

Public Packet

May 8, 2020 - Alaska Board of Pharmacy Meeting - Day 2

May 8, 2020 9:00 AM - May 8, 2020 4:30 PM AKDT

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STATE OF ALASKA

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

ALASKA BOARD OF PHARMACY



May 7-8, 2020

Teleconference/Videoconference

Board Packet

STATE OF ALASKA 2020

State Holidays

Date	Holiday
01/01	New Year's Day
01/20	MLK Jr.'s Birthday
02/17	Presidents' Day
03/30	Seward's Day
05/25	Memorial Day
07/04	Independence Day (observed 7/3)
09/07	Labor Day
10/18	Alaska Day (observed 10/19)
11/11	Veterans' Day
11/26	Thanksgiving Day
12/25	Christmas Day

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

 Holiday
 Payday



State calendar maintained by the
Division of Finance,
Department of Administration
<http://doa.alaska.gov/calendars.html>
Revised 10/31/2019

STATE CALENDAR

JANUARY

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ALASKA BOARD OF PHARMACY MEETING TENTATIVE AGENDA

MAY 8, 2020 (DAY 2)

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

Discussion of the following topics may require executive session. The executive session phone number has not been provided for the public.

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*
(Vice Chair)

James Henderson,
RPh

Lana Bell, *RPh*
(Secretary)

Justin Ruffridge,
PharmD

Tammy Lindemuth,
Public Member

Sharon Long, *Public
Member*

Upcoming Meetings:

TBD

Meeting Details

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

Meeting Start Time: 9:00 AM Alaskan Daylight Time

Meeting Start Date: 5/08/2020

Meeting End Time: 4:30 PM Alaskan Daylight Time

Meeting End Date: 05/08/2020

Meeting Location: Teleconference only

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

Agenda

- I. Agenda Item #1 - 9:00 a.m. Roll Call/Call to Order
- II. Agenda Item #2 - 9:05 a.m. Review/Approve Agenda
- III. Agenda Item #3 – 9:10 a.m. Ethics Disclosures
- IV. Agenda Item #4 – 9:15 a.m. Regulations
 - A. Emergency Regulations Recap
 - B. Regulation Gaps
 - C. Permanent Regulations

LUNCH – 12:00 p.m. – 1:00 p.m.

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*
(Vice Chair)

James Henderson,
RPh

Lana Bell, *RPh*
(Secretary)

Justin Ruffridge,
PharmD

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

**Upcoming
Meetings:**

TBD

V. Agenda Item #5 – 1:00 p.m. Resume Regulations

- A. Delivery driving
- B. Shared pharmacy services
- C. Transfer of prescription drug orders

VI. Agenda Item #6 – 3:30 p.m. Legal Opinion Reviews

- A. Supervision
- B. Alternate care sites

VII. Agenda Item #6 – 4:30 p.m. Adjourn

MEMORANDUM

State of Alaska
Department of Law

TO: _____ DATE: _____
FILE NO.: _____
TEL. NO.: _____
FROM: Angie White
Litigation Assistant
Department of Law
Opinions, Appeals, & Ethics Section
FAX: _____
SUBJECT: Executive Branch Ethics Act, AS
39.52 Quarterly Report
[INSERT QUARTERLY DATE
RANGE]

******SAMPLE LANGUAGE – PLEASE COPY ONLY THE PARTS THAT APPLY
ONTO YOUR BOARD OR COMMISSION’S LETTERHEAD ******

As designated ethics supervisor and chair [executive director] for the _____, I wish to advise you that I have received no notifications of potential violations or requests for ethics determinations under the Ethics Act (AS 39.52) and have made no written determinations for this quarter.

OR

As designated ethics supervisor and chair [executive director] for the _____, I have received ___ notification(s) of a potential violation and ___ requests for ethics determinations under the Ethics Act (AS 39.52) I have attached a copy of the notices and requests along with my written determination(s) for review by the attorney general. I did [did not] receive an advisory opinion from the Attorney General.

AND

Except as addressed above, no other [board member] [commissioner] disclosed a potential conflict of interest at a recorded public meeting during this quarter.

OR

In addition to the above, at the [date] meeting, [Board member] [Commissioner] _____ disclosed a potential conflict with respect to _____ [insert brief description]_____. *Insert disposition:* [S/He refrained from participation.] or [I determined s/he could [could not] participate.] or [The Board [Commission] members voted to permit [not to permit] participation.]

State of Alaska Department of Law

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 Guy Bell, 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 Guy Bell, 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 Guy Bell, 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: Leslie Ridle, Deputy Commissioner

Commerce, Community & Economic Development: Jon Bittner, Deputy Commissioner

Corrections: April Wilkerson, Director of Administrative Services

Education & Early Development: Les Morse, Deputy Commissioner

Environmental Conservation: Tom Cherian, Director of Administrative Services

Fish & Game: Kevin Brooks, Deputy Commissioner

Health & Social Services: Dallas Hargrave, Human Resource Manager

Labor & Workforce Development: Michael Monagle, Director, Division of Workers Compensation

Law: Jonathan Woodman, Assistant Attorney General

Military & Veterans Affairs: Marty Meyer, Special Assistant to Commissioner

Natural Resources: John Crowther, Inter-Governmental Coordinator

Public Safety: Terry Vrabec, Deputy Commissioner

Revenue: Dan DeBartolo, Administrative Services Director

Transportation & Public Facilities:

- Highways & Public Facilities: Steve Hatter, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Rob Campbell, Regional Director
- Northern Region: Rob Campbell, Acting Regional Director
- Southcoast Region: Acting Regional Director
- Alaska Marine Highway System: Michael Neussl, Deputy Commissioner
- Headquarters: Mary Siroky, Administrative Services Director

Updated April 2015

Department of Law attorney.general@alaska.gov P.O. Box 110300, Juneau, AK 99811-0300
Phone: 907-465-3600 Fax: 907-465-2075 TTY: 907-258-9161
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State of Alaska

Department of Law

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

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State of Alaska

Department of Law

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 Manual for Designated Ethics Supervisors (April 2008), 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 269-7195.
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 Kim Halstead, Litigation Assistant, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-279-2834.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Jon Woodman, at 269-5100 or jonathan.woodman@alaska.gov. Please direct questions about reporting procedures to Kim Halstead at 269-7195 or kimberly.halstead@alaska.gov.

6/14

Department of Law attorney.general@alaska.gov P.O. Box 110300, Juneau, AK 99811-0300
Phone: 907-465-3600 Fax: 907-465-2075 TTY: 907-258-9161
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Steps in the Board Regulation Adoption Process

<i>Day 1</i>	<p>1 At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.</p>	<i>Day 65</i>	<p>7 Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.</p>	<p><i>Once Regulations Are Effective</i></p> <p>14a Agency posts summary on Alaska Online Public Notice System</p> <p>14b Regulation published in Alaska Administrative Code</p> <p>14c Forms & FAQ updated on program web page</p>
<i>Day 30</i>	<p>2 Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.</p>	<i>Day 75</i>	<p>8 Regulations Specialist compiles public comments for distribution to board.</p>	
	<p>3 Approved language is reviewed by Division attorney.</p>	<i>Day 90</i>	<p>9 Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).</p>	
	<p>4 Department of Law opens file.</p>		<p>10 Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.</p>	
<i>Day 45</i>	<p>5 Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System</p>		<p>11 Agency attorney reviews regulation</p>	
	<p>6 Public comment period and/or hearing (if applicable).</p>	<i>Day 110</i>	<p>12 Regulations attorney reviews and either approves or disapproves regulation</p>	
		<i>Day 150</i>	<p>13 Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days</p>	

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

Steps in the Regulation Process for a Board and Commission (board)¹

Beginning the Process

1. At an open meeting, the board initiates and votes on proposed regulation changes.
2. **Reason:** Identify the reason for the proposed action, such as compliance with new or changed state law. If applicable, identify the law, order, decision, or other action of the federal government, or federal or state court, if that is the basis for the proposed action. The description need only be a sentence or two.
3. **Cost information:** In the meeting minutes there must be estimated costs in the aggregate to comply with the proposed action to:
 - A private person
 - Another state agency
 - A municipality

Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community.

Example: The Board of Chiropractic Examiners is proposing to add three CE credits to their continuing competency requirements for a biennial license renewal. The proposal may cost

- A private person: \$50 per applicant/licensee
 - Another state agency: None known
 - A municipality: None known
4. Within 10 days of the meeting, board staff must transmit board minutes² or an excerpt of the minutes, draft language or proposals, and a completed Regulations FAQ Worksheet for the proposed regulation changes requested by the board to the Regulations Specialist.

What comes next: Regulations Specialist

5. The Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.
6. The Regulations Specialist prepares a draft of regulation changes, using the Department of Law's *Drafting Manual for Administrative Regulations* for conformity and style, and works with board staff before submitting the final draft to the board for review/approval. In some instances the draft regulation changes will be reviewed by an AAG before the final draft is submitted to the board for review/approval.
7. Once completed, the draft proposed regulation changes are presented to the board at its next public meeting to review and approve the final draft, amends if needed, and requests that the approved draft be finalized and public noticed.

Public Notice

8. NOTE: The board must **always** provide an opportunity for submission of written comments in the regulation-adoption process. Also, the board should determine if it wants to hold a public hearing on the proposed regulation changes at its next meeting. If it does, the location, date and time of the hearing needs to be included in the public notice. Public hearings are usually held in conjunction with a regularly-scheduled meeting of the board and are always recorded. Oral public hearing is optional; however, answering the following questions will help the board determine if an oral public hearing is needed:
- Are the regulations controversial and is there likely to be substantial public interest in them?
 - Would those most affected by the regulations be better able to participate if an oral hearing were held?
 - Would the board benefit from a face-to-face or teleconferenced opportunity to receive comments on the proposed regulations from interested persons?
9. Regulations Specialist sends notice to Alaska Dispatch News (or other newspapers if warranted) for publication, all interested parties, and licensees, if warranted. The Regulations Specialist posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, Legislative Council, Lt. Governor, Governor, and Department of Law (Law). It is also emailed to board members and affected staff, including the commissioner's office. Public notice will be posted on the board's webpage.

Comment Period

10. The Regulations Specialist or board staff shall make a good faith effort to answer relevant questions received at least 10 days before the end of the public comment period. Questions must be in writing or asked at the legally noticed public meeting. The Regulations Specialist or board staff shall answer questions in writing and make the questions and answers available on the Alaska Online Public Notice System and the board's webpage. FAQs will be posted on the board's webpage and updated when relevant questions are answered. The Regulations Specialist or board staff may, but are not required to, answer written questions received after the 10-day cutoff date.
11. After the comment deadline (at least 30 days in duration), comments received on proposed regulation changes are compiled and copied by the Regulations Specialist and given to board staff to include in the board packets for the next open board meeting to be considered prior to adopting. Comments received after the deadline should not be forwarded to the board and comments should not be taken at the board meeting from the public prior to adoption unless a hearing was noticed and the comments are heard by the board during the comment period.

Adoption

12. The board's options regarding the proposed regulation changes at its next meeting are:

- a. It can adopt the proposed regulation changes as written/publicly noticed, amend, and adopt them; or
 - b. Choose to take no action on them.
 - c. Substantive changes may require additional drafting and public notice (see Step 7 above).
13. When making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received, and considered the cost to private persons of the regulatory action being taken.
14. When regulation changes are adopted:
 - a. The chair signs the adoption/certification order; and
 - b. The board staff signs an affidavit of board action and/or affidavit of oral hearing (if applicable) and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

Finalizing the regulation change process

15. Regulations Specialist prepares the final regulation package for transmittal to Department of Law for final review/approval, which includes the adopted regulations, certain affidavits, and other appropriate documents.
16. Assigned agency attorney reviews the regulations.
17. Regulations attorney reviews and either approves or disapproves regulation changes. Law reviews and will occasionally make edits. (On rare occasions, this may require the edited version to be re-adopted by the board at a subsequent meeting.) At the same time, the adopted regulations are submitted to the governor for review. The governor has 30 days to review the regulations under AS 44.62.040(c), and return the regulation for specified reasons.
18. Unless returned by the governor, when the governor and Law's review are complete, the adopted regulations are forwarded to the Lt. Governor for filing. Regulation changes are effective 30 days after filing unless a later effective date is specified in the adoption order.

Once regulations are effective

19. Agency posts summary of approved regulation changes on Alaska Online Public Notice System.
20. Agency updates statutes and regulations board webpage.
21. Regulation published in Alaska Administrative Code.

¹ The process may take six months to a year or longer to complete. It may be expedited if a board meets often or holds a teleconference following the written comment period to adopt the final regulations. Department of Law workload also plays a big part in the timeframe.

² Board minutes reflecting concisely what the project entails plays an important part in getting a project rolling. This is true for the initial stages and the final motion adopting the regulations following the public comment period due to the relevant minutes or an excerpt of the minutes being forwarded to the Department of Law with the final project.



Notice of Adoption of Emergency Regulation to the Practice of Pharmacy in The Regulations of the Board of Pharmacy

Emergency Regulations - FAQ

April 2020

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

On March 27, 2020, the Board adopted and finds that an emergency exists and that the emergency regulation is necessary for the immediate preservation of the public peace, health, safety, or general welfare. The facts constituting the emergency include the following:

Licensees under AS 08.80 are experiencing increased workloads as patients request medications in amounts sufficient to avoid frequent trips to a pharmacy. At the same time, licensed facilities are experiencing staffing shortages due to illness, child care obligations, and pre-planned PTO. These regulations will alleviate the strain by:

- Increasing capacity by expanding the tasks which a pharmacy technician who holds a national certification may perform;
- Allowing a cashier or bookkeeper to work in a pharmacy without being licensed as a pharmacy technician;
- Decreasing unnecessary administrative requirements;
- Increasing the ranks of licensees who may provide immunizations during the emergency by removing the requirement to obtain CPR certification;
- Streamlining application and renewal requirements;
- Expanding shared pharmacy service functions;
- Clarifying pharmacists and pharmacist interns may administer drugs pursuant to a prescription drug order;
- Allowing for temporary relocations during the emergency without a need to apply for a new and separate license; and
- Allowing the distribution, if insurance allows, of sufficient medication to avoid forcing patients to make multiple return trips.

2. What are the costs to comply with the emergency regulations?

None known.

3. When will the emergency regulations be effective?

The emergency regulations took effect on **April 3, 2020**, and will expire **July 31, 2020** (120 days) unless made permanent by the Board. The Board intends to make the emergency regulations permanent.

This emergency regulation is entering a public comment period. The Board encourages all licensees and interested parties to comment on this emergency regulation. After public comment deadline, comments received are compiled and given to the Board for consideration.

After Board action, and no changes made to the original emergency regulations, the permanent regulations goes to Dept. of Law (DOL) for final review and forwarded to the Lt. Governor for filing before the expiration date of the emergency regulations.

However, after Board action, and if changes were made to the original emergency regulations, the adopted amended emergency regulations goes to DOL for final review/approval. DOL either approves or disapproves the changes made to the original emergency regulations. Once approved by DOL, it goes to the Lt. Governor for filing. Permanent regulation takes effect on the 30th day after they have been filed by the Lt. Governor.

Do you have a question that is not answered here? Please email RegulationsAndPublicComment@alaska.gov so it can be added.

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



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

**OFFICE OF THE LIEUTENANT GOVERNOR
ALASKA**

M E M O R A N D U M

TO: Amy Demboski
Department of Commerce Community and Economic Development

FROM: April Simpson, Office of the Lieutenant Governor 
465.4081

DATE: April 3, 2020

RE: Filed Emergency Regulations: Board of Pharmacy

Board of Pharmacy regulations re: Pharmacist Duties, Interns, Technician with National Certification, Prescriptions, Emergency Preparedness and Definitions (12 AAC 52.060 - .995)

Attorney General File:	Emergency Regulations
Regulation Filed:	4/3/2020
Effective Date:	4/3/2020
Expiration Date:	July 31, 2020 unless made permanent by the adopting agency
Print:	234, July 2020

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

FINDING OF EMERGENCY

The Board of Pharmacy finds that an emergency exists and that the attached regulation is necessary for the immediate preservation of the public peace, health, safety, or general welfare. The facts constituting the emergency include the following:

Licensees under AS 08.80 are experiencing increased workloads as patients request medications in amounts sufficient to avoid frequent trips to a pharmacy. At the same time, licensed facilities are experiencing staffing shortages due to illness, child care obligations, and pre-planned PTO. These regulations will alleviate the strain by:

- Increasing capacity by expanding the tasks which a pharmacy technician who holds a national certification may perform;
- Allowing a cashier or bookkeeper to work in a pharmacy without being licensed as a pharmacy technician;
- Decreasing unnecessary administrative requirements;
- Increasing the ranks of licensees who may provide immunizations during the emergency by removing the requirement to obtain CPR certification;
- Streamlining application and renewal requirements;
- Expanding shared pharmacy service functions;
- Clarifying pharmacists and pharmacist interns may administer drugs pursuant to a prescription drug order;
- Allowing for temporary relocations during the emergency without a need to apply for a new and separate license; and
- Allowing the distribution, if insurance allows, of sufficient medication to avoid forcing patients to make multiple return trips.

ORDER CERTIFYING ADOPTION

I certify that the Board of Pharmacy, under the authority of AS 08.01.075, AS 08.01.100, AS 08.80, AS 11.71.900, AS 17.30.200, and AS 17.30.900, adopted at its March 27, 2020 teleconference meeting the attached fifteen pages of regulation changes as an emergency regulation to take effect immediately upon filing by the lieutenant governor, as provided in AS 44.62.180(3).

This action is not expected to require an increased appropriation.

DATE: April 3, 2020
Juneau, Alaska



Laura Carrillo, Executive Administrator
Board of Pharmacy

April Simpson for FILING CERTIFICATION

I, [^]Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on April 3rd, 2020 at 2:25 p.m., I filed the attached regulation according to the provisions of AS 44.62.

for April Simpson
Kevin Meyer, Lieutenant Governor

Effective: April 3, 2020.

Register: 234, July 2020

Expires July 31, 2020
unless made "permanent"
by the adopting agency

FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY

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

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

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



K. Meyer
.....

**KEVIN MEYER
LIEUTENANT GOVERNOR**

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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 52.060 is amended by adding a new subsection to read:

12 AAC 52.060. Fire or other disaster.

...

(d) In this section, “other disaster” includes any disaster situation which causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory. (Eff. 1/16/98, Register 145; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330

AS 08.80.030

12 AAC 52.210 is amended to read:

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;**

...

(6) [MAKING A FINAL CHECK ON ALL ASPECTS OF A COMPLETED PRESCRIPTION AND] assuming the responsibility for a filled prescription [, INCLUDING THE ACCURACY OF THE DRUG PRESCRIBED AND OF THE PRESCRIBED DRUG'S STRENGTH, LABELING, AND PROPER CONTAINER]; [AND]

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

(8) administer a prescription drug order in accordance with prescriber's order. (Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.220(e)(3) is repealed:

(e) A pharmacist supervising a pharmacist intern

...

(3) **repealed** 4 / 3 / 2020 [SHALL PHYSICALLY REVIEW PRESCRIPTION DRUG ORDERS AND THE DISPENSED PRODUCT BEFORE DELIVERY OF A PRODUCT TO THE PATIENT OR THE PATIENT'S AGENT];

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232; am 4 / 3 / 2020, Register 234)

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(a)(2) is amended to read:

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy [, INCLUDING A CASHIER OR A BOOKKEEPER].

(Eff. 1/16/98, Register 145; am 4/4/2002, Register 162; am 1/23/2003, Register 165; am 4 / 3 / 2020, Register 234)

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Authority: AS 08.80.030 AS 08.80.480

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

12 AAC 52.235. Pharmacy technician with national certification. (a) A pharmacy technician who holds a national certification and who works under the direct supervision of a pharmacist may

(1) perform a final check and distribute a non-controlled substance prescription if

(A) the pharmacy uses a bar code scanning and verification system that confirms the drug selected to fill the prescription is the same as indicated on the prescription label;

(B) the pharmacy uses software that displays the image or graphical description of the correct drug being verified; provided that if there is any deviation from the image or graphical description and actual product being dispensed, a pharmacist must review and dispense the order; and

(C) 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;

(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 this subsection must have the following information documented on the prescription drug order

(1) the result of the clarification;

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- (2) the initials of the pharmacy technician who holds a national certification;
- (3) the name of the prescriber or authorized agent they spoke to; and
- (4) the date and time 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, a “bar code scanning and verification system” means any technology which scans the bar code on a manufacturer drug container to ensure the product being distributed matches the expectation of what was prescribed and input into the dispensing software. (Eff. 4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.300(c)(3) is amended to read:

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

12 AAC 52.300(c)(4) is repealed:

(4) **repealed** 4 / 3 / 2020 [IF SEEKING RENEWAL 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]. (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)

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

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

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 as defined in 12 AAC 52.995(33) 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, 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

(1) maintain manual or electronic records identifying, individually for each order processed, filled or dispensed

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

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

(f) A pharmacy participating in shared pharmacy services which distributes prescription drug orders using a pharmacy technician who holds 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. (Eff. 4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.470(a) is repealed:

(a) **Repealed** 4 / 3 / 2020 [A PHARMACIST MAY DISPENSE A REFILL OF A PRESCRIPTION DRUG ORDER ONLY IN ACCORDANCE WITH THE PRESCRIBING PRACTITIONER'S AUTHORIZATION AS INDICATED ON THE PRESCRIPTION DRUG ORDER. IF THERE ARE NO REFILL INSTRUCTIONS ON THE PRESCRIPTION DRUG ORDER, OR IF ALL REFILLS AUTHORIZED ON THE ORIGINAL PRESCRIPTION DRUG ORDER HAVE BEEN DISPENSED, A PHARMACIST SHALL OBTAIN AUTHORIZATION FROM THE PRESCRIBING PRACTITIONER BEFORE DISPENSING A REFILL].

12 AAC 52.470(b) is repealed:

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(b) **Repealed** 4 / 3 / 2020 [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].

12 AAC 52.470(c) is amended to read:

(c) Each time a prescription drug order refill is dispensed, the pharmacist **or pharmacist intern** shall record the **quantity and date of the dispensing** [REFILL ELECTRONICALLY OR ON THE BACK OF THE PRESCRIPTION DRUG ORDER BY LISTING THE DATE OF DISPENSING, THE WRITTEN INITIALS OR IDENTIFICATION CODE OF THE DISPENSING PHARMACIST, AND THE AMOUNT DISPENSED IF DIFFERENT FROM THE QUANTITY ON THE ORIGINAL PRESCRIPTION DRUG ORDER].

12 AAC 52.470(d) is amended to read:

(d) **A pharmacist or pharmacist intern** [IF AN ORIGINAL PRESCRIPTION DRUG ORDER IS PRESCRIBED AS A 30-DAY SUPPLY, THE PHARMACIST] may dispense **any quantity of a prescription drug order so long as** [UP TO A 100-DAY SUPPLY ON REFILLS IF] the

(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; **and**

(2) drug is not a federal or state scheduled controlled substance [; AND

(3) THE PHARMACIST IS EXERCISING PROFESSIONAL JUDGMENT].

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12 AAC 52.470 is amended by adding new subsections to read:

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

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.480(4) is amended to read:

(4) initials, **which may be handwritten**, of the dispensing pharmacist **or pharmacist intern**;

(Eff. 1/16/98, Register 145; am 1/14/2004, Register 169; am 2/15/2006, Register 177; am

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4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

The introductory language of 12 AAC 52.490(a) is amended to read:

(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:

...

(Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 8/12/2007, Register 183; am

4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500(d)(1) is repealed:

(1) **repealed** 4 / 3 / 2020 [IF TRANSFERRED VERBALLY, THE TRANSFER SHALL BE COMMUNICATED DIRECTLY BETWEEN TWO LICENSED PHARMACISTS];

12 AAC 52.500(d)(3) is amended to read:

(3) the pharmacist, **pharmacist intern, or pharmacy technician who holds a national certification** transferring the prescription drug order information shall record the

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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 national certification** receiving the prescription drug order information;

(C) the name of the pharmacist, **pharmacist intern, or pharmacy technician who holds national certification** transferring the prescription drug order information; and

(D) the date of the transfer;

12 AAC 52.500(d)(4) is amended to read:

(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 [AND DATE OF DISPENSING, IF DIFFERENT FROM THE DATE OF ISSUE];

(B) the original **unique identification number of the** prescription [DRUG ORDER NUMBER AND THE NUMBER OF REFILLS AUTHORIZED ON THE ORIGINAL PRESCRIPTION DRUG ORDER];

(C) the **quantity** [NUMBER] of **drug or device** [VALID REFILLS] remaining [AND THE DATE OF THE LAST REFILL];

(D) the name, address, and if a controlled substance, the DEA registration

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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

12 AAC 52.500(d)(5) is amended to read:

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order [REFILLS].

12 AAC 52.500(f)(2) is amended to read:

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized [NUMBER OF AUTHORIZED REFILLS IS NOT EXCEEDED].

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 10/31/2019, Register 232; am

4 / 3 / 2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.510(a) is amended to read:

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

...

12 AAC 52.510(a)(1) is amended to read:

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(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 the practitioner does not want it substituted;**

12 AAC 52.510 is amended by adding a new subsection to read:

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product so long as there is nothing on the prescription drug order from the prescriber that would indicate they want only the substituted product dispensed. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am 4 13 12020, Register 234)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.985(a) is amended to read:

(a) If, as a consequence of a [NATURAL] disaster or terrorist attack, a disaster emergency is declared by the governor under AS 26.23.020 which results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

12 AAC 52.985(b) is amended to read:

(b) If, as a consequence of a [NATURAL] 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

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existing prescription, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

12 AAC 52.985(c) is repealed:

(c) **Repealed** 4 / 3 / 2020 [WHEN A DISASTER EMERGENCY HAS BEEN DECLARED, A PHARMACIST IN THE AREA OF THE DECLARED EMERGENCY MAY DISPENSE A ONE-TIME EMERGENCY REFILL PRESCRIPTION OF UP TO A 30-DAY SUPPLY OF A PRESCRIBED MEDICATION IF

(1) IN THE PHARMACIST'S PROFESSIONAL OPINION THE MEDICATION IS ESSENTIAL TO THE MAINTENANCE OF LIFE OR TO THE CONTINUATION OF THERAPY; AND

(2) THE PHARMACIST MAKES A GOOD FAITH EFFORT TO REDUCE THE PATIENT'S PRESCRIPTION DRUG INFORMATION TO A WRITTEN PRESCRIPTION MARKED "EMERGENCY PRESCRIPTION" AND THEN FILES AND MAINTAINS THE PRESCRIPTION IN ACCORDANCE WITH 12 AAC 52.450].

12 AAC 52.985(d) is repealed:

(d) **Repealed** 4 / 3 / 2020 [IF A DECLARED DISASTER EMERGENCY CONTINUES FOR MORE THAN 21 DAYS AFTER A PHARMACIST DISPENSES AN EMERGENCY PRESCRIPTION UNDER (c) OF THIS SECTION, THE PHARMACIST MAY DISPENSE ONE ADDITIONAL EMERGENCY REFILL PRESCRIPTION OF UP TO A 30-DAY SUPPLY OF THE PRESCRIBED MEDICATION].

EMERGENCY REGULATION

Register 234, July 2020 **PROFESSIONAL REGULATIONS**

12 AAC 52.985 is amended by adding a new subsection to read:

(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 the governor determines the disaster emergency no longer exists;

(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. (Eff. 10/31/2019, Register 232; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.992(d) is amended to read:

(d) A pharmacist **or pharmacist intern** administering a vaccine must **offer** [PROVIDE] the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(Eff. 7/9/2017, Register 223; am 4/3/2020, Register 234)

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

12 AAC 52.995(a)(33) is amended to read:

(33) "shared pharmacy services" means a system allowing the processing by a participating pharmacist, **pharmacist intern, or pharmacy technician who holds a national certification,** or a pharmacy of a request from another participating pharmacist, **pharmacist**

EMERGENCY REGULATION

Register 234, July 2020 **PROFESSIONAL REGULATIONS**

intern, or pharmacy technician who holds a national certification, or pharmacy to **enter or review a prescription drug order,** 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;

12 AAC 52.995(a) is amended by adding a new paragraph to read:

(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 Institute for the Certification of Pharmacy Technicians (ICPT).

(Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am 10/31/2019, Register 232; am 4 1 3 12020, Register 234)

Authority: AS 08.80.005 AS 08.80.159 AS 17.30.200
AS 08.80.030 AS 11.71.900 AS 17.30.900
AS 08.80.157

From: [Richard Holt](#)
To: [Leif Holm](#)
Cc: [Carrillo, Laura N \(CED\)](#)
Subject: Re: agenda/discussion item
Date: Tuesday, April 28, 2020 12:09:57 PM

yes. we have scheduled a very general agenda as we continue our discussions around regulations and the projects to simplify and eliminate unnecessary regs. This will be part of our regulation discussion.

Thanks.
Rich

> On Apr 28, 2020, at 10:24 AM, Leif Holm <lholm36@gmail.com> wrote:

>

> My question is ultimately surrounding delivery driving. We have always licensed our delivery drivers as techs, but i am hearing around town that pharmacies are using taxi drivers to function as delivery drivers. I am wondering if we can discuss as a board the position of delivery driver and does it fall under "manipulative, nondiscretionary functions" as listed below. I know we just removed cashier and bookkeeper, but never had delivery driver on the list. What are we to do with drivers, license or not? and does it depend upon a limitation of other functions if they are to be only taking medicine out for delivery and not performing any other tasks in the pharmacy. Or what if they function as a janitor as well and/or dishwashing duties, etc. They are not pharmacy related functions but would be behind the counter.

>

> 12 AAC 52.230. PHARMACY TECHNICIANS. (a) The following persons must be licensed as a pharmacy technician: (1) any individual who assists in performing manipulative, nondiscretionary functions associated with the practice of pharmacy; and (2) a supportive staff member assigned to work in the dispensing area of a pharmacy, including a cashier or a bookkeeper

>

> Also, I am hoping we are discussing the shared pharmacy services and the details of that and what services should be classified as such and clarifying the roles played between the pharmacies. As Rich and I earlier discussed, it is quite a hazy subject and personally for my stores, again with delivery driving, I need to know we are doing things the right way.

>

> Thanks

>

> Leif

>

> --

> Leif J. Holm Pharm.D., President

> Alaska Family Pharmacy

> 907-488-8101

> 907-347-6296 (cell)

>

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>

From: [Justin Ruffridge](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: Question for next board meeting
Date: Tuesday, March 10, 2020 1:18:23 PM

Laura,

Is there a way to get an agenda item added to the next board meeting? I am wondering if the board could take a look at the transferring of prescriptions in our statute. Somehow this section is getting interpreted and policies are being implemented by pharmacies that are not accepting a transfer of an original prescription that has never been filled. I am not understanding where this interpretation is coming from (except the very grey language from the CSA regarding transfers of controlled substances). However, legend drugs are also being affected. Potentially the board should take action to clarify that original prescriptions for legend drugs can be transferred as an original prescription.

Justin

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall

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

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

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

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

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs ~~or devices~~ to a

(A) licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

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

(B) consumer in this state, a pharmacy located outside of the state shall

- (1) obtain a license under AS 08.80.157; and
- (2) appoint an agent on whom process can be served in the state.

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

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

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

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

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

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

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

Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF DRUGS VACCINES AND RELATED EMERGENCY MEDICATIONS.~~

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

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

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

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist or person acting at the direction of a pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

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

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

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

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person’s license.

(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.

(c) In this section, “regularly” means to dispense more than a 3-day supply to a patient.

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

(b) *Repealed 1980.*

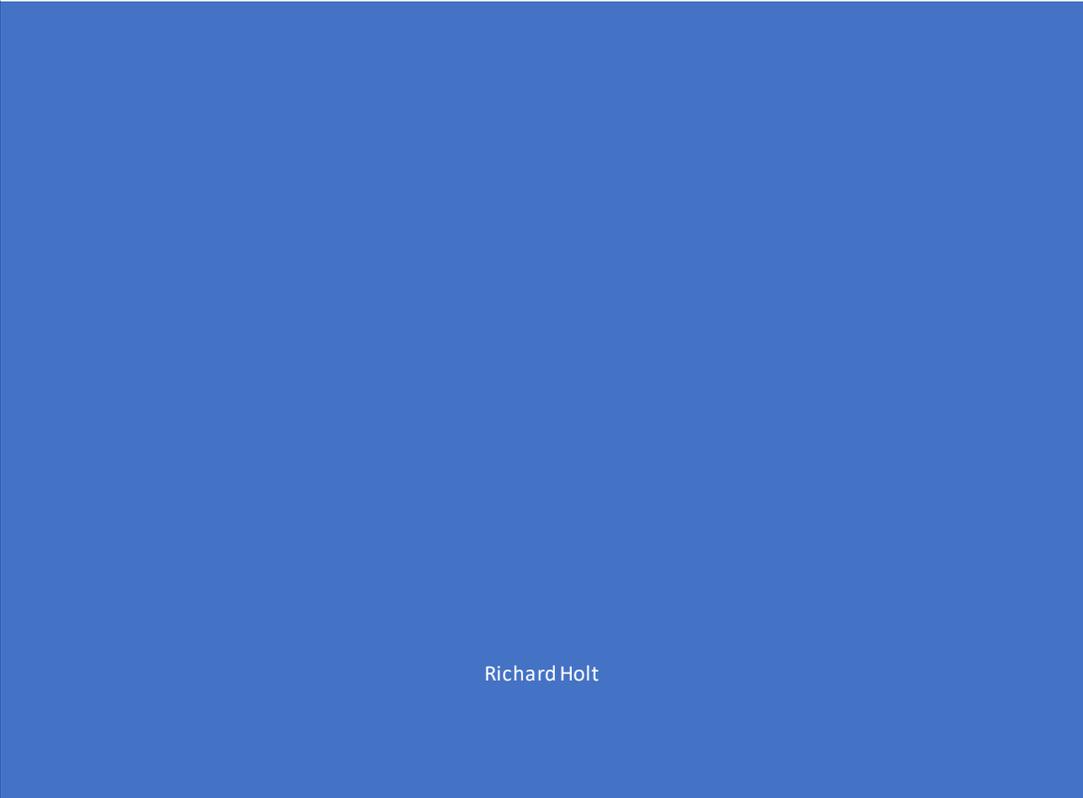
Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,

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

(30) “practice of pharmacy” means the interpretation, evaluation, and dispensing of prescription drug orders in the patient’s best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the ~~independent prescribing, dispensing and administration of vaccines and related emergency medication; the independent dispensing of opioid overdose~~ drugs and devices in accordance with AS 08.80.168; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;



2020 REGULATION SIMPLIFICATION PROJECT



Richard Holt

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ARTICLE 1 – LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE. No change

- (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.

12 AAC 52.020. PHARMACY LICENSE.

- (a) An applicant for a pharmacy license who has submitted documents that meet the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy license. An applicant who does not meet the requirements on the checklist will not be issued a license unless the board reviews the application and determines that the application meets the qualifications in this section for a pharmacy license.
- (b) The board will issue a pharmacy license to an applicant who
- (1) pays the applicable fees required in 12 AAC 02.310;
 - (2) submits a complete, notarized application on a form provided by the department;
 - (3) within 14 days after commencement of business, submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

Commented [RH1]: Amended - simplified to what seemed realistic & added 12 AAC 52.030 and 52.040 so everything dealing with pharmacies is under 1 regulation

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

(c) Repealed 1/17/2007.

(d) 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.

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

(f) 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.

(g) The pharmacist-in-charge of pharmacy that has changed its name or physical location shall apply for a new and separate pharmacy license as required in (a) of this subsection.

(h) a new owner of a pharmacy shall apply for a new and separate pharmacy license as required in (a) of this subsection.

12 AAC 52.050. CLOSED PHARMACIES. No change

(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.

12 AAC 52.060 FIRE OR OTHER DISASTER.

(a) If a pharmacy has a fire or other disaster which results in a change of the pharmacy address in order to continue operations, the pharmacist-in-charge of the pharmacy shall notify the board 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 pharmacy license as required in 12 AAC 52.020.

Commented [RH2]: Amended – simplified to what seemed realistic for the board to know

(c) A pharmacy may not dispense any drug that has been exposed to excessive heat, smoke, or other conditions that may have caused deterioration.

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. **No change**

(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.

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, as defined in 12 AAC 52.925, as that affects the applicants ability to practice pharmacy competently and safely.

Commented [RH3]: Amended – added our new 12 AAC 52.925

Because its required and in AS 08.80.110 related to pharmacists, I recommend keeping and continuing to place in each licensee regulation.

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE.]

Commented [RH4]: Amended – removed (d)

- (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.

12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION. No change

- (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.

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. No change

- (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.

12 AAC 52.095 APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY.

(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; verification of licensure submitted under this paragraph must be either

(A) submitted on form provided by the department; or

(B) obtained from an electronic data base maintained by the licensing authority in another jurisdiction that indicates that the electronic data base is a primary source of verification of licensure in that jurisdiction.

12 AAC 52.100 TEMPORARY PHARMACIST LICENSE.

(a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a temporary pharmacist 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 temporary 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 temporary pharmacist license.

(b) The board will issue a temporary pharmacist license to an applicant who

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

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

(3) is of good moral character as described in 12 AAC 52.075;

(4) submits a verification of a current license in good standing to practice in another state or jurisdiction;

Commented [RH5]: Amended (8) only

Commented [RH6]: Required under AS 08.80.150
Amended for simplicity & what seemed realistic

- (c) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.
- (d) A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, the board may extend the temporary license for an additional period not to exceed 60 days.
- (e) A temporary license is not renewable.
- (f) An individual may not receive more than one temporary license.

12 AAC 52.110 EMERGENCY PHARMACIST PERMIT.

(a) If an emergency exists, the board will issue an emergency pharmacist permit, for the purpose of providing coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, if an applicant meets the requirements set out in (b) of this section to demonstrate the necessary qualifications for an emergency pharmacist permit. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive an emergency pharmacist permit 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 emergency pharmacist permit.

- (b) The board will issue an emergency pharmacist permit to an applicant who
- (1) submits a complete, notarized application on a form provided by the department;
 - (2) pays the applicable fees in 12 AAC 02.310;
 - (3) submits a certified true copy of a current pharmacist license in good standing in another state; and
 - (4) is of good moral character as described in 12 AAC 52.075.

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

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

Commented [RH7]: Required under AS 08.80.155 Amended for simplicity & what seemed realistic

12 AAC 52.120 PHARMACIST INTERNS.

(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 applicable fees 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;

Commented [RH8]: Amended – re-titled, simplified & added 12 AAC 52.220

- (4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as described in 12 AAC 52.925;
 - (5) submits a completed authorization of release of records on a form provided by the department and signed by the applicant; and
 - (6) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character as described in 12 AAC 52.075.
- (c) A pharmacist intern license is valid for 5 years and may not be renewed. On or before the expiration date, the applicant may apply for a new pharmacist intern license as described in 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) If a pharmacist intern leaves the enrollment of an ACPE accredited college of pharmacy the pharmacist intern must return the pharmacist intern license to the board within 5 days.

Commented [RH9]: added

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. **No change.**

(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 -18- 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.

12 AAC 52.140. PHARMACY TECHNICIANS.

(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 complete, notarized application on a form provided by the department; including
 - (A) the applicant's name, mailing address, telephone number, and, if possible, an email address; 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 practice as described in 12 AAC 52.925;
- (3) certifies that the has earned a high school diploma, General Equivalency Diploma (GED), or its equivalent and provides the name of the issuing institution and the date the diploma, GED, or its equivalent degree was issued.
- (4) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;
- (5) pays the applicable fees in 12 AAC 02.310;
- (6) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character as described in 12 AAC 52.075; and
- (7) certifies that the applicant is fluent in the reading, writing, and speaking of the English language.

(c) A pharmacy technician license expires on June 30 of even-numbered years and may be renewed.

(d) The following individuals must be licensed as a pharmacy technician

- (1) any supportive staff member, besides a pharmacist or pharmacist intern, who
 - (A) works in the pharmacy, including a cashier or book-keeper; or
 - (B) is involved in the delivery of drugs or devices to a patient or agent of the patient, including delivery drivers; }

Commented [RH10]: Amended – re-titled, simplified & added licensing requirements for other tech regulation

12 AAC 52.150. PROOF OF LICENSURE FOR INDIVIDUAL PHARMACISTS WORKING FOR TRIBAL HEALTH PROGRAMS. No change.

(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

Commented [RH11]: Essentially what board indicated on 2/7/20

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. -19- (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.

ARTICLE 2- PERSONNEL

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.

Commented [RH12]: Amended – removed applicable fees as requested by department

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 patient or patients agent as described in 12 AAC 52.585;
- (3) independent prescribing and administration of a prescription drug order for vaccines, related emergency medications, or opioid overdose drugs as described in 12 AAC 52.992 and 12 AAC 52.994;
- (4) determining the product substitution required for a prescription as described in 12 AAC 52.510;
- (5) interpreting drug regimen review data as described in 12 AAC 52.570;
- (6) assuming the responsibility for a filled prescription; and
- (7) preparation for administration and administration of legend drugs.

Commented [RH13]: Amended per the boards decision 2/7/20

Commented [RH14]: We could remove – Idaho indicating they are holding their nationally certified techs responsible since they are licensed

12 AAC 52.220 PHARMACIST INTERN REQUIREMENTS

- (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.
- (j) 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.
- (k) A pharmacist supervising a pharmacist intern
- (1) must be licensed as a pharmacist and be in good standing with the board;
 - (2) shall ensure direct supervision is provided to an intern during professional activities; and
 - (3) is responsible for the work of the pharmacist intern.
- (l) An individual working as a pharmacist intern must wear an identification badge that shows the individual's name and identifies the individual as a pharmacist intern.

Commented [RH15]: Amended – simplification & allows for the intern to verify tech work (just like the tech check tech)

12 AAC 52.230. PHARMACY TECHNICIAN REQUIREMENTS

- (a) A pharmacy technician shall work under the direct supervision of a licensed pharmacist.
- (b) Except as allowed in 12 AAC 52.235, a pharmacy technician may not perform any pharmacist duties listed in 12 AAC 52.210.
- (c) An individual working as a pharmacy technician must wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.
- (d) Before an individual performs the tasks of a pharmacy technician, or functions as detailed in 12 AAC 52.235, the individual must complete training required by the pharmacist-in-charge. Duties performed must be consistent with the training.

Commented [RH16]: Amended

12 AAC 52.235. APPROVED FUNCTIONS FOR PHARMACY TECHNICIANS HOLDING A NATIONAL CERTIFICATION.

- (a) A pharmacy technician who holds a national certification, working under the direct supervision of a pharmacist, may
- (1) perform a final check and dispense a non-controlled substance prescription if
 - (A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination in substitution, in accordance with 08.80.480(11) and (37);
 - (B) the pharmacy uses a bar code scanning and verification system that confirms the drug selected to fill the prescription is the same as indicated on the prescription label;
 - (C) the pharmacy uses dispensing software that displays the image or graphical description of the correct drug being verified; provided that if there is any

Commented [RH17]: New regulation as approved by board on 2/7/20

deviation from the image or graphical description and actual product being dispensed, a pharmacist must review and dispense the order; and

(D) each prescription dispensed is electronically verified and documented in the patient record in accordance with 12 AAC 52.460 and 12 AAC 52.470;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500;

(3) administer

(A) an immunization or related emergency medication as described in 12 AAC 52.992; or

(B) other legend drugs if the pharmacy technician is trained in the manufacturers administration technique and directions; or

(4) clarify or obtain missing information, except for drug name, drug strength, or directions, from the practitioner or the practitioners agent on a non-controlled substance prescription drug order.

(c) Prescription drug order information clarifications under (b) of this section must have the following information documented on the prescription drug order

(1) the result of the clarification;

(2) the nationally certified technician initials;

(3) the name of the prescriber or authorized agent they spoke to; and

(4) the date and time of the call.

(d) 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.

(e) A pharmacy technician who does not hold a national certification may not perform the duties set out in this section.

(f) In this section, a “bar code scanning and verification system” means any technology which scans the bar code on a manufacturer drug container to ensure the product being dispensed matches the expectation of what was prescribed and input into the dispensing software.

12 AAC 52.240 PHARMACIST COLLABORATIVE PRACTICE AGREEMENTS

(a) A pharmacist planning to prescribe or modify drug therapy with the authorization of a licensed practitioner under AS 08.64 must be approved by the board and comply with 12 AAC 40.983.

(b) A pharmacist may independently enter into a collaborative practice agreement to prescribe or modify drug therapy with the authorization of a licensed practitioner under AS 08.36, AS 08.68, or AS 08.72.

(c) In (b) of this section, the collaborative practice agreement protocol must include

(1) the types of authority decisions that the pharmacists are authorized to make;

(2) the name and license number of the practitioner authorizing the protocol;

(3) the name(s) of the pharmacists who are party to the agreement. If it applies to all pharmacists at the facility then the protocol may state “all pharmacists at the facility” in place of each pharmacists name;

Commented [RH18]: Amended for simplification
Split into 2 categories:

- 1) With MD and their regs
- 2) With all other practitioners

Removed board approval for 2 above

- (3) the time period during which the protocol will be in effect;
 - (4) details on how the agreement may be terminated; and
 - (5) details on how modifications to the protocol are handled.
- (e) The pharmacist's authority granted by the collaborative practice agreement must be within the scope of the practitioner's practice.
- (f) Documentation related to the protocol must be maintained in a readily retrievable format for at least two years and made available to the board upon request.
- (g) 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.

12 AAC 52.250. JOB SHADOWING IN A PHARMACY

Commented [RH19]: Amended for simplicity

- (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) If the student is less than 18 years of age, the pharmacist-in-charge or job shadowing preceptor must have written permission from the parent or guardian authorizing the student to complete the job shadowing.
- (c) The pharmacist-in-charge or job shadowing preceptor must 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; or
 - (C) perform any functions reserved for licensed, certified, or registered pharmacy personnel.
- (e) 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 education program, including home-school or GED program, or post-secondary education program.

ARTICLE 3- LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS

12 AAC 52.300. LICENSE RENEWAL.

- (a) Pharmacist, pharmacy technician, outsourcing facilities, third-party logistics providers, 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, outsourcing facility, third-party logistics provider, or drug room license shall submit
- (1) a completed renewal application provided by the department;
 - (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 on or before the license expiration date
- (1) submit a completed renewal application provided by the department; and
 - (2) pay the applicable fees required in 12 AAC 02.310;

Commented [RH20]: Amended for simplification

Commented [RH21]: Added

Commented [RH22]: added

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 provided by the department;
 - (2) any applicable license renewal fees required in 12 AAC 02.310; and
 - (3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350.
- (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

Commented [RH23]: Amended

- (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.

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. **No change**

- (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.

12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS. **No change**

- (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.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE.

No change

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.

12 AAC 52.340 APPROVED PROGRAMS. No change

(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.

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. No change.

(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.

ARTICLE 4 – GUIDELINES FOR PHARMACIES AND PHARMACISTS

12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES.

(a) The prescription department and all areas where drugs are stored must be well lighted, well ventilated, dry, and maintained in a clean and orderly condition. Walls, floors, ceilings, and windows must be clean and in general good repair and order.

(b) A pharmacy must

- (1) be 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 drugs;
- (2) must have a sink with hot and cold running water within the pharmacy department and maintained in a sanitary condition. If the pharmacy should lose water supply, the pharmacy may remain open but must use distilled water for any reconstituted prescriptions and hand sanitation;
- (3) have refrigeration facilities with a thermometer to monitor for proper storage of drugs that require refrigeration;
- (4) maintain a temperature range compatible with the proper storage of drugs;
- (5) have equipment and supplies necessary for the practice of pharmacy. The equipment must be in good repair and in sufficient quantity to meet the needs of the pharmacy;
- (6) ensure that all equipment is kept in a clean and orderly manner;
- (7) maintain access to a reference library deemed sufficient to address clinical questions or concerns; and
- (8) have the telephone number to the poison control center readily available.

12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES. No change

(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.

Commented [RH24]: Amended for simplification – can repeal the “ pamphlet”

12 AAC 52.415 PRESCRIPTION DRUG DISPENSING MACHINES

(a) A pharmacy may install and use prescription drug dispensing machines which are accessible to the patient outside of the pharmacy operating hours for the purpose of purchasing their completed prescription drug orders when the pharmacy is closed if

- (1) prior to a filled prescription drug order being placed in the machine the pharmacist has counseled the patient in accordance with 12 AAC 52.230;
- (2) no state or federal control substances are placed in the unit and there is a conspicuously posted sign near the machine which states “this machine does not contain controlled substances”; and
- (3) all containers stored in the units are packaged, labeled, and stored in accordance with AS 08 and federal laws.

(b) the pharmacist shall have the responsibility to

- (1) assign, discontinue, or change access to the system;
- (2) ensure that access to the medications comply with state and federal regulations; and
- (3) ensure that the automated prescription drug dispensing units are filled or stocked accurately;

(c) This section does not apply to prescription drug dispensing machines used in institutional facilities.

(d) In AS 08.80, “prescription drug dispensing machines” means a machine or mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of drugs, and which collect, control and maintain all transaction information.

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) Except for automated prescription drug dispensing machines, all drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(c) The prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(d) 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.

(e) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(f) In this section, “prescription department” means the area of the pharmacy where prescription drugs are stored.

Commented [RH25]: New regulation – adopted from other states

Commented [RH26]: Amended

Preventing theft or diversion is already in 12 AAC 52.200

Allows for us to evaluate adding regs around modern technology of machines that store prescriptions to pick up when Rx is not close – already done in some states.

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.
- (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.

Commented [RH27]: Added to comply with state regulation

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. No change.

- (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 -26- (2) distinguishable from the inventory of the central pharmacy and other remote pharmacies. (j) Repealed 10/31/2019.

12 AAC 52.430. **STERILE COMPOUNDING** .

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.

Commented [RH28]: Amend title

12 AAC 52.440. **NON-STERILE COMPOUNDING** .

- (a) Non-sterile compounding does not include the addition of flavoring agents, tablet splitting, reconstitution of oral or topical products as intended by the manufacturer, or repackaging of nonsterile dosage forms for redistribution, dispensing, or administration.
- (b) Non-sterile compounding includes the preparation:
- (1) of 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;
 - (2) according to a prescription drug order of drugs or devices that are not commercially available; or
 - (3) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a prescription drug order for a specified individual patient and the patient has been made aware that the compounded product will be prepared by the pharmacist.
- (c) A pharmacy engaging in non-sterile compounding must
- (1) have a specifically designated, adequate, clean and sanitary area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment;
 - (2) have adequate lighting and ventilation in all drug compounding areas;
 - (3) have adequate washing facilities, easily accessible to the compounding area of the pharmacy;
 - (4) be free of infestation by insects, rodents, and other vermin;
 - (5) be capable of holding and disposing trash in a timely and sanitary manner;

Commented [RH29]: Amended for simplification – took from “pamphlet”

Added the boards previous discussion points around reconstitution and flavoring agents

(6) have either dedicated equipment or meticulous cleaning procedures of contaminated equipment when using drugs which have special precautions for contamination, such as penicillin.

(7) 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) a listing of the components;
- (B) their amounts in weight or volume;
- (C) the order of the component mixing;
- (D) a description of the compounding process;
- (E) a list of all equipment and utensils; and
- (F) the container or closure system relevant to the sterility and stability of the intended use of the drug.

(8) 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; and

(9) maintain records of the following for compounding in quantities larger than required for immediate dispensing by a prescription drug order or for future dispensing

- (A) the date of preparation;
- (B) 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;
- (C) 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;
- (D) the signature or initials of the pharmacist performing the compounding;
- (E) initials of the person preparing each process;
- (F) initials of the pharmacist supervising each process;
- (G) a formula for the compounded product maintained in a readily retrievable form;
- (H) the name of the manufacturer of the raw materials;
- (I) the quantity in units of finished products or grams of raw materials; and
- (J) the package size and the number of units prepared.

(d) **A pharmacist engaged in non-sterile compounding must**

(1) 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.

Commented [RH30]: None of four current compounding regulations authorize technicians (nationally certified) techs to perform compounding.

Current regulation 12 AAC 52.230(f) only authorizes a pharmacy tech in the preparation of sterile compounding – which is 12 AAC 52.430.

This regulation, 12 AAC 52.440 specifically mentions pharmacists.

Are we thinking of amending this to add technicians in some capacity instead of just pharmacist?

(A) Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

- (2) maintain proficiency through current awareness and training.
- (3) ensure bulk medications and other chemicals or materials used in compounding are stored in adequately labeled containers in a clean, dry, and temperature-controlled area or, if required, under proper refrigeration;
- (4) keep records of all compounded products in a readily retrievable format for two years;
- (5) ensure that formulas for the compounded drugs are maintained in a readily retrievable format. A formula must include ingredients, amounts, methodology, and equipment, if needed;
- (6) accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist must 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;
- (7) 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:
 - (A) capsule weight variation;
 - (B) adequacy of mixing to assure uniformity and homogeneity;
 - (C) clarity, completeness, or pH of solutions;
- (8) 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;
- (9) use professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia;

(e) “Component” means any ingredient intended for use in the compounding of a drug product, including those that may not appear in the product.

12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY. **No change**

(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.

12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. **No change**

(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.

12 AAC 52.445. SHARED PHARMACY SERVICES. **No change.**

(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.

ARTICLE 5 – PHARMACY PRACTICE STANDARDS

12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS. No change.

- (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.

12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION.)

- (a) Before a prescription drug order may be filled, the following information must be obtained and recorded

- (1) name of the patient or, if the prescription drug order is for an animal, the species of the animal and the 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, the prescription drug order information shall be recorded.

Commented [RH31]: Amended for simplification and clarification

(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.

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

(g) In accordance with 12 AAC 44.440(c), prescription drug orders written by an Advanced Practice Registered Nurse (APRN) must contain the signature of the prescriber followed by the initials “APRN” and the prescriber’s identification number assigned by the nursing board.

- (1) If the “APRN” is absent after the signature but the prescription drug order contains “APRN”, “Advanced Practice Nurse Practitioner” or “Nurse Practitioner” elsewhere on the prescription drug order then it does not need to be present after the signature.
- (2) If the APRN’s identification number is missing on the prescription drug order and the identification number is recorded in the pharmacy computer system then it does not need to be physically present on the prescription drug order.

Commented [RH32]: New additions

12 AAC 52.465. CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS.

No change.

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.

12 AAC 52.470. REFILLS.

(a) A pharmacist, pharmacist intern or pharmacy technician who holds a national certification may verify and dispense a prescription drug order.

Commented [RH33]: Amending allows for continuation of therapy subsection below

(b) A prescription drug order does not expire and is available to be filled until the total quantity prescribed, including all refills, is exhausted.

Commented [RH34]: Currently states 1-year validity. For patient care, consider amending to no expiration – if the practitioner authorized it can we consider repealing an expiration date?

(c) Each time a prescription drug order refill is dispensed, the pharmacist, pharmacist intern or pharmacy technician who holds a national certification shall record the refill.

(d) A pharmacist, pharmacy technician who holds a national certification, or pharmacist intern may dispense any quantity of a prescription drug order so long as

- (1) the total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription drug order, including refills; and
- (2) the 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 drug 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, pharmacist intern, or pharmacy technician who holds a national certification may dispense a one-time dispensing not to exceed a 30-day supply. In this section,

- (1) “unable to reach the practitioner” means the practitioners office is closed and the pharmacist cannot reach the practitioner or the practitioners agent;
- (2) “existing” means the pharmacy has record of the prescription drug order or can validate the prescription drug order from another pharmacy;
- (3) “chronic” means a drug that the patient takes regularly, for greater than 3 months, and in the professional judgment of the pharmacist the patient should not go without.

- (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;
 - (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.

12 AAC 52.475 DISPENSING REFILLS IN A DECLARED EMERGENCY

(a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor under AS 26.23.020 which results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

(b) If, as a consequence of a 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) When a disaster emergency has been declared, a pharmacist in the area of the declared emergency may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication if

- (1) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and
- (2) the pharmacist makes a good faith effort to reduce the patient's prescription drug information to a written prescription marked "emergency prescription" and then files and maintains the prescription in accordance with 12 AAC 52.450.

(d) If a declared disaster emergency continues for more than 21 days after a pharmacist dispenses an emergency prescription under (c) of this section, the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110.

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) name of the prescribing practitioner;

Commented [RH35]: New regulation number 12 AAC 52.985. EMERGENCY PREPAREDNESS.

Place to here to make more sense with refills

Removed "natural"

Commented [RH36]: Amended.

1) Removed initials of the pharmacist due to tech check tech

- (5) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;
- (6) directions for use;
- (7) quantity dispensed;
- (8) appropriate ancillary instructions or cautions;
- (9) 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”;
- (10) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner;
- (11) 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;
- (12) expiration date of the drug or device.]

Commented [RH37]: Has been brought up at pharmacist association continuing education

12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION.]

Commented [RH38]: Amended to allow tech check tech

- (a) Legend drug and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws.
- (b) A pharmacist, pharmacist intern, or pharmacy technician who holds a national certification 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 generated 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.

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.

Commented [RH39]: Amended to allow board approved nationally certified function

(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) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(2) 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 and date of dispensing, if different from the date of issue;

(B) the original prescription drug order number and the quantity of drug authorized on the original prescription drug order;

(C) the quantity of drug remaining and the date of the last refill;

(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 refills.

(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.

12 AAC 52.510. SUBSTITUTION.

Commented [RH40]: Amended for simplicity

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

- (1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording;
- (2) the patient is notified and consents to the substitution;
- (3) repealed 10/31/2019; and
- (4) the pharmacy patient record contains the drug product that was actually dispensed.

(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.

12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK). No change.

(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.

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.
- (c) A pharmacy that occasionally takes back a dispensed drug or device for customer satisfaction concerns is not deemed to be in violation of this regulation provided that the returned drug or device is segregated from the normal pharmacy inventory and may not be dispensed.

Commented [RH41]: Amended.

To clarify that a business decision related to a customer satisfaction concern is not deemed to be a violation.

New subsection (c)

12 AAC 52.535. INDEPENDENT PRESCRIBING & ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.

Commented [RH42]: Amend with new regulation number instead of 12 AAC 52.992

Provide clarity w/ prescribing – RPh is the prescriber and administer so let's use the proper language

(a) Before a pharmacist may independently prescribe and 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 display each pharmacist's certification of completing the immunization course described in (a)(1) of this section.

(c) Before preparing and administering an immunization or related emergency medication,

(A) 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.

(B) a pharmacy technician who holds a national certification must

- (1) have been trained on the proper method of preparing & administering vaccines for intramuscular or subcutaneous injections;
- (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.

Commented [RH43]: Add per the board 2/7/20

Is this what the board intends for training requirements?

(d) A pharmacist administering a vaccine must offer the patient the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist, pharmacy technician who holds a national certification, or pharmacist 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 or pharmacy technician who holds a national certification who meets 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.

12 AAC 52.536. INDEPENDENT PRESCRIBING & DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS.

(a) A pharmacist may independently prescribe and 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 prescribes and 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) 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;

(c) 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.

(d) 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.

12 AAC 52.540 NOTIFICATION OF THEFT OR SIGNIFICANT LOSS Repeal

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) dosage form and strength of the drug product; and

Commented [RH44]: Amend – make it this regulation number instead of 12 AAC 52.994

Amended for simplicity & clarity – RPh is prescriber so let's use the proper language

Commented [RH45]: Amended.

Removed manufacture listing and hours of operation

(3) price charged for a specific quantity of the drug product;

12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS. No change.

- (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.

12 AAC 52.570. DRUG REGIMEN REVIEW. No change

- (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.

12 AAC 52.580. DATA PROCESSING SYSTEMS. No change

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.

12 AAC 52.585. PATIENT COUNSELING.

(a) Following the review of a patient's record, if deemed necessary by the pharmacist, each patient or the patient's agent is counselled on matters considered significant in the pharmacist's professional judgment.

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

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

(B) 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.

(b) If a pharmacist or pharmacist intern provides counseling, they may provide the counseling by any verbal, written or electronic means.

Commented [RH46]: Amended for simplicity – used Montana's regulation

Commented [RH47]: On 2/7/20 the board indicated they would support the counseling concerns if it were oral OR written information. Or current regulation already states verbal, written OR electronic means.

(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 or pharmacist intern to provide patient counseling when a patient or the patient's agent refuses the counseling to the pharmacist, pharmacist intern, or pharmacy technician. In this section, "agent" means the person picking up the prescription on behalf of the patient.

12 AAC 52.590. PREPACKAGING OF DRUGS FOR PRACTITIONER OFFICES.

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; and
- (4) the initials of the pharmacist.

Commented [RH48]: Amended for simplicity and clarity to what this regulation does in the title

ARTICLE 6 – WHOLESALE DRUG DISTRIBUTERS AND FACILITIES

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 applicable fees required in 12 AAC 02.310;
- ~~(3) provides the name of the designated facility manager;~~
- (4) submits a completed self-inspection of the premises questionnaire on a form provided by the department;
- (5) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and
- (6) 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

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Deleted: (3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility; ¶

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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).

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 applicable fees required in 12 AAC 02.310;
- ~~(3) submits a complete, notarized application on a form provided by the department;~~
- (4) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

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

Deleted: (3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility; ¶

(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.

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ARTICLE 8 – DRUG ROOMS AND FACILITIES WITHOUT PHARMACIES

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL.

Commented [RH49]: amended

(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.

12 AAC 52.800 DRUG ROOM LICENSE & PHARMACIST REQUIREMENTS

(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.

(1) the institutional facility must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Deleted: (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. ¶

Commented [RH50]: This is 12 AAC 52.810.

Can repeal this regulation and add here.

(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.

ARTICLE 10 – DISCIPLINARY GUIDELINES

12 AAC 52.970 REINSTATEMENT OF A SUSPENDED OR REVOKED LICENSE

(a) The board may reinstate a suspended license only if the requirements of the suspension order have been met.

(b) One year after a revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

- (1) The applicant for reinstatement shall appear before the board; and
- (2) the board will, in its discretion, impose restrictions upon the licensee when reinstating a license.

Commented [RH51]: Combine 12 AAC 52.970 and 12 AAC 52.980

Amend (b)(2) to just say licensee instead of spelling out each license category

ARTICLE 11 – GENERAL PROVISIONS

12 AAC 52.985 REPORTING REQUIREMENTS TO THE BOARD

(a) In accordance with AS 08.80.157, the pharmacist-in-charge, facility manager, or owner of any facility licensed by the board must notify the board, in writing, within 10 days if that facility

(1) experiences a known significant adverse drug reaction that results in hospitalization or death of a patient.

(A) The notification to the board must include

- (i) the name and license number of any individual licensee, if they were involved in the incident; and
- (ii) the details of the incident that resulted in the hospitalization or death;

(2) experiences any loss of records that are required to be maintained under AS 08 or federal law;

(3) has been disciplined, 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;

(4) is made aware of any conviction of an employee in violation of a state or federal drug law; or

(5) experiences a theft of drugs or devices.

(A) If a DEA FORM 106, "Report of Theft or Loss of Controlled Substances", is required to be completed, then the pharmacist-in-charge or owner must also send a copy of the completed form to the board.

Commented [RH52]: New Regulation – required under AS 08.80.157(g)(6)
Replaced 12 AAC 52.985 which is now currently emergency preparedness

Commented [RH53]: We can repeal 12 AAC 52.540 since it's here

(b) In accordance with AS 08.80.157, an individual that is licensed by the board must notify the board, in writing, within 10 days if

(1) 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 as described in 12 AAC 52.925, is issued against the licensee; or

Commented [RH54]: added

(2) the individual knows or suspects that another licensee is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public,

Commented [RH55]: AS 08.80.261(12)

12 AAC 52.990. DISPLAY OR PROOF OF LICENSE

(a) A licensee shall conspicuously display, in their normal 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.

Commented [RH56]: Amended title

Added (b) based on intent of board from 2/7/20 meeting

(b) A licensee who is working in a facility that is not their normal practice site must have a copy of their license with them and available upon request.

12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT, REPEAL

Commented [RH57]: Made new regulation 12 AAC 52.985 reporting requirements so can repeal this regulation