRAMS.** (a) An applicant for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under terms and conditions the board shall determine.

(b) The board shall establish licensure requirements for interns and standards for internship or other training programs that are necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

**Sec. 08.80.117. Malpractice insurance.** *[Repealed, Sec. 7 ch 94 SLA 1980.]*

**Sec. 08.80.120. GRADING AND CONTENT OF EXAMINATION.** The examination or examinations shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with an organization or consultant in the preparation and grading of an examination, but shall retain sole discretion and responsibility for determining which applicants have successfully passed the examinations.

**Sec. 08.80.130. Reexamination.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.140. License by credentials.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER.** If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

(1) submits a written application to the board on a form required by the board;

(2) is at least 18 years of age;

(3) is of good moral character;

(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;

(5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

**Sec. 08.80.147. RENEWAL OF LICENSURE.** If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

**Sec. 08.80.150. TEMPORARY LICENSE.** The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

**Sec. 08.80.155. EMERGENCY PERMIT.** The board shall adopt regulations regarding the issuance of an emergency permit to practice pharmacy.

**Sec. 08.80.157. LICENSING OF FACILITIES.** (a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390.

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

(k) This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

**Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE.** (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription drugs to consumers in the state shall register with the board.

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; and

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

(c) A pharmacy subject to this section shall, during its regular hours of operations, provide a toll-free telephone service to facilitate communication between persons in the state and a pharmacist at the pharmacy who has access to records concerning the dispensing of prescription drugs to persons in the state. The toll-free number and the hours that the service is available shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state. The telephone service shall be available at least 40 hours a week and at least six days a week.

(d) The board may, after a hearing, deny, revoke, or suspend the registration of a pharmacy located outside of the state and subject to this section if the pharmacy fails to comply with the requirements of this section, AS 17.20.080 - AS 17.20.135, or AS 17.30.020 - 17.30.080, or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

(e) A pharmacy located outside of the state that is subject to this section but is not registered with the board under this section may not ship, mail, or deliver prescription drugs into the state and may not advertise its services in the state.

(f) A pharmacy subject to this section shall appoint a registered agent in the state who is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent under this subsection, if the registered agent cannot with reasonable diligence be found at the registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner of commerce and economic development is an agent upon whom process, notice, or demand may be served. Service is made upon the commissioner in the same manner as provided for corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

(g) The board shall by regulation define "regularly" for this section.

**Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE.** (a) Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;
(2) appoint an agent on whom process can be served in the state; and
(3) authorize inspection of the facility by a designee of the board under (c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

(1) register as an outsourcing facility with the United States Food and Drug Administration; and
(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

(1) require an inspection of the applicant's facility located outside the state; and
(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

**Sec. 08.80.160. FEES.** The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer;
(4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) registration or licensure of a facility classified under AS 08.80.157(b).

**Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS.** The board shall establish requirements for continuing education in pharmacy that must be satisfied before a license issued under this chapter may be renewed.

**Sec. 08.80.168. ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.**

(a) A pharmacist may independently administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(b) A pharmacist may independently dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(c) In this section,

(1) "opioid overdose drug" has the meaning given in AS 17.20.085;
(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

**Sec. 08.80.170-08.80.210. Fees.** *[Repealed, Sec. 7 ch 24 SLA 1968.]*

**Sec. 08.220. Prescription department required for issuance of license**. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.230. Sanitary conditions required for issuance of license.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.240. Form and display of registration certificate and license.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.250-08.80.260. Renewal of lapsed registration; ground for refusing or revoking a license.** *[Repealed, Sec. 21 ch 166 SLA 1980.]*

**Sec. 08.80.261. DISCIPLINARY SANCTIONS.** (a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable,

(1) secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or a drug that impairs the applicant's or licensee's ability to practice safely;

(D) physical or mental disability; or

(E) other factors determined by the board;

(8) engaged in conduct involving moral turpitude or gross immorality;

(9) made a controlled substance available to a person except upon prescription issued by a person licensed to prescribe controlled substances;

(10) was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(12) failed to report relevant information to the board about a pharmacist or pharmacy intern that the applicant or licensee knew or suspected was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(13) aided another person to engage in the practice of pharmacy or to use the title of "pharmacist" or "pharmacy intern" without a license; or

(14) engaged in unprofessional conduct, as defined in regulations of the board.

(b) The board may place under seal all drugs that are owned by or in the possession, custody, or control of a licensee at the time a license is suspended or revoked or at the time the board refuses to renew a license. Except for perishable items, the drugs may not be disposed of until the licensee has exhausted administrative and judicial remedies relating to the licensing action. Perishable items may be sold upon order of the court with the proceeds to be deposited with the court. The board shall notify the Department of Health and Social Services about drugs placed under seal under this subsection.

**Sec. 08.80.265. Limits or conditions on license; discipline.** *[Repealed, Sec. 21 ch 166 SLA 1980.]*

**Sec. 08.80.266. Disciplinary sanctions.** *[Repealed, Sec. 49 ch 94 SLA 1987.]*

**Sec. 08.80.270. EXECUTIVE ADMINISTRATOR OF THE BOARD.** (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

## ARTICLE 3. DUTIES OF LICENSED PHARMACISTS

**Section**

**294. Information about equivalent generic drugs and interchangeable biological products**

**295. Substitution of equivalent drug products or interchangeable biological products**
**297. Prescription prices and less costly alternatives**
**315. Confidentiality of records**
**330. Licensed pharmacist appointed as "pharmacist-in-charge"**
**335. Prescription for an opioid; voluntary request for lesser quantity**

**Sec. 08.80.270-08.80.290. Report of employees and goods sold; affixing labels.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.294. INFORMATION ABOUT EQUIVALENT GENERIC DRUGS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS.** (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed;

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

**Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS OR INTERCHANGEABLE BIOLOGICAL PRODUCTS.** (a) Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product.

(b) A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing practitioner through

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

**Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES.** (a) A pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;
(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);
(C) a plan offered under AS 39.30.090 or 39.30.091;
(D) a federal governmental plan as defined under AS 21.54.500;
(E) the Medicaid or Medicare program; or
(F) a self-insured employer benefit plan;
(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

**Sec. 08.80.300. Record of prescriptions.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.310. Record of sales.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.315. CONFIDENTIALITY OF RECORDS.** Information maintained by a pharmacist in the patient's records or that is communicated to the patient as part of patient counseling is confidential and may be released only to
(1) the patient or as the patient directs;
(2) a practitioner or pharmacist when, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well-being; and
(3) other persons or governmental agencies authorized by law to receive confidential information.

**Sec. 08.80.320. Pharmacist required.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS "PHARMACIST-IN-CHARGE".** (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.
(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

**Sec. 08.80.335. PRESCRIPTION FOR AN OPIOID; VOLUNTARY REQUEST FOR LESSER QUANTITY.** (a) A pharmacist filling a prescription for an opioid that is a schedule II or III controlled substance under federal law may, at the request of the individual for whom the prescription is written, dispense the prescribed opioid in a lesser quantity than prescribed.
(b) Nothing in this section shall be construed to prevent substitution of an equivalent drug under AS 08.80.295.

**Sec. 08.80.340-08.80.370. Requirements for handling drugs; general prohibitions**. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

## ARTICLE 4. UNLAWFUL ACTS

**Section**
**390. Pharmacists required in hospitals and clinics**
**400. Other licensees not affected**
**410. Use of term "pharmacist" prohibited**
**420. Certain advertising prohibited**
**430. Use of pharmacy symbols prohibited**
**450. Disciplinary action**
**460. Penalties**

**Sec. 08.80.380 Issuance of shopkeepers permits.** *[Repealed, Sec. 21 ch 166 SLA 1980.]*

**Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS.** (a) A hospital, clinic, nursing home, infirmary, or related facility that provides dispensing of drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.
(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

**Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED.** This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant,

advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

**Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED.** A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

**Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED.** (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

**Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED.** A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

**Sec. 08.80.440. Denial of examination or license.** *[Repealed, Sec. 28 ch 45 SLA 1996.]*

**Sec. 08.80.450. DISCIPLINARY ACTION.** The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

**Sec. 08.80.460. PENALTIES.** (a) Except for a violation of AS 08.80.297, a person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 or 08.80.297 may be punished by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

## ARTICLE 5. GENERAL PROVISIONS

**Section**

**470. Construction**
**475. Federal facilities not affected**
**480. Definitions**
**490. Short title**

**Sec. 08.80.470. CONSTRUCTION.** Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.20 (the Alaska Food, Drug and Cosmetic Act), or AS 17.30.

**Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED.** This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

**Sec. 08.80.480. DEFINITIONS.** In this chapter, unless the context otherwise requires,

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(3) "board" means the Board of Pharmacy;

(4) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(5) "controlled substance" has the meaning given in AS 11.71.900;

(6) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(7) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(9) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(10) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(11) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug, drug-food, and drug-disease interactions;

(G) adverse drug reactions; and

(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(13) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(14) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(15) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor or a nonprescription drug or commercially packed legend drug or device;

(16) "legend drug" means a prescription drug;

(17) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(18) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(19) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(20) "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;

(21) "owner" means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(22) "patient counseling" means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(23) "person" has the meaning given in AS 01.10.060 and also includes a governmental agency;

(24) "pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(25) "pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy;

(26) “pharmacist-in-charge” means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy’s personnel;

(27) “pharmacy” means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157(b);

(28) “pharmacy located outside of the state” means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(29) “pharmacy technician” means a supportive staff member who works under the immediate supervision of a pharmacist;

(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;

(31) “practitioner” means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(32) “preceptor” means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(33) “prescription drug” means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) “Caution: Federal law prohibits dispensing without prescription”; (B) “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(34) “prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient;

(35) “prospective drug use review” means a review of the patient’s drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(36) “significant adverse drug reaction” means a drug-related incident that may result in serious harm, injury, or death to the patient;

(37) “substitute” means to dispense, without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug; or

(B) an interchangeable biological product in place of the prescribed biological product;

(38) “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;

(39) “wholesale” means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(40) “wholesale drug distributor” means anyone engaged in wholesale distribution of drugs, including 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.

**Sec. 08.80.490. SHORT TITLE.** This chapter may be known as the Pharmacy Act.

## CHAPTER 52.
## BOARD OF PHARMACY.

**Article**

1. **Licensing, Registration, and Permit Requirements (12 AAC 52.010 – 12 AAC 52.150)**
2. **Personnel (12 AAC 52.200 – 12 AAC 52.250)**
3. **License Renewal and Continuing Education Requirements (12 AAC 52.300 – 12 AAC 52.350)**
4. **Guidelines for Pharmacies and Pharmacists (12 AAC 52.400 – 12 AAC 52.445)**
5. **Pharmacy Practice Standards (12 AAC 52.450 – 12 AAC 52.590)**
6. **Wholesale Drug Distributors and Facilities (12 AAC 52.610 – 12 AAC 52.697)**
7. **Institutional Pharmacies (12 AAC 52.700 – 12 AAC 52.730)**
8. **Drug Rooms and Facilities Without a Pharmacy (12 AAC 52.800 – 12 AAC 52.850)**
9. **Controlled Substance Prescription Database (12 AAC 52.855 – 12 AAC 52.895)**
10. **Disciplinary Guidelines (12 AAC 52.900 – 12 AAC 52.980)**
11. **General Provisions (12 AAC 52.985 – 12 AAC 52.995)**

## ARTICLE 1.
## LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

**Section**

**10. Classifications of licensure**
**20. Facility license**
**30. Change of pharmacy location or name**
**40. Change of pharmacy ownership**
**50. Closed pharmacies**
**60. Fire or other disaster**
**70. Application for pharmacist license by examination**
**75. Good moral character**
**80. Internship requirements for a pharmacist license**
**90. Examination requirements and registration**
**92. Approval to sit for examination**
**95. Application for pharmacist license by reciprocity**
**100. Temporary pharmacist license**
**110. Emergency pharmacist permit**
**120. Review of pharmacist intern license application**
**130. Registration of pharmacies located outside of the state**
**140. Pharmacy technician license**
**150. Proof of licensure for individual pharmacists working for tribal health programs**

**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 provider license;

(8) outsourcing facility license;
(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 08.80.030 AS 08.80.155 AS 08.80.159
AS 08.80.116 AS 08.80.157 AS 08.80.390

**12 AAC 52.020. FACILITY LICENSE.** (a) An applicant for a facility license shall submit
(1) the fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

**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;
(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.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

**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.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**12 AAC 52.050. CLOSED PHARMACIES.** (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall
(1) submit written notice to the board of the cessation of pharmacy operations on a form provided by the department; the form must be submitted within 10 days after the cessation of operations and include
(A) the date the pharmacy ceased operations;
(B) a statement signed by the pharmacist-in-charge attesting that an inventory of all controlled substances on hand has been conducted; and
(C) a statement signed by the pharmacist-in-charge attesting to the manner of disposition for all prescription drugs possessed by the pharmacy;
(2) arrange for the transfer of prescription drug orders or computer prescription records to another pharmacy to facilitate continuous patient care; and
(3) provide for the maintenance and availability of prescription drug orders or hard copies of computer prescription records in accordance with 12 AAC 52.450(a) that are not transferred to another pharmacy;
(4) repealed 1/17/2007.
(b) In the absence of a pharmacist-in-charge, the owner of the pharmacy shall meet all requirements of this section.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

**12 AAC 52.060. FIRE OR OTHER DISASTER.** (a) If a pharmacy has a fire or other disaster, the pharmacist-in-charge of the pharmacy shall

(1) within 10 days, report to the board the date of a fire or any disaster that may affect the strength, purity, or labeling of drugs, devices, or other materials used in the practice of the pharmacy;

(2) provide the board with a copy of a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances," reporting the loss or destruction of controlled substances or DEA order forms; if the extent of the loss of controlled substances cannot be determined, the pharmacist-in-charge shall submit to the board a complete inventory of all remaining controlled substances and a statement, signed by the pharmacist-in-charge, attesting to the accuracy of the inventory; and

(3) notify the board in writing within 10 days after any change in the pharmacy's address, including a move to a temporary location or a return to the pharmacy's permanent location.

(b) If a pharmacy maintains a temporary location for more than 90 days, the pharmacist-in-charge of the pharmacy shall apply for a new and separate facility license as required in 12 AAC 52.030.

(c) A pharmacy may not dispense any drug that has been exposed to excessive heat, smoke, or other conditions that may have caused deterioration.

(d) In this section, "other disaster" includes any disaster situation that causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

**12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION.** (a) An applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements of this section 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.

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

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(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 relating 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) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080, sent directly to the department from the agency where the hours of internship or experience were completed;

(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.

**Authority:** AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

**Editor's note:** Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

**12 AAC 52.075. GOOD MORAL CHARACTER.** As used in AS 08.80, "good moral character" includes not having been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.110

**12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE.** (a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.

(c) Repealed 4/16/2016.

(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.

**Authority:** AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

**12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION.** (a) In addition to the requirements in AS 08.80.110, an applicant for a pharmacist license shall pass the

(1) North American Pharmacy licensing examination (NAPLEX) administered by the National Association of Boards of Pharmacy with a NAPLEX scaled score of 75 or above; and

(2) Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(b) An applicant for a temporary pharmacist license shall pass the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(c) An applicant for a pharmacist license that has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of examination scores directly to the department.

(d) An applicant for licensure by examination must submit an application under 12 AAC 52.070 and be approved under 12 AAC 52.092 before sitting for examination under this section.

(e) An applicant who has failed the Alaska pharmacy jurisprudence examination specified in (f) of this section may not retake the examination for at least 30 days.

(f) The Multistate Pharmacy Jurisprudence Examination administered by the National Association of Boards of Pharmacy (NABP) is the examination adopted by the board as the Alaska pharmacy jurisprudence examination. An applicant shall satisfy all other license requirements within one year after passing the Alaska pharmacy jurisprudence examination or retake the examination.

(g) An applicant applying for a pharmacy license by examination shall make application within one year of successfully passing the NAPLEX. An applicant applying more than one year after passing the NAPLEX shall retake the NAPLEX or apply for a pharmacy license under AS 08.80.145.

**Authority:** AS 08.01.065 AS 08.80.110 AS 08.80.150
AS 08.80.005 AS 08.80.120 AS 08.80.160
AS 08.80.030

**12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION.** (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(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 relating 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.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.110

**12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY.** (a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements 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 of this section 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.

(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 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

**12 AAC 52.100. TEMPORARY PHARMACIST LICENSE.** (a) The board will issue a temporary pharmacist license to an applicant for licensure if the applicant

(1) submits a completed application for licensure;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) repealed 2/26/2000;

(4) provides for the National Association of Boards of Pharmacy (NABP) to notify the board that the applicant has submitted a preliminary application to NABP for license transfer;

(5) pays the application fee, pharmacist license fee, and temporary license fee required in 12 AAC 02.310;

(6) passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above;

(7) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely; and

(8) submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

(b) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 90 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.

**Authority:** AS 08.80.005 AS 08.80.145 AS 08.80.150
AS 08.80.030

**12 AAC 52.110. EMERGENCY PHARMACIST PERMIT.** (a) If the board determines 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) repealed 10/31/2019; 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

**12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION.** (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

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

(2) pays the application fee and the pharmacist intern license fee established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

(7) submits a completed 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 Substances Act); and

(8) 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 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) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state;

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

**Authority:** AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

**12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE.** (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary

qualifications for an out-of-state pharmacy registration. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive an out-of-state pharmacy registration will not be issued a registration unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that registration.

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(1) applies on an application provided by the department that includes

(A) the company name and owner name;

(B) the pharmacy name;

(C) the location of the facility;

(D) a mailing address and telephone number;

(E) a toll free number accessible by patients in this state;

(F) the federal employer identification number;

(G) the names of all partners or corporate officers;

(H) the name, address, and telephone number for pharmacist-in-charge;

(I) the names of all pharmacists working in the facility;

(J) completion of the professional fitness section of the application; and

(K) the name of the appointed registered agent;

(2) pays the application fee and the out-of-state pharmacy registration fee established in 12 AAC 02.310;

(3) submits a certified true copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an inspection report or self-inspection report completed within the last two years.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.158

**12 AAC 52.140. PHARMACY TECHNICIAN LICENSE.** (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 form for application, 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 or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent 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.

(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

**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 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 programs. 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.

**Authority:** AS 08.80.003 AS 08.80.005 AS 08.80.030

## ARTICLE 2.
## PERSONNEL.

**Section**


**200. Pharmacist-in-charge**
**210. Pharmacist duties**
**220. Pharmacist interns**
**230. Pharmacy technicians**
**235. Pharmacy technician with national certification**
**240. Pharmacist collaborative practice authority**
**250. Job shadowing in pharmacy**


**12 AAC 52.200. PHARMACIST-IN-CHARGE.** (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;
(2) training of all pharmacy personnel;
(3) establishing policies and procedures for pharmacy operations;
(4) maintaining required records;
(5) storage of all materials, including drugs and chemicals;
(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and
(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 02.105(3).

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030 AS 08.80.160

**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 or prescription;
(3) interpreting a prescription drug order;
(4) determining the product required for a prescription;
(5) interpreting data in a patient medication record system;
(6) assuming the responsibility for a filled prescription;
(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and
(8) administering a prescription drug order in accordance with the practitioner's order.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.330

**12 AAC 52.220. PHARMACIST INTERNS.** (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 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) repealed 4/3/2020;

(4) is responsible for the work of the pharmacist intern;

(5) 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

**12 AAC 52.230. PHARMACY TECHNICIANS.** (a) The following persons must be licensed as a pharmacy technician:

(1) an 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.

(b) A pharmacy technician shall work under the direct supervision of a person who is licensed as a pharmacist.

(c) Except as provided in 12 AAC 52.235, a pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

(d) An individual working as a pharmacy technician shall wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.

(e) Before an individual may regularly perform the tasks of a pharmacy technician, 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.

**Authority:** AS 08.80.030 AS 08.80.480

**12 AAC 52.235. PHARMACY TECHNICIAN WITH NATIONAL CERTIFICATION.** (a) A pharmacy technician who holds a national certification may, at the direction of the pharmacist on duty and under the direct supervision of that pharmacist,

(1) perform a final check of and distribute a non-controlled substance prescription if

(A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination of substitution;

(B) the pharmacy uses a bar code scanning and verification system that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label;

(C) the pharmacy uses software that displays the image or graphical description of the correct drug being verified; however, if there is any deviation between the image or graphical description and the actual product being distributed, a pharmacist must review and dispense the order; and

(D) each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500; or

(3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.

(b) Prescription drug order information clarifications under (a)(3) of this section must have the following information documented on the prescription drug order:

(1) the result of the clarification;

(2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the practitioner or authorized agent that the pharmacy technician spoke to; and

(4) the date of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

(d) In this section, "bar code scanning and verification system" means any technology that scans the bar code on a manufacturer drug container to ensure that the product being distributed matches the expectation of what was prescribed and inputted into the dispensing software.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY**. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;

(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and

(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;

(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months;

(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol;

(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.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

(h) This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(i) A signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times.

**Authority:** AS 08.80.030 AS 08.80.480

**12 AAC 52.250. JOB SHADOWING IN PHARMACY.** (a) A pharmacist-in-charge or job shadowing preceptor of a pharmacy may allow job shadowing by a student in the pharmacy only as specified in this section.

(b) Before a student begins a job shadowing program under this section, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board, which includes the names of the pharmacy, the participating student, and the pharmacist-in-charge or job shadowing preceptor. The student and the pharmacist-in-charge or preceptor, shall sign the form. The parent or guardian of the student shall also sign the form if the student is less than 18 years of age.

(c) The pharmacist-in-charge or, if applicable, the job shadowing preceptor shall familiarize the student with the confidentiality requirements of 45 C.F.R., Parts 160 and 164 (HIPAA) and ensure compliance with this section and the relevant sections of AS 08.80 and this chapter.

(d) A pharmacist-in-charge or job shadowing preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than 50 hours;

(C) perform any functions reserved for licensed, certified, or registered pharmacy personnel;

(2) a ratio of job shadowing student to pharmacist-in-charge or job shadowing preceptor other than one to one.

(e) After completion of the job shadowing program by a student, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board where the pharmacist-in-charge or job shadowing preceptor provides the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The job shadowing documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed by that student.

(f) In this section,

(1) "job shadowing" means for educational purposes and through observation only, the observation by a student of the functions and duties of a pharmacy and pharmacy staff with the intended purpose of giving the student an opportunity to observe career possibilities available in the field of pharmacy;

(2) "job shadowing preceptor" means a licensed pharmacist, other than the pharmacist-in-charge, designated by the pharmacist-in-charge to supervise a student while that student is job shadowing;

(3) "student" means a person currently enrolled in a high school or post-secondary education program.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.330

**Editor's note:** The job shadowing documentation form required by 12 AAC 52.250 may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, P.O. Box 110806, Juneau, AK 99811-0806; phone: (907) 465-2589; or the division's website at http://www.commerce.state.ak.us/occ/ppha.htm.

## ARTICLE 3.
## LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS.

**Section**

**300. License renewal**
**310. Reinstatement of an expired pharmacist or pharmacy technician license**
**320. Continuing education requirements for pharmacists**
**325. Continuing education requirements for pharmacy technicians**
**330. Alternative continuing education schedule**
**340. Approved programs**
**350. Audit of records by the board**

**12 AAC 52.300. LICENSE RENEWAL.** (a) Pharmacy, wholesale drug distributor, and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license shall submit

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) a completed self-inspection of the premises questionnaire on a form provided by the department.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

**Authority:** AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

**12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE.** (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

(1) submits a completed application for reinstatement on a form provided by the department;

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated.

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

**12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS.** (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.

**Authority:** AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

**12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS.** (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacy technician license shall certify that, during the concluding licensing period, the applicant

(1) completed 10 contact hours of continuing education accepted by the board under 12 AAC 52.340; or

(2) obtained initial certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB).

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) Instead of complying with the continuing education requirements in (a) of this section, an applicant for renewal of a pharmacy technician license for the first time may

(1) verify in an affidavit, on an application for renewal, that the applicant has read the state statutes and regulations compiled by the board; and

(2) submit an affidavit, signed by the pharmacist-in-charge, verifying the applicant's pharmacy technician training in accordance with 12 AAC 52.230.

(d) An applicant for reinstatement of a pharmacy technician license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

**Authority:** AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005

**Editor's note:** Information regarding certification with the Pharmacy Technician Certification Board described in 12 AAC 52.325 may be obtained from the Pharmacy Technician Certification Board, 1100 15th Street, NW, Suite 703, Washington, DC 20005-1707, phone: (202) 429-4120 or at PTCB's website at www.ptcb.org. The Alaska Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

**12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE.** An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.165

**12 AAC 52.340 APPROVED PROGRAMS.** (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(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;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

**Authority:** AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

**12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD.** (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section, the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

**Authority:** AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

## ARTICLE 4.
## GUIDELINES FOR PHARMACIES AND PHARMACISTS.

**Section**

**400. General guidelines for pharmacies**
**410. Care of drug stocks and devices**
**420. Security**
**423. Remote pharmacy license**
**425. Telepharmacy system for a remote pharmacy**

**430. Guidelines relating to sterile pharmaceuticals**
**440. Guidelines relating to compounding practices**
**443. Approval for shared pharmacy services by pharmacy**
**444. Approval for shared pharmacy services by pharmacists**
**445. Shared pharmacy services**
**446. Shared pharmacy services during emergency**

**12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES.** A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, "*Facility Standards for Pharmacies,*" dated November 2016, and incorporated by reference in this section.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**Editor's note:** The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

**12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES.** (a) A drug or device that has exceeded its expiration date shall be removed from stock and quarantined until properly disposed of in accordance with 12 AAC 52.560.

(b) A pharmacist may not dispense a drug or device beyond the expiration date on the drug or device.

(c) All drugs and devices on shelves or display for sale shall be protected against contamination, deterioration, and adulteration.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**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 security requirements.

(c) 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 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.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

**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.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY.** (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 pharmacy may supervise one or more remote pharmacies.

(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:

(1) still image capture;
(2) real time link;
(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and
(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy 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.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must have access to the records of the prescriptions dispensed by the remote pharmacy.

(g) The prescription label of a prescription drug dispensed by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the remote pharmacy. A prescription drug may not be dispensed by a remote pharmacy until a pharmacist employed by the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and
(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

(j) Repealed 10/31/2019.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**12 AAC 52.430. GUIDELINES RELATING TO STERILE PHARMACEUTICALS.** A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the guidelines established by the board in the pamphlet titled, "*Sterile Pharmaceuticals,"* dated February 2008, and incorporated by reference in this section.

**Authority:** AS 08.80.030 AS 08.80.157

**Editor's note:** The pamphlet incorporated by reference in 12 AAC 52.430, *"Sterile Pharmaceuticals"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

**12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES.** A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "*Compounding Practices,"* dated February 2008, and incorporated by reference in this section

**Authority:** AS 08.80.030 AS 08.80.157

**Editor's note:** The pamphlet incorporated by reference in 12 AAC 52.440, *"Compounding Practices"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

**12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY.** (a) A requesting pharmacy in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacy to participate in shared pharmacy services if the pharmacy establishes

(1) that the pharmacy has a current in-state pharmacy license issued under AS 08.80.157 and this chapter;
(2) that the pharmacy is able to comply with the requirements of 12 AAC 52.445;

(3) that the pharmacy either

(A) is owned by the same owner as the filling pharmacy with which pharmacy services are to be shared; or

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligation of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(4) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST.** (a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacist to participate in shared pharmacy services if the requesting pharmacist establishes

(1) that the pharmacist

(A) has a current in-state pharmacy license issued under AS 08.80 and this chapter;

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligations of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(C) is able to comply with the requirements of 12 AAC 52.445; and

(2) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.445. SHARED PHARMACY SERVICES.** (a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.

(b) Except as provided in (c) of this section, if a filling pharmacy or filling pharmacist delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist shall provide, on the prescription container or on a separate sheet delivered with the prescription container,

(1) the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist; and

(2) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."

(c) The requirements of (b) of this section do not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(d) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled, or dispensed, the name, initials, or identification code of each pharmacist responsible for the final verification of dispensing; those records must include descriptions of actions taken in interpretation of the order, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, and refill authorization functions performed at that pharmacy or by that pharmacist;

(2) report to the board as soon as practical the results of any license disciplinary action taken by a regulatory agency in another licensing jurisdiction involving a pharmacy or pharmacist participating in shared pharmacy services;

(3) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy or by that pharmacist;

(4) provide for adequate security to protect the confidentiality and integrity of patient information;

(5) provide for inspection of any required record or information no later than 72 hours after any request by the board or its designee.

(e) Each pharmacy participating in shared pharmacy services, if a

(1) requesting pharmacy, shall have a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) filling pharmacy, shall either

(A) have a current in-state pharmacy license issued under AS 08.80.157 and this chapter; or

(B) be registered as an out-of-state pharmacy under AS 08.80.158 and this chapter.

(f) Each participant in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Each participant is required to maintain only those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures must

(1) outline the responsibilities of each participant;

(2) include a list that contains

(A) each pharmacy participating in shared pharmacy services, and each pharmacist acting independently of a pharmacy and participating in shared pharmacy services;

(B) the name, address, and telephone number of each of those participants; and

(C) the license numbers for all licenses held by each of those participants; and

(3) address

(A) patient notification that meets the requirements of this section;

(B) the adequate protection of the confidentiality and integrity of patient information;

(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;

(D) the maintenance of manual or electronic records that meet the requirements of this section;

(E) compliance with federal and state laws; and

(F) the operation of a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(g) Nothing in this section prevents an individual pharmacist licensed in this state who is employed by or working under a contract with a pharmacy, or prevents a licensed pharmacy intern or pharmacy technician working under the supervision of that licensed pharmacist, from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription order in compliance with AS 08.80 and this chapter if

(1) the pharmacy has established controls to protect the privacy and security of confidential records; and

(2) the pharmacist, pharmacy intern, or pharmacy technician does not duplicate, download, or remove data from the pharmacy's electronic database.

(h) A pharmacist working independently outside of the state may participate in shared pharmacy services with an institutional pharmacy in this state if the pharmacist holds

(1) a current license as a pharmacist issued under AS 08.80 and this chapter; and

(2) a current license to practice as a pharmacist issued by the licensing jurisdiction where the pharmacist is working.

(i) The pharmacist-in-charge of the requesting pharmacy must ensure compliance with the applicable requirements of AS 08.80 and this section.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.158
AS 08.80.030

**12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY.** (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy services without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient’s agent, the filling pharmacy or filling pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container, the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall maintain manual or electronic records identifying, individually for each order processed, filled or dispensed,

(1) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services that distributes prescription drug orders under 12 AAC 52.235 using a pharmacy technician who holds a national certification shall maintain manual or electronic records identifying, individually for each order processed, filled, or distributed

(1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order.

**Authority:** AS 08.80.005 AS 08.80.030

## ARTICLE 5.
## PHARMACY PRACTICE STANDARDS.

**Section**


**450. Prescription drug order records**
**460. Prescription drug order information**
**465. Controlled substance prescription drug orders**
**470. Refills**
**480. Labeling**
**490. Prescriptions by electronic transmission**
**500. Transfer of a prescription drug order**
**510. Substitution**
**520. Customized patient medication package (patient med-pak)**
**530. Return or exchange of drugs**
**540. Notification of theft or significant loss**
**550. Advertising**
**560. Destruction and disposal of drugs**
**570. Drug regimen review**
**580. Data processing systems**
**585. Mandatory patient counseling**
**590. Prepackaging of drugs**


**12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS.** (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug orders by

(1) keeping the original hard copy prescription drug order presented by a patient;

(2) keeping a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal;

(3) keeping a prescription drug order put into writing either manually or electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**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 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 shall 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;
(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 drug product's manufacturer or distributor;
(B) the national drug code number;
(C) the short name code; or
(D) the trade name.
(c) After oral consultation 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 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 prescribed.
(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.465. CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS.** 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 C.F.R. 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
(E) each partial fill only occurs at the pharmacy where the original prescription order is on file.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.470. REFILLS**. (a) Repealed 4/3/2020.
(b) Repealed 4/3/2020.
(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.
(d) A pharmacist or pharmacist intern may dispense any quantity of a 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, including refills; and
(2) drug is not a federal or state scheduled controlled substance.
(e) To indicate that an increased supply may not be dispensed under 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 requires a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit.
(g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,
(1) "existing" means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;
(2) "chronic" means a drug that the patient takes regularly, for greater than three months.
(h) Under (g) of this section, the pharmacist must
(1) reduce the patient's prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;
(2) document "continuation of therapy", "COT", or words of similar meaning on the prescription drug order; and

(3) file and maintain the prescription in accordance with 12 AAC 52.450.

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.480. LABELING.** 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, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(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;

(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.

**Authority:** AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

**12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION.** (a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

(1) name, address, and telephone number of the prescribing practitioner;

(2) electronic signature or manual signature of the prescribing practitioner;

(3) the information required in 12 AAC 52.460(a)(1) - (8); and

(4) any other information required by federal law.

(b) A pharmacist may dispense a prescription that has been received electronically.

(c) The system for electronic transmission of prescriptions must address the following:

(1) patient's choice of pharmacy; the system may not restrict the patient's choice of pharmacy;

(2) security of the system; the system must have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information; the system must include

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other applicable equipment from an unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control, and audit access to confidential patient information; and

(D) processes to prevent unauthorized access to the prescription information when transmitted electronically;

(3) confidentiality of patient information; the system must maintain the confidentiality of patient information consistent with state and federal laws;

(4) authentication; to be valid prescriptions transmitted by an authorized prescriber or the prescribing practitioner's authorized agent from computer to a facsimile machine or from computer to computer must use an electronic signature; the prescribing practitioner's system must authenticate the sender's authority and credentials to transmit a prescription to a pharmacy and

(A) the prescribing practitioner's system must provide an audit record of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(B) the right of the board to access the prescribing practitioner's electronically transmitted prescriptions for purposes of investigations;

(5) a prescribing practitioner's system that utilizes intermediaries in the electronic communication of prescriptions to pharmacies is responsible to ensure that the contracts with the intermediaries require security measures that are equal to or better than those provided by this section and prohibit the modification of a record of a prescription after it has been transmitted by the prescribing practitioner to the pharmacist;

(6) if a paper copy prescription that is generated by the pharmacist or pharmacy technician from the electronic prescription system is printed, an electronic signature may be substituted for a manual signature;

(7) the system must maintain the integrity and confidentiality of patient information transmitted electronically for its system as required by this chapter, other state law, and federal law.

(d) In this section,

(1) "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription;

(2) "electronic transmission of prescriptions" means the communication from an authorized prescribing practitioner or the prescribing practitioner's authorized agent to a pharmacy of the patient's choice, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with this section, other state law, and federal law;

(3) "security" means a system to maintain the confidentiality and integrity of prescription information, including

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other pertinent equipment from unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control and audit access to confidential patient information; and

(D) processes for its system to prevent unauthorized access to the prescription information when transmitted electronically.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER.** (a) For the purpose of dispensing 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.

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. The transfer must be communicated directly between two licensed pharmacists.

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or by means of facsimile between pharmacies without limitation up to the number of originally authorized refills.

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) repealed 4/3/2020;

(2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:

(A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;

(B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the prescription drug order information;

(C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(D) the date of the transfer;

(4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:

(A) the original date of issue;

(B) the original unique identification number of the prescription;

(C) the quantity of drug or device remaining;

(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

(e) A pharmacy using an automated data processing system shall meet the same requirements for a manual prescription drug order transfer listed in (d) of this section.

(f) If two or more pharmacies use a common electronic database for prescription record keeping, prescription drug orders may be refilled at any of the pharmacies using the common electronic database if provisions are made

(1) for an audit trail that documents the location of each filling; and

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.510. SUBSTITUTION.** (a) A pharmacist or pharmacist intern 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 indicating that the practitioner does not want it substituted;

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

(3) repealed 10/31/2019; 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 "equivalent drug product" or "interchangeable biological product" is defined in AS 08.80.480.

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product if there is nothing on the prescription drug order from the prescribing practitioner that indicates that the practitioner wants only the substituted product dispensed.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.295

**12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK).** (a) Instead of dispensing one or more prescribed drug products in separate containers, a pharmacist may, with the written consent of the patient, patient's caregiver, or prescribing practitioner, provide a customized patient medication package or patient med-pak.

(b) A patient med-pak is a series of containers prepared by a pharmacist for a specific patient containing one or more prescribed solid oral dosage forms and designed or labeled to indicate the day and time, or period of time, when the contents within each container are to be taken.

(c) The pharmacist shall prepare a label for a patient med-pak that includes

(1) the name of the patient;

(2) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for the drug products in the patient med-pak;

(3) the name, strength, physical description or identification, and total quantity of each drug product in the patient med-pak;

(4) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product in the patient med-pak;

(5) any other information, statements, or warnings required or appropriate for any of the drug products in the patient med-pak;

(6) the name of the prescribing practitioner of each drug product in the patient med-pak;

(7) the date of preparation of the patient med-pak and the expiration date assigned to the patient med-pak; the expiration date may not be more than 60 days from the date of preparation of the patient med-pak;

(8) the name, address, and telephone number of the pharmacy; and

(9) the initials of the dispensing pharmacist.

(d) If the patient med-pak allows for the removal or separation of the intact containers from the patient med-pak, the pharmacist shall label each individual container of the patient med-pak to identify each of the drug products contained in the patient med-pak.

(e) When preparing a patient med-pak, the dispensing pharmacist shall take into account any applicable compendium requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container in the med-pak and any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(f) In addition to any individual prescription filing requirements, the pharmacist shall make and file a record of each patient med-pak. Each record must contain

(1) the name and address of the patient;

(2) a unique identification number for the patient med-pak itself and a separate, unique, identification number for each of the prescription drug orders for each drug product contained in the patient med-pak;

(3) information identifying or describing the design, characteristics, or specifications of the patient med-pak that is sufficient to prepare an identical patient med-pak for the patient;

(4) the date of preparation of the patient med-pak and the expiration date assigned;

(5) any special labeling instructions; and

(6) the name or initials of the pharmacist who prepared the patient med-pak.

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

**12 AAC 52.530. RETURN OR EXCHANGE OF DRUGS.** (a) A pharmacy or pharmacist may 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 the medication was recalled by the manufacturer or the United States Food and Drug Administration; and

(2) the drug is segregated from the normal pharmacy inventory and may not be dispensed.

(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

(1) the pharmacist can readily determine that there has been no entry or attempt at entry to the unit dose package or blister card;

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the standards of the United States Pharmacopoeia (1995 revision) for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(3) the drug has not come into the physical possession of the person for whom it was prescribed, and control of the drug is known to the pharmacist to have been the responsibility of a person or persons licensed to prescribe, dispense, or administer drugs; and

(4) the drug labeling or packaging has not been altered or defaced, and the identity of the drug, its strength, lot number, and expiration date are retrievable.

**Authority:** AS 08.80.005 AS 08.80.030

**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.

**12 AAC 52.540. NOTIFICATION OF THEFT OR SIGNIFICANT LOSS.** If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157

**12 AAC 52.550. ADVERTISING.** A pharmacy may advertise prescription drug prices if the advertisement contains all of the following information:

(1) proprietary, trade, or generic name of the drug product;

(2) name of the manufacturer or distributor of the drug product;

(3) dosage form and strength of the drug product;

(4) price charged for a specific quantity of the drug product; and

(5) the hours that pharmaceutical services are available from the advertiser.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS.** (a) A licensed pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a manner that makes the drugs unfit for human consumption.

(b) A drug that is a controlled substance shall be disposed of in accordance with federal statutes and regulations.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.570. DRUG REGIMEN REVIEW.** (a) A pharmacist shall perform a drug regimen review, as defined in AS 08.80.480, for each prescription drug order.

(b) If a pharmacist identifies any of the items listed in AS 08.80.480 during the drug regimen review, the pharmacist shall avoid or resolve the problem by consulting with the prescribing practitioner, if necessary.

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

**12 AAC 52.580. DATA PROCESSING SYSTEMS.** A pharmacy may use an automated data processing system to maintain the records required in AS 08.80 and this chapter if the system

(1) is capable of on-line retrieval of all information required in 12 AAC 52.460, 12 AAC 52.470, and 21 C.F.R. 1306.22, as amended as of February 6, 1997;

(2) is capable of producing an audit trail printout for all dispensing of any specified strength and dosage form of a drug; and

(3) has adequate safeguards to prevent loss of data and reasonable security to prevent unauthorized access to, modification of, or manipulation of patient records.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.585. MANDATORY PATIENT COUNSELING.** (a) Before dispensing a prescription 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 pharmacist or pharmacy 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.

(b) A pharmacist 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 Pharmacopoeia 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 52.590. PREPACKAGING OF DRUGS.** For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

(1) the name, address, and telephone number of the pharmacy;
(2) the name, strength, and quantity of the drug;
(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;
(4) cautionary information required for patient safety and information; and
(5) the initials of the pharmacist.

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

## ARTICLE 6.
## WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

**Section**

**610. Wholesale drug distributor license**
**620. Wholesale drug facilities**
**625. Personnel requirements; grounds for denial or other disciplinary action**
**630. Drug storage**
**640. Written policies and procedures**
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**690. Salvage and reprocessing**
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**12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE.** (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements of this section 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 board will issue a wholesale drug distributor license 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, 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 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.

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| **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.** (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

(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 license under AS 08.80.

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| **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. 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.

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| **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. DRUG STORAGE.** (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements to help ensure that the identity, strength, quality, and purity of the products are not affected.

(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.

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

**12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES.** A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs;

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;

(7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

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

**12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS.** (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

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

**12 AAC 52.650. RECORDS AND INVENTORIES.** (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

(1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;

(2) the identity and quantity of the drug received, distributed, or disposed of; and

(3) the date of receipt and of distribution or other disposition.

(b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

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

**12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS.** (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

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

**12 AAC 52.670. DRUG RECALLS.** A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

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

**12 AAC 52.680. INSPECTIONS.** A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

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

**12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION.** A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

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

**12 AAC 52.690. SALVAGE AND REPROCESSING.** A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

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

**12 AAC 52.695. PROVISIONS NOT APPLICABLE.** The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) any of the following transfers of a drug, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee during any 12-consecutive-month period:

(A) the sale of a drug by a retail pharmacy to another retail pharmacy or to a practitioner, or the offer by a retail pharmacy to sell a drug to another retail pharmacy or to a practitioner;

(B) the purchase of a drug by a retail pharmacy or by a practitioner from another retail pharmacy, or the offer by a retail pharmacy or by a practitioner to purchase a drug from another retail pharmacy;

(C) the trade of a drug by a retail pharmacy with another retail pharmacy, or the offer by a retail pharmacy to trade a drug with another retail pharmacy;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.159

AS 08.80.030

**12 AAC 52.696. OUTSOURCING FACILITIES.** (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements of (b) of this section 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 board will issue an outsourcing facility license 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.

(c) Within 10 days after 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 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 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 must 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

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(g) Outsourcing facility personnel 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 must be registered as an outsourcing facility with the United States Food and Drug Administration under Sec. 503b, 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 52.697. THIRD-PARTY LOGISTICS PROVIDERS.** (a) An applicant must meet the requirements set out in (b) of this section to demonstrate 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 board will issue a third-party logistics provider license 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 after 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 must 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 must 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 must 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

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider must 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.

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

## ARTICLE 7.
## INSTITUTIONAL PHARMACIES.

**Section**

**700. (Repealed)**
**710. Absence of a pharmacist from an institutional pharmacy**
**720. Emergency room outpatient medications**
**730. Drug distribution and control**

**12 AAC 52.700. INSTITUTIONAL PHARMACIES.** Repealed 2/26/2000.

**12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY.** (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;

(B) name, strength, and amount of the drug;

(C) date and time of removal; and

(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical, to check the stock container or similar unit dose package of the drug removed; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

**12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS.** (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the

(A) name, address, and telephone number of the institutional facility;

(B) name, strength, and quantity of the drug;

(C) cautionary information required for patient safety and information;

(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and

(E) initials of the pharmacist;

(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and

(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the

(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.

(c) Prepackaged medications shall be kept in a secure place within the emergency room.

(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.

(e) This section does not apply to the administration of a single dose to a patient.

(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

**12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL.** (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

## ARTICLE 8.
## DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

**Section**

**800. Drug room license**
**810. Pharmacist required**
**820. Responsibilities of the consultant pharmacist**
**830. Emergency drug kits**
**840. First dose kits**
**850. Emergency distribution**

**12 AAC 52.800. DRUG ROOM LICENSE.** (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

**12 AAC 52.810. PHARMACIST REQUIRED.** An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

**12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST.** A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

**12 AAC 52.830. EMERGENCY DRUG KITS.** (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

**12 AAC 52.840. FIRST DOSE KITS.** (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

**12 AAC 52.850. EMERGENCY DISTRIBUTION.** In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

**Authority:** AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

## ARTICLE 9.
## CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

**Section**

**855. Registration with the prescription drug monitoring program controlled substance prescription database**

**860. Access to and conditions for use of the prescription drug monitoring program database**

**865. Reporting and reviewing PDMP information**
**870. Waiver of electronic submission requirement by pharmacist or practitioner**
**875. Solicited requests for information from non-registered persons**
**880. Reports**
**885. Purged database records**
**890. Grounds for discipline**
**895. Correcting information in database**

**12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.** (a) A licensed pharmacist shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) before dispensing a schedule II, III, or IV controlled substance under federal law.

(b) Before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(c) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(d) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(e) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.860. ACCESS TO AND CONDITIONS FOR USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM DATABASE.** (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes in AS 17.30.200(d)(1) of an inquiry under a search warrant, subpoena, or order issued by an administrative law judge or a court,

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

(2) "personnel of another board or agency" means an employee of this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(c) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(1) employees of the Department of Commerce, Community, and Economic Development, assigned to the Board of Pharmacy, and providing PDMP data storage or data management services; or

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

(d) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an agent or employee to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(e) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom that department's commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION.** (a) Unless excused from reporting under AS 17.30.200(t), 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(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information 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(t), 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

**12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER.** (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a pharmacist or practitioner must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

(c) The department may not grant a waiver under this section unless the pharmacist or practitioner first agrees in writing that, if the waiver is granted, the pharmacist or practitioner will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board on at least a daily basis using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the pharmacist or practitioner files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A pharmacist or practitioner must inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS.** (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a $10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.880. REPORTS.** (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

(1) the date on which the request was received;
(2) the name of the patient and the patient's date of birth;
(3) the name, title, and address of the individual requesting the profile;
(4) the date on which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.885. PURGED DATABASE RECORDS.** The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;
(2) the date of the prescription;
(3) the date the prescription was filled and the method of payment;
(4) the name, address, and date of birth of the person for whom the prescription was written;
(5) the name and national drug code of the controlled substance;
(6) the quantity and strength of the controlled substance dispensed;
(7) the name of the drug outlet dispensing the controlled substance; and
(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.890. GROUNDS FOR DISCIPLINE.** A violation of 12 AAC 52.855 – 12 AAC 52.885 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a practitioner not licensed by this board shall be reported to the practitioner's licensing board.

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.895. CORRECTING INFORMATION IN DATABASE.** (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

(1) on a form or in a format prescribed by the board,
  (A) a description of the information asserted to be incorrect, and the correction requested;
  (B) the mailing and physical address and telephone number of the requester; and
  (C) a signed, sworn statement attesting to the truth of the corrected information;
(2) documentation to support the correction requested; and
(3) proof of the requester's identity.

(b) If the board determines that it

(1) has sufficient information to make a determination, the board will
  (A) notify the requester that the request is granted; or
  (B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;
(2) lacks sufficient information to grant or deny the request, the board
  (A) will request additional information from the requester; and
  (B) will not act on the request until after the additional information is received.

(c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

**Authority:** AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

## ARTICLE 10.
## DISCIPLINARY GUIDELINES.

**Section**

**900. Purpose of disciplinary guidelines**
**910. Violations**
**920. Disciplinary guidelines**

**925. Grounds for denial or discipline for criminal history**
**930. Terms of probation**
**940. Use of alcohol or controlled substances**
**950. Probation terms for professional incompetence**
**960. Mental or physical disabilities**
**970. Reinstatement of a suspended license**
**980. Reinstatement of a revoked license**

**12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES.** The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board's disciplinary policies are known and are administered consistently and fairly.

**Authority:** AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

**12 AAC 52.910. VIOLATIONS.** (a) A person who is licensed under AS 08.80 and this chapter who, after a hearing under AS 44.62 (Administrative Procedure Act), is found to have violated a provision of AS 08.80 or this chapter is subject to the disciplinary penalties listed in AS 08.01.075, including public notice of the violation and penalty in appropriate publications.

(b) Nothing in the guidelines set out in 12 AAC 52.920 prohibits the board from imposing greater or lesser penalties than those described in 12 AAC 52.920 or restricting the practice of a licensee depending upon the circumstances of a particular case.

**Authority:** AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

**12 AAC 52.920. DISCIPLINARY GUIDELINES.** (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;

(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making a false or fraudulent claim concerning a drug;

(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;

(12) violating the provisions of a board order or memorandum of agreement;

(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;

(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;

(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;

(18) violating AS 08.80.315 dealing with the confidentiality of records;

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;
(20) offering, giving, soliciting, or receiving compensation for referral of a patient;
(21) violating AS 08.80.261(a)(3); or
(22) violating AS 17.30.200 or a regulation adopted under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.
(b) The board will, in its discretion, revoke a license if the licensee
(1) commits a violation that is a second offense;
(2) violates the terms of probation from a previous offense;
(3) violates AS 08.80.261(a)(1) or (4);
(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;
(5) is professionally incompetent if the incompetence results in risk of injury to a patient.
(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee
(1) wilfully or repeatedly violates AS 08.80 or this chapter; or
(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.
(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

| **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 52.925. 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.

| **Authority:** | AS 08.01.075 | AS 08.80.030 | AS 08.80.261 |
|---|---|---|---|

**12 AAC 52.930. TERMS OF PROBATION.** The board will, in its, discretion, subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:
(1) obey all laws pertaining to the practice of pharmacy in this state;
(2) fully comply with the probation program established by the board and cooperate with representatives of the board;
(3) notify the board in writing of the dates of departure and return if the licensee leaves the state to reside or practice pharmacy outside the state;
(4) report in person at meetings of the board or to its designated representatives during the period of probation, as directed by the board;

(5) submit written reports and verification of actions as required by the board during the period of probation;

(6) if employed in the practice of pharmacy at any time during the period of probation, have the employer submit to the board verification that the employer understands the conditions of probation;

(7) be employed as a pharmacist only in a setting in which full supervision is provided and not personally act as a supervisor.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

**12 AAC 52.940. USE OF ALCOHOL OR CONTROLLED SUBSTANCES.** (a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for the habitual abuse of alcohol or illegal use of controlled substances may also be subject to one or more of the following:

(1) physical and mental health examinations as determined by the board to evaluate the licensee's ability to perform the professional duties of a pharmacist;

(2) as determined by the board, participation until completion in an ongoing program of rehabilitative counseling, Alcoholics Anonymous, Narcotics Anonymous, or an impaired practitioner group that includes progress reports from the care provider when requested by the board;

(3) abstaining from the personal use of alcohol or controlled substances in any form except when lawfully prescribed by a practitioner licensed to practice in Alaska;

(4) submitting to tests and samples required for the detection of alcohol or controlled substances at the request of the board or the board's representative.

(b) Access to a controlled substance in the work setting will, in the board's discretion, be restricted.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

**12 AAC 52.950. PROBATION TERMS FOR PROFESSIONAL INCOMPETENCE.** In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation after being found professionally incompetent may be subject to one or more of the following terms of probation:

(1) successful completion of an appropriate course or courses in pharmacy, as determined by the board, before the end of the probationary period; or

(2) participation in 15 contact hours of appropriate continuing education in pharmacy.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

**12 AAC 52.960. MENTAL OR PHYSICAL DISABILITIES.** In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for practicing or attempting to practice pharmacy while afflicted with a physical or mental illness, deterioration, or disability that interferes with the licensee's performance of pharmacy may be subject to a physical or mental health examination to evaluate the licensee's ability to perform the professional duties of a pharmacist and if medically determined to be necessary, may be required to participate in and complete a recommended treatment program that includes written progress reports from the care provider when requested by the board.

**Authority:** AS 08.01.075 AS 08.80.261 AS 08.80.450
AS 08.80.030

**12 AAC 52.970. REINSTATEMENT OF A SUSPENDED LICENSE.** The board may reinstate a suspended license only if the requirements of the suspension order have been met.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

**12 AAC 52.980. REINSTATEMENT OF A REVOKED LICENSE.** (a) One year after revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

(b) The applicant for reinstatement shall appear before the board.

(c) The board will, in its discretion, impose restrictions upon the pharmacist or pharmacy when reinstating a license.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

## ARTICLE 11.
## GENERAL PROVISIONS.

**Section**

**985. Emergency preparedness**
**990. Display of license certificate**
**991. Disciplinary decision or conviction reporting requirement**
**992. Independent administration of vaccines and related emergency medications**
**993. Executive administrator**
**994. Independent dispensing of opioid overdose drugs by pharmacists**
**995. Definitions**

**12 AAC 52.985. EMERGENCY PREPAREDNESS.** (a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor that 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 disaster or terrorist attack, a disaster 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) Repealed 4/3/2020.

(d) Repealed 4/3/2020.

(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.

(f) During a disaster emergency declared by the governor of this state,

(1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;

(2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the date that the disaster emergency ends;

(3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized.

**Authority:** AS 08.80.005 AS 08.80.030

**12 AAC 52.990. DISPLAY OF LICENSE CERTIFICATE.** A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee shall display the department's Internet web site posting confirming licensure. The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.

**Authority:** AS 08.80.005 AS 08.80.030

**Editor's note:** The current posting confirming licensure can be found at the Internet web site of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing: www.commerce.state.ak.us/occ/search3.htm.

**12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT.** (a) 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 not later than 30 days after the date of the disciplinary decision or conviction.

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility.

**Authority:** AS 08.01.075 AS 08.80.030 AS 08.80.315
AS 08.80.005 AS 08.80.261 AS 08.80.460

**12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.** (a) Before a pharmacist may independently 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 10 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 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 devices, 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 certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern must

(1) have completed an ACPE-accredited immunization course or other comparable course that meets the requirements of (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 or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

(f) For 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; or

(2) a pharmacist intern meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern 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.

**Authority:** AS 08.01.075 AS 08.80.168 AS 08.80.480
AS 08.80.030 AS 08.80.261

**12 AAC 52.993. EXECUTIVE ADMINISTRATOR.** The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance must 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.

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.270

**12 AAC 52.994. INDEPENDENT DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS.** (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall

(1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;

(2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and

(3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.

(b) A pharmacist may

(1) supply an opioid overdose drug as

(A) an intramuscular injection;

(B) an intranasal spray;

(C) an auto-injector; or

(D) any other product forms approved by the United States Food and Drug Administration; and

(2) recommend other optional items when appropriate, including

(A) alcohol pads;

(B) rescue breathing masks; or

(C) rubber gloves.

(c) When dispensing an opioid overdose drug

(1) the pharmacist shall

(A) label the drug in accordance with 12 AAC 52.480;

(B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";

(C) ensure that the label includes directions to call 911 or other available emergency services; and

(D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450;

(2) the pharmacist may

(A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including

(i) dosing;

(ii) administration;

(iii) effectiveness;

(iv) adverse effects;

(v) storage conditions;

(vi) shelf life; and

(vii) safety;

(B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.

(d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or 12 AAC 52.490.

(e) In this section,

(1) "opioid overdose drug"

(A) has the meaning given in AS 08.80.168;

(B) includes naloxone hydrochloride;

(2) "recipient" means the person to whom an opioid overdose drug is furnished.

**Authority:** AS 08.80.030 AS 08.80.168 AS 08.80.480

**12 AAC 52.995. DEFINITIONS.** (a) In this chapter, unless the context requires otherwise,

(1) “ACPE” means Accreditation Council for Pharmacy Education;

(2) “approved program” means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved or accredited provider;

(3) “approved provider” means an individual, institution, organization, association, corporation, or agency offering an approved program under 12 AAC 52.340 and is not an accredited provider;

(4) “authorized inspector” means a member of the board or an investigator with the division assigned occupational licensing functions in the department;

(5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(6) "blood component" means that part of blood separated by physical or mechanical means;

(7) "board" means the Alaska Board of Pharmacy;

(8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;

(9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;

(10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;

(11) "DEA" means the United States Drug Enforcement Administration;

(12) "department" means the Department of Commerce, Community, and Economic Development;

(13) "direct supervision" means supervision that insures adequate safety controls either by personal supervision or through a telepharmacy system;

(14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;

(15) "institutional facility" means a

(A) hospital;

(B) long-term care facility, including a nursing home, convalescent home, or other related facility;

(C) mental health facility;

(D) rehabilitation center;

(E) psychiatric center;

(F) developmental disability center;

(G) drug abuse treatment center;

(H) family planning clinic;

(I) penal institution;

(J) hospice; or

(K) public health facility;

(16) "institutional pharmacy" means a pharmacy located in an institutional facility;

(17) "licensee" means a person who is licensed under AS 08.80 and this chapter;

(18) "live program" means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;

(19) "sterile pharmaceutical" means a drug dosage form free from living microorganisms (aseptic);

(20) "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in 12 AAC 52.695;

(21) "central pharmacy" means a pharmacy providing remote pharmacy services through a telepharmacy system;

(22) "personal supervision" means supervision that includes visual or physical proximity to ensure adequate safety controls;

(23) "pharmacy" includes a central pharmacy and a remote pharmacy;

(24) "remote pharmacy" means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

(25) "still image capture" means a specific image captured electronically from a video or other image capture device;

(26) "store and forward" means a video or still image record that is saved electronically for future review;

(27) "telepharmacy system" means a system under the direct supervision of a licensed pharmacist that monitors the dispensing and distribution of prescription drugs and provides for related drug use review and patient counseling services through a computer link and a video link with sound;

(28) "accredited provider" means an individual, institution, organization, association, corporation, or agency that is recognized by the ACPE as able to provide quality continuing education programs;

(29) "filling pharmacist" means a pharmacist participating in shared pharmacy services that processes or fills a prescription order for a patient;

(30) "filling pharmacy" means a pharmacy participating in shared pharmacy services that processes or fills a prescription order for a patient;

(31) "requesting pharmacist" means a pharmacist participating in shared pharmacy services that forwards a prescription order to another participating pharmacy or pharmacist to be processed or filled;

(32) "requesting pharmacy" means a pharmacy participating in shared pharmacy services that forwards a prescription order to another participating pharmacy to be processed or filled;

(33) "shared pharmacy services" means a system allowing the processing by a participating pharmacist or a pharmacy of a request from another participating pharmacist or pharmacy to enter or review a prescription drug order or process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims

adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

(34) "dispenser" means a practitioner who delivers a controlled substance to an ultimate user or research subject under the lawful order of a practitioner; in this paragraph, "delivers" includes the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery;

(35) "profile" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance;

(36) "PDMP" means the prescription drug monitoring program's controlled substance prescription database;

(37) "moral turpitude" includes conduct that is considered contrary to community standards of justice, honesty, or good morals;

(38) "pharmacy technician who holds a national certification" means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA).

(b) In AS 08.80.315(3), "other persons or governmental agencies" include investigators for the department who are assigned to conduct investigations under AS 08.

(c) In AS 08.80.030(b)(7), "monitoring of drug therapy" means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitoring of drug therapy" includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

(d) In AS 17.30.200 and 12 AAC 52.855 – 12 AAC 52.895, "practitioner" has the meaning given in AS 11.71.900.

(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 state and federal laws and regulations pertaining to the operations.

| **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 | | |

## CHAPTER 30.
## CONTROLLED SUBSTANCES

**Article**

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**5. Controlled Substance Prescription Database (§§ 17.30.200)**

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### CONTROLLED SUBSTANCE PRESCRIPTION DATABASE

**Section**

**200. Controlled substance prescription database**

**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 (t) 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 (t) 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:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; or

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(*l*) A person

(1) with authority to access the database under (d) of this section who knowingly

(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;

(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;

(C) allows another person who is not authorized to access the database to access the database commits a class C felony;

(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.

(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures

(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to

(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;

(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;

(C) increase coordination among prescription drug monitoring program partners;

(D) involve stakeholders in the planning process;

(2) shall include information related to the

(A) security of the database; and

(B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.

(n) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (n) of this section.

(p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section

(1) must be provided to the practitioner;

(2) is confidential;

(3) may not disclose information that is confidential under this section;

(4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.

(q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.

(r) The Department of Commerce, Community, and Economic Development shall

(1) assist the board and provide necessary staff and equipment to implement this section; and

(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (n) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

(A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and

(B) consult with the board to establish the fees under this paragraph.

(s) Notwithstanding (p) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is

(1) administered to a patient at

(A) a health care facility; or

(B) a correctional facility;

(2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(A) inpatient pharmacy; or

(B) emergency department.

(u) In this section,

(1) "board" means the Board of Pharmacy;

(2) "database" means the controlled substance prescription database established in this section;

(3) "knowingly" has the meaning given in AS 11.81.900;

(4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;

(5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.

**General Requirements.**

(a) Each pharmacy is of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparation of prescription drug orders.

(b) There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(c) The prescription department and all areas where drugs are stored are well lighted, well ventilated, dry, and maintained in a clean and orderly condition. Walls, floors, ceilings, and windows are clean and in general good repair and order.

(d) Each pharmacy has a sink with hot and cold running water within the pharmacy and maintained in a sanitary condition.

(e) There are refrigeration facilities with a thermometer in the prescription department for the proper storage of drugs requiring refrigeration. Temperatures in the refrigerator are maintained within United States Pharmacopeia standards.

(f) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.

**Equipment and Supplies.**

(a) All pharmacies have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(b) All equipment is kept in a clean and orderly manner. Equipment used in the compounding or preparation of prescription drug orders (counting, weighing, measuring, mixing, stirring, and molding equipment) is clean and in good repair.

**Library.** A reference library is maintained which includes the following:

(1) A current copy (hard-copy or electronic media access) of the Alaska Pharmacy Statutes and Regulations.

(2) At least one current or updated reference (hard-copy or electronic media access) from each of the following categories:

(A) Patient information – examples are;

(i) USP Dispensing Information; or

(ii) Patient Drug Facts; or

(iii) reference text or information leaflets which provide patient information.

(B) General information – examples are;

(i) Facts and Comparisons; or

(ii) USP Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or

(iii) Remington's Pharmaceutical Sciences.

(C) Clinical Information – examples are;

(i) AHFS Drug Information; or

(ii) Micromedex; or

(iii) Clinical Pharmacology; or

(iv) reference material pertinent to the practice setting.

(3) The telephone number of the nearest poison control center is readily available.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines on facilities, reference materials, equipment, supplies and other matters. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.400.

**STERILE PHARMACEUTICALS**
**February 2008**

**Scope and Purpose.**

The purpose of this pamphlet is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (eg. home, hospital, extended care facility, hospice, practitioner's office).

**Definitions.**

(a) "Biological Safety Cabinet" – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(b) "Class 100 Environment" – an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209D.

(c) "Cytotoxic" – a pharmaceutical that has the capability of killing living cells.

(d) "Parenteral" – a sterile preparation of drugs for injection through one or more layers of the skin.

(e) "Sterile Pharmaceutical" – dosage form free from living micro-organisms (aseptic).

**Policy and Procedure Manual.**

(a) A policy and procedure manual is prepared and maintained for the compounding, dispensing, and delivery of sterile pharmaceutical drug orders. The manual is reviewed and revised as necessary on an annual basis by the pharmacist-in-charge and is available for inspection at the pharmacy.

(b) The manual includes policies and procedures, as applicable, for:

(1) Clinical services;
(2) Sterile product handling, preparation, dating, storage and disposal;
(3) Major and minor spills of cytotoxic agents;
(4) Disposal of unused supplies and medications;
(5) Drug destruction and returns;
(6) Drug dispensing;
(7) Drug labeling;
(8) Duties and qualifications for professional and nonprofessional staff;
(9) Equipment use and maintenance;
(10) Handling of infectious waste pertaining to drug administration;
(11) Infusion devices and drug delivery systems;
(12) Training and orientation of professional and non-professional staff commensurate with the services provided;
(13) Dispensing of investigational medications;
(14) Quality control and quality assurance;
(15) Recall procedures;
(16) Infection control;
(17) Suspected contamination of sterile products;
(18) Orientation of employees to sterile technique;
(19) Sanitation;
(20) Security; and
(21) Transportation.

**Physical Requirements.**

(a) The pharmacy designates an area for the preparation of sterile products that is functionally separate from areas for the preparation of non-sterile products and is constructed to minimize traffic and airflow disturbances. It is used only for the preparation of these specialty products. It is of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy preparing parenteral products has:

(1) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environments during normal activity;

(2) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biological safety cabinets;

(3) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand washing prior to compounding;

(4) The designated area shall have hard cleanable surfaces, walls, floors and ceilings;

(5) Appropriate disposal containers for used needles, syringes, etc. and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patient's homes;

(6) Refrigerator/freezer with thermometer;

(7) Temperature controlled delivery container, if appropriate;

(8) Infusion devises, if appropriate;

(9) Supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(c) Laminar flow hood certification (or clean room certification, if applicable) are conducted at least every six months by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports are maintained for at least two years. In addition, prefilters are replaced on a regular basis and the replacement date documented.

(d) The pharmacy has current reference materials related to sterile products. These reference materials will contain information on stability, incompatibilities, preparation guidelines, and the handling of chemotherapy drug products.

**Personnel.**

(a) All personnel participating in the preparation and/or dispensing of compounded sterile pharmaceuticals are trained in this specialized function, including the principles of aseptic technique. All duties and responsibilities of personnel are consistent with their training and experience.

(b) Pharmacies providing parenteral products to non-hospitalized patients have a pharmacist accessible twenty-four hours per day to respond to patient's and other health professional's questions and needs.

**Drug Distribution and Control.**

(a) In addition to labeling required for all dispensed prescription drug orders, the labeled container of a sterile pharmaceutical bears the expiration date of the preparation based upon published data.

(b) Delivery Service. The pharmacist-in-charge assures the environmental control of all products shipped. Therefore, any compounded sterile pharmaceutical is shipped or delivered to a patient in appropriate temperature controlled (as defined by United States Pharmacopeia Standards) delivery containers and stored appropriately in the patient's home or outpatient location.

(c) Disposal of Infectious/Hazardous Waste. The pharmacist-in-charge is responsible for assuring there is a system for the disposal of cytotoxic waste and infectious waste in a manner so as not to endanger the public health.

(d) Emergency Kit. When sterile pharmaceuticals are provided to home care patients, the pharmacy may supply the licensed nurse with emergency drugs, if the prescribing practitioner has authorized the use of these drugs by a protocol for use in an emergency situation (e.g. anaphylactic shock).

**Cytotoxic Drugs.**

The following additional requirements are necessary for those pharmacies that prepare cytotoxic drugs to assure the protection of the personnel involved:

(a) All cytotoxic drugs are compounded within a vertical flow, Class II, Biological Safety Cabinet. Policy and procedures are developed for the cleaning of the laminar airflow hood between compounding cytotoxic drugs and other parenteral products, if applicable.

(b) Protective apparel is worn by personnel compounding cytotoxic drugs. This includes disposable gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs are used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents are developed and included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

**Patient Training.**

If appropriate, the Pharmacist demonstrates or documents the patient's training and competency in managing the type of therapy provided by the Pharmacist to the patient in the home environment. A pharmacist is involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The Pharmacist is responsible for seeing the patient's competency in the above areas is reassessed on an ongoing basis.

**Quality Control and Quality Assurance Procedures.**

(a) Quality Control. There is a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures are in place to assure the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures include, but are not limited to, the following:

(1) recall procedures;

(2) storage and dating;

(3) documentation of appropriate functioning of refrigerator, freezer, and other equipment;

(4) documentation of aseptic environmental control device certification and the regular replacement of prefilters;

(5) a process to evaluate and confirm the quality of the prepared pharmaceutical product; and

(6) if bulk compounding of parenteral solutions is performed utilizing non-sterile chemicals, extensive end product testing is documented prior to the release of the product from quarantine. This process includes appropriate tests for particulate matter and pyrogens.

(b) Quality Assurance.

(1) There is a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure efficient drug delivery, patient safety, and positive patient outcomes.

(2) There is documentation of quality assurance audits at regular, planned intervals which may include infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions, and drug therapy appropriateness.

(3) A plan for corrective action of problems identified by quality assurance audits is developed which includes procedures for the documentation of identified problems and action taken.

(4) A periodic evaluation of the effectiveness of the quality assurance activities is completed and documented.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.430.

(a) A pharmacist may compound drugs in limited quantities before receiving a valid prescription drug order if the pharmacist has a historical basis of valid prescription drug orders generated solely within an established relationship between the pharmacist, a patient, and a prescribing practitioner for the amount of drugs compounded. Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

(b) Compounding includes the preparation

(1) according to a prescription drug order of drugs or devices that are not commercially available;

(2) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

(c) When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription drug order or in the computerized patient medication record. The prescribing practitioner's authorization is in addition to signing to permit substitution on a prescription drug order or advising verbally that substitution is permitted. The reconstitution of commercially available products according to the manufacturer's guidelines is permissible without notice to the prescribing practitioner.

(d) A pharmacist may not offer compounded drug products to prescribing practitioners, pharmacists, or pharmacies for resale except in the course of professional practice for a prescribing practitioner to administer to an individual patient. The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is considered manufacturing.

(e) A pharmacist may receive, store, and use drug substances for compounding prescriptions that meet official compendia requirements. A pharmacist shall use the pharmacist's professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia.

**PERSONNEL**

A pharmacist engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.

**COMPOUNDING FACILITIES**

(a) A pharmacy engaging in compounding shall have a specifically designated and adequate area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area of the pharmacy must be provided. The facilities must include hot and cold water, soap or detergent, and air-driers or single use towels.

(d) The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse must be disposed of in a safe and sanitary manner.

(e) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be used in order to prevent cross-contamination.

**RECORDS AND REPORTS**

(a) A pharmacist shall keep records of all compounded products for two years. The records must be readily available for authorized inspection at the pharmacy.

(b) A pharmacist shall ensure that there are formulas maintained electronically or manually. A formula must include ingredients, amounts, methodology and equipment, if needed, and special information regarding sterile compounding.

(c) A pharmacy engaging in compounding must have written procedures for the compounding of drugs to assure that the finished products have the identity, strength, quality, and purity they are represented to possess. The procedures must include a listing of the components, their amounts in weight or volume, the order of component mixing, and a description of the compounding process. The procedures must list all equipment and utensils and the container or closure system relevant to the sterility and stability of the intended use of the drug. The procedures must be followed in the execution of the drug compounding procedure.

(d) A pharmacist shall accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist shall check these operations at each stage of the compounding process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another container, the new container must be identified with the component name and the weight or measure.

(e) To assure the reasonable uniformity and integrity of compounded drug products, written procedures must be established and followed that describe the tests or examinations to be conducted on the product compounded. The control procedures must be established to monitor the output and to validate the performance of those compounding processes that include the following when appropriate:

(1) capsule weight variation;

(2) adequacy of mixing to assure uniformity and homogeneity;

(3) clarity, completeness, or pH of solutions;

(f) A pharmacy engaging in compounding shall establish and follow appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile. The procedures must include validation of any sterilization process.

(g) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include

(1) the date of preparation;

(2) the lot numbers – the lot numbers may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If a lot number is assigned by the pharmacy, the pharmacy shall record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components;

(3) the expiration date of the finished product. This date may not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber or to be stored in until dispensing. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist;

(4) the signature or initials of the pharmacist performing the compounding;

(5) initials of the person preparing each process;

(6) initials of the pharmacist supervising each process;

(7) a formula for the compounded product maintained in a readily retrievable form;
(8) the name of the manufacturer of the raw materials;

(9) the quantity in units of finished products or grams of raw materials; and

(10) the package size and the number of units prepared.

(h) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in the product.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist on compounding practices. Professional conduct by a licensee includes adherence to these guidelines.
See 12 AAC 52.440.