February 18, 2022 - Alaska Board of Pharmacy Meeting - Day 2

Alaska Division of Corporations, Business and Professional Licensing
https://us02web.zoom.us/meeting/register/tZYucOCupj4oEtxE2ypVvkh9hQ5Zn6DQ8_Fk
Feb 18, 2022 9:00 AM - Feb 18, 2022 4:30 PM AKST

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STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

February 17-18, 2022 Meeting

Board Packet

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
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 (Chair)	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
Ashley Schaber	07/01/2021		03/01/2024

Updated 07/12/2021

State of Alaska 2022 STATE CALENDAR

State Holidays

Date	Holiday
01/01/2022	New Year's Day (observed 12/31/2021)
01/17/2022	MLK Jr.'s Birthday
02/21/2022	Presidents' Day
03/28/2022	Seward's Day
05/30/2022	Memorial Day
07/04/2022	Independence Day
09/05/2022	Labor Day
10/18/2022	Alaska Day
11/11/2022	Veterans' Day
11/24/2022	Thanksgiving Day
12/25/2022	Christmas Day (observed 12/26/2022)

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

Holiday
Payday

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 MEETING

TENTATIVE AGENDA

FEBRUARY 18, 2022 – DAY 2

Meeting ID: 823 7968 5288
Passcode: 248906

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:

Justin Ruffridge *PharmD (Chair)*

Leif Holm, *PharmD (Vice Chair)*

Ashley Schaber, *PharmD*

James Henderson, *RPh*

Lana Bell, *RPh (Secretary)*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

Staff:

Laura Carrillo, *Executive Administrator*

Heather Noe, *Occupational Licensing Examiner*

Upcoming Meetings:

TBD

Meeting Details

Meeting Name: February 18, 2022 - Alaska Board of Pharmacy Meeting - Day 2

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 02/18/2022

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 02/18/2022

Meeting Location: State Office Building, 333 Willoughby Ave, 9th Floor, Juneau, Alaska 99801 (tentatively planned in-person unless canceled due to COVID-19)

Meeting Registration Link:

https://us02web.zoom.us/meeting/register/tZYucOCupj4oEtxE2ypVvkh9hQ5Zn6DQ8_Fk

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll call/call to order (Chair Ruffridge)

II. Agenda Item #2 – 9:05 a.m. Review/approve agenda (Chair Ruffridge)

III. Agenda Item #3 – 9:10 a.m. Ethics disclosures (Chair Ruffridge)

IV. Agenda Item #4 – 9:15 a.m. Public comment #3

V. Agenda Item #5 – 9:30 a.m. Legal opinion updates

   a. White/brown bagging authority

   b. Technician with national certification

Board Members:

Justin Ruffridge *PharmD (Chair)*

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James Henderson, *RPh*

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Sharon Long, *Public Member*

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Laura Carrillo, *Executive Administrator*

Heather Noe, *Occupational Licensing Examiner*

Upcoming Meetings:

TBD

c. Medication therapy management
d. Purchaser of wholesale drugs
e. Monoclonal antibodies

VI. Agenda Item #6 – 9:45 a.m. Regulations
a. Regulations Overview
b. Released for Public Comment
i. Fee reductions (ends March 4th)
ii. Military, emergency permit, courtesy license, renewal, and executive administrator (ends March 8th)
c. DOL Review
i. Remaining 2021 project (initial applications, exam eligibility, PICs, cooperative practice, patient counseling)
ii. PDMP registration and reporting
d. Old Regulations
i. Part II regulations (kiosks, security, remote pharmacy)
ii. Refill of controlled substances (12 AAC 52.740(d)(2))
e. New Regulations
i. Intern enrollment & DEA 106 notification

VII. Agenda Item #7 – 1:00 p.m. Lunch

VIII. Agenda Item #8 – 1:30 p.m. .Pharmacy Program Presentation (William Cover & Justin Macy)

IX. Agenda Item #9 – 2:00 p.m. Statutes
a. Industry
i. White bagging/brown bagging (AKPhA)
b. Board interests
i. Technician with national certification
ii. Repeal affidavit of moral character
iii. Internet pharmacies
c. Legislation
i. HB237 – Pharmacists; dispensing of opioids
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TBD

iii. HB91/SB132 – Exempt veterinarians from PDMP

iv. HB266 – Information regarding vaccines

v. HB265 – Healthcare services by telehealth

vi. HB277 – License renewal penalty

vii. HB306 – Pharmacy sunset

viii. Other

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

XI. Agenda Item #11 – 4:15 p.m. Administrative Update (Laura Carrillo)

a. Annual reports

b. Cooperative practice agreements

c. Renewal roll-out

d. ListServ notices

e. MPJE pass rates

f. Upcoming travel/conferences/training

g. Task list review

h. Set next meeting dates

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

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

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Juneau Office

P.O. Box 110806
Juneau, Alaska 99811-0806
Main: 907.465.2550
Fax: 907.465.2974

January 28, 2022

Dear licensees and interested parties:

Alaska's professional licensing statutes (AS 08.01.065) require the Division of Corporations, Business and Professional Licensing (CBPL) to "annually review each fee level to determine whether the regulatory costs of each occupation are approximately equal to fee collections related to that occupation." Alaska's licensing fee statutes go on to say, "If the review indicates that an occupation's fee collections and regulatory costs are not approximately equal, the department shall calculate fee adjustments and adopt regulations…to implement the adjustments."

The division has conducted a thorough fee analysis and proposes a decrease in licensing fee amounts for pharmacist, pharmacy technician, and certain pharmacy licenses to comply with AS 08.01.065. The analysis reflected the need to decrease the fees for FY2022 renewal to prevent the accumulation of large surplus. The proposed fee amounts are enclosed and can also be found on the Board of Pharmacy web page at http://professionallicense.alaska.gov/boardofpharmacy.

This fee proposal is entering a public comment period. The division encourages all licensees and interested parties to comment on this proposal through the division's regulations specialist. After the comment period closes and the division reviews all comments received, the division may adopt the regulation as drafted, may amend a proposed fee, or may withdraw the regulations in part or in whole.

All comments received will be reviewed and taken into consideration prior to adopting the final regulations. The final decision will result in fee implementation prior to the upcoming license renewal.

Follow the instructions enclosed to make written comments during the public comment period. Comments must be addressed to CBPL Regulations Specialist, PO Box 110806, Juneau, AK 99811 or regulationsandpubliccomment@alaska.gov.

Sincerely,

Sara Chambers

Sara Chambers
Division Director

NOTICE OF PROPOSED CHANGES TO OCCUPATIONAL LICENSING FEES FOR PROFESSIONS REGULATED BY THE BOARD OF PHARMACY IN THE REGULATIONS OF THE DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT

BRIEF DESCRIPTION: The Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing proposes to decrease occupational licensing fees charged to occupations regulated by the Board of Pharmacy.

The Department of Commerce, Community, and Economic Development (Department) proposes to adopt regulation changes in Title 12, Chapter 02 of the Alaska Administrative Code including the following:

> **12 AAC 02.310. Board of Pharmacy,** is proposed to decrease the application, license, registration, and renewal fees for pharmacists, pharmacy technicians, remote and other pharmacies, wholesale drug distributors, outsourcing facilities, and third-party logistics providers.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Department will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/205262, and using the comment link. **The comments must be received not later than 4:30 p.m. on March 4, 2022.** Comments received after this deadline will not be considered by the Department.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. **The questions must be received at least 10 days before the end of the public comment period.** The Department will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Department may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than February 25, 2022 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-Fees-2022.pdf.

After the public comment period ends, the Department will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.01.065; AS 08.80.159; AS 08.80.160
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.01.065; AS 08.80.159; AS 08.80.160

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

DATE: 1/28/2022 /s/

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

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Department of Commerce, Community, and Economic Development – Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Occupational licensing fees.

3. **Citation of regulation:** 12 AAC 02.310.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Compliance with state statute.

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: Fees decrease will range from $25 to $100 depending on type of license; decrease application fee for pharmacy technicians to zero.
   Another state agency: None known.
   A municipality: None known.

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2022 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Laura Carrillo, Executive Administrator
   Alaska Board of Pharmacy
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
   Telephone: (907) 465-1073
   E-mail: laura.carrillo@alaska.gov

10. **The origin of the proposed action:** Division of Corporations, Business and Professional Licensing.

11. **Date:** 1/28/2022 **Prepared by:** /s/
    Jun Maiquis
    Regulations Specialist

Chapter 02. General Occupational Licensing Functions.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted.)

12 AAC 02.310 is amended to read:

12 AAC 02.310. Board of Pharmacy. (a) The following fees are established for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, wholesale drug distributors, [AND] drug dispensaries**, outsourcing facilities, and third-party logistics providers**:

(1) nonrefundable application fee for initial license, $100**, except that the fee for pharmacy technicians is $0**;

(2) [REPEALED 10/28/2000;

(3)] temporary pharmacist license fee, $50;

(3) [(4)] emergency permit to practice pharmacy fee, $100;

(4) [(5)] pharmacy intern license fee, $30.

(b) The following license and registration fees for all or part of the initial biennial licensing or registration period and subsequent biennial license and registration renewal fees are established for pharmacists, pharmacy technicians, remote and other pharmacies, [AND] wholesale drug distributors**, outsourcing facilities, and third-party logistics providers**:

(1) pharmacist, **$100** [$200];

(2) wholesale drug distributor, **$425** [$500];

(3) pharmacy, $200;

(4) drug room, **$150** [$200];

(5) registered pharmacy located outside of the state, **$550** [$600];

(6) pharmacy technician, **$25** [$50];

(7) remote pharmacy, $200;

(8) non-resident wholesale drug distributor, **$550** [$600];

(9) outsourcing facility, **$550** [$600];

(10) third-party logistics provider, **$550** [$600]. (Eff. 11/20/86, Register 100; am 10/1/88, Register 107; am 5/28/93, Register 126; am 10/19/97, Register 144; am 10/28/2000, Register 156; am 6/13/2002, Register 162; am 6/23/2004, Register 170; am 2/15/2006, Register 177; am 5/18/2006, Register 178; am 6/11/2010, Register 194; am 5/18/2014, Register 210; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.01.065 AS 08.80.159 AS 08.80.160

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

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update regulations regarding its qualifications and requirements to apply for an emergency permit and renewal application requirements for pharmacists, pharmacy technicians, pharmacies, outsourcing facilities, wholesale drug distributors, and third-party logistics providers. It also proposes to repeal the emergency courtesy license, update duties of its executive administrator as it relates to renewal application processing, and establish temporary courtesy licenses for an active duty military member or their spouse.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. **12 AAC 52.105. Temporary military courtesy licenses,** is a proposed new section that establishes temporary courtesy licenses for an active duty military member or spouse of an active duty military member of the armed forces of the United States to practice as a pharmacist, pharmacy intern, or pharmacy technician. The proposed regulations will allow for an expedited temporary licensing pathway for those in the military and their spouse.

2. **12 AAC 52.110. Emergency permit to practice as a pharmacist, pharmacy intern, or pharmacy technician,** is proposed to amend the emergency permit language as the intent was duplicative to the emergency courtesy license option.

3. **12 AAC 52.300. License renewal,** is proposed to update language to be all inclusive of pharmacy license and registration types; clarifies renewal must be on department form; replaces copy of inspection report for pharmacies or facilities with an attestation; clarifies eligibility for renewal or new application required if there is a change; and adds administrative and executive administrator processing language.

4. **12 AAC 52.993. Executive administrator,** is proposed to amend the executive administrator's duties by adding the ability to review and approve licenses or registrations as long as the applicant meets the requirements of the established checklist as codified in the regulations; clarifies role of executive administrator; creates efficiencies by allowing task delegation of the board to staff.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/205318, and using the comment link. **The comments must be received not later than 4:30 p.m. on March 8, 2022.** Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. **The questions must be received at least 10 days before the end of the public comment period.** The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this

process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than March 1, 2022 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0222.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.01.062; AS 08.01.063; AS 08.01.100; AS 08.80.005; AS 08.80.030; AS 08.80.147; AS 08.80.150; AS 08.80.155; AS 08.80.157; AS 08.80.165; AS 08.80.261; AS 08.80.270

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

DATE: 2/2/2022

/s/

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

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Board of Pharmacy – Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Temporary military courtesy licenses, emergency permit, license renewal, and executive administrator.

3. **Citation of regulation:** 12 AAC 52.105, 12 AAC 52.110, 12 AAC 52.300, and 12 AAC 52.993.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Update and clarification of current regulations, and to implement statutory changes made under Sections 1 and 2, Chapter 29, SLA 2021 (SB 21).

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: $100 application fee and $100 temporary military courtesy license fee.
   Another state agency: None known.
   A municipality: None known.

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2022 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Laura Carrillo, Executive Administrator
   Alaska Board of Pharmacy
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
   Telephone: (907) 465-1073
   E-mail: laura.carrillo@alaska.gov

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

11. **Date:** 2/2/2022 **Prepared by:** /s/
    Jun Maiquis
    Regulations Specialist

Chapter 52. Board of Pharmacy.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)

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

12 AAC 52.105. Temporary military courtesy licenses. (a) The board shall issue a temporary military courtesy license to an active duty military member or spouse of an active duty military member of the armed forces of the United States to practice as a pharmacist, pharmacy intern, or pharmacy technician who meets the requirements of AS 08.01.063 and this section within 30 days after the board receives a completed application.

(b) An applicant for a temporary military courtesy license under this section must

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

(2) pay the temporary license application and license fees set out under 12 AAC 02.105;

(3) submit a copy of the applicant's military identification or military dependent identification card and a copy of current active duty military orders showing assignment to a duty station in this state;

(4) submit verification on a form provided by the department that the applicant is currently licensed 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; and

(5) not have been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacist, pharmacy intern, or pharmacy technician competently and safely.

(c) A temporary military courtesy license to active duty military personnel or spouse of

military personnel under this section will be issued for a period of 180 days and may be renewed for one additional period specified by the board, not to exceed 180 days.

(d) For an applicant applying for licensure under this section as a pharmacy technician, the board will accept as substantially equivalent any training completed while in the United States armed forces to work as a pharmacy technician or any technician license issued by another jurisdiction.

(e) While practicing under a temporary military courtesy license issued under this section, the holder of the temporary military courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(f) The board may refuse to issue a temporary military courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261. (Eff. ____/____/_____, Register _____)

Authority: AS 08.01.062 AS 08.80.005 AS 08.80.150
AS 08.01.063 AS 08.80.030 AS 08.80.261

12 AAC 52.110 is amended to read:

12 AAC 52.110. Emergency <u>permit</u> [LICENSURE] to practice as a pharmacist, pharmacy intern, or pharmacy technician. (a) **<u>An emergency permit may be issued to practice as a pharmacist, pharmacy intern, or pharmacy technician in an urgent situation as determined by the board if the applicant</u>** [IF THE BOARD DETERMINES THAT AN EMERGENCY EXISTS REQUIRING THE PROVISION OF LICENSED COVERAGE IN A PHARMACY THAT IS TEMPORARILY WITHOUT THE SERVICES OF A PHARMACIST DUE TO DEATH, ILLNESS, OR OTHER EMERGENCY CIRCUMSTANCES, THE BOARD MAY ISSUE AN EMERGENCY PHARMACIST, PHARMACY INTERN, OR PHARMACY

TECHNICIAN PERMIT TO AN APPLICANT WHO]

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

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits verification on a form provided by the department that the applicant is currently licensed 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;

(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 [UNDER (a) OF THIS SECTION] is nonrenewable, and is valid for **120 consecutive** [90] days or until the **urgent situation is determined by the board to** [EMERGENCY CIRCUMSTANCES] no longer exist, whichever is **sooner** [SHORTER].

(c) Repealed 11/19/2020.

(d) **Repealed / /** [IN AN URGENT SITUATION, THE BOARD MAY ISSUE AN EMERGENCY COURTESY LICENSE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN TO AN APPLICANT WHO MEETS THE REQUIREMENTS OF THIS SECTION. THE BOARD MAY RESTRICT THE LICENSE TO ONLY THOSE SERVICES REQUIRED TO RESPOND TO THE URGENT SITUATION. THE LICENSEE MAY NOT PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN OUTSIDE THE SCOPE OF THE LIMITED PURPOSE FOR WHICH THE EMERGENCY COURTESY LICENSE IS ISSUED].

(e) **Repealed / /** [AN APPLICANT FOR AN EMERGENCY COURTESY LICENSE UNDER THIS SECTION MUST SUBMIT TO THE DEPARTMENT A

COMPLETED APPLICATION ON A FORM PROVIDED BY THE DEPARTMENT. A COMPLETE APPLICATION INCLUDES THE APPLICABLE APPLICATION AND LICENSING FEES ESTABLISHED IN 12 AAC 02.105].

(f) **Repealed / /** [AN EMERGENCY COURTESY LICENSE ISSUED UNDER THIS SECTION IS VALID FOR THE PERIOD SPECIFIED BY THE BOARD AND MAY NOT EXCEED 120 CONSECUTIVE DAYS. AN EMERGENCY COURTESY LICENSE MAY BE RENEWED FOR ONE ADDITIONAL PERIOD SPECIFIED BY THE BOARD, NOT TO EXCEED 120 CONSECUTIVE DAYS].

(g) The board will not issue, and an emergency **permit** [COURTESY LICENSE] holder may not use, an emergency **permit** [COURTESY LICENSE] as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency **permit** [COURTESY LICENSE ISSUED UNDER THIS SECTION], the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency **permit** [COURTESY LICENSE] for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns**,** [.] or pharmacy technicians. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 8/12/2007, Register 183; am 10/31/2019, Register 232; am 11/19/2020, Register 236; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.300 is amended to read:

12 AAC 52.300. License renewal. (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 **must** [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) **an 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. 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**;

(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.

(g) All renewal applications will be administratively processed and will not require board review unless the executive administrator has reason to believe that renewing the license poses an immediate threat to public health or safety. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

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 52.993 is amended to read:

12 AAC 52.993. Executive administrator. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance 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**;**

(6) review and approve applications for licensure or registration as long as the applicant meets the requirements established for the license type for which they are applying. (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

Chapter 52. Board of Pharmacy.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted. Complete new sections are not in boldface or underlined.)

12 AAC 52.020 is repealed and readopted to read:

12 AAC 52.020. Pharmacy license. (a) An applicant for a pharmacy license ~~that meets the below requirements established as a checklist~~ shall submit the items required in (~~a~~b) ~~(e)~~ of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board.

(b) An applicant for a pharmacy license shall submit

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

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

(3) an attestation that within 14 days after commencement of business, a self-inspection 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.

(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. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030 is repealed:

12 AAC 52.030. Change of pharmacy location or name. Repealed ____/____/_____

[(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]. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 1/17/2007, Register 181; repealed ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.040 is repealed:

12 AAC 52.040. Change of pharmacy ownership. Repealed ____/____/_____ [(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]. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/11/2004, Register 169; am 1/17/2007, Register 181; repealed ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.070 is amended to read:

12 AAC 52.070. Application for pharmacist license by examination. (a) An applicant **for a pharmacist license by examination** ~~who meets the **below** requirements **established as a checklist** ~~**shall submit the items required in this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualification for licensure must be reviewed and approved by the board** [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) **a copy of the original pharmacy school diploma issued to the applicant** [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.

(c) An applicant who meets the requirements of subsection (b) of this section will be eligible ~~Eligibility~~ to take the examination required under 12 AAC 52.090 ~~will be issued to the applicant after complete submission of the items required in (b)(1) – (6) of this section~~.

(Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 7/1/2007, Register 182; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

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 52.080 is amended to read:

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) **Repealed ____/____/_____** [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]. (Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 2/15/2006, Register 177; am 4/16/2016, Register 218; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.092 is amended to read:

12 AAC 52.092. Eligibility [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 **12 AAC 52.070** [(b) OF THIS SECTION] may be **granted eligibility by the board staff** [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].

Commented [HCD1]: Why "may?" why not say "will be approved to take the . . . . exam"

(b) **Repealed ____/____/_____** [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]. (Eff. 7/1/2007, Register 182; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095 is amended to read:

12 AAC 52.095. Application for pharmacist license by reciprocity. (a) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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 **a pharmacist license by reciprocity** ~~**who meets the below requirements established as a checklist**~~ **shall submit the items required in this section for review and approval by the executive administrator. An application that does not clearly demonstrate~~s~~ qualifications for licensure must be reviewed and approved by the board. An**

applicant for a pharmacy license shall submit [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) **a copy of the original pharmacy school diploma issued to the applicant from a college of pharmacy accredited by the ACPE;** [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 and that the license in that jurisdiction is current and unencumbered;

(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) **repealed ____/____/_____** [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 Pharmaceutics 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) **repealed ____/____/_____** [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].

Commented [HCD2]: You could also say "in good standing" but "unencumbered" covers more circumstances and is less subject to interpretation. You could say "current, unencumbered, and in good standing."

Commented [HCD3]: This is OK; I just think it works better in the earlier paragraph. Either way, "good standing" gets argued about, so I have advised using "unencumbered" because that includes licenses that may be in "good standing" but still subject to some continuing disciplinary requirements. Small point.

(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.

(e) The board will accept documentation of passing the NAPLEX in the Official Application for Transfer of Pharmaceutic Licensure in (c)(9) of this section. (Eff. 7/1/2007, Register 182; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

Commented [HCD4]: What does this mean? That this is the ONLY proof they will accept? If so, this should be rephrased.

Commented [CLN(5R4]: Yes, it is the only proof- maybe this subsection isn't necessary with how (c)(9) is already stated? OR reword the last sentence in (9) to say:

This license transfer application will serve as a verification of licensure from the reciprocating state. The license must be unencumbered.

12 AAC 52.120 is amended to read:

12 AAC 52.120. Review of pharmacist intern license application. (a) **Repealed** ____/____/_____ [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 REVIEW 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

Commented [HCD6]: This sentence is unnecessary because there is no checklist, and the regs don't need to say who is issuing the license, as long as whoever it is has authority under the statute. This section seems to be different from the others, where a license would be issued more or less automatically, by the staff, if the identified things were submitted. And in those sections, the alternative – as where some things might be missing or incomplete – would mean the application would have to be reviewed by the board, which would take longer. Correct?

department;

(2) pays the **applicable fees** [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) **repealed ____/____/_____** [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) **repealed ____/____/_____** [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 **five** [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.

(f) ~~An~~ A pharmacist intern license may not be renewed. 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. (Eff. 1/16/98, Register 145; am 2/11/2004, Register 169; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am 11/16/2012, Register 204; am 7/9/2017, Register 223; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130 is amended to read:

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) **submits a complete, notarized application on a form provided by the department** [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 **applicable fees** [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 **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**.

(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.

Commented [HCD7]: Huh? This is confusing – this could mean two really different time periods. Consider rewording – (or at least explaining it to me).

Commented [CLN(8R7]: Agree the last part is confusing.

Commented [HCD9]: You don't need this, as it is probably like all other permit and license documentation that must be maintained. And what is the reason for the provision that follows? Consider whether the agency's document retention plans require this anyway.

(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. (Eff. 1/16/98, Register 145; am 6/2/2004, Register 170; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140 is amended to read:

12 AAC 52.140. Pharmacy technician license. (a) An applicant ~~who meets the~~ **below** ~~requirements~~ ~~**established as a**~~ ~~[ON THE] checklist~~ ~~**for licensure as**~~ [SET OUT IN (b) OF THIS SECTION HAS DEMONSTRATED THE NECESSARY QUALIFICATIONS FOR] ~~a pharmacy technician~~ **shall submit the requirements in (b) of this section for review and approval by the executive administrator. An application that does not clearly demonstrate qualifications for licensure must be reviewed and approved by the board** [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) **A** [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 **applicable fees** [APPLICATION FEE AND THE PHARMACY TECHNICIAN LICENSE FEE] established in 12 AAC 02.310.

(c) **Repealed ____/____/_____** [A PHARMACY TECHNICIAN LICENSE EXPIRES ON JUNE 30 OF EVEN-NUMBERED YEARS AND MAY BE RENEWED]. (Eff. 1/16/98, Register 145; am 2/15/2006, Register 177; am 1/17/2007, Register 181; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.200 is amended to read:

12 AAC 52.200. Pharmacist-in-charge. (a) **Repealed ____/____/_____** [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

Commented [HCD10]: Are these requirements no longer current?

Commented [CLN(11R10]: I believe it is because this requirement is already included in 12 AAC 52.020

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) **ensuring adequate** [ESTABLISHING] policies and procedures **are in place** for pharmacy operations;

(4) maintaining required records;

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

(6) **ensuring** [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)].

(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.

(Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330

12 AAC 52.230 is amended to read:

12 AAC 52.230. Pharmacy technicians. (a) **An** [THE FOLLOWING PERSONS MUST BE LICENSED AS A PHARMACY TECHNICIAN:

(1) AN] individual who assists in performing [MANIPULATIVE, NONDISCRETIONARY] functions ~~associated with~~included in the definition of 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].

(b) **Repealed ____/____/_____** [A PHARMACY TECHNICIAN SHALL WORK UNDER THE DIRECT SUPERVISION OF A PERSON WHO IS LICENSED AS A PHARMACIST].

(c) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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, **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.

Commented [HCD12]: "associated with" could include purely administrative tasks, and those would not need a license.

(f) **Repealed ____/____/_____** [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

(1) bookkeepers; or

(2) any person ~~who's~~ whose only function is distributing completed prescription drug orders to a patient or patient's agent. (Eff. 1/16/98, Register 145; am 4/4/2002, Register 162; am 1/23/2003, Register 165; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.240 is repealed and readopted to read:

12 AAC 52.240. Pharmacist collaborative practice authority. (a) To initiate or modify drug therapy in accordance with a written protocol, an authorizing pharmacist may file a joint application with a practitioner authorized to prescribe drugs under AS 08 to engage in a cooperative practice agreement in the pharmacist's practice. 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.~~

(b) The Board of Pharmacy will endorse approve a cooperative practice agreement if the

Commented [HCD13]: Consider saying "persons whose responsibilities are purely administrative, including bookkeepers, accountants, administrative staff and persons who transport or deliver completed prescriptions to a patient or patient's agent."

Commented [HCD14]: "cooperative" or "collaborative?"

Commented [CLN(15R14]: Cooperative so it aligns with the MED regulations.

applicant provides~~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

(4) documentation of 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 endorsing the cooperative practice agreement.

(d) 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.

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

(f) 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. (Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register 204; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.470(d) is amended to read:

12 AAC 52.470. Refills.

. . .

(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 and consistent with applicable law, including refills [;

(2) DRUG IS NOT A FEDERAL OR STATE SCHEDULED CONTROLLED SUBSTANCE].

. . .

(Eff. 1/16/98, Register 145; am 6/29/2018, Register 226; am 4/3/2020, Register 234; am 8/30/2020, Register 235; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.585 is amended to read:

12 AAC 52.585. Patient [MANDATORY PATIENT] counseling. (a) **Following the review of a patient's record, if deemed necessary by the pharmacist, 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 **pharmacist** [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) **If a** [A] pharmacist **or pharmacist intern provides counseling, they may provide the counseling by any verbal, written, or electronic means** [SHALL COUNSEL THE PATIENT OR THE PATIENT'S AGENT FACE-TO-FACE. IF FACE-TO-FACE COUNSELING IS NOT POSSIBLE, A PHARMACIST SHALL MAKE A REASONABLE

Commented [HCD16]: Without all the illustrative factors, this is awfully vague. Perhaps there is a middle ground?

Commented [HCD17]: What is the basis for interns having this authority?

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) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [THIS SECTION DOES NOT REQUIRE A PHARMACIST TO PROVIDE PATIENT COUNSELING WHEN A PATIENT OR THE PATIENT'S CAREGIVER REFUSES THE COUNSELING].

(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 or opioid dependency

(~~1) the pharmacist or pharmacist intern may use the PDMP to determine if the patient has previously had an opioid drug; and~~

~~(2) 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~~. (Eff. 1/16/98, Register 145; am 5/15/2004, Register 170; am 7/9/2017, Register 223; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.610 is amended to read:

Commented [HCD18]: This is not necessary, as pharmacists can always do this. That is what the PDMP is for.

Commented [HCD19]: Huh?? Whatever this means, it is likely a no-go, because periodic violations are still violations, as are unintentional ones, and you cant really have a regulation that makes this broad a category of "violations" be not violations.

12 AAC 52.610. Wholesale drug distributor license. (a) **Repealed ____/____/_____** [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 **applicable** fees required in 12 AAC 02.310;

(3) **repealed ____/____/_____** [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 [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

Commented [HCD20]: See previous comments

Commented [HCD21]: By whom? This applies to earlier instance of this same language.

Commented [CLN(22R21]: Must be retained by the licensee

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

(6) **repealed ____/____/_____** [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) **Repealed ____/____/_____** [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 **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].

(e) **Repealed ____/____/_____** [WHEN A WHOLESALE DRUG DISTRIBUTOR CEASES OPERATIONS, THE FACILITY MANAGER OF THE WHOLESALE DRUG DISTRIBUTOR SHALL NOTIFY THE BOARD ON A FORM PROVIDED BY THE

DEPARTMENT OF THE CESSATION OF OPERATIONS; THE FORM MUST BE SUBMITTED WITHIN 10 DAYS AFTER THE CESSATION OF OPERATIONS]. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am ____/____/_____, Register _____)

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 is amended to read:

12 AAC 52.696. Outsourcing facilities. (a) **Repealed ____/____/_____** [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 **applicable** fees required in 12 AAC 02.310;

(3) **repealed ____/____/_____** [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 **an 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**;

Commented [HCD23]: Same issue

(6) **repealed ____/____/_____** [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) **Repealed ____/____/_____** [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) **Within 30 days after a change in physical address, ownership, or** [THE FACILITY MANAGER OF AN OUTSOURCING FACILITY THAT HAS CHANGED ITS] name**, the facility manager** [OR PHYSICAL ADDRESS] must apply for a new and separate outsourcing facility license in accordance with [(b) OF] this section.

(e) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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)]. (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.697 is amended to read:

12 AAC 52.697. Third-party logistics providers. (a) **Repealed ____/____/_____** [AN APPLICANT MUST MEET THE REQUIREMENTS SET OUT IN (b) OF THIS SECTION TO DEMONSTRATE THE NECESSARY QUALIFICATIONS FOR A THIRD-PARTY LOGISTICS PROVIDER 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 PROVIDERS 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) **repealed ____/____/_____** [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; **and**

(5) submits **an 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) **repealed ____/____/_____** [SUBMITS COMPLETED FINGERPRINT CARDS OF THE FACILITY MANAGER FOR EVALUATION AND INVESTIGATION BY THE DEPARTMENT OF PUBLIC SAFETY].

(c) **Repealed ____/____/_____** [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

Commented [HCD24]: Same issue

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] must apply for a new and separate third-party logistics provider license in accordance with [(b) OF] this section.

(e) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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) **Repealed ____/____/_____** [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]. (Eff. 10/31/2019, Register 232; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52.860 is amended by adding a new subsection to read:

(f) For the purposes of AS 17.30.200(d)(9), "state medical examiner" means an employee of the State Medical Examiner's Office who has requested access in writing to the board before the release of information. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

Commented [HCD25]: Consider some qualifier, like "with appropriate authority" – otherwise this could be anyone.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865 is amended to read:

12 AAC 52.865. Reporting and reviewing PDMP information. (a) Unless excused from reporting under AS 17.30.200(t), a **pharmacist-in-charge** [PHARMACIST] must submit information **on behalf of the employing pharmacy** required under AS 17.30.200(b) **and other details required by the American Society of Automation in Pharmacy (ASAP)**, if the pharmacist-in-charge is not present**, a pharmacist or third-party vendor may report on behalf of the pharmacy. A practitioner, practitioner's delegate, or third-party vendor may also report on behalf of the practitioner**.

(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) **If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled substances on the previous day, the pharmacist or practitioner must submit a zero report.**

(d) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(e) [(d)] For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the

purposes of 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.

(f) [(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] **notify** 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).

(g) [(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.

(h) To submit data for an animal prescription, a pharmacist or veterinarian must report

(1) the first name of the animal;

(2) last name of the owner;

(3) date of birth of the owner;

(4) species of the animal;

(5) address of the owner;

(6) name, quantity, and dose of the drug; and

(7) other details required by ASAP standards, including the correct species code, PAT 02.

Commented [HCD26]: What is this?

Commented [CLN(27R26]: Patient = 02 "PAT 02" means it is a prescription for an animal as opposed to a human, which is coded as "PAT 01"

(i) [(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.

(j) A veterinarian required to review the PDMP under AS 17.30.200(k) satisfies this requirement by reviewing data pertaining to the animal's owner identified in 12 AAC 68.100.

(k) Substance Use Disorder (SUD) treatment programs operating as a Part 2 program may redisclose a patient's data to the PDMP as a lawful holder only if

(1) patient consent authorizing disclosure of data to the PDMP is given;

(2) follows security protocols required under 42 C.F.R. Section 2.16;

(3) release records to law enforcement only under a valid court order ~~under 42 C.F.R. Section 2.12, 2.13, and 2.65.~~

(*l*) A Part 2 program redisclosing data to the PDMP must

(1) notify the board on a form provided by the department certifying it will comply with (k) of this section; and

(2) submit a blank copy of the patient consent form.

(m) As used in this section,

(1) "reporting vendor" means any third-party agency contracted or otherwise permitted by the pharmacy, clinic, hospital, or other facility in which the pharmacist or provider is employed, to report data daily to the PDMP;

(2) "lawful holder" means any individual or entity who receives Part 2 protected records pursuant to a written patient consent or one of the exceptions to the consent requirement in 42 C.F.R. Section 2.12(d)(2)(i)(C);

(3) "Part 2 program" means a federally assisted Substance Use Disorder (SUD) treatment programs, including an opioid treatment program (OPT), regulated under 42 U.S.C. 290dd-2 and 42 C.F.R. Part 2. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

Commented [HCD28]: Is this correct?

Commented [CLN(29R28]: Maybe should be "as described in 12 AAC 68.990(1)"? This is the definition for "client"

Commented [HCD30]: Who??

Commented [CLN(31R30]: SUD provider

Commented [HCD32]: Needs rewording

Commented [HCD33]: This is OK, but not really necessary as it is included in the word "valid."

Commented [HCD34]: What patient consent form, and to whom must it be submitted?

Commented [CLN(35R34]: Maybe the patient consent form is the piece the board doesn't regulate (DHSS instead?)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

MEMORANDUM

State of Alaska
Department of Law

To: The Honorable Kevin Meyer
Lieutenant Governor

Date: February 7, 2022

File No.: 2021200355

From: Rebecca C. Polizzotto
Chief Assistant Attorney General
and Regulations Attorney
Legislation, Regulations,
and Legislative Research Section

Tel. No.: 907-465-3600

Re: Department of Commerce, Community, and Economic Development; Board of Pharmacy: amendment to 12 AAC 52; PDMP database registration, renewal, and dispensing status notice requirements

The Department of Law has reviewed the attached regulations of the Department of Commerce, Community, and Economic Development against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The Board of Pharmacy adopted the regulations after the close of the public comment period on December 7, 2021. The regulations amend 12 AAC 52 to update requirements concerning Alaska's prescription drug monitoring program (PDMP), as they relate to registration and renewal. Additionally, these regulations add a new section to 12 AAC 52 requiring that a pharmacist or pharmacy that has a change in PDMP status prohibiting that pharmacist or pharmacy from dispensing controlled substances be required to report that change in status to the department.

A number of technical edits are suggested to these regulations in order to clarify and keep consistent the language throughout 12 AAC 52 and to comport with the standards of the Drafting Manual for Administrative Regulations. None of these edits are substantive in nature.

The August 15, 2021 public notice states that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

RCP:bws

cc w/ enclosures: Jun Maiquis, Regulations Contact
Division of Corporations, Business, and Professional Licensing
Department of Commerce, Community & Economic Development

Harriet Milks, Senior Assistant Attorney General
Department of Law

ORDER CERTIFYING THE CHANGES TO REGULATIONS OF THE BOARD OF PHARMACY

The attached three pages of regulations, dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its November 18, 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: _____

Laura Carrillo Digitally signed by Laura Carrillo Date: 2021.12.07 14:55:14 -09'00'

Laura Carrillo, Executive Administrator
Alaska Board of Pharmacy

FILING CERTIFICATION

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

_____
Kevin Meyer, Lieutenant Governor

Effective: _____.

Register: _____.

Chapter 52. Board of Pharmacy.

12 AAC 52.855(c) is amended to read:

(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 database ((bold/U.L.)) **by providing** [WEBSITE; AND]

(A) ~~**a non-shared e-mail address;**~~ an electronic mail address corresponding to an electronic mail account accessible to and utilized exclusively by the registering pharmacist or practitioner; ((bold/U.L.))

(B) password; ((bold/U.L.)) created by the registrant at the time of registration that meets the minimum requirements set by the PDMP database; ((bold/U.L.))

(C) user role; ((bold/U.L.)) selected from the options provided by the PDMP database that most closely corresponds to the registrant's professional role; ((bold/U.L.))

(D) ((bold/U.L.)) the registrant's **healthcare specialty;**

(E) the DEA number issued to the ~~**prescriber**~~ registrant ((bold/U.L.)) **or if a pharmacist, the** number ((bold/U.L.)) **employer's DEA; and**

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

12 AAC 52.855(d) is amended to read:

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a ~~**registration number**~~ PDMP designation ((bold/U.L.)) [USER ACCOUNT, LOGIN NAME, AND PASSWORD BY THE DEPARTMENT].

12 AAC 52.855(e) is amended to read:

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP database ((bold/U.L.)) using the **credentials identified in (c)(1)(A) and (B) of this section** [USER ACCOUNT, LOGIN NAME, AND PASSWORD ISSUED BY THE DEPARTMENT].

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am

____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

12 AAC 52.856. PDMP ~~registration~~ designation (Board only?) renewal. (a) A PDMP ~~registration will expire~~ designation expires on the same date as the pharmacist's or practitioner's corresponding professional license.

(b) To renew a PDMP ~~registration~~ designation, a licensee ~~required to register~~ must submit the fee established in 12 AAC 02.107 on or before the PDMP designation expiration date. (Eff. ____/____/_____, Register

_____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

12 AAC 52.857. Change in dispensing or distributing of controlled substances. (a) A pharmacist ~~registered~~ with ~~the~~ a PDMP registration under 12 AAC 52.855 must notify the board on a form provided by the department when the pharmacist changes their PDMP status to no longer ~~dispenses~~ dispense controlled substances in this state, ~~within~~ not later than 10 days ~~of~~ from (date of the) the change in dispensing status.

(b) A pharmacist who is not required to register with the PDMP and who has met the requirements in 12 AAC 52.855(b) must comply with the requirements in 12 AAC 52.855(c) ~~within~~ not later than 10 days ~~of any~~ from the date of a change in practice that requires the pharmacist to register with the PDMP.

(c) A pharmacy required to report to the PDMP that no longer dispenses or distributes controlled substances in or to this state must notify the board on a form provided by the department ~~within~~ not later than 10 days ~~of~~ from the date 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 must notify the board on a form provided by the department ~~within~~ not later than 10 days from the date the DEA registration is issued to the pharmacy. ~~of its intent to dispense or distribute controlled substances.~~ (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update regulations relating to registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, and to establish PDMP registration renewal and change in dispensing or distributing of controlled substances.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. **12 AAC 52.855. Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database,** is proposed to amend the registration process with the PDMP.

2. **12 AAC 52.856. PDMP registration renewal,** is a proposed new section that establishes PDMP biennial registration renewal requirements.

3. **12 AAC 52.857. Change in dispensing or distributing of controlled substances,** is a proposed new section that establishes requirements for pharmacists who no longer dispenses or distributes controlled substances in Alaska to notify the board of the change in practice.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/203411, and using the comment link. **The comments must be received not later than 4:30 p.m. on September 16, 2021.** Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. **The questions must be received at least 10 days before the end of the public comment period.** The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than September 9, 2021 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0821.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. **You should comment during the time allowed if your interests could be affected.** Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.80.005; AS 08.80.030; AS 17.30.200
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.80.005; AS 08.80.030; AS 17.30.200

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

DATE: 8/13/21

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

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION
(AS 44.62.190(d))

1. **Adopting agency:** Board of Pharmacy – Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.

2. **General subject of regulation:** Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances.

3. **Citation of regulation:** 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857.

4. **Department of Law file number:** To be assigned.

5. **Reason for the proposed action:** Update and clarification of current regulations; compliance with state statute.

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing – #2360.

7. **Estimated annual cost to comply with the proposed action to:**
   A private person: $25 PDMP biennial registration renewal fee.
   Another state agency: None known.
   A municipality: None known.

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2022 or in subsequent years.

9. **The name of the contact person for the regulation:**
   Laura Carrillo, Executive Administrator
   Alaska Board of Pharmacy
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
   Telephone: (907) 465-1073
   E-mail: laura.carrillo@alaska.gov

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

11. **Date:** 8/13/21 **Prepared by:** _____
    Jun Maiquis
    Regulations Specialist

AFFIDAVIT OF NOTICE OF PROPOSED REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857, dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances, has been given by being

1. published in a newspaper or trade publication;
2. furnished to every person who has filed a request for notice of proposed action with the state agency;
3. furnished to appropriate state officials;
4. furnished to interested persons;
5. furnished to the Department of Law, along with a copy of the proposed regulation;
6. furnished electronically to incumbent State of Alaska legislators;
7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (2), (4), and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

DATE: 12/9/21

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 9 day of December, 2021.

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

Jolene Siirila
My Commission Expires
NOTARY PUBLIC
With Office
State of Alaska

AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy regulations on dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances.

DATE: 12/9/21

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this 9 day of December, 2021.

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

Jolene Siirila
My Commission Expires
NOTARY PUBLIC
With Office
State of Alaska

ANCHORAGE DAILY NEWS

AFFIDAVIT OF PUBLICATION

Account #: 105545 ST OF AK/DEC/OCCU
Attention To: ATTN TO: JUN MAIQUIS
PO BOX 110806, JUNEAU, AK 99811

Order #: W0024503 Cost: $478.12

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STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Adam Garrigus being first duly sworn on oath deposes and says that she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

08/15/2021

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate charged private individuals.

Signed

Subscribed and sworn to before me
this 16th day of August 2021.

Notary Public in and for
The State of Alaska.
Third Division
Anchorage, Alaska

MY COMMISSION EXPIRES
7/14/2024

NOTARY PUBLIC
JADA L. NOWLING
STATE OF ALASKA
MY COMMISSION EXPIRES July 14, 2024

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

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. 12 AAC 52.855. Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, is proposed to amend the registration process with the PDMP.
2. 12 AAC 52.856. PDMP registration renewal, is a proposed new section that establishes PDMP biennial registration renewal requirements.
3. 12 AAC 52.857. Change in dispensing or distributing of controlled substances, is a proposed new section that establishes requirements for pharmacists who no longer dispenses or distributes controlled substances in Alaska to notify the board of the change in practice.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/203411, and using the comment link. The comments must be received not later than 4:30 p.m. on September 16, 2021. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. The questions must be received at least 10 days before the end of the public comment period. The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx.
The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than September 9, 2021 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0821.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected. Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.80.005; AS 08.80.030; AS 17.30.200
Statutes Being Implemented, Interpreted, or Made Specific: AS 08.80.005; AS 08.80.030; AS 17.30.200

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

DATE: 8/13/2021
/s/ Jun Maiquis,
Regulations Specialist
Division of Corporations, Business and
Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

Pub. August 15, 2021

AFFIDAVIT OF BOARD ACTION

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, being duly sworn, state the following:

The attached motion dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances was passed by the Board of Pharmacy during its November 18, 2021 teleconference meeting.

Date: _____

Laura Carrillo Digitally signed by Laura Carrillo Date: 2021.12.07 14:54:21 -09'00'

Laura Carrillo, Executive Administrator

The board reviewed the proposed changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 as publicly noticed and included in the board packet.

On a motion duly made by James Henderson to adopt the changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 as proposed and publicly noticed, seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to adopt 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857.

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

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by the Department of Law
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12 AAC 52.855(c) is amended to read:

(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 **by providing** [WEBSITE; AND]

(A) a non-shared e-mail address;

(B) password;

(C) user role;

(D) healthcare specialty;

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

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

12 AAC 52.855(d) is amended to read:

(d) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a **registration number** [USER ACCOUNT, LOGIN NAME, AND PASSWORD BY THE DEPARTMENT].

12 AAC 52.855(e) is amended to read:

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the **credentials identified in (c)(1)(A) and (B) of this section** [USER ACCOUNT, LOGIN NAME, AND PASSWORD ISSUED BY THE DEPARTMENT].

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

12 AAC 52.856. PDMP registration renewal. (a) A PDMP registration will expire on the same date as the pharmacist's or practitioner's corresponding professional license.

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

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

12 AAC 52.857. Change in dispensing or distributing of controlled substances. (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 this state within 10 days of the change in dispensing status.

(b) A pharmacist who is not required to register with the PDMP and who has met the requirements in 12 AAC 52.855(b) must comply with the requirements in 12 AAC 52.855(c) within 10 days of any change in practice that requires the pharmacist to register with the PDMP.

(c) A pharmacy required to report to the PDMP that no longer dispenses or distributes controlled substances in or to this 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 must notify the board on a form provided by the department within 10 days of its intent to dispense or distribute controlled substances. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

Leftover regulations project (Part II from previous; Part I approved at 09/24/2021 meeting)

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

Commented [RH1]: Reviewed & approved by board 12/4/20

12 AAC 52. PRESCRIPTION DRUG ORDER INFORMATION FOR EXPEDITED PARTNER THERAPY. (a) A prescription order for expedited partner therapy cannot be filled unless the following information is provided:

Commented [CLN(2]: Just a start; Dr. Ruffridge mentioned a separate section addressing partner therapy may be the more ideal option vs. amending 12 AAC 52.460.

(1) first and last name of the patient and patient's partner
(2) date of birth of the patient and patient's partner
(3) address of the patient and patient's partner

(b) mandatory patient counseling required in 12 AAC 52.585 must also be provided to the partner.

(c) nothing in this chapter prevents a patient's partner from withholding their information; however, a prescription is not valid unless the information in (a) of this subsection is provided.

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.

Commented [RH3]: Same language as 12 AAC 52.420(a)

(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 52.210. 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;

Commented [RH4]: Besides interpreting substitution and DUR data (which are (4) and (5) below), what else is a RPh interpreting on the prescription?

(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

Commented [RH5]: Provides clarity around substitution

Commented [RH6]: AS 08.80.480(11). Provides clarity of what data.

Commented [RH7]: Provides clarity around counseling requirements vs. just any information in the medication record.

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

(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 52.510. 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 **by verbal or written communication**;

(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 52.992. 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

(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.

Commented [RH8]:

Commented [RH9R8]: Is this necessary or is an ACPE accredited program acceptable?

Commented [RH10]: Is this necessary? How do we ever know these exist?

Commented [RH11]: Is this reference a must?

Commented [RH12]: Does it have to be displayed or available upon request? If required to display we should put in the display regulation.

(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

(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

Authority: AS 08.80.005 AS 08.80.030

A licensee shall retain all licenses, certifications, registrations, or permits in the practice site. This documentation shall be made available to the board, law enforcement, or inspector upon request. The division's licensing website printout confirming active credentials is acceptable in lieu of a printed document.

Commented [RH13]: Same ? as above

Commented [CLN(14]: Board reviewed/approved 05/21/2021

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

12 AAC 52.480 – LABELING. 12 AAC 52.480. LABELING. **(a)** One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

(1) name, address, and phone number of the dispensing pharmacy;

(2) unique identification number of the prescription drug order;

(3) date the prescription drug order is dispensed;

(4) initials, 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.

(b) Unless otherwise specified in 21 CFR 211.166, 211.137, and 211.160 or the manufacturer's label, a drug or device is valid for __months from the date it is dispensed, including

(a) unit dose medication packs
(b) opioid overdose drugs
(c) ……..

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480 AS 08.80.030

Commented [CLN(15]: Board reviewed 05/21/2021; Chair Holt stated he would try to get a draft to Dr. Ruffridge with expiration date language. This language just included as a placeholder.

Commented [CLN(16]:

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~~ participate**s** 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**~~

~~(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,~~

Commented [RH17]: Doesn't exist with prescription drug delivery in general, so why here

~~(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;~~

Commented [RH18]: Not a requirement normally, so why here?

Commented [RH19]: We always have to protect confidentiality

Commented [RH20]: Board can always inspect

Commented [RH21]: Move to 12 AAC 52.443(b)?

Commented [RH22]: Is this administrative task necessary? Does putting things in a book serve a purpose?

~~**(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

Commented [RH23]: From inside the pharmacy? From outside the pharmacy is shared pharmacy services so what is the point to this subsection at all?

(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

Commented [RH24]: What exactly does this mean?

(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

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

Commented [RH25]: Is any of this now necessary if we eliminate the need to review & approve shared pharmacy services?

~~**(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;**~~

~~**(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** enter**ing,** ~~**or**~~ review**ing, 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 located in this state shall permit an authorized investigator assigned to the board of pharmacy, 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 30 days.

(d) A licensee required to correct any discrepancies is not required to notify the board of its corrections, however, if the licensee is again inspected and discrepancies are found, the licensee may be subject to disciplinary action.

(e) OR a licensee required to correct discrepancies must notify the board on a form provided by the department within 10 days of the inspection.

Commented [CLN(26]: To notify or not to notify? Dr. Ruffridge recommended not to, Dr. Holt recommended to notify during 05/21/2021 meeting.

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

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.**~~

(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 [RH27]: Establish or ensure?

Commented [RH28]: Covered by the inspection regulation

Commented [RH29]: What does this have to do with drug distribution and control?

New Regulations: Refill of controlled substances (12 AAC 52.270)
As written, 12 AAC 52.270(d)(2) includes imitating language around refills of controlled substances. Dr. Ruffridge stated this is not necessary because 75 CFR Sec. 1306.22 under the DEA already has language around refills of controlled substances. Ruffridge stated that it is redundant to the federal rule; (d)(2) is limiting the ability for patients to receive refills on federally scheduled controlled substance.

On a motion duly made by James Henderson to remove section 12 AAC 52.470(d)(2) on refills, "the drug is not a federal or state scheduled controlled substance.", seconded by Tammy Lindemuth, and approved unanimously, it was:

RESOLVED to strike 12 AAC 52.470(d)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson	x			
Ashley Schaber	x			
Leif Holm				x
Sharon Long	x			

The motion passed with no further discussion.

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] **is**

(A) **presently** enrolled in a college of pharmacy accredited by the ACPE **and satisfactorily progressing toward meeting the requirements for licensure as a pharmacist**; or

(B) **is a recent graduate of an approved professional degree program of a school or college of pharmacy; or**

~~(B)~~ (C) 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;

……

(f) In this section, "recent" means having graduated within one-year preceding the date of application.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116 AS 08.80.030

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 **within one day of discovering the loss. The time computation under 12 AAC 02.920(b) applies to submission of this form**.

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,]**.** [t]**T**he 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.

State Board Laws and Rules- Reference to NABP Digital Accreditation (formerly VIPPS)

October 2021

District of Columbia

DC Rule 1903.
Registration of nonresident Pharmacies.

1903.4 A nonresident pharmacy shall:
(i) If the nonresident pharmacy is solely internet-based or operates primarily as an internet-based pharmacy, the pharmacy shall also:

(1) Submit proof acceptable to the Department of certification by the Verified Internet Pharmacy Practice Sites Program (VIPPS) of the National Association of Boards of Pharmacy, or other national certification program for internet pharmacies acceptable to the Department, for each website and domain registration; and

Indiana

IN Law 25-26-17-4.5.
Internet prescription volume greater than twenty-five percent; accreditation; display of seal of approval.

Sec. 4.5. A nonresident pharmacy that dispenses more than twenty-five percent (25%) of the pharmacy's total prescription volume as a result of an original prescription order received or solicited through the Internet:

(1) must be accredited:

(A) through the National Association of Boards of Pharmacy's Verified Internet Pharmacy Practice Sites (VIPPS); or

(B) under a program that is substantially similar to the program under clause (A) and that has been approved by the board; and

(2) shall obtain and display a seal of approval for:

(A) the National Association of Boards of Pharmacy; or

(B) the substantially similar program described in subdivision (1)(B);

anywhere that the nonresident pharmacy advertises.

Kentucky

KY Law 315.0351.
Out-of-state pharmacy; permit; requests for information; records; toll-free telephone service; pharmacist on duty; requirements for out-of-state pharmacy doing business through the Internet; application to sale or distribution of dialysate solution or devices.

(h) Each out-of-state pharmacy shall comply with KRS 218A.202;

(i) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current;

Montana

MT Rule 24.174.1002.
Conditions of registration.

(1) As conditions of registration, the out-of-state mail service pharmacy must comply with the following:

(a) be a legal entity registered and in good standing with the Montana Secretary of State with a registered agent in Montana for service of process designated;

(b) be registered and in good standing with the National Association of Boards of Pharmacy verified internet pharmacy practice sites (VIPPS) if registered after June 1, 2001;

(c) maintain, in readily retrievable form, records of legend drugs and/or devices dispensed to Montana patients;

(d) supply upon request, all information needed by the Montana Board of Pharmacy to carry out the board's responsibilities under the statutes and regulations pertaining to out-of-state mail service pharmacies;

(e) maintain pharmacy hours that permit the timely dispensing of drugs to Montana patients and provide reasonable access for the Montana patients to consult with a licensed pharmacist about such patients' medications;

(f) provide toll-free telephone communication consultation between a Montana patient and a pharmacist at the pharmacy who has access to the patient's records, and ensure that said telephone number(s) will be placed upon the label affixed to each legend drug container. A toll-free telephone number shall also be provided to the board to allow for compliance with all information requests by the board.

NC Rule 21 NCAC 46.1601.
Pharmacy Permits.

(d) In addition to all of the other requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, the Board shall not issue any original or annual renewal pharmacy permit to any Internet pharmacy until the Board is satisfied that:

> (1) The Internet pharmacy is certified by the National Association of Boards of Pharmacy under its Digital Pharmacy Accreditation program;
>
> (2) The Internet pharmacy has certified the percentage of its annual business conducted via the Internet on a form provided by the Board, when it applies for permit or renewal; and
>
> (3) The Internet pharmacy has provided the Board with the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal corporate officers of the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of all principal officers of any company, partnership, association, or other business entity holding any ownership interest in the Internet pharmacy; the names, addresses, social security numbers, phone numbers, facsimile numbers, email addresses, and titles of any individual holding any ownership interest in the Internet pharmacy.

North Dakota

ND Rule 61-08-01-08.
Administrative inspection.

c. Nonresident pharmacies that dispense more than twenty-five percent of the pharmacy's total prescription volume as a result of original prescriptions or refills solicited through the internet, must be inspected by the national association of boards of pharmacy verified pharmacy program.

Virginia

VA Law 54.1-3434.1.
Nonresident pharmacies to register with Board.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care Services, the following rules are essential.

Section 1. Facility.

(a) To obtain a license for a Pharmacy, an applicant shall:
- (1) have submitted an application in the form prescribed by the Board of Pharmacy;
- (2) have attained the age of majority; and
- (3) have paid the fees specified by the Board of Pharmacy for the issuance of the license.

(b) The facility owner, if an individual, shall have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;

(c) The facility shall have undergone a Pharmacy inspection by the Board or authorized agent thereof; and

(d) Possess the following minimum requirements for a Pharmacy:
- (1) Each Pharmacy shall be of sufficient size, as determined by the Board, 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.
- (2) Each Pharmacy shall maintain an area designated for the provision of Patient Counseling services. This area shall be designed to provide a reasonable expectation of privacy of Protected Health Information.
- (3) Each Pharmacy shall have ready access to references , to include at least one current reference[1] in each of the following in each of the following categories, if applicable to the services provided:
  - (i) State and Federal Drug laws relating to the Practice of Pharmacy and the legal Distribution of Drugs and any rules or regulations adopted pursuant thereto;
  - (ii) pharmacology;
  - (iii) dosage and toxicology;
  - (iv) veterinary Drugs[2]; and
  - (v) general.
- (4) Each Pharmacy shall maintain patient-oriented reference material for guidance in proper Drug usage.[3]
- (5) Each Person involved in the development, maintenance, or use of a Drug formulary shall maintain a currently accepted reference containing guidelines for a sound Drug formulary system.
- (6) All areas where Drugs and Devices are stored shall be dry, well lighted, well ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the Drugs prior to their Dispensing as

[1] Boards may wish to give examples in each of these categories of reference texts.

[2] Such as Plumb's Veterinary Drug Handbook.

[3] Patient-oriented reference material can include publications such as Facts and Comparisons' Patient Drug Facts, or the United States Pharmacopoeia Dispensing Information (USPDI).

stipulated by the United States Pharmacopeia–National Formulary (USP-NF) and/or the Manufacturer's or Distributor's Product Labeling unless otherwise indicated by the Board.

(7) Each Pharmacy shall have access to a sink with hot and cold running water that is convenient to the Compounding area for the purpose of hand scrubs prior to Compounding.

(8) Equipment/Supplies.
The Pharmacy shall carry and utilize the equipment and supplies necessary to conduct a Pharmacy in a manner that is in the best interest of the patients served and to comply with all State and Federal laws.

(9) The Pharmacy shall provide a means for patients to prevent disclosure of Confidential Information or personally identifiable information that was obtained or collected by the Pharmacist or Pharmacy incidental to the Delivery of Pharmacist Care Services other than as authorized by law or rules of the Board.

(10) ***The Pharmacy, if conducting business over the Internet, shall be accredited by a program approved by the Board.***

(e) Upon renewal, the licensee shall provide to the Board the NABP e-Profile ID of the Pharmacy and the Pharmacist-in-Charge

Division of Corporations, Business and Professional Licensing

2022 Legislative Guidance for Professional Licensing Board & Commission Members

As a member of a professional licensing board or commission, you have considerable latitude—as well as responsibility—to recommend changes to your licensing program's enabling statutes. Members of the public, consumers, other professionals, and your industry's association confidently approach members of the legislature to affect the change they wish to see in your practice. Whether taking the initiative or reacting to an active bill, board members also need to be prepared to champion their cause.

THE OPEN MEETINGS ACT ALWAYS APPLIES

AS 44.62.310(h) provides detailed definitions of "governmental body," "meeting," and "public entity" that, when combined, define what constitutes a public meeting. A meeting of a decision or policy-making body occurs when more than three members or a majority of the members, whichever is less, engage collectively in discussion of a subject on which the body is authorized to act and set policy and is therefore subject to the Open Meetings Act. Under this definition, it doesn't matter where the meeting occurs, if it was prearranged, or who arranged it and could include unplanned casual or social contact in any location, including the office of a legislator or an industry gathering.

Members of boards and commissions should take care not to conduct business over email, lest the public be removed from the process. Board members should not email each other about board business; if a special meeting is needed, a member can alert staff and a meeting can be arranged and publicly noticed. Remember, all board member email correspondence is discoverable, and your board business is also the public's business.

This information is contained in the *CBPL Guide to Excellence in Regulation*. Board members are provided a bound copy of this guidance manual; however, If you need another copy, you may download it here: https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardMemberResources.aspx.

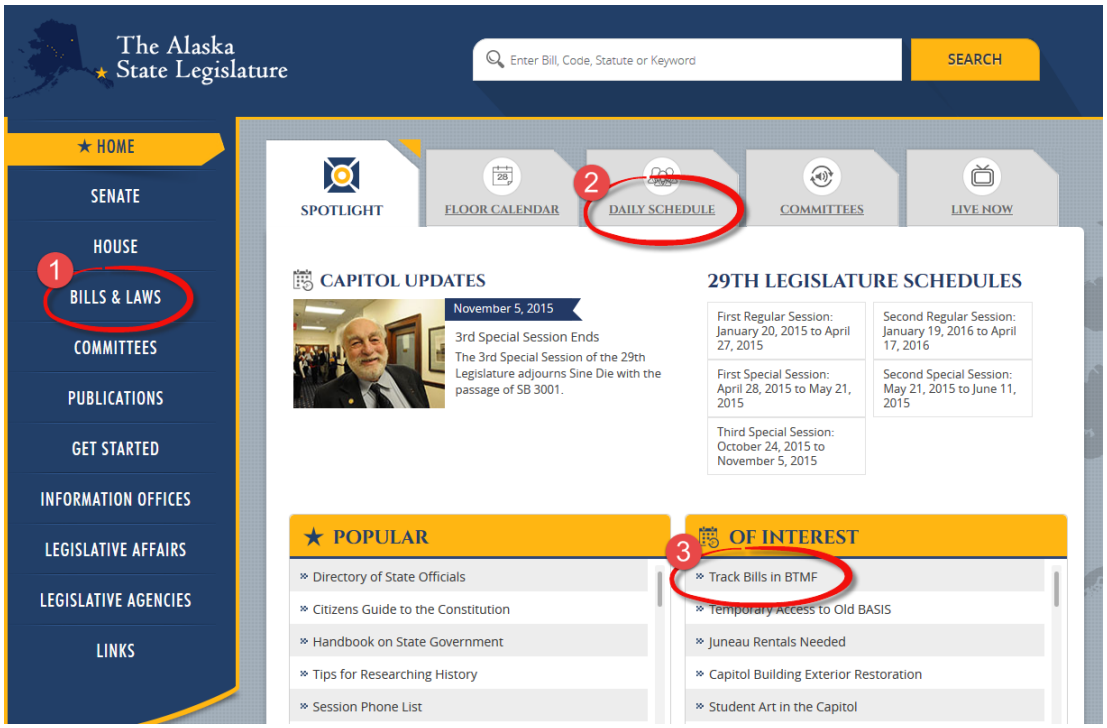
BE INFORMED: IF NOT YOU, THEN WHO?

- As soon as possible before legislative season, select on the record a member who will serve as the point person for legislative activity. In the absence of this person, the division will look to the chair of the board for input and interpretation. If the board is championing a piece of legislation, a history of the meeting minutes reflecting the issues and board's perspective should be compiled by this leader and made available to board members and division management, who will be at every hearing. This research and history will be especially helpful to new board members who are appointed.

- When a bill is filed, division management will alert program staff. The examiner or executive should ensure that their board members are made aware of legislation that is filed that will affect them. With sometimes more than 50 bills to track, analyze, and testify on, division management may not be able to keep the board apprised of every late-breaking detail. Division management will periodically send updates to staff regarding legislation or request discussion with the board.

- That said, know where to find any bill using the Alaska State Legislature's web page: akleg.gov. (See graphic below.)
    1. The **BILLS & LAWS** section on the sidebar links to a searchable list of documents. If you know the bill number, you can search using the bar at the top of the screen.
    2. The **DAILY SCHEDULE** shows all committee activity for the day you choose. It is subject to change, but it is a good starting place to see what is happening where.

3. The **BTMF**—or Bill Tracking Management Facility is your best friend when trying to keep up with a bill. Take the time to set up your profile and register the bill you want to track, then you will receive email updates when its status changes or is scheduled for a hearing.



GUIDELINES FOR BOARD MEMBER TESTIMONY

- Encourage the board to become engaged: Track the bill online, participate in hearings, write a letter supporting the board's official position, and discuss the legislation in a public meeting. It is a best practice for organizations to speak with "one voice." Any testimony or correspondence by a board member on behalf of a board must represent deliberation and action taken on the record in a public meeting.

- Staff may not express opinions on behalf of the board or discuss legislation with elected officials without prior arrangements with division management and clearance from the Governor's Legislative Office. If the board has published a resolution or letter regarding the legislation as a result of a vote at a public meeting, staff may provide that document to legislators per department procedures.

- Individual board members may offer their personal or professional opinions on the legislation. They must clearly state that while they are appointed to a board, they do not speak on behalf of the board.

- Boards <u>must</u> provide a member to testify telephonically (or in person, if in Juneau) at every hearing when being considered for reauthorization per AS 08.03. Without member interest and advocacy for the board or commission's continuation, it is possible that the sponsor could withdraw the bill and the board could sunset.

- The chair or elected board spokesperson should be prepared to answer questions posed by staff or legislators, testify telephonically (or in person, if in Juneau) on bills that require subject matter expertise or upon request, and otherwise be available <u>on short notice</u> to engage in this process or assign another board member to do so.

- Be sure to differentiate the state licensing board from the industry association. Sometimes, they share the same goals. Sometimes, they do not. Legislators must keep track of a lot of names and organizations, so be sure that you are clear that you represent the State of Alaska licensing board.

- Nervous? Don't worry! Please email or call the division director or deputy director to discuss tips or even run through some potential questions/roleplay.

LEGISLATIVE TESTIMONY CALL-IN DO'S AND DON'TS

* For the 2022 session, masks are required in the Capitol.

Do remember this "off-net" system is designed to serve those who do not have any other way to testify or have a legitimate reason for using the system.

Do remember that off-net calls to the committee must be authorized prior to the meeting by the chairman. A minimum of 24 hours in advance is appreciated. Please work through the Director, Division Operations Manager, or the committee chairman's office for authorization.

Do use the streaming video available at http://akl.tv/ to watch for your bill to come up. The chairman will announce the order of bills at the beginning of the meeting. Callers may be disconnected from the meeting if they call in prior to their bill being taken up. If video streaming is not an option for you, please contact the committee aide to make arrangements to call in early. Once the bill is before the committee, call **844-586-9085**, let the operator know what committee you are calling for, give your name, state board position/affiliation, bill number, whether you wish to testify or to be available only to answer questions. Examples: "Hi, I'm calling in to be available for questions on SB21 in Senate Finance. My name is Richard Wein, and I am the chair of the State Medical Board." "Good morning. My name is Danette Schloeder, I am the chair of the Board of Nursing, and I'm on the list to provide invited testimony on HB83 in House Labor and Commerce."

Do Not call in before the bill you are testifying on comes before the committee.

Do remember the off net call-in lines are for testifiers only. If you wish to listen in, please use the live streaming at http://akl.tv/.

Do use the "mute" function of your phone until called on to testify. If this function is not available on your phone, ask the Legislative Information Office (LIO) moderator to mute your call.

Do Not use the "hold" function.

Do try to be in a quiet room without distractions or interruptions. Car noise, open windows, and barking dogs can all be heard by the legislative committee and guests at the hearing. These avoidable disturbances will detract from the credibility of your message. Please treat the important responsibility of testifying with utmost respect and professionalism.

Do remember that everything transmitted over your phone will be broadcast directly into the meeting room and recorded to become part of the permanent record.

Do remember to be in a location with good reception if using a cell phone. Disruptions coming into the meeting via the phone lines will result in all callers being disconnected from the system. This will require testifiers to call back to be reconnected. Turn off your computer or TV speakers if listening online so you do not create an audio "loop."

Do try to adhere to time limits imposed by the chairman.

Remember: There are a limited number of phone lines coming into the Capitol. These lines are also used by LIOs around the state. When all the phone lines are used up, an LIO may not be able to call in with a room full of people.

HOUSE BILL NO. 237

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVES GILLHAM, Carpenter

Introduced: 1/18/22
Referred: Health and Social Services, Labor and Commerce

A BILL

FOR AN ACT ENTITLED

"An Act relating to pharmacists dispensing medication for treatment of COVID-19 and related diseases."

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

*** Section 1.** AS 08.80.261 is amended by adding a new subsection to read:

(c) The board may not deny a license to an applicant or impose a disciplinary sanction on a person licensed under this chapter for dispensing medication as prescribed by a physician licensed under AS 08.64 for the treatment or prevention of COVID-19 and related diseases.

*** Sec. 2.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.332. Duty to dispense medication for COVID-19 and related diseases. A person licensed under this chapter shall dispense medication as prescribed by a physician licensed under AS 08.64 for the treatment or prevention of COVID-19 and related diseases. Notwithstanding AS 08.80.480(30), a person dispensing medication under this section is not required to evaluate whether dispensing the

1 medication is in the patient's best interest.

2 *** Sec. 3.** AS 08.80.480 is amended by adding a new paragraph to read:

3 (40) "COVID-19" means the novel coronavirus disease caused by the

4 severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

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.

HOUSE BILL NO. 91

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVES WOOL, Hopkins, Prax, McCarty, Kreiss-Tomkins, Nelson

Introduced: 2/18/21
Referred: Labor and Commerce, Resources

A BILL

FOR AN ACT ENTITLED

"An Act exempting veterinarians from the requirements of the controlled substance prescription database."

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

*** Section 1.** AS 17.30.200(o) is amended to read:

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, **<u>and</u>** the Board of Examiners in Optometry [, AND THE BOARD OF VETERINARY EXAMINERS] when a practitioner registers with the database under (n) of this section.

*** Sec. 2.** AS 17.30.200(t) is amended to read:

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if

<u>(1) the practitioner is a veterinarian licensed under AS 08.98; or</u>

<u>(2)</u> a controlled substance is

<u>(A)</u> [(1)] administered to a patient at

1 **(i)** [(A)] a health care facility; or
2 **(ii)** [(B)] a correctional facility; **or**
3 **(B)** [(2)] dispensed to a patient for an outpatient supply of 24
4 hours or less at a hospital
5 **(i)** [(A)] inpatient pharmacy; or
6 **(ii)** [(B)] emergency department.
7 *** Sec. 3.** AS 17.30.200(u) is amended by adding a new paragraph to read:
8 (6) "practitioner"
9 (A) means a physician, dentist, advanced practice registered
10 nurse, optometrist, scientific investigator, or other person licensed, registered,
11 or otherwise permitted to distribute, dispense, conduct research with respect to,
12 or to administer or use in teaching or chemical analysis a controlled substance
13 in the course of professional practice or research in the state;
14 (B) means a pharmacy, hospital, or other institution licensed,
15 registered, or otherwise permitted to distribute, dispense, conduct research with
16 respect to, or to administer a controlled substance in the course of professional
17 practice or research in the state;
18 (C) does not include a veterinarian.
19 *** Sec. 4.** AS 08.98.050(a)(10) is repealed.

SENATE BILL NO. 132

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - FIRST SESSION

BY SENATORS HOLLAND, Gray-Jackson

Introduced: 4/28/21
Referred: Health & Social Services, Labor & Commerce

A BILL

FOR AN ACT ENTITLED

"An Act exempting veterinarians from the requirements of the controlled substance prescription database."

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

*** Section 1.** AS 17.30.200(o) is amended to read:

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, **<u>and</u>** the Board of Examiners in Optometry [, AND THE BOARD OF VETERINARY EXAMINERS] when a practitioner registers with the database under (n) of this section.

*** Sec. 2.** AS 17.30.200(t) is amended to read:

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if

<u>(1) the practitioner is a veterinarian licensed under AS 08.98; or</u>

<u>(2)</u> a controlled substance is

<u>(A)</u> [(1)] administered to a patient at

1 **(i)** [(A)] a health care facility; or
2 **(ii)** [(B)] a correctional facility; **or**
3 **(B)** [(2)] dispensed to a patient for an outpatient supply of 24
4 hours or less at a hospital
5 **(i)** [(A)] inpatient pharmacy; or
6 **(ii)** [(B)] emergency department.
7 *** Sec. 3.** AS 17.30.200(u) is amended by adding a new paragraph to read:
8 (6) "practitioner"
9 (A) means a physician, dentist, advanced practice registered
10 nurse, optometrist, scientific investigator, or other person licensed, registered,
11 or otherwise permitted to distribute, dispense, conduct research with respect to,
12 or to administer or use in teaching or chemical analysis a controlled substance
13 in the course of professional practice or research in the state;
14 (B) means a pharmacy, hospital, or other institution licensed,
15 registered, or otherwise permitted to distribute, dispense, conduct research with
16 respect to, or to administer a controlled substance in the course of professional
17 practice or research in the state;
18 (C) does not include a veterinarian.
19 *** Sec. 4.** AS 08.98.050(a)(10) is repealed.

HOUSE BILL NO. 266

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE EASTMAN

Introduced: 1/18/22
Referred: Health and Social Services, Judiciary, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to vaccines and vaccinations; relating to pharmacists and other health care providers; relating to health care insurers; relating to schools; relating to the Board of Pharmacy; relating to the Department of Education and Early Development; relating to the Department of Health and Social Services; relating to unfair trade practices; and providing for an effective date."

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

*** Section 1.** The uncodified law of the State of Alaska is amended by adding a new section to read:

SHORT TITLE. This Act may be known as the Vaccine Consumer Protection Act of 2022.

*** Sec. 2.** 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;

(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 **<u>and compliance with AS 18.15.500 - 18.15.600</u>**;

(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(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. 3.** AS 08.80.480 is amended by adding a new paragraph to read:

(40) "vaccine" has the meaning given in AS 18.15.600.

*** Sec. 4.** AS 09.65 is amended by adding a new section to read:

Sec. 09.65.360. Liability for disclosure of vaccination status. (a) A person who learns whether an individual has been vaccinated against novel coronavirus disease (COVID-19) and discloses that information to a third party is liable to the individual for damages caused by the loss of privacy.

(b) A person who, in violation of AS 11.41.530, coerces an individual to disclose whether the individual has been vaccinated against COVID-19 is liable for damages.

*** Sec. 5.** AS 14.07.020(a) is amended to read:

(a) The department shall

(1) exercise general supervision over the public schools of the state except the University of Alaska;

(2) study the conditions and needs of the public schools of the state, adopt or recommend plans, administer and evaluate grants to improve school performance awarded under AS 14.03.125, and adopt regulations for the improvement of the public schools; the department may consult with the University of Alaska to develop secondary education requirements to improve student achievement in college preparatory courses;

(3) provide advisory and consultative services to all public school governing bodies and personnel;

(4) prescribe by regulation a minimum course of study for the public schools; the regulations must provide that, if a course in American Sign Language is given, the course shall be given credit as a course in a foreign language;

(5) establish, in coordination with the Department of Health and Social Services, a program for the continuing education of children who are held in juvenile detention facilities or juvenile treatment facilities, as those terms are defined in AS 47.12.990, in the state during the period of detention or treatment;

(6) accredit those public schools that meet accreditation standards prescribed by regulation by the department; these regulations shall be adopted by the department and presented to the legislature during the first 10 days of any regular session, and become effective 45 days after presentation or at the end of the session, whichever is earlier, unless disapproved by a resolution concurred in by a majority of the members of each house;

(7) prescribe by regulation, after consultation with the state fire marshal and the state sanitarian, standards that will ensure healthful and safe conditions in the public and private schools of the state, including a requirement of physical examinations and**, subject to AS 18.15.560 and 18.15.590(b),** immunizations in pre-elementary schools; the standards for private schools may not be more stringent than those for public schools;

(8) exercise general supervision over pre-elementary schools that receive direct state or federal funding;

(9) exercise general supervision over elementary and secondary correspondence study programs offered by municipal school districts or regional educational attendance areas; the department may also offer and make available to any Alaskan through a centralized office a correspondence study program;

(10) accredit private schools that request accreditation and that meet accreditation standards prescribed by regulation by the department; nothing in this paragraph authorizes the department to require religious or other private schools to be licensed;

(11) review plans for construction of new public elementary and secondary schools and for additions to and major rehabilitation of existing public elementary and secondary schools and, in accordance with regulations adopted by the department, determine and approve the extent of eligibility for state aid of a school construction or major maintenance project; for the purposes of this paragraph, "plans" include educational specifications, schematic designs, projected energy consumption and costs, and final contract documents;

(12) provide educational opportunities in the areas of vocational education and training, and basic education to individuals over 16 years of age who are no longer attending school; the department may consult with businesses and labor unions to develop a program to prepare students for apprenticeships or internships that will lead to employment opportunities;

(13) administer the grants awarded under AS 14.11;

(14) establish, in coordination with the Department of Public Safety, a school bus driver training course;

(15) require the reporting of information relating to school disciplinary and safety programs under AS 14.33.120 and of incidents of disruptive or violent behavior;

(16) establish by regulation criteria, based on low student performance, under which the department may intervene in a school district to improve instructional practices, as described in AS 14.07.030(a)(14) or (15); the regulations must include

(A) a notice provision that alerts the district to the deficiencies and the instructional practice changes proposed by the department;

(B) an end date for departmental intervention, as described in AS 14.07.030(a)(14)(A) and (B) and (15), after the district demonstrates three consecutive years of improvement consisting of not less than two percent increases in student proficiency on standards-based assessments in language arts and mathematics, as provided in AS 14.03.123(f)(1)(A); and

(C) a process for districts to petition the department for continuing or discontinuing the department's intervention;

(17) notify the legislative committees having jurisdiction over

education before intervening in a school district under AS 14.07.030(a)(14) or redirecting public school funding under AS 14.07.030(a)(15).

*** Sec. 6.** AS 14.30.125 is amended to read:

Sec. 14.30.125. Immunization. If**,** in the judgment of the commissioner of health and social services**,** it is necessary for the welfare of the children or the general public in an area, the governing body of the school district **may** [SHALL] require the children attending school in that area to be immunized**, subject to AS 18.15.560 and 18.15.590(b),** against the diseases the commissioner of health and social services may specify.

*** Sec. 7.** AS 18.09.990(11) is repealed and reenacted to read:

(11) "vaccine" has the meaning given in AS 18.15.600.

*** Sec. 8.** AS 18.15.360 is amended by adding a new subsection to read:

(e) The department shall adopt regulations creating a screening checklist of contraindications for vaccines for patients who are under 18 years of age. The checklist must include questions concerning the patient's current health status, allergies, previous vaccinations, serious adverse reactions to vaccines, long-term health issues, family history of seizures and brain or nervous disorders, family members who have experienced an adverse reaction to a vaccine, and immune system problems or family history of immune system problems. In this subsection, "vaccination" and "vaccine" have the meanings given in AS 18.15.600.

*** Sec. 9.** AS 18.15 is amended by adding new sections to read:

Article 7A. Vaccines and Vaccinations.

Sec. 18.15.500. Information on vaccine. (a) A health care provider or health care facility that recommends or administers a vaccine to a patient shall, before administering the vaccine, provide to the patient or, if the patient is a minor, to the patient's parent or guardian information that identifies the risks and benefits of the vaccine based on the patient's health record and the right of the patient or, if the patient is a minor, the patient's parent or guardian to accept or refuse the vaccine.

(b) The information provided under (a) of this section must be in writing, must be signed by the patient or, if the patient is a minor, the patient's parent or guardian and must include

(1) the name and manufacturer of the vaccine;

(2) the ingredients of the vaccine, including adjuvants and excipients; in this paragraph,

(A) "adjuvant" means a substance that enhances the pharmacological effect of a drug or increases the ability of an antigen to stimulate the immune system;

(B) "excipient" means an ingredient that is intentionally added to a drug for a purpose other than the therapeutic or diagnostic effect at the intended dose;

(3) the Internet website of the manufacturer for access to the vaccine manufacturer's product insert for disclosed contraindications and adverse events and any related information;

(4) the Internet website of the United States Health Resources and Services Administration for access to the vaccine injury compensation program and the vaccine injury table and information regarding reports of adverse effects and recalls of vaccines;

(5) the Internet website of the United States Food and Drug Administration for access to vaccine recall information;

(6) information regarding patient exemption rights, including the right to an exemption from a vaccination for a medical, personal, religious, or other reason;

(7) information regarding rights concerning vaccination data collection by the department;

(8) information regarding limitations on liability for a person who administers a vaccine;

(9) information regarding incentives received by the health care provider or health care facility related to vaccination services;

(10) information regarding the risks of contracting the disease or illness for which the vaccine is given;

(11) the name, manufacturer, and ingredients of any vaccine scheduled to be administered to the patient at a future appointment; and

(12) a notification of any potential right of action the patient may have

against a vaccine manufacturer for an injury resulting from the vaccine that was not specified in the manufacturer's product insert.

(c) If the department publishes an advertisement that promotes a vaccine, the department shall list potential adverse reactions associated with the vaccine and identify persons for whom the Centers for Disease Control and Prevention, United States Department of Health and Human Services, recommends against receiving the vaccine.

Sec. 18.15.510. Vaccine contraindication checklist. A health care provider or health care facility shall, before administering a vaccine to a patient who is a minor, ensure that the patient's parent or guardian has completed the vaccine contraindication checklist created by the department under AS 18.15.360(e).

Sec. 18.15.520. Adverse events. A health care provider or health care facility that observes a patient experience an adverse event as a result of receiving a vaccine, or that receives a report from a patient or a patient's family member that the patient has recently experienced an adverse event as a result of receiving a vaccine, shall report the adverse event in a timely manner to the Vaccine Adverse Event Reporting System in the United States Department of Health and Human Services and record the adverse event in the patient's medical record.

Sec. 18.15.530. Prohibitions. (a) A health care provider or health care facility may not

(1) limit or deny health care services or benefits to a patient or harass, coerce, scold, or threaten a patient or a patient's parent or guardian because the patient or the patient's parent or guardian delays or declines a vaccination; or

(2) recommend or administer a vaccine to a patient who is a minor without the consent of the patient's parent or guardian.

(b) A health care insurer may not deny insurance coverage or increase insurance premiums for an individual who has delayed or declined a vaccination or otherwise treat the individual differently than an individual who has received a vaccination.

Sec. 18.15.540. Prohibition on sale and advertising. (a) A person, the state, or a political subdivision of the state may not use the word "vaccine" to sell or

advertise for sale a product that

(1) is not a vaccine; or

(2) contains both a vaccine and a product that is not a vaccine.

(b) A person that knowingly violates this section is guilty of a class A misdemeanor punishable as provided in AS 12.55. In this subsection, "knowingly" has the meaning given in AS 11.81.900.

Sec. 18.15.550. Civil penalty. (a) A health care provider, health care facility, or health care insurer that violates a provision of AS 18.15.500 - 18.15.530 is liable for a civil penalty to be assessed after a hearing by the state agency or licensing or regulatory board that has jurisdiction over the health care provider, health care facility, or health care insurer of up to $1,000 for the first violation and up to $5,000 for each subsequent violation.

(b) When determining the amount of a civil penalty to be assessed at a hearing conducted under (a) of this section, the state agency or licensing or regulatory board shall consider

(1) the scope and severity of the violation, including the number of people affected by the violation;

(2) any action taken by the health care provider, health care facility, or health care insurer to remedy the violation; and

(3) the number of previous violations by the health care provider, health care facility, or health care insurer.

Sec. 18.15.560. Long-term follow-up data. (a) If a drug is recognized by the United States Food and Drug Administration to be a gene therapy drug and the long-term follow-up period for the drug has concluded, the department shall make data from the long-term follow-up period available to each patient being prescribed the drug, or to the parent or guardian of each patient being prescribed the drug who is a minor, before the state or a political subdivision of the state may impose a legal requirement related to the drug.

(b) If a drug is not recognized by the United States Food and Drug Administration to be a gene therapy drug and has undergone or is undergoing a phase IV clinical study, the department shall make data from the phase IV clinical study

available to each patient being prescribed the drug, or to the parent or guardian of each patient being prescribed the drug who is a minor, before the state or a political subdivision of the state may impose a legal requirement related to the drug. In this subsection, "phase IV clinical study" means a post-marketing study to delineate additional information about a drug's risks, benefits, and optimal use, including studying different doses or schedules of administration than were used in a prior clinical study, use of the drug in other patient populations or other stages of the disease, or use of the drug over a longer period of time.

Sec. 18.15.570. Publication of summary. The department shall publish on its Internet website a summary of the rights, duties, prohibitions, and penalties contained in AS 18.15.500 - 18.15.600.

Sec. 18.15.580. Confidentiality of an individual's COVID-19 vaccine status. The state or a political subdivision of the state may not divulge information to a third party that could be used to determine whether an individual has been vaccinated against novel coronavirus disease (COVID-19).

Sec. 18.15.590. Prohibition against penalizing employees for not receiving a COVID-19 vaccine. (a) An employer may not penalize or threaten to penalize an employee for not receiving a vaccine for novel coronavirus disease (COVID-19) or a booster dose of the COVID-19 vaccine.

(b) A school or school district may not penalize or threaten to penalize a student or prospective student for not receiving a COVID-19 vaccine or booster dose of the COVID-19 vaccine. In this subsection, "school" means a public or private pre-elementary, elementary, or secondary school, or a college or university.

(c) A business or nonprofit entity may not require an individual to be vaccinated against COVID-19 for the individual to access an area or service that is open to the public.

Sec. 18.15.600. Definitions. In AS 18.15.500 - 18.15.600,

(1) "health care facility" means an office or institution that provides care or treatment for physical, mental, emotional, dental, physiological, or psychological diseases or conditions;

(2) "health care insurer" has the meaning given in AS 21.54.500;

(3) "health care provider" means an individual licensed, certified, or otherwise authorized or permitted by law to provide health care services; in this paragraph, "health care services" means care, treatment, a service, or a procedure to maintain, diagnose, or otherwise affect an individual's physical or mental condition;

(4) "minor" means an individual under 18 years of age whose disabilities have not been removed under AS 09.55.590;

(5) "vaccination" means treatment with a vaccine;

(6) "vaccine" means a substance

(A) used to stimulate the production of antibodies and provide immunity against a disease;

(B) prepared from the causative agent of a disease or its products or from a synthetic substitute;

(C) treated to act as an antigen to a disease without inducing the disease; and

(D) that is designed to be administered to a patient only after the patient gives voluntary and knowing consent to receive the substance or, if the patient is a minor, only after a parent or guardian of the minor gives voluntary and knowing consent to administer the substance to the minor.

*** Sec. 10.** AS 45.50.471(b) is amended by adding a new paragraph to read:

(58) violating AS 18.15.540 (vaccine sale and advertisements).

*** Sec. 11.** The uncodified law of the State of Alaska is amended by adding a new section to read:

APPLICABILITY. (a) AS 09.65.360, added by sec. 4 of this Act, and AS 18.15.550, added by sec. 9 of this Act, apply to conduct occurring on or after the effective date of this Act.

(b) AS 18.15.540, added by sec. 9 of this Act, applies to offenses committed on or after the effective date of this Act.

*** Sec. 12.** This Act takes effect immediately under AS 01.10.070(c).

HOUSE BILL NO. 265

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE SPOHNHOLZ

Introduced: 1/18/22
Referred: Health and Social Services, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to telehealth; relating to the practice of medicine; relating to medical assistance coverage for services provided by telehealth; and providing for an effective date."

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

*** Section 1.** AS 08.01 is amended by adding a new section to read:

Sec. 08.01.085. Telehealth. (a) A health care provider may provide health care services within the health care provider's authorized scope of practice to a patient in this state through telehealth without first conducting an in-person examination if the health care provider holds a license in good standing. If a health care provider is licensed in another state, the health care provider may provide services under this section only to a patient who is referred by a health care provider licensed under this title or a federal or tribal health care program.

(b) If a health care provider determines in the course of a telehealth encounter with a patient under this section that some or all of the encounter will extend beyond

the health care provider's authorized scope of practice, the health care provider shall advise the patient that the health care provider is not authorized to provide some or all of the services to the patient, recommend that the patient contact an appropriate provider for the services the health care provider is not authorized to provide, and limit the encounter to only those services the health care provider is authorized to provide. The health care provider may not charge for any portion of an encounter that extends beyond the health care provider's authorized scope of practice.

(c) A fee for a service provided through telehealth under this section must be reasonable and consistent with the ordinary fee typically charged for that service and may not exceed the fee typically charged for that service.

(d) A physician, osteopath, physician assistant, or advanced practice registered nurse may examine, diagnose, and provide treatment through telehealth under this section for opioid use disorder. No other person licensed under this title or licensed in another state may examine, diagnose, or provide treatment through telehealth under this section for opioid use disorder.

(e) A physician, podiatrist, osteopath, or physician assistant may prescribe, dispense, or administer through telehealth under this section a prescription for a controlled substance listed in AS 11.71.140 - 11.71.190 or a botulinum toxin if the physician, podiatrist, osteopath, or physician assistant complies with AS 08.64.364. An advanced practice registered nurse may prescribe, dispense, or administer through telehealth under this section a prescription for a controlled substance listed in AS 11.71.140 - 11.71.190 other than buprenorphine to a patient if the advanced practice registered nurse first conducts an in-person examination of the patient. No other person licensed under this title or in another state may prescribe, dispense, or administer through telehealth under this section a prescription for a controlled substance listed in AS 11.71.140 - 11.71.190 or a botulinum toxin.

(f) Nothing in this section requires the use of telehealth when a health care provider determines that providing health care services through telehealth is not appropriate or when a patient chooses not to receive health care services through telehealth.

(g) In this section,

(1) "health care provider" means an audiologist or speech-language pathologist licensed under AS 08.11 or in another state; a behavior analyst licensed under AS 08.15 or in another state; a chiropractor licensed under AS 08.20 or in another state; a professional counselor licensed under AS 08.29 or in another state; a dental hygienist licensed under AS 08.32 or in another state; a dentist licensed under AS 08.36 or in another state; a dietitian or nutritionist licensed under AS 08.38 or in another state; a naturopath licensed under AS 08.45 or in another state; a marital and family therapist licensed under AS 08.63 or in another state; a physician, podiatrist, osteopath, or physician assistant licensed under AS 08.64 or in another state; a direct-entry midwife certified under AS 08.65 or in another state; a nurse licensed under AS 08.68 or in another state; a dispensing optician licensed under AS 08.71 or in another state; an optometrist licensed under AS 08.72 or in another state; a pharmacist licensed under AS 08.80 or in another state; a physical therapist or occupational therapist licensed under AS 08.84 or in another state; a psychologist or psychological associate licensed under AS 08.86 or in another state; or a social worker licensed under AS 08.95 or in another state;

(2) "telehealth" has the meaning given in AS 47.05.270(e).

*** Sec. 2.** AS 08.64.364(b) is amended to read:

(b) The board may not impose disciplinary sanctions on a physician or physician assistant for prescribing, dispensing, or administering a prescription drug that is a controlled substance or botulinum toxin if the requirements under (a) of this section and AS 08.64.363 are met [AND THE PHYSICIAN OR PHYSICIAN ASSISTANT PRESCRIBES, DISPENSES, OR ADMINISTERS THE CONTROLLED SUBSTANCE OR BOTULINUM TOXIN WHEN AN APPROPRIATE LICENSED HEALTH CARE PROVIDER IS PRESENT WITH THE PATIENT TO ASSIST THE PHYSICIAN OR PHYSICIAN ASSISTANT WITH EXAMINATION, DIAGNOSIS, AND TREATMENT].

*** Sec. 3.** AS 18.08 is amended by adding a new section to read:

Sec. 18.08.100. Telehealth. (a) An individual certified or licensed under this chapter may practice within the individual's authorized scope of practice under this chapter through telehealth with a patient in this state if the individual's certification or

license is in good standing.

(b) If an individual certified or licensed under this chapter determines in the course of a telehealth encounter with a patient that some or all of the encounter will extend beyond the individual's authorized scope of practice, the individual shall advise the patient that the individual is not authorized to provide some or all of the services to the patient, recommend that the patient contact an appropriate provider for the services the individual is not authorized to provide, and limit the encounter to only those services the individual is authorized to provide. The individual certified or licensed under this chapter may not charge for any portion of an encounter that extends beyond the individual's authorized scope of practice.

(c) A fee for a service provided through telehealth under this section must be reasonable and consistent with the ordinary fee typically charged for that service and may not exceed the fee typically charged for that service.

(d) Nothing in this section requires the use of telehealth when an individual certified or licensed under this chapter determines that providing services through telehealth is not appropriate or when a patient chooses not to receive services through telehealth.

(e) In this section, "telehealth" has the meaning given in AS 47.05.270(e).

*** Sec. 4.** AS 47.07 is amended by adding a new section to read:

Sec. 47.07.069. Payment for telehealth. (a) The department shall pay for services provided through telehealth in the same manner as if the services had been provided in person. Except as provided in (b) of this section, the department shall pay for all services covered by the medical assistance program, including

(1) behavioral health services;

(2) services covered under federal waivers or demonstrations;

(3) services provided by a community health aide or a community health practitioner certified by the Community Health Aide Program Certification Board;

(4) services provided by a behavioral health aide or behavioral health practitioner certified by the Community Health Aide Program Certification Board;

(5) services provided by a dental health aide therapist certified by the

Community Health Aide Program Certification Board;

(6) services provided by a chemical dependency counselor certified by the Alaska Commission for Behavioral Health Certification;

(7) services provided by a rural health clinic or a federally qualified health center;

(8) services provided by an individual or entity that is required by statute or regulation to be licensed or certified by the department or that is eligible to receive payments, in whole or in part, from the department;

(9) services provided through audio, visual, or data communications, alone or in any combination, or through communications over the Internet or by facsimile, telephone, including a telephone that is not part of a dedicated audio conference system, electronic mail, text message, or two-way radio; and

(10) assessment, evaluation, consultation, planning, diagnosis, treatment, case management, and the prescription, dispensing, and administration of medications, including controlled substances.

(b) The department shall adopt regulations for services provided by telehealth, including setting rates of payment. Regulations calculating the rate of payment for a rural health clinic or federally qualified health center must treat services provided through telehealth in the same manner as if the services had been provided in person, including calculations based on the rural health clinic or federally qualified health center's reasonable costs or on the number of visits for recipients provided services. The department may not decrease the rate of payment for a telehealth service based on the location of the person providing the service, the location of the eligible recipient of the service, the communication method used, or whether the service was provided asynchronously or synchronously. The department may exclude or limit coverage or reimbursement for a service provided by telehealth, or limit the telehealth modes that may be used for a particular service, only if the department

(1) specifically excludes or limits the service from telehealth coverage or reimbursement by regulations adopted under this subsection;

(2) determines, based on substantial medical evidence, that the service cannot be safely provided using telehealth or using the specified mode; or

(3) determines that providing the service using the specified mode would violate federal law or render the service ineligible for federal financial participation under applicable federal law.

(c) In this section,

(1) "federally qualified health center" has the meaning given in 42 U.S.C. 1396d(*l*)(2)(B);

(2) "rural health clinic" has the meaning given in 42 U.S.C. 1396d(*l*)(1);

(3) "telehealth" has the meaning given AS 47.05.270(e).

*** Sec. 5.** The uncodified law of the State of Alaska is amended by adding a new section to read:

MEDICAID STATE PLAN FEDERAL APPROVAL. To the extent necessary to implement this Act, the Department of Health and Social Services shall amend and submit for federal approval the state plan for medical assistance coverage consistent with AS 47.07.069, enacted by sec. 4 of this Act.

*** Sec. 6.** The uncodified law of the State of Alaska is amended by adding a new section to read:

CONDITIONAL EFFECT; NOTIFICATION. (a) Section 4 of this Act takes effect only if, on or before January 1, 2023, the United States Department of Health and Human Services

(1) approves amendments to the state plan for medical assistance coverage under AS 47.07.069, enacted by sec. 4 of this Act; or

(2) determines that its approval of the amendments to the state plan for medical assistance coverage under AS 47.07.069, enacted by sec. 4 of this Act, is not necessary.

(b) The commissioner of health and social services shall notify the revisor of statutes in writing within 30 days after the United States Department of Health and Human Services approves amendments to the state plan or determines that approval is not necessary under (a)(1) or (2) of this section.

*** Sec. 7.** If sec. 4 of this Act takes effect, it takes effect on the day after the date the revisor of statutes receives notice from the commissioner of health and social services under sec. 6(b)

of this Act.

*** Sec. 8.** Except as provided in sec. 7 of this Act, this Act takes effect immediately under AS 01.10.070(c).

HOUSE BILL NO. 277

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE MCCARTY

Introduced: 1/18/22
Referred: Labor and Commerce, Finance

A BILL

FOR AN ACT ENTITLED

"An Act relating to the renewal of occupational licenses."

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

*** Section 1.** AS 08.01.100(b) is amended to read:

(b) [A LICENSE SUBJECT TO RENEWAL SHALL BE RENEWED ON OR BEFORE THE DATE SET BY THE DEPARTMENT.] If **a** [THE] license **subject to renewal** is not renewed by the date set by the department, the license lapses. **A licensee shall submit an application for renewal of a license at least 60 days before the date the license lapses. If a licensee submits the renewal application less than 60 days before the date the license lapses, the licensee shall pay an additional $250 processing fee to the department.** In addition to renewal fees required for reinstatement of **a** [THE] lapsed license, the department may impose a delayed renewal penalty, established by regulation, that shall be paid before a license that has been lapsed for more than 60 days may be renewed. The department may adopt a delayed renewal penalty only with the concurrence of the appropriate board.

HOUSE BILL NO. 306

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTY-SECOND LEGISLATURE - SECOND SESSION

BY REPRESENTATIVE STORY

Introduced: 2/4/22
Referred: Labor and Commerce, Finance

A BILL

FOR AN ACT ENTITLED

"An Act extending the termination date of the Board of Pharmacy; and providing for an effective date."

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

*** Section 1.** AS 08.03.010(c)(16) is amended to read:

(16) Board of Pharmacy (AS 08.80.010) - June 30, **2028** [2022];

*** Sec. 2.** This Act takes effect immediately under AS 01.10.070(c).

Report Highlights

Why DLA Performed This Audit

The audit was performed to determine if there is a continued need for the board and if its termination date should be extended. The board is set to sunset on June 30, 2022, and will have one year from that date to conclude its administrative operations.

What the Legislative Auditor Recommends

1. The board chair and DCBPL's director should improve procedures and training to ensure applicants meet requirements prior to licensure.
2. The board should adopt regulations for renewing outsourcing facilities and third-party logistics provider licenses.
3. Applicable occupational boards and DCBPL's director should continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements.
4. DCCED's commissioner should allocate sufficient resources to ensure licensees holding a DEA registration number are

(continued on following page)

A Sunset Review of the Department of Commerce, Community, and Economic Development (DCCED), Board of Pharmacy (board)

July 15, 2021

Audit Control Number 08-20126-22

REPORT CONCLUSIONS

Overall, the audit concluded that the board served the public's interest by effectively conducting its meetings and actively amending regulations; however, improvements over the board's licensing function are needed. Further, the audit concluded that Division of Corporations, Business and Professional Licensing (DCBPL) staff investigated complaints unrelated to the controlled substance prescription database (CSPD) in a timely manner and activity worked toward implementing new CSPD requirements.

At the time of the audit, occupational boards were not effectively monitoring or enforcing CSPD requirements. Additionally, DCBPL licensing staff were not consistently entering the existence of a Drug Enforcement Administration (DEA) registration number into DCBPL's licensing database, which prevented the licensing database from being used to monitor compliance with CSPD registration requirements.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend that the legislature extend the board's termination date six years, to June 30, 2028, which is less than the eight-year maximum allowed in statute. The reduced extension reflects the need for more timely oversight of the board's evolving role in combating the public health opioid crisis.

Report Highlights (Continued)

consistently recorded in DCBPL's licensing database.

5. DCCED's commissioner should allocate sufficient resources to ensure the CSPD requirements are enforced.

ALASKA STATE LEGISLATURE

LEGISLATIVE BUDGET AND AUDIT COMMITTEE

Division of Legislative Audit

P.O. Box 113300
Juneau, AK 99811-3300
(907) 465-3830
FAX (907) 465-2347
legaudit@akleg.gov

November 22, 2021

Members of the Legislative Budget
and Audit Committee:

In accordance with the provisions of Title 24 and Title 44 of the Alaska Statutes (sunset legislation), we have reviewed the activities of the Board of Pharmacy and the attached report is submitted for your review.

DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT
BOARD OF PHARMACY
SUNSET REVIEW
July 15, 2021

Audit Control Number
08-20126-22

The audit was conducted as required by AS 44.66.050(a). Per AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend the legislature extend the board's termination date to June 30, 2028.

The audit was conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Fieldwork procedures utilized in the course of developing the findings and recommendations presented in this report are discussed in the Objectives, Scope, and Methodology.

Kris Curtis, CPA, CISA
Legislative Auditor

ABBREVIATIONS

AAC	Alaska Administrative Code
ACN	Audit Control Number
AS	Alaska Statute
CDC	Centers for Disease Control and Prevention
CISA	Certified Information Systems Auditor
COVID-19	Coronavirus Disease 2019
CPA	Certified Public Accountant
CSPD	Controlled Substance Prescription Database
DCBPL	Division of Corporations, Business and Professional Licensing
DCCED	Department of Commerce, Community, and Economic Development
DEA	Drug Enforcement Administration
DLA	Division of Legislative Audit
FY	Fiscal Year
HB	House Bill
MME	Morphine Milligram Equivalent
PDMP	Prescription Drug Monitoring Program
SB	Senate Bill

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ORGANIZATION AND FUNCTION

Board of Pharmacy (board)

The board was established for the purpose of controlling and regulating the practice of pharmacy in Alaska. According to AS 08.80.005, effective control and regulation is necessary to promote, preserve, and protect the public's health, safety, and welfare.

As shown in Exhibit 1, the board is composed of seven members. By statute, five board members must be licensed pharmacists actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding appointment. The remaining two positions are to be filled by individuals from the general public. Statutes prohibit public members from having a direct financial interest in the health care industry.

Exhibit 1

Board of Pharmacy Members as of March 31, 2021

Richard Holt, Chair
Licensed Pharmacist

Lana Bell
Licensed Pharmacist

James Henderson
Licensed Pharmacist

Leif Holm
Licensed Pharmacist

Justin Ruffridge
Licensed Pharmacist

Tammy Lindemuth
Public Member

Sharon Long
Public Member

Source: Office of the Governor, Boards and Commissions website.

The board regulates admission into the practice of pharmacy, establishes and enforces competency by ensuring compliance with professional standards, and adopts regulations. The board is also required to establish and maintain a controlled substance prescription database; establish standards for the independent administration by a pharmacist of vaccines, related emergency medications, and opioid overdose drugs; and maintain a link to the United States Food and Drug Administration's website that lists all currently approved interchangeable biological products.

The board licenses pharmacists, pharmacy interns, and pharmacy technicians. The board also licenses pharmacies and wholesale drug distributors located inside the state, and wholesale drug distributors,

outsourcing facilities,[1] and third-party logistics providers[2] located out of the state. Additionally, drug rooms located within an institutional facility are licensed. The board registers pharmacies located outside of the state if a pharmacy ships, mails, or delivers prescription drugs to consumers in the state.

The Department of Commerce, Community, and Economic Development's Division of Corporations, Business and Professional Licensing (DCBPL)

DCBPL provides administrative and investigative assistance to the board. Administrative assistance includes budgetary services and functions such as collecting fees, maintaining files, receiving application forms, publishing notices for meetings, and assisting with board regulations.

Alaska Statute 08.01.087 gives DCBPL authority to act on its own initiative or in response to a complaint. DCBPL may:

1. Conduct an investigation if it appears a person is engaged or about to engage in a prohibited professional practice.
2. Bring an action in Superior Court to enjoin the act.
3. Examine or have examined the books and records of a person whose business activities require a business license or licensure by a board listed in AS 08.01.010 or whose occupation is listed in AS 08.01.010.
4. Issue subpoenas for the attendance of witnesses and records.

To support board operations, DCBPL employs two licensing examiners and an executive administrator who reports directly to the board. To assist the board in developing, implementing, administering, and managing the controlled substance prescription

[1] "Outsourcing facility" is defined as a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location.
[2] "Third-party logistics provider" is defined as 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.

database, DCBPL employs a program coordinator who reports to the board's executive administrator.

Alaska Statute 08.01.065 requires the department to adopt regulations that establish the amount and manner of payment of application, registration, and license fees.

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BACKGROUND INFORMATION

The controlled substance prescription database (CSPD) was required by law in 2008.

Senate Bill 196, passed in 2008, required the Board of Pharmacy (board) to establish and maintain a CSPD.[3] The law was passed with the intent to improve patient care and foster the goal of reducing misuse, abuse, and diversion of controlled substances. The statute requires each dispenser submit to the board, by electronic means, information regarding each prescription dispensed for a controlled substance. The CSPD electronically collects information from in-state pharmacies, as well as other dispensers of controlled substance prescriptions.

The Division of Corporations, Business and Professional Licensing (DCBPL) administers the CSPD on behalf of the board as part of its federally funded Prescription Drug Monitoring Program (PDMP).

Lack of effective statutes and regulations limited the CSPD's impact.

After implementation of the 2008 legislation, it became apparent that important authority was omitted from the law, which prevented the CSPD from meeting its intent. The most significant deficiencies were:

- The law did not provide the ability to identify all dispensers that must submit information. Consequently, the CSPD could not be monitored for completeness.
- Regulations required monthly reporting of information; however, monthly reporting was not effective for monitoring prescription practices.
- Only pharmacists were required to register with the CSPD and report prescription data.
- There was no requirement that dispensers or practitioners check the CSPD prior to dispensing, prescribing, or administering medication.
- Only the licensee that registered with the database could review or report to the CSPD, thus preventing delegation of duties.

[3] Alaska Statute 08.80.030(11).

- The Department of Law determined that statutes did not allow CSPD information to be forwarded to practitioners or pharmacists (referred to as unsolicited reports), thus CSPD information could not be used to alert practitioners or pharmacists of unlawful or unprofessional activity.

Significant changes to the CSPD were implemented in 2017 and 2018.

Legislation was passed to improve effectiveness of the CSPD and to address the deficiencies noted above. CSPD access was expanded to include dispensers, dispenser delegates, and other persons or entities with a valid business need. Licensees of the following six occupational boards that prescribe or dispense controlled substances were required to register with the CSPD:

- State Medical Board;
- Board of Nursing;
- Board of Dental Examiners;
- Board of Pharmacy;
- Board of Examiners in Optometry; and
- Board of Veterinary Examiners.

Regulations were updated to require daily reporting of prescription data. Practitioners were required to check the CSPD prior to dispensing, prescribing, or administering medication, with specific exclusions. The board was authorized to provide an unsolicited notification to a pharmacist or practitioner if a patient received one or more prescriptions for controlled substances inconsistent with generally recognized standards of safe practice. The board was also authorized to issue unsolicited reports to a practitioner's licensing board. A PDMP coordinator was hired to help administer the database.

Exhibit 2 provides a timeline of key CSPD events from April 2008 through January 2021. Appendix A provides CSPD related statutes as of January 31, 2021.

Exhibit 2

Controlled Substance Prescription Database Timeline
April 2008 through January 2021

April 2008	Senate Bill 196 required the board to establish the CSPD.
August 2010	The Department of Commerce, Community, and Economic Development (DCCED) entered into a contract with a vendor to provide electronic data collection of controlled substance prescription information from dispensers, provide database management, and provide secure web services.
December 2011	CSPD regulations became effective. Regulations required dispensers to report monthly.
January 2012	CSPD became available to licensees that registered.
January 2016	CSPD transitioned to a new vendor.
April 2016	Senate Bill 74 passed, which amended statutory requirements for registration, reporting, access to CSPD information, and performance measures. New statutes added registration requirements, allowed for unsolicited reports, and required weekly reporting and registration fees. Funding for a dedicated position was included in the bill. The new law had various effective dates.
June 2017	House Bill 159 passed, which required daily reporting with specific exclusions.
July 2017	Mandatory registration, review, and reporting for licensees with a Drug Enforcement Administration (DEA) registration number regulated by specific occupational boards became effective.
October 2017	CSPD contract amendment added prescriber report cards and requirements for sharing information with the DCBPL licensing database.
December 2017	First prescriber report cards were issued.
April 2018	CSPD clinical alerts to practitioners and dispensers were enabled. CSPD registration fees were implemented.
August 2018	Program coordinator was hired to administer the CSPD.
December 2018	A board executive administrator was hired.
October 2020	Contract with vendor to maintain the CSPD ended. Contractor continued to provide services until a new vendor was procured.

Source: DCBPL management; supporting documents; and SB 196, SB 74, and HB 159, which were presented during legislative hearings.

The existence of a DEA registration number helps identify whether a licensee is subject to CSPD registration requirements.

When applying for or renewing a license, applicants indicate whether the individual holds a federal DEA registration number. DCBPL staff manually record, within the licensing database, the existence of a DEA registration number, or, in the case of a pharmacist, whether the pharmacist dispenses controlled substances. As long as the existence of a DEA registration number is accurately recorded in DCBPL's licensing database, the licensing database can be matched to the CSPD to electronically monitor compliance with the CSPD registration requirement.

CSPD operations were mainly funded by federal grants.

Federal funds were used to initially purchase CSPD software. After implementation, federal grants continued to fund operational costs. Effective September 1, 2016, statutes required DCCED to establish fees for CSPD registration with the stipulation that the total amount of fees collected by DCCED should equal the total operational costs of the database minus all federal funds acquired for operational costs. A registration fee of $25 was implemented April 2018. A schedule of CSPD revenues and expenditures is shown in Exhibit 3.

Exhibit 3

Controlled Substance Prescription Database
Schedule of Revenues and Expenditures
FY 18 through January 31, 2021
(Unaudited)

	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Revenues				
Federal Funds	$ 259,500	$ 243,475	$ 502,918	$ 55,464
Registration Fees		90,765	26,150	32,730
Total Revenues	259,500	334,240	529,068	88,194
Expenditures				
Personal Services	84,351	139,363	225,358	94,999
Travel	6,042	10,829	796	-
Services	169,107	99,337	324,382	16,718
Commodities	-	-	676	-
Total Expenditures	$ 259,500	$ 249,529	$ 551,212	$ 111,717

Source: DCCED management.

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REPORT CONCLUSIONS

In developing our conclusion regarding whether the Board of Pharmacy's (board) termination date should be extended, its operations were evaluated using the 11 factors set out in AS 44.66.050(c), which are included in this report as Appendix B. Under the State's "sunset" law, the 11 factors are to be considered in assessing whether an entity has demonstrated a public policy need for continuing operations.

Overall, the audit concluded that the board served the public's interest by effectively conducting its meetings and actively amending regulations; however, improvements over the board's licensing function are needed. Further, the audit concluded that Division of Corporations, Business and Professional Licensing (DCBPL) staff investigated complaints unrelated to the controlled substance prescription database (CSPD) in a timely manner and activity worked toward implementing new CSPD requirements.

At the time of the audit, occupational boards were not effectively monitoring or enforcing CSPD requirements. Additionally, DCBPL licensing staff were not consistently entering the existence of a Drug Enforcement Administration (DEA) registration number into DCBPL's licensing database, which prevented the licensing database from being used to monitor compliance with CSPD registration requirements.

In accordance with AS 08.03.010(c)(16), the board is scheduled to terminate on June 30, 2022. We recommend that the legislature extend the board's termination date six years, to June 30, 2028, which is less than the eight-year maximum allowed in statute. The reduced extension reflects the need for more timely oversight of the board's evolving role in combating the public health opioid crisis.

Detailed report conclusions are as follows.

The board conducted its meetings effectively and did not duplicate the efforts of another entity.

A review of nine of 22 board meetings held from FY 18 through January 2021 found that all nine meetings were public noticed timely, allowed time for public comment, and a quorum was consistently met. The 22 board meetings exceeded the minimum number required by statute; however, the board's workload supported the number held.

As the only entity authorized to license and regulate the pharmacy profession, the board did not duplicate the efforts of another agency.

Investigations were conducted in a timely manner.

Auditors' review of investigative activity concluded that board investigations unrelated to the CSPD were conducted in a timely manner. A total of 115 non-CSPD board related cases were open as of July 2017 or opened from July 2017 through January 2021. Fifty cases remained open as of January 2021. Of the 115 cases, 23 were open for more than 180 days. Auditors reviewed 12 of the 23 cases and found all were actively investigated. The timeliness of CSPD investigations is addressed on page 19.

Licenses were not consistently issued in compliance with state law.

As shown in Exhibit 4, there were 4,280 active board licenses as of January 2021, representing a 14 percent increase when compared to the 2017 sunset audit.[4] The increase was due to the addition of three out-of-state license types: wholesale drug distributor, outsourcing facility, and third-party logistics provider.

Auditors tested 50 licenses issued during the audit period (25 individual licenses and 25 facility licenses), including both initial licenses and renewals. Testing found licenses were issued in compliance with statutes and regulations, except five license files were missing information required by regulation and three licensing files did not demonstrate adequate review of applicants' professional fitness. (See Recommendation 1)

[4] The number of total licenses reported in the 2017 sunset audit (ACN 08-20104-17) was 3,747.

Exhibit 4

Board of Pharmacy
Licensing and Registration Activity
FY 18 through January 31, 2021

	New Licenses Issued (Exclusive of Renewals)			Total Active as of January 31, 2021
	FY 18	FY 19	FY 20	
Individual Licenses:				
Pharmacist	81	91	67	1,047
Pharmacy Intern	217	252	291	481
Pharmacy Technician	314	355	270	1,174
Facility Licenses:				
Pharmacy (In-State)	11	16	6	132
Registered Out-of-State Pharmacy	198	161	149	627
Drug Room	4	4	4	40
Wholesale Drug Distributor (In-State)	1	6	1	16
Wholesale Drug Distributor (Out-of-State)			408	570
Outsourcing Facility			17	31
Third-Party Logistics Provider			116	162
Totals	826	885	1,329	4,280

Source: Compiled from DCBPL licensing database.

Board fees covered the cost of operations.

Primarily, the board receives its revenue from licensure, registration, and renewal fees. Renewals are conducted on a biennial basis, creating a two-year cycle in board revenues. As shown in Exhibit 6 on page 15, the board had a surplus of $794,789 at the end of January 31, 2021. The large surplus was due to an increase in license revenues associated with the addition of three license types. DCBPL management and board members discussed license fee reductions

during the February 2021 board meeting. Fees were not reduced in recognition that the planned addition of a new licensing examiner position would increase future expenditures. There was also concern that establishment of a disciplinary matrix for CSPD noncompliance would lead to more investigations and increase related expenditures. Exhibit 5 presents a schedule of board fees from FY 18 through FY 21.

Exhibit 5

Board of Pharmacy
License, Registration, and Permit Fees
FY 18 through FY 21

	FY 18	FY 19	FY 20 - FY 21
Nonrefundable application fee for initial license	60	60	100
Pharmacist	240	240	200
Pharmacy intern	30	30	30
Pharmacy technician	60	60	50
Temporary pharmacist	60	60	50
Pharmacy	240	240	200
Registered pharmacy located out of the state	600	600	600
Remote pharmacy	240	240	200
Drug room	240	240	200
Wholesale drug distributor (in-state)	500	500	500
Wholesale drug distributor (out-of-state)	0	0	600
Outsourcing provider	0	0	600
Third-party logistics provider	0	0	600
Emergency permit to practice pharmacy	110	110	100

Source: DCBPL regulations.

Exhibit 6

Board of Pharmacy
Schedule of Revenues and Expenditures
FY 18 through January 31, 2021
(Unaudited)

	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Revenues				
Licensing Fees	$ 801,317	$ 213,770	$ 631,105	$ 932,837
Other Sources	210	962	-	-
Total Revenues	801,527	214,732	631,105	932,837
Direct Expenditures				
Personal Services	273,406	264,742	257,072	192,448
Travel	13,704	8,299	3,901	-
Services	21,960	31,243	48,783	16,094
Commodities	-	26	521	-
Total Direct Expenditures	309,070	304,310	310,277	208,542
Indirect Expenditures*	259,680	263,571	256,442	148,736
Total Expenditures	568,750	567,881	566,719	357,278
Annual Surplus (Deficit)	232,777	(353,149)	64,386	575,559
Beginning Cumulative Surplus	275,216	507,993	154,844	219,230
Ending Cumulative Surplus	$ 507,993	$ 154,844	$ 219,230	$ 794,789

* Indirect expenditures are estimated as of January 31, 2021, using the board's prior year indirect expenditures allocated for seven months.
Source: DCCED management.

The board actively amended regulations.

During the audit period, the board completed six regulation projects. The projects implemented statutory changes, addressed outdated verbiage, and made changes to help respond to the COVID-19 pandemic. When reviewing the new regulations, auditors noted that regulations governing license renewals (12 AAC 52.300) were not amended to include two new out-of-state license types: third-party logistics providers and outsourcing facilities. (See Recommendation 2)

Changes to statutes and regulations improved the CSPD.

During the audit period, administration of the CSPD significantly changed in terms of legal authority and organizational structure. The changes were intended to make the CSPD more effective at preventing the misuse, abuse, and diversion of controlled substances. As discussed in the Background Information section of this letter, significant changes included requirements to:

- **Register** - licensees of the six occupational boards that prescribe or dispense controlled substances were required to register with the CSPD;
- **Report** - data regarding prescriptions and dispensed substances were required to be reported daily to the CSPD; and
- **Review** - practitioners were required to check the database prior to dispensing, prescribing, or administering medication, with specific exclusions.

The audit concluded that changes to statutes and regulations materially addressed previously identified deficiencies, making the CSPD more capable of combating the opioid crisis. Further, the audit found the addition of a dedicated program coordinator helped provide the resources necessary to effectively administer the CSPD.

Occupational boards were slow to implement CSPD enhancements.

Implementing the new CSPD laws required the coordination of six occupational boards. The Prescription Drug Monitoring Program (PDMP) is housed within the Board of Pharmacy; however, each applicable licensing board is responsible for monitoring and

enforcing the requirements for their respective licensees. As of January 2021, each applicable board was at a different stage in implementing new CSPD laws and none of the boards were fully monitoring or enforcing CSPD requirements. Audit findings related to the CSPD are listed below:

1. Requirements for registering, reporting, and reviewing the CSPD were not actively monitored.

At the time of the audit, monitoring procedures for registering and reporting were evolving and only the Board of Pharmacy was actively monitoring both requirements. Exhibit 7 summarizes the degree each applicable occupational board monitored CSPD registration and reporting requirements.

Additionally, the boards did not monitor the degree each licensee reviewed the CSPD prior to dispensing, prescribing, or administering controlled substances. According to the PDMP coordinator, that information is tracked within the CSPD and could be monitored

Exhibit 7

Board Monitoring of CSPD Registration and Reporting Requirements
Status as of December 31, 2020
(Unaudited)

Board Type	Registration	Reporting
Dentistry	Not monitoring	Planned to start in 2021
Medical	Not monitoring	Planned to start in 2021
Nursing	Not monitoring	Monitoring since 2020
Optometry	Not monitoring	Not applicable – no optometrist dispensing as of 2020
Pharmacy	Monitoring since 2019	Monitoring since 2018
Veterinary	Not monitoring	Monitoring since 2020

Source: Alaska Prescription Drug Monitoring Program - 2021 Legislative Report.

by the licensing boards, if boards chose to do so. The PDMP coordinator reported to relevant boards the percent of prescribers that reviewed the CSPD on a quarterly basis beginning the second quarter of 2020. According to a 2021 legislative report of the Alaska PDMP, a majority of prescribers did not review the CSPD.[5] (See Recommendation 3) The extent providers reviewed the CSPD is shown in Exhibit 8.

Exhibit 8

Controlled Substance Prescription Database
Extent Prescribers Reviewed Database
FY 18 through FY 20
(Unaudited)

	FY 18	FY 19	FY 20
Percent of Prescribers Reviewing	35.63%	34.85%	43.88%

Source: Alaska Prescription Drug Monitoring Program – 2021 Legislative Report.

2. Compliance with CSPD registration requirements could not be determined due to DCBPL's incomplete licensing database.

In an effort to evaluate compliance with CSPD registration requirements, auditors compared DCBPL's licensing database to the CSPD. A high rate of unmatched licensees was found. Auditors tested a sample of the unmatched licensees and identified that board licensing staff were not consistently entering the existence of a DEA registration number into the licensing database and licensees that retired or did not renew their license were not consistently removed

[5] According to the *2021 PDMP Legislative Report*, the database may not capture review by prescribers that work in multiple health care positions (for example, a prescriber who works in a position that is exempt from the review requirements and in a position that is not exempt).

from the CSPD.[6] Consequently, DCBPL's licensing database and the CSPD did not adequately identify licensees that were subject to the CSPD requirements and could not be used to accurately monitor compliance with CSPD registration requirements. (See Recommendation 4)

3. CSPD requirements for registering, reporting, and reviewing were not actively enforced.

Even though DCBPL's licensing database limited the ability to accurately identify all licensees that were noncompliant with the CSPD registration requirements, potentially noncompliant licensees were identified by board staff using available data and over 750 licensees were referred to DCBPL's investigative section for further review. DCBPL's chief investigator stated that insufficient staff resources and insufficient information provided by occupational board licensing staff and/or the PDMP coordinator limited the ability to investigate. DCBPL's chief investigator believes standard procedures are needed to ensure all board licensing staff obtain and verify specific information prior to referring a licensee to the investigative section. Standard procedures were drafted during May 2020, but had not been finalized as of May 2021. (See Recommendations 3 and 5)

Enforcement was further limited by inadequate disciplinary matrices. Board disciplinary matrices needed to help guide the resolution of CSPD related cases were not available for all boards during the audit period. Exhibit 9 summarizes the status of the disciplinary matrices as of January 31, 2021. Several board matrices covered a failure to register, but not a failure to review CSPD information or a failure to report controlled substances to the CSPD. The Board of Examiners in Optometry disciplinary matrix did not address the CSPD.

[6] A license integration project designed to identify and remove expired licensees from the CSPD was unsuccessfully launched in August 2020 and deactivated in September 2020. According to DCBPL management, another license integration project is planned for 2021.

Exhibit 9

Disciplinary Matrices Addressing CSPD Requirements Status as of January 31, 2021		
Board Type	**Effective Date**	**CSPD Requirements Covered**
Dentistry	Proposed (not final)	Registration and review
Medical	May 2019	Registration only
Nursing	August 2018 (allowed 120 day grace period)	Registration only
Optometry	None	None
Pharmacy	November 2020	Registration only
Veterinary	February 2020	Registration, review, and reporting

Source: DCCED documents.

Statutes authorize the Board of Pharmacy to provide unsolicited notifications to a pharmacist or practitioner if a patient has received one or more prescriptions for controlled substances inconsistent with generally recognized standards of safe practice. The term "generally recognized standards of safe practice" must be defined by the respective boards. At the time of the audit, the standards had not been fully defined. Only two of the applicable boards set prescription limitations in regulation. The State Medical Board set a limitation of 50 morphine milligram equivalents (MME) for initial opioid prescriptions only and the Board of Dental Examiners set a limitation of 60 MME. (See Recommendation 3)

The Board of Pharmacy may, but is not required to, send patient-specific utilization notifications to pharmacists and practitioners. Instead of sending patient-specific notifications, the PDMP coordinator provided summary data to applicable occupational boards as part of standard board reports and to practitioners as part of prescriber report cards. The following three metrics, referred to as "clinical alerts," were provided:

1. Number of patients treated with over 90 and 120 MME;[7]

2. Number of patients treated with dangerous combinations;[8] and

3. Number of patients who received controlled substances from five prescribers, at five pharmacies, over a three month period.

The process of sending board reports evolved during the audit period. Not all boards were sent reports on a routine basis and not all board reports included the three metrics. Exhibit 10 identifies the number of board reports issued during the audit period and the number of reports that included one or more of the three clinical alert metrics.

Exhibit 10

Controlled Substance Prescription Database
Number of Board Reports
FY 18 through January 31, 2021

Board Type	Board Reports	Reports with Clinical Alert Metrics
Dentistry	8	2
Medical	6	3
Nursing	4	3
Optometry	2	0
Pharmacy	9	8
Veterinary	8	1

Source: Compiled from PDMP board reports.

[7] The Centers for Disease Control and Prevention (CDC) recommend that primary care clinicians reassess evidence of the benefits and risk to the individual when increasing dosage to greater or equal to 50 MME and avoid increasing to greater or equal to 90 MME per day.
[8] CDC recommends avoiding concurrent benzodiazepine and opioid prescription.

Beginning FY 18, CSPD information, referred to as Prescriber Report Cards, was provided to prescribing practitioners. The report cards were intended to give practitioners the ability to review their prescribing activity and compare the activity to other practitioners within the same occupation and within a specific specialty. Quarterly report cards included:

- the three clinical alerts;
- the prescriber's current prescribing controlled substance volumes and duration, including comparison to peers;
- the top three prescribed controlled substances; and
- the number of patients searched in the CSPD.

Exhibit 11 illustrates the number of practitioners who received a prescriber report card by occupational board.

Exhibit 11

Number of Prescriber Report Cards
FY 18 through January 31, 2021

Board Type	FY 18	FY 19	FY 20	July 1, 2020 - January 31, 2021
Dentistry	793	1,482	1,451	1,014
Medical	2,948	5,742	6,874	5,421
Nursing	790	1,546	1,871	1,567
Optometry	10	13	21	10
Veterinary	293	555	630	549

Source: DCBPL management.

Occupational boards recognized the need to coordinate and standardize.

The need for division-wide procedures and coordination between applicable boards became apparent as the program evolved. In September 2020 a PDMP Board Chair group was created and began to meet biweekly. Participants included the chairperson of each of the six applicable occupational boards and DCBPL staff. The meetings provided a venue for discussing CSPD related matters and for disseminating information.

The board was unable to report certain performance measures.

Effective July 2017, the Board of Pharmacy was required to annually report performance measures to the legislature. Specifically, the board was required to report on CSPD security and reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the CSPD. The board reported its performance measures annually as part of a PDMP report to the legislature. Auditors confirmed that the 2021 PDMP legislative report addressed security over the CSPD; however, due to inherent limitations of the CSPD, the board did not report the reduction of inappropriate use or prescription.

The board explained in the 2021 legislative report that it was not possible to quantify the reduction of inappropriate use or prescription of controlled substances because the CSPD does not contain or relate prosecutorial data regarding diversion cases and is not informed when an individual, whether a patient or provider, has avoided inappropriate use or prescribing. Further, the board reported that there may be other factors that can be attributed to any reduction of inappropriate controlled substance use or prescribing, including provider education, which is independent of the database. Additionally, the CSPD does not log when a practitioner or pharmacist has considered, but ultimately declined, prescribing, administering, or dispensing a controlled substance.

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FINDINGS AND RECOMMENDATIONS

The prior 2017 sunset audit of the Board of Pharmacy (board) made two recommendations:

- The Division of Corporations, Business and Professional Licensing's (DCBPL) chief investigator should work with the director to improve the timeliness of investigations.
- DCBPL's director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.

The prior audit recommendation to improve the timeliness of investigations has been addressed. Review of 12 investigations unrelated to the controlled substance prescription database (CSPD) open during the audit period identified no unjustified periods of inactivity.

The prior audit recommendation to improve procedures to ensure required licensure documentation is appropriately obtained and retained has not been addressed and is reiterated below as Recommendation 1.

Four new recommendations were made as part of this audit.

Recommendation No. 1:

The board chair and DCBPL's director should improve procedures and training to ensure applicants meet requirements prior to licensure.

Three of 25 individual applications tested (12 percent) were missing affidavits of moral character. Regulation 12 AAC 52.120(b)(8) requires an applicant provide two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character. Auditors noted that the DCBPL checklist used to ensure applications were complete was missing the requirement for affidavits of moral character, which contributed to the deficiency.

Five of 25 facility license applications tested (20 percent) did not include all the required regulatory documentation. Specifically:

- One third-party logistics provider did not include résumés of the officers responsible for the facility with its initial license application. Regulation 12 AAC 52.697(b)(3) states the board will issue a third-party logistics provider license to an applicant who provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility.

- One out-of-state wholesale drug distributor's application did not include a résumé of the officer responsible for the facility and a background check report was not retained in the applicant's licensing file. Regulation 12 AAC 52.610(b)(3) states the board will issue a wholesale drug distributor license to an applicant who provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility. Regulation 12 AAC 52.610(b)(6) requires wholesale drug distributor applicants submit a completed fingerprint card for the facility manager to allow a background check by the Department of Public Safety.

- One out-of-state wholesale drug distributor, one out-of-state pharmacy, and one in-state pharmacy were issued licenses when the applicants answered yes to a professional fitness question and the applicants' licensing files lacked documentation of approval by a supervisor prior to issuance. Alaska Statute 08.80.261(a) states that the board may deny a license if the board finds the applicant has been convicted of a crime or acted in a way that does not conform to minimum professional standards. To help evaluate an applicant's professional fitness, the application asks a series of questions. Division policy (DOL-28) requires the licensing supervisor review and approve applications that contain "yes" answers to professional fitness questions. Two of the three licenses were issued without follow-up due to human error. DCBPL management stated that the fitness questions were reviewed by a supervisor for the third license; however, no evidence was included in the file to demonstrate the review and there was no evidence that additional information was obtained upon which to base the review.

According to DCBPL management, turnover in the licensing examiner position, a lack of training, and human error contributed

to the facility license errors noted above. Issuing licenses without ensuring that applicants meet statutory and regulatory requirements increases the risk to public safety.

We recommend the board chair and the division director improve procedures and training to ensure applicants meet requirements prior to licensure.

Recommendation No. 2:

The board should adopt regulations for renewing outsourcing facilities and third-party logistics provider licenses.

License renewal regulations were not amended to include the new licensure types: outsourcing facilities and third-party logistics providers. According to the board chair, regulations for outsourcing facility and third-party logistics provider licensure renewal have not been adopted due to the COVID-19 pandemic and other competing priorities.

Per AS 08.80.030(b)(4), the board has the power to adopt regulations necessary to carry out its purposes. Lack of regulations over license renewal may result in licensing unqualified applicants, which may increase the risk to public safety.

We recommend the board adopt regulations for renewing licenses for outsourcing facilities and third-party logistics providers.

Recommendation No. 3:

Applicable occupational boards and DCBPL's director should continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements.

Enforcement of CSPD requirements was hampered by a lack of standard investigative referral procedures and incomplete disciplinary matrices. The audit also found that generally recognized standards of safe practice for controlled substances were not thoroughly defined by the applicable occupational boards.

Per AS 17.30.200(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.*

Per AS 17.30.200(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*** *[emphasis added].*

The need for standardized investigative referral procedures was not identified until a large number of licensees were referred to the investigative unit without adequate support. Many of the referrals came from the Prescription Drug Monitoring Program coordinator position without review by the applicable occupational boards. According to DCBPL management, board licensing staff generally did not have a thorough understanding of the information needed by the investigative section.

The incomplete disciplinary matrices and undefined standards of safe practice reflect the competing priorities of the various boards. Furthermore, resources were limited due to the COVID-19 pandemic.

The lack of standard procedures, disciplinary matrices, and investigative resources resulted in most CSPD referrals not being investigated. Ineffective enforcement increases the risk of noncompliant licensees, which increases the risk to public safety. Further, undefined generally recognized standards of safe practice hamper the board's ability to monitor prescribing activity and provide unsolicited notifications to pharmacists, practitioners, and applicable licensing boards, which increases the risk to public safety.

In September 2020 the applicable board chairs formed an advisory group to help foster teamwork, strategize ways to improve compliance amongst licensees, and address database challenges. We recommend the board chairs and the DCBPL director continue to coordinate efforts to improve the monitoring and enforcement of CSPD requirements, including the establishment of standard investigative referral procedures, CSPD related standards of safe practice, and disciplinary matrices that cover all CSPD requirements.

Recommendation No. 4:

The Department of Commerce, Community, and Economic Development's (DCCED) commissioner should allocate sufficient resources to ensure licensees holding a Drug Enforcement Administration (DEA) registration number are consistently recorded in DCBPL's licensing database.

Occupational board licensing staff did not identify the existence of a DEA registration number within the DCBPL licensing database in a consistent manner.

DCBPL management provided written instructions and training to board licensing staff regarding how to record the existence of a DEA registration number in the licensing database; however, DCBPL licensing staff did not consistently follow the guidance. According to DCBPL management, regular turnover of the boards' licensing examiner and supervisor positions led to inadequate training and oversight, which contributed to the finding.

Insufficient information within the licensing database limits the ability to monitor licensees' compliance with the CSPD registration requirements. Incomplete information within the CSPD limits its ability to reduce the misuse, abuse, and diversion of controlled substances.

We recommend DCCED's commissioner allocate sufficient resources to ensure licensees holding a DEA registration number are consistently recorded in DCBPL's licensing database.

Recommendation No. 5:

DCCED's commissioner should allocate sufficient resources to ensure the CSPD requirements are enforced.

Over 750 licensees potentially noncompliant with CSPD registration, review, and reporting requirements were identified by DCBPL staff; however, few cases were investigated. Investigations were not conducted due to insufficient licensing examiner and investigator resources. Additionally, most of the referrals to the investigative section did not include the information necessary to proceed.

Per AS 17.30.200(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.*

Noncompliance with CSPD registration, reporting, and review requirements limits the ability to reduce the misuse, abuse, and diversion of controlled substances.

We recommend DCCED's commissioner allocate sufficient resources to ensure the CSPD requirements are enforced.

OBJECTIVES, SCOPE, AND METHODOLOGY

In accordance with Title 24 and Title 44 of the Alaska Statutes, the activities of the Board of Pharmacy (board) were reviewed to determine if there is a demonstrated public need for its continued existence.

As required by AS 44.66.050(a), this report shall be considered by the committee of reference during the legislative oversight process in determining whether the board should be reestablished. Currently, under AS 08.03.010(c)(16), the board will terminate on June 30, 2022, and will have one year from that date to conclude its administrative operations.

Objectives

The three central, interrelated objectives of the audit are to:

1. Determine if the termination date of the board should be extended;
2. Determine if the board is operating in the public's interest; and
3. Determine the status of recommendations made in the prior sunset audit.

Scope

The assessment of board operations and performance was based on criteria set out in AS 44.66.050(c). Criteria set out in this statute relates to the determination of a demonstrated public need for the board. The board's activities were reviewed from July 1, 2017, through January 31, 2021. Financial information is presented, unaudited, from July 1, 2017, through January 31, 2021.

Methodology

During the course of the audit the following were evaluated:

- The prior sunset audit report (ACN 08-20104-17) to identify issues affecting the board and to identify prior sunset audit recommendations.

- Applicable statutes and regulations to identify board functions and responsibilities, determine whether statutory or regulatory changes enhanced or impeded board activities, and help ascertain if the board operated in the public interest.
- Legislative bills to identify new board functions and responsibilities.
- Board expenditures, revenues, and fee levels to determine whether fee levels covered the costs of operations.
- Controlled substance prescription database (CSPD) expenditures and revenues to evaluate operating costs and funding sources.
- The State's Online Public Notices System to verify board meetings were public noticed in compliance with state law.
- Various state and news related websites to identify complaints against the board or other board related concerns.
- Various websites to identify potential duplication of board activities.
- Board licensing data from July 1, 2017, through January 31, 2021, to identify the number of newly issued licenses by type and total active as of January 31, 2021.
- Prescription Drug Monitoring Program (PDMP) legislative reports to gain an understanding of the CSPD.
- PDMP coordinator reports provided to relevant occupational boards to gain an understanding of the information reported to the boards and evaluate the extent unsolicited notifications were presented in the reports.
- CSPD vendor contracts to identify scope of work.
- Various occupational board license application forms to evaluate whether the CSPD information was required as part of the application process.

- Listing of CSPD noncompliant licensees to determine the timing and extent of referrals to the Division of Corporations, Business and Professional Licensing (DCBPL) investigative section and the status of referrals.

- Various occupational board disciplinary matrices to determine the extent the matrices covered CSPD requirements.

- DCBPL standard operating procedures specific to the investigative referral process to gain an understanding of the process.

- Prescriber report card data to determine the extent data was obtained and reported to prescribers.

Internal controls over the licensing database and investigations case management system were assessed to determine if controls were properly designed and implemented. Additionally, to identify and evaluate board activities, interviews were conducted with state agency staff and board members. Specific topics of inquiry included board operations, statutory duties, regulations, duplication of effort, fee levels, and complaints against the board.

The audit utilized the following samples:

- A random samples of 25 individual licenses and 25 facility licenses were selected from 2,702 and 1,578 licenses, respectively, that were active as of January 31, 2021. License applications were assessed for statutory and regulatory compliance. The sample size was based on low/moderate control risk, inherent risk, and audit risk. The sample included initial and renewal licensees. Testing results were projected to the population.

- A sample of nine of 22 board meetings held from FY 18 through January 31, 2021, was reviewed to gain an understanding of board proceedings and activities, the nature and extent of public input, whether a quorum was maintained, and whether board vacancies impeded operations. Six meetings were randomly selected and three were judgmentally selected. Test results were projected to the population.

- A random sample of 12 of 23 cases open for over 180 days during July 1, 2017, through January 31, 2021, was reviewed to identify unjustified periods of inactivity. The results were projected to the population.

- Samples were selected from each applicable occupational board's unmatched licensees based on a data match between DCBPL's licensing database and the CSPD to identify reasons why a licensee appears in one database but not the other.[9] The following samples were reviewed: 45 licensees were randomly selected from 1,312 unmatched State Medical Board licensees; 25 licensees were randomly selected from 405 unmatched Board of Pharmacy licensees; 20 licensees were randomly selected from 200 unmatched Board of Nursing licensees; 10 licensees were randomly selected from 100 unmatched Board of Dental Examiners licensees; and all 28 unmatched Board of Veterinary Examiners licensees were reviewed. Results were projected to the population.

[9] Applicable occupational boards are listed on page 6. Although the Board of Examiners in Optometry is an applicable board, its licensees were excluded from the data match because a separate sunset audit was conducted in 2021 that reviewed the Board of Examiners in Optometry's compliance with the CSPD.

APPENDICES SUMMARY

Appendix A provides the controlled substance prescription database statutes effective as of January 31, 2021.

Appendix B provides the sunset criteria used in developing the conclusion regarding whether the Board of Pharmacy termination date should be extended.

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APPENDIX A

Controlled Substance Prescription Database Statutes

Alaska Statute 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.

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APPENDIX B

Analysis of Public Need Criteria AS 44.66.050(c)

A determination as to whether a board or commission has demonstrated a public need for its continued existence must take into consideration the following factors:

1. the extent to which the board or commission has operated in the public interest;

2. the extent to which the operation of the board or commission has been impeded or enhanced by existing statutes, procedures, and practices that it has adopted, and any other matter, including budgetary, resource, and personnel matters;

3. the extent to which the board or commission has recommended statutory changes that are generally of benefit to the public interest;

4. the extent to which the board or commission has encouraged interested persons to report to it concerning the effect of its regulations and decisions on the effectiveness of service, economy of service, and availability of service that it has provided;

5. the extent to which the board or commission has encouraged public participation in the making of its regulations and decisions;

6. the efficiency with which public inquiries or complaints regarding the activities of the board or commission filed with it, with the department to which a board or commission is administratively assigned, or with the office of victims' rights or the office of the ombudsman have been processed and resolved;

7. the extent to which a board or commission that regulates entry into an occupation or profession has presented qualified applicants to serve the public;

APPENDIX B (Continued)

8. the extent to which state personnel practices, including affirmative action requirements, have been complied with by the board or commission to its own activities and the area of activity or interest;

9. the extent to which statutory, regulatory, budgetary, or other changes are necessary to enable the board or commission to better serve the interests of the public and to comply with the factors enumerated in this subsection;

10. the extent to which the board or commission has effectively attained its objectives and purposes and the efficiency with which the board or commission has operated; and

11. the extent to which the board or commission duplicates the activities of another governmental agency or the private sector.

Agency Response from the Department of Commerce, Community, and Economic Development

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, and Economic Development
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RECEIVED
JAN 0 5 2022
LEGISLATIVE AUDIT

January 5, 2022

Kris Curtis
Division of Legislative Audit
P.O. Box 113300
Juneau, AK 99811

RE: Preliminary Audit Report, Department of Commerce, Community, and Economic Development, Board of Pharmacy Sunset Review

Dear Ms. Curtis:

Thank you for the opportunity to comment on the Preliminary Audit Report regarding the Board of Pharmacy (board). The department concurs with the conclusions that the board is generally operating in the public interest in accordance with statutes and regulations and has the following comments on the report:

Report Conclusions

Conclusion 1: The board conducted its meetings effectively and did not duplicate the efforts of another entity.
The department agrees with this conclusion.

Conclusion 2: Investigations were conducted in a timely manner.
The department agrees with this conclusion.

Conclusion 3: Licenses were not consistently issued in compliance with state law.
The department agrees with this conclusion. The executive administrator of the Board of Pharmacy will continue to provide training and oversight of professional licensing staff to improve consistency. The board has recently proposed changes to regulations in applicant requirements that will provide clarity and increase compliance.

Conclusion 4: Board fees covered the cost of operations.
The department agrees with this conclusion.

Conclusion 5: The board actively amended regulations.
Since this conclusion is directed toward board governance, the department does not have a response.

Conclusion 6: Changes to statutes and regulations improved CSPD's capabilities.
Since this conclusion is directed toward board governance, the department does not have a response.

Conclusion 7: Occupational boards were slow to implement CSPD enhancements.
The division has made significant improvements in establishing administrative and investigative priorities for the Prescription Drug Monitoring Program (which includes the CSPD), which has already improved the allocation of resources. The entry of DEA information into the database across six licensing programs has been consistent in recent years and, with the addition of administrative help for the program, now features a quality assurance check. The division continues to work with the database contractor to provide enhancements within the funding of the program grant.

The department does not have a response to the board governance elements of this conclusion.

Conclusion 8: CSPD notifications were sent to pharmacists, practitioners and licensing boards.
Since this conclusion is directed toward board governance, the department does not have a response.
See recommendation #3

Conclusion 9: Occupational boards recognized the need to coordinate and standardize.
Division staff has improved coordination of processes across the programs that use CSPD/PDMP by holding regularly scheduled meetings, discussing procedures and any changes for capturing and analyzing data. This coordination extends to regularly scheduled meetings of PDMP board chairs.

The department does not have a response to the board governance elements of this conclusion.

Conclusion 10: The board was unable to report certain performance measures.
Since this conclusion is directed toward board governance, the department does not have a response.

Report Recommendations

Recommendation No.1:
The board chair and the division director should improve procedures and training to ensure applicants meet requirements prior to license issuance.
The department agrees that continuous improvement in procedures and training by the division will improve licensure requirements. This summer, the division director implemented division-wide monthly training for all professional licensing staff. The executive administrator for the Board of Pharmacy has implemented additional procedures for checking the correctness of file documentation. Adding a licensing examiner position has also reduced the per-person processing volume, which will reduce the error rate.

Recommendation No. 2:
The board should adopt regulations for outsourcing facilities and third-party logistic provider licensure renewal.
Since this recommendation is directed to the board, the department has no response on their behalf.

Recommendation No. 3:
Applicable occupational boards and the DCBPL director should continue coordination efforts to improve the monitoring and enforcement of CSPD requirements.
The department agrees with this recommendation, and the division has implemented processes for improving CSPD/PDMP coordination between licensing and enforcement efforts. Investigator and professional licensing staff training, new priority policies, and clarified investigative procedures have already improved outcomes.

The division is currently facilitating regularly scheduled meetings with the chairs of the boards that are required to register for the CSPD/PDMP. This is an ongoing effort to better communicate the need for board involvement in monitoring their program's requirements as it pertains to CSPD/PDMP, such as setting guidelines for safe standards of practice and disciplinary matrices. Quarterly reports are also provided by the

CSPD/PDMP coordinator to each of the applicable licensing boards for a review of usage of the CSPD by their licensees.

The department disagrees that licensing program staff should provide referral information to investigators: Per statute, they do not have access to licensee compliance reporting or user activity. These duties are currently appropriately assigned to the CSPD/PDMP coordinator or the executive administrator for the Board of Pharmacy.

Recommendation No. 4:
The DCCED commissioner should allocate sufficient resources to ensure licensees holding a DEA registration number are consistently recorded in DCBPL's licensing database.
The department has approved two additional grant-funded positions to support the administrative duties of this program. Training for professional licensing staff continues to be a priority, and it is resulting in consistency in entry of DEA information. The division expects to launch a more streamlined method of CSPD/PDMP entry into the system. The director anticipates implementing a license integration enhancement in early 2022, which will automate certain steps for the applicant and for staff.

Recommendation No. 5:
The DCCED commissioner should allocate sufficient resources to ensure CSPD requirements are effectively enforced.
The department approved a new investigator position specifically assigned to oversee enforcement of CSPD/PDMP matters. This assignment will contribute to a more coordinated effort in monitoring compliance and enforcement.

Again, thank you for the opportunity for the DCCED to provide input on this matter. Should you have any questions about the contents of this letter, please do not hesitate to contact me at 907-269-8125.

Sincerely,

Julie Anderson
Commissioner

cc: Sara Chambers, Director, Division of Corporations, Business and Professional Licensing
Glenn Hoskinson, Legislative Liaison, DCCED

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Agency Response from the Board of Pharmacy

January 1, 2022

RECEIVED

JAN 0 3 2022

LEGISLATIVE AUDIT

Kris Curtis
Legislative Auditor
Division of Legislative Audit

Dear Auditor Curtis,

In regards to the report conclusions, it is my conclusion the audit process has accurately reflected the actions, intentions and limitations of the Board of Pharmacy during my time serving with the board.

In regards to the recommendations:

1.) Agree. Certain elements of the licensing process have been under review during my time serving on the board. One of those elements is a reduction of superfluous paperwork and unnecessary burdens for limited licensing staff. The moral character section is one of those elements. Although still a requirement, it is an area the board has already submitted requests to change. That does not, however, address the issues with staffing/ training in general. Steps should be taken to retain and train staff in all licensing areas to ensure these processes are able to be accomplished with minimal error or items missed.

2.) This recommendation has already been accomplished at the board level. The board at its September 2021 meeting passed language changes to licensing renewal (12 AAC 52.300) to add outsourcing facility and third-party logistics providers. This has been forwarded on to the regulations specialist for processing.

3.) Agree. The board chairs continue to meet bi-weekly. This has served each board well and we continue to work towards standardizing our approach as well as discussing best approaches to utilizing the database for highest efficiency and efficacy. Since this recommendation involves boards outside of our own it is hard to determine the length of time required to fully implement change in this area.

4 & 5.) Agree. Resources continue to be a challenge across the division. One of the areas that is felt most keenly is in the management of the Controlled Drug Database. Currently there is one person who manages the database. By contrast, many states employ or create an entire department dedicated to their controlled drug database. It is certainly a great tool but having access to the data is only half the battle. Being able to use the data consistently to identify issues, promote better prescribing practices, and investigate those who are falling outside the established guidelines takes people and processes. Both of these are in short supply. The board of pharmacy will continue to promote use of the CSPD across our licensees as well as continue to request resources be dedicated to this important tool to combat opiate use in our state.

Finally, the conclusions and recommendations you have put forth are an accurate reflection of the current state of the Board. I fully support the request to extend to June 30th, 2028.

Sincerely

Justin Ruffridge PharmD

Chair, Board of Pharmacy

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Legislative Auditor's Additional Commments

ALASKA STATE LEGISLATURE
LEGISLATIVE BUDGET AND AUDIT COMMITTEE
Division of Legislative Audit

P.O. Box 113300
Juneau, AK 99811-3300
(907) 465-3830
FAX (907) 465-2347
legaudit@akleg.gov

January 6, 2022

Members of the Legislative Budget
and Audit Committee:

I have reviewed the responses to the Board of Pharmacy audit report. Nothing contained in the responses causes me to revise or reconsider the report conclusions or recommendations. However, I offer the following rebuttal to a statement made by the commissioner of the Department of Commerce, Community, and Economic Development (DCCED) in response to Recommendation No. 3:

> *The department disagrees that licensing program staff should provide referral information to investigators: Per statute, they do not have access to licensee compliance reporting or user activity. These duties are currently appropriately assigned to the [controlled substance prescription database (CSPD)]/[Prescription Drug Monitoring Program (PDMP)] coordinator or the executive administrator for the Board of Pharmacy.*

During fieldwork, auditors were told by DCCED staff that referrals to investigations regarding the CSPD should be made by the respective licensing boards as it was the boards' responsibility to enforce compliance with the database requirements. DCCED's investigations unit *draft* standard operating procedures for database related referrals states, "Once it is determined that further investigation is necessary, the [respective board's] executive administrator or licensing supervisor will refer the alleged PDMP violation to the Investigations Unit via email to the Chief Investigator and the Senior Investigator." Regardless, effective communication between license staff and the CSPD/PDMP coordinator is essential to ensure the appropriate information is obtained that would enable licensing staff to evaluate compliance. We reaffirm the recommendation and encourage the commissioner to take action to ensure procedures are in place to allow for effective referrals to the Division of Corporations, Business and Professional Licensing investigative section for noncompliance.

Additionally, I acknowledge that Recommendation No. 4 on page 29 of the report failed to identify criteria to support the finding. The finding should have included a reference to AS 17.30.200(n), which requires a pharmacist who dispenses or a practitioner who prescribes,

administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law to register with the database. Criteria is also codified in board specific statutes, including: Board of Pharmacy AS 08.80.030(b)(14); State Medical Board AS 08.64.101(7); Board of Nursing AS 08.68.100(a)(11); Board of Dental Examiners AS 08.36.070(a)(10); Board of Examiners of Optometry AS 08.72.060(c)(3); and Board of Veterinary Examiners AS 08.98.050(a)(10).

Sincerely,

Kris Curtis, CPA, CISA
Legislative Auditor

THE STATE of ALASKA

Board of Pharmacy
State Office Building, 333 Willoughby Avenue, 9th Floor
PO Box 110806, Juneau, AK 99811-0806
Phone: (907) 465-2550
Email: *BoardOfPharmacy@Alaska.Gov*
Website: *ProfessionalLicense.Alaska.Gov/BoardOfPharmacy*

PHA

FOR DIVISION USE ONLY

Pharmacy — Annual Information Update

In accordance with Alaska Statute AS 08.80.158(b) out-of-state pharmacies registered with the Alaska Board of Pharmacy shall furnish the board annually with updated information. This form must be completed in full, including all attachments listed in (d), notarized and returned to the above address.
Use this form for odd years only. Annual updates for even years are included in your renewal application.

Pharmacy Name		**Report Year**	
Alaska License or Registration #			
Street Address	Street		
	City	State	ZIP Code
Mailing Address	Address or PO Box		
	City	State	ZIP Code
Pharmacy Phone Number			
Type of Business	☐ Sole Proprietor ☐ Partnership ☐ Corporation ☐ LLC/LLP		
Type of Facility	☐ Community ☐ Mail-Order ☐ Sterile Compounding ☐ Compounding ☐ Internet ☐ Other: _____		
Licenses are not transferrable and any change of name, location or ownership (company registration) will require a new license. Applications and forms are available at: *ProfessionalLicense.Alaska.gov*			
Name of Pharmacist-in-charge		**License Number**	
Address of Pharmacist-in-charge	Street		
	City	State	ZIP Code

NO FEES ARE REQUIRED WITH THIS INFORMATION UPDATE.

WARNING: The Division may deny, suspend, or revoke the license of a person who has obtained or attempted to obtain a license by fraud or deceit. The person may also be subject to criminal charges for perjury or unsworn falsification. (AS 11.56.200)

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

a. 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.

b. That the pharmacy maintains its records of prescription drugs dispensed to persons in Alaska so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

c. That if this pharmacy began distributing/dispensing controlled substances to Alaska since the last annual report or renewal, it has been reporting data daily to the Prescription Drug Monitoring Program through NABP ClearingHouse as required by AS 17.30.200(b).

d. I further attest that the information contained herein is true and correct. I understand that information supplied with this form is considered public, unless required to be kept confidential pursuant to state or federal law.

e. I have attached the required documentation:

- ☐ A list of all pharmacists who are dispensing prescription drugs to Alaska.
- ☐ A copy of a current valid license or registration from the jurisdiction where the facility is located.
- ☐ A copy of the most recent inspection report from the jurisdiction where the facility is located. If the inspection report is older than two years complete the Pharmacy Self Inspection Report located on our website at *ProfessionalLicense.Alaska.gov/BoardOfPharmacy*
- ☐ Corporations must include a list of all principal corporate officers (name, title, and location).

f. **No fees are required for this annual information update.**

Notary Stamp

_____
Signature of Owner of Officer Date

SUBSCRIBED AND SWORN TO before me on this day: _____

Notary Public for the State of: _____

My Commission Expires: _____

From: Carrillo, Laura N (CED)
To: akboardofpharmacy@list.state.ak.us
Subject: COVID-19 Therapeutics
Date: Tuesday, November 23, 2021 5:50:00 PM

Greetings,

The Board of Pharmacy is issuing this notice regarding COVID-19 and certain authority under the PREP Act to administer therapeutics. After consultation with the Department of Law, the board received clarification on the following:

Q1: What can be ordered and administered?
A1: Under the 9th amendment of the PREP Act, COVID-19 therapeutics that have been authorized, approved, licensed, or cleared by the FDA can be ordered and administered without a prescriber's drug order. At this time, approved treatments include monoclonal antibodies and remdesivir. As the FDA recognizes additional treatments in the future, please be sure to check their website to ensure administration of therapeutics are approved/authorized:
https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19

Q2: Who can order and administer therapeutics?
A2: Only pharmacists can order therapeutics; however, pharmacists, interns, and qualified technicians who are licensed or permitted in Alaska and have completed any required training may administer them.

Q3: Are there restrictions on routes of administration?
A3: COVID-19 therapeutics for subcutaneous, intramuscular, or oral administration can be ordered and administered by pharmacists, interns, and qualified technicians independently, but the treatment must still be authorized, approved, licensed, or cleared by the FDA.

Thank you,

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

From: Carrillo, Laura N (CED)
To: akboardofpharmacy@list.state.ak.us
Subject: Board of Pharmacy - Continuing Education Disciplinary Matrix
Date: Tuesday, November 23, 2021 12:48:00 PM

Greetings,

Continuing education is crucial to upholding high standards of patient care and in ensuring a robust pharmacy profession in Alaska. Failure to comply with continuing education places both patients and your license at risk. As renewal season will begin in the spring, this serves as a reminder to register for courses now to ensure compliance by **June 30, 2022.** In addition, during its meeting on **November 18, 2021**, the Board of Pharmacy approved changes to its continuing education disciplinary matrix for failure to comply as follows:

Type	Base Fine	Fine/Hour of Credit Missed	Mandatory Audits	Reprimand	Consent Agreement
Pharmacist	$500.00	$100.00	2	Yes	Yes
Pharmacy Technician	$125.00	$25.00	2	Yes	Yes

For current requirements on renewal and continuing education, please review 12 AAC 52.300 – 12 AAC 52.350 in the board's statutes and regulations here:
https://www.commerce.alaska.gov/web/portals/5/pub/PharmacyStatutes.pdf

Thank you,

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

From: Carrillo, Laura N (CED)
To: akboardofpharmacy@list.state.ak.us
Subject: Notice of Proposed Regulations - 12 AAC 52
Date: Wednesday, February 2, 2022 5:36:00 PM
Attachments: PHA Notice-0222.pdf

Greetings,

The Board of Pharmacy proposes to update regulations regarding its qualifications and requirements to apply for an emergency permit and to update renewal application requirements for pharmacists, pharmacy technicians, pharmacies, outsourcing facilities, wholesale drug distributors, and third-party logistics providers. It also proposes to repeal the emergency courtesy license, update duties of its executive administrator as it relates to renewal application processing, and establish temporary courtesy licenses for an active duty military member or their spouse.

Please submit your public comments as directed in the attached notice no later than **March 8, 2022 at 4:30 p.m.**

Thank you,

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

ExamYear	PassRate
2018	77.4%
2019	77.6%
2020	86.3%
2021	72.3%

ExamYear	PassRate
2018	77.7%
2019	76.2%
2020	84.8%
2021	72.0%

ExamYear	erageAttem	laxAttempts
2018	2.333333	5
2019	2.142857	3
2020	2.5	4
2021	2.166667	3

Board of Pharmacy Task List
(Tasks from previous meeting: November 18, 2021)

Number of tasks assigned	Completed	Pending
24	22	2

No.	Task	Assigned	Status
1	Ms. Carrillo will send the approved minutes to Chair Ruffridge for signature and to the publications unit for posting to the website.	Laura Carrillo/Justin Ruffridge	Completed 11/19/2021
2	Ms. Carrillo and Dr. Schaber will continue to work on the board's draft disciplinary matrix and will provide an update during its February 17-18, 2022 meeting.	Laura Carrillo	Completed 01/05/2022
3	Ms. Carrillo will send a notice through the ListServ with the board's update to its continuing education disciplinary matrix.	Laura Carrillo	Completed 11/19/2021
4	Ms. Carrillo will update Mr. Brown to inform him of his tabled application.	Laura Carrillo	Completed 11/19/2021
5	Ms. Carrillo will send a copy of the emergency permit denial motions to Investigator Bowles.	Laura Carrillo	Completed 11/19/2021
6	Ms. Carrillo will process the application for #154661 per approval of request for an alternative continuing education schedule.	Laura Carrillo	Completed 11/19/2021
7	Ms. Carrillo will file the final version of the Renewal Review/Approval Process for Professional Fitness Responses for reference during the renewal cycle.	Laura Carrillo	Completed 11/19/2021
8	Ms. Carrillo will forward to the department's legislative liaison contact information for Dr. Ruffridge and Dr. Schaber as leads for the upcoming session.	Laura Carrillo	Completed 11/19/2021
9	Ms. Carrillo will draft a response to the individual who wrote with concerns that pharmacists are refusing medications to help treat COVID-19. Ms. Carrillo will then send it to the board for their review/approval.	Laura Carrillo	Completed 11/22/2021

10	Ms. Carrillo will follow-up with DOL on whether pharmacists can independently order and administer monoclonal antibodies under the PREP Act.	Laura Carrillo	Completed 11/19
11	Ms. Carrillo will add automated distribution kiosks to the board's next agenda for February 17-18, 2022.	Laura Carrillo	Completed 11/19
12	Ms. Carrillo will forward the regulation amendments striking 12 AAC 52.470(d)(2) to the division's regulations specialist.	Laura Carrillo	Completed 11/22/2021
13	Ms. Carrillo will forward the board's motion and minutes excerpt on fee reductions to the regulations specialist.	Laura Carrillo	Completed 11/23/2021
14	Ms. Carrillo will remove drug takeback programs as a future agenda item.	Laura Carrillo	Completed 11/23/2021
15	Ms. Carrillo will track the number of pharmacies providing internet services at the time of the next renewal.	Laura Carrillo	Pending renewal season 04/01/2022 – 06/30/2022
16	Ms. Carrillo will reach out to the NABP to invite a representative to discuss the .Pharmacy and VIPPS program with the board during its February 17-18, 2022 meeting.	Laura Carrillo	Completed 11/24/2021
17	Ms. Carrillo will sign the certification order and affidavit of board action for adopted changes to 12 AAC 52.855 – 12 AAC 52.857.	Laura Carrillo	Completed 11/19/2021
18	Ms. Carrillo will submit part III PDMP regulations to the regulations specialist for DOL review and public comment.	Laura Carrillo	Completed 11/24/2021
19	Ms. Carrillo will create a draft joint cooperative practice form for use by physicians and pharmacists and will create a checklist and process to endorse cooperative practice applications after approval by the State Medical Board.	Laura Carrillo	Completed 11/08/2021
20	Ms. Carrillo will share the draft documents with the Medical Board's EA, Natalie Norberg, to finalize the cooperative practice application, checklist, and policy/procedure. Ms. Carrillo will then provide an update to	Laura Carrillo	Pending (met on 12/14/2021 and 02/09/2022)

	the board on this at its February 17-18, 2022 meeting.		
21	Ms. Carrillo will follow up on the DOL request regarding white/brown bagging.	Laura Carrillo	Completed 11/24/2021
22	Ms. Carrillo will add PIC requirements and limitations to the next meeting agenda for February 17-28, 2022.	Laura Carrillo	Completed 01/19/2022
23	Ms. Carrillo will reach out to the AKPhA for results on the workforce conditions survey and will share it with the board during their February 17-18, 2022 meeting.	Laura Carrillo	Completed 11/26/2021
24	Ms. Carrillo will submit a travel and meeting request for all board members to attend the February 17-18, 2022 in-person meeting in Juneau.	Laura Carrillo	Completed 11/26/2021

Ongoing previous tasks:

From Feb. 18-19, 2021 meeting	Dr. Ruffridge will review the website FAQs for accuracy and applicability and recommend at the board's next meeting what FAQs need to be added, updated, removed, or turned into position statements.	Justin Ruffridge	Is 1/4th complete as of May 20-21 meeting
From Feb. 18-19, 2021 meeting	All board members will review the investigative checklist and sample letter in advance of the May meeting	All	By February 2022 meeting
From May 20-21, 2021 meeting	Ms. Carrillo will update the board's PDMP disciplinary matrix to reflect daily tracking of reporting compliance for monthly referrals to the Investigative Unit.	Laura Carrillo	Initiated 06/04/2021; pending
From September 23-24, 201 Meeting	Ms. Carrillo will review AKPhA's model language on white bagging from Dr. Schaber and will submit a request for DOL guidance as to whether it falls under title 21 with the Division of Insurance or if there are any components that fall under AS 08.80.	Laura Carrillo	Completed 12/21/2022

Statutes and Regulations
Pharmacy

May 2021

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

NOTE: The official version of the statutes in this document is printed in the Alaska Statutes, copyrighted by the State of Alaska. The official version of the regulations in this document is published in the Alaska Administrative Code, copyrighted by the State of Alaska. If any discrepancies are found between this document and the official versions, the official versions will apply.

Rev. 5/14/2021

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CHAPTER 80. PHARMACISTS AND PHARMACIES

Article
1. **The Board of Pharmacy (§§ 08.80.003 - 08.80.105)**
2. **Licensing and Registration (§§ 08.80.110 - 08.80.270)**
3. **Duties of Licensed Pharmacists (§§ 08.80.294 - 08.80.335)**
4. **Unlawful Acts (§§ 08.80.390 - 08.80.460)**
5. **General Provisions (§§ 08.80.470 - 08.80.490)**

ARTICLE 1. THE BOARD OF PHARMACY

Section
03. **Practice of pharmacy as a profession**
05. **Statement of purpose**
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**
70. **Quorum**
80. **Expenses of members**
105. **Removal of board members**

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
120. Grading and content of examination
145. Reciprocity; license transfer
147. Renewal of licensure
150. Temporary license
155. Emergency permit
157. Licensing of facilities
158. Registration of pharmacies located outside of state

159. Licensing and inspection of facilities outside of state
160. Fees
165. Continuing education requirements
168. Administration of vaccines and related emergency medications
261. Disciplinary sanctions
270. Executive administrator of the board

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)**
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ARTICLE 1.
LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

Section

10. Classifications of licensure
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40. Change of pharmacy ownership
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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 LICENSURE TO PRACTICE AS A PHARMACIST, PHARMACY INTERN, OR PHARMACY TECHNICIAN. (a) If the board determines that an emergency exists requiring the provision of licensed coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, the board may issue an emergency pharmacist, pharmacy intern, or pharmacy technician permit to an applicant who

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

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits verification on a form provided by the department that the applicant is currently licensed 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;

(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 under (a) of this section is nonrenewable, and is valid for 90 days or until the emergency circumstances no longer exist, whichever is shorter.

(c) Repealed 11/19/2020.

(d) In an urgent situation, the board may issue an emergency courtesy license to practice as a pharmacist, pharmacy intern, or pharmacy technician to an applicant who meets the requirements of this section. The board may restrict the license to only those services required to respond to the urgent situation. The licensee may not practice as a pharmacist, pharmacy intern, or pharmacy technician outside the scope of the limited purpose for which the emergency courtesy license is issued.

(e) An applicant for an emergency courtesy license under this section must submit to the department a completed application on a form provided by the department. A complete application includes the applicable application and licensing fees established in 12 AAC 02.105.

(f) An emergency courtesy license issued under this section is valid for the period specified by the board and may not exceed 120 consecutive days. An emergency courtesy license may be renewed for one additional period specified by the board, not to exceed 120 consecutive days.

(g) The board will not issue, and an emergency courtesy license holder may not use, an emergency courtesy license as a substitute for a temporary license or other license required under AS 08.80.

(h) While practicing under an emergency courtesy license issued under this section, the holder of the emergency courtesy license must comply with the standards of practice set out in AS 08.80 and this chapter.

(i) The board may refuse to issue an emergency courtesy license for the same reasons that it may deny, suspend, or revoke a license under AS 08.80.261.

(j) In this section, "urgent situation" means a health crisis requiring an increased availability of pharmacists, pharmacy interns, or pharmacy technicians.

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
645. Examination of drug shipments
650. Records and inventories
660. Returned, damaged, and outdated drugs
670. Drug recalls
680. Inspections
685. Prohibition against direct distribution
690. Salvage and reprocessing
695. Provisions not applicable
696. Outsourcing facilities
697. Third-party logistics providers

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.

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.

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.

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.

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.

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.

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.

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 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.

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

CHAPTER 30.
CONTROLLED SUBSTANCES

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.

FACILITY STANDARDS FOR PHARMACIES
November 2016

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.

Board or Commission: Alaska Board of Pharmacy

Meeting Date: _____

Agenda Item # _____ Tab #_____ Topic: _____

Primary Motion

Motion:

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

Subsidiary Motion or Amendment

Motion:

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

EXECUTIVE SESSION MOTION

Sec. 44.62.310. Government meetings public.
(c) The following subject may be considered in an executive session:

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

MOTION WORDING:

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

(1) **matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;** ***OR***

(2) **subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;** ***OR***

(3) **matters which by law, municipal charter, or ordinance are required to be confidential;** ***OR***

(4) **matters involving consideration of government records that by law are not subject to public disclosure.**

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

Staff will then state **"The board is off the record at _____(time)."**

PURPOSE	YOU SAY	INTER-RUPT?	2ND?	DEBATE?	AMEND?	VOTE?
Bring business before the board	I move to…	No	Yes	Yes	Yes	Majority
Modify wording of motion	I move to amend the motion by…	No	Yes	Yes	Yes	Majority
Lay aside temporarily	I move to lay the question on the table.	No	Yes	No	No	Majority
Close debate	I move the previous question.	No	Yes	No	No	2/3
Limit or extend debate	I move that debate be limited to…	No	Yes	No	Yes	2/3
Postpone to a certain time	I move to postpone the motion to…	No	Yes	Yes	Yes	Majority
Refer to committee	I move to refer the motion to…	No	Yes	Yes	Yes	Majority
Kill main motion	I move that the motion be postponed indefinitely.	No	Yes	Yes	Yes	Majority
Make follow agenda	I call for the orders of the day.	Yes	No	No	No	None or 2/3 to overrule
Take matter from table	I move to take from the table…	No	Yes	No	No	Majority
Cancel previous action	I move to rescind…	No	Yes	Yes	Yes	2/3 w/o prior notice
Reconsider motion	I move to reconsider…	No	Yes	Varies	No	Majority
Take a break	I move to recess for…	No	Yes	No	Yes	Majority
Close meeting	I move to adjourn.	No	Yes	No	No	Majority

ORDER OF OPERATIONS TO ACT AS A BOARD

1. A member seeks recognition from the chair.
2. The member is recognized by the chair and "has the floor."
3. The member makes a motion.
4. The motion is seconded (if appropriate, see chart on other side).
5. The chair (or staff, if delegated) restates the motion to the body.
6. Board or commission debates the motion.
7. Subsidiary motions are made, if any: Amend, table, send to committee (see chart on other side).
8. Board or commission votes on subsidiary motion, if any.
9. Board or commission votes on the main motion either by roll call or unanimous consent.
10. The chair (or staff) announces the result of the vote.

Best practices:

1. Makers of motions should write them down before verbalizing, then hand the written motion to the secretary once the motion has been made on the floor.
2. It is appropriate for the chair to call for a brief break ("at ease") to untangle the motions when operations become confused. Do not proceed in confusion.