STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

March 8, 2019

Anchorage

Board Packet

PUBLIC

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Richard Holt, PharmD, MBA (Chair)	03/01/2016		03/01/2020
Leif Holm, PharmD (Vice Chair)	03/01/2015	01/08/2019	03/01/2023
Lana Bell, RPh	05/31/2016	03/01/2018	03/01/2022
Phil Sanders, RPh	03/01/2016		03/01/2020
James Henderson, RPh	03/01/2017		03/01/2021
Tammy Lindemuth, Public Member	01/24/2018		03/01/2021
Sharon Long, Public Member	03/01/2018		03/01/2022

Updated 09/04/2018

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

MARCH 8, 2019 (DAY 2)

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

Board Members:

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

Upcoming Meetings:

TBD

Meeting Details

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

Meeting Start Time: 9:00 AM Alaskan Standard Time

Meeting Start Date: 3/8/2019

Meeting End Time: 4:30 PM Alaskan Standard Time

Meeting End Date: 3/8/2019

Meeting Location: Robert Atwood Building, 550 W 7th Ave, ACC 102 (ANCHORAGE) or the State Office Building, 9th Floor, 333 Willoughby Ave, Conference Room C (JUNEAU)

Agenda

I. Agenda Item #16 - 9:00 a.m. Roll Call/Call to Order

II. Agenda Item #17 - 9:05 a.m. Review/Approve Agenda

III. Agenda Item #18 - 9:10 a.m. New Business (Part II)

   A. Suicide Training Proposal (Nancy Kavan)

IV. Agenda Item #19 - 9:40 a.m. Board Business (Part II)

   A. Review/Approve November Draft Meeting Minutes

   B. Discuss/Draft Regulations (Regulations Workflow)

Board Members:

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

Upcoming Meetings:

TBD

1. Updated statutes - outsourcing, third-party, wholesale (February)
2. SB 37 cursory review by LAW
3. USP Published date
4. Electronic License Verification
5. Verification prior to purchase from wholesaler
6. Fingerprints required for out-of-state
7. Review pharmacy intern/tech license proposal (Thomas Wadsworth)

V. Agenda Item #20 - 12:00 p.m. Lunch

VI. Agenda Item #21 - 1:00 p.m. (Resume Board Business Part II; draft regulations)

VII. Agenda Item #22 - 4:00 p.m. Administrative Business

A. Board Nominations

B. Wall Certificates

C. Travel Receipts

D. Task List

VIII. Agenda Item #21 - 4:30 p.m. Adjourn

PROPOSAL FOR SUICIDE PREVENTION TRAINING

FOR
PHARMACISTS
AND
PHARMACY TECHNICIANS

Prepared by : **Nancy Kavan, R.Ph.**

Presented by : **Jo Ann Nelson, R.Ph.**
&
Nancy Kavan, R.Ph.

March 7, 2019 to Alaska Board of Pharmacy

Suicide Statistics

- Suicide rates have risen nearly 30% between 1999 and 2016 [1]
- 1:4 male attempts successful/1:10 female attempts successful
- Fifth leading cause of death for Alaskans in 2017 [2]
  - High accessibility of alcohol and guns
  - Complicated process of early intervention, prevention, treatment
  - Lack of access in rural areas
- Alaska had the second highest age-adjusted suicide rate in the nation in 2016 [3]

- 1) Stone DM, Simon TR, Fowler KA, Kegler SR, et al. Vital signs: trends in state suicide rates - United States, 1999-2016 and circumstances contributing to suicide - 27 States, 2015. MMWR Centers for Disease Control and Prevention. June 8, 2018;67(22):617-624. https://www.cdc.gov/mmwr/volumes/67/wr/mm6722a1.htm?s_cid=mm6722al_x. Accessed June 8, 2018.
- 2) Report: Suicide is Alaska's fifth-leading cause of death By Leila Kheiry, KRBD - Ketchikan - November 6, 2018
- 3) U.S. Centers for Disease Control and Prevention (CDC). Suicide mortality by state: 2016. https://www.cdc.gov/nchs/pressroom/sosmap/suicide-mortality/suicide.htm. Accessed October 1, 2018.

National Public Health Crisis

- Tremendous emotional toll
  - Family, friends, attempt survivors
  - Surviving the loss of a loved one to suicide is a risk factor for suicide
  - Complex grief reactions : guilt, anger, abandonment, denial, helplessness, shock
- Economic cost
  - For individuals, families, community, work place, nation
  - $70 billion a year in combined medical and work cost [1]
  - Estimated cost/suicide is $1.4 million

- 1) https://www.cdc.gov/violenceprevention/suicide/consequences.html#6

Promoting Wellness to Prevent Suicide in Alaska

- Statewide Suicide Prevention Council [1]
  - Advises governor and legislature on issues relating to suicide
- Recasting the Net : Promoting Wellness to Prevent Suicide in Alaska [2]
  - A comprehensive state plan addressing goals and strategies to prevent suicide developed by the council
  - Strategy 2.6 ~ Health care providers understand how to recognize the signs of suicide risk, talk with/screen patients about suicide, and connect patients to appropriate treatment and support services [3]

- 1) http://dhss.alaska.gov/suicideprevention/Pages/default.aspx
- 2) https://www.sprc.org/sites/default/files/Recasting-the-Net-Promoting-Wellness-to-Prevention-Suicide-2018-2022.pdf
- 3) 2.6 a-b; Pages 25-26

State of Washington Health Profession Mandatory Suicide Prevention Training

- Legislation (RCW 43.70.442) effective January 1, 2017
- Pharmacists :
  - Three hours ACPE ONE time training (live/online)
  - Suicide screening and referral
  - Assessment of issues related to imminent harm via lethal means

Mandatory Suicide Prevention Training in Alaska for Pharmacy Personnel

- Alaskan pharmacists & technicians*:
  - ONE time ACPE three hour training (online/live)
  - Develop online training
    - Work with Alaska Department of Health and Human Services (DHSS)
    - Mirror closely to Washington's pharmacy training program
    - Include content on Veterans*
  - Promote thru AKPhA
  - Tentatively effective with 2022 licensure renewal and every **new** licensure thereafter

* Proposed changes for Alaskans that differs from Washington pharmacy training

Pharmacy Personnel Making a Difference

- Recognize if a person seems different than usual
- Assess patient mood
  - Seem down/depressed
  - Loss of interest in activities
- Ask open ended questions :
  - Be caring, non-judgmental and don't jump to conclusions
- Screen patient profile for
  - Prescriptions used to treat mental disorders
    - Assess compliance
  - Physical conditions that compromise quality of life
    - Severe pain, COPD, CHF, Autoimmune disorders, etc.
- Be involved with the treatment team so they are aware
  - Ask pt permission to contact someone : PCP, family member, friend

Pharmacy Personnel Making a Difference

- Two Responsibilities
  - Talk about suicide and complete a quick screen
  - Connect the person to help
- Educate
  - Reducing medication stock to nonlethal amount
  - Lock up prescription medications
  - Return unused medications
  - Dispose of medications in safe manner
  - Storing firearms in locked location ~ ammunition in separate place

- Murphy, Andrea, et al. Community pharmacists and the assessment and management of suicide risks. Can Pharm J (Ott). 2015 Jul; 148 (4): 171–175. PMID: 26448768
- Diana Yap, Editorial Director. How pharmacists can help patients at risk for suicide. Pharmacy Today. February 1, 2015.

Protect Pharmacy Personnel

- Availability and ease of training
- Adequate training
- Good Samaritan law mitigating liability
- Resources available to support pharmacy personnel if a patient dies by suicide

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

Alaska Board of Pharmacy

DRAFT MINUTES OF THE MEETING FOR NOVEMBER 29-30, 2018 (DAY 1)

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy was held at the Robert Atwood Building, 550 W. 7th Ave., Suite 1535 in Anchorage, Alaska on November 29-30, 2018.

These are draft minutes that have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:25 a.m.**

The **November 29, 2018** meeting day was called to order by Chair, Rich Holt at 9:25 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606
James Henderson, RPh #PHAP1683
Tammy Lindemuth, Public Member
Sharon Long, Public Member (*Via Phone)*

Division staff present:

Andy Khmelev, Occupational Licensing Examiner
Renee Hoffard, Records and Licensing Supervisor
Brian Howes, Investigator
Marylene Wales, Accountant III (*via phone*)
Marilyn Zimmerman, Paralegal (*via phone*)
Charles Ward, Acting Deputy Director (*via phone*)

Members from the public present:

CJ Kim, PHAP1274, State of Alaska
Jordan Hussey, 123640, Walgreens
Molly Gray, Alaska Pharmacists Association
Nicholas Marceaux, Pharmacist Applicant

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Cheryl Mandala, Office of Administrative Hearings

Board members absent:

Phil Sanders, RPh #PHAP776 (Excused)
Lana Bell, RPh #PHAP893 (Excused)

Agenda Item 2 Review/Approve Agenda

Following roll call, board chair, Rich Holt, prompted the board to review the agenda for day. Renee Hoffard and Brian Howes commented that there is a consent agreement for a license denial from the prior meeting that was sent to the office of administrative hearings that needs to be moved to the new business section on the agenda that starts at 2:00pm.

TASK 1
Move the consent agreement discussion to the new business section (*Completed 11/29/2018*)

On a motion duly made by Tammy Lindemuth, seconded by James Henderson, and approved unanimously, it was

RESOLVED to accept the November 29, 2018 agenda as amended.

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

The motion passed with no further discussion.

Agenda Item 3 Review/Approve Minutes
Chair Holt asked the board that they review and approve the minutes from the October teleconference.

On a motion duly made by Tammy Lindemuth, seconded by Leif Holm, and approved unanimously, it was

RESOLVED to accept the minutes as read from the August 30-31st board meeting and the October 12 teleconference.

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

The motion passed with no further discussion.

Agenda Item 4 **Ethics Report**

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

Agenda Item 5 **PDMP Update**

Investigator Brian Howes goes over how many PDMP registrations there were, which at this time there are over 10,000 registered users. Prescriber report card came out the prior day, which allows the prescriber to know where they are with their peers, compared to their specialty. In most cases prescribers seem to think it's a good idea. It's not a punitive measure, but rather more for information. The report will also disclose if a patient is seeing more than 5 prescribers at a time, or 5 dispensers in a three month time period. It provides good information to the prescriber to see if something is wrong. These report cards can tell the prescriber if some behaviors, or prescriptions need to be modified. The PDMP report that Investigator Howes has provides information about patient history requests vs opioids dispensed. As of right now only federally scheduled drugs are on the PDMP program, and Investigator Howes suggested that "drugs of concern" are added to it that may not be scheduled federally, but state wise. The amount of opioid prescriptions went up 8%, while the number of prescribers are less, which Tammy Lindemuth expressed concern for. The main question is whether or not the program is actually working. With the program only being around since 2016, it may take more time and more numbers to determine factors on what is causing higher numbers of opioid prescriptions, and ways that they can be lowered.

Investigator Howes then commented about the security of the PDMP registrations, listing an example of where a doctor left his computer open, and someone ended up going into the system and looking up confidential patient information. The question then comes as to whether this was a mistake on the doctors end for leaving his computer open, or if the doctor purposely allowed someone to access the system, and if that was the case, steps need to be taken to find out who that was.

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Chair Holt inquired why Schedule V were removed from PDMP. Tammy Lindemuth had a theory was because those are less likely to be abused. The conversation talked about possibly reinstating Schedule V drugs back into the PDMP, which Investigator Howes confirmed can be done, however it would put more pressure on pharmacists to input more information.

Chair Holt suggested that the report on delinquencies in PDMP be held off on discussion until Laura Carrillo returns from leave and assumed the executive administrator for pharmacy position.

Agenda Item 6 **<u>Investigative Report</u>**

Investigator Howes indicated that for one of the discussions the board will need to go into executive session. The report indicates 23 open cases, 10 of which were not registering with the PDMP in a timely manner. Investigator Howes states that at this time, there is not enough information to see if the pharmacist actually dispenses prescriptions, versus if they are merely a consulting pharmacist.

Chair Holt inquired if any of the cases required discussion, however the cases that the investigator has open at the time are still pending, and waiting for more information.

On a motion duly made by Leif Holm and seconded by James Henderson in accordance with AS 44.62.310(c)(3), the board unanimously moved to enter executive session for the purpose of discussing matters which by law, municipal charter, or ordinance are required to be confidential.

Staff members Andy Khmelev, Renee Hoffard, and Brian Howes were authorized to remain in the room.

Off record for executive session at 10:21 a.m.
Back on the record at 10:58 a.m.

Upon return from executive session, Chair Holt requested a 15 minute recess.

Off record at 10:59 a.m.
Back on record at 11:11 a.m.

Agenda Item 7 **<u>Board Business</u>**

Task 2
Review tabled applications. The first tabled ballot from the prior voting cycle required the board to enter executive session.

On a motion duly made by Leif Holm and seconded by James Henderson in accordance with AS 44.62.310(c)(2), the board unanimously moved to enter executive

session for subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

Staff members Andy Khmelev, Renee Hoffard, and public member Nicholas Marceaux were authorized to remain in the room.

Off record for executive session at 11:13 a.m.
Back on record at 11:41 a.m.

Upon return from executive session the board moved on to application review. CJ Kim, the pharmacist in charge for the State of Alaska – Division of Public Health made an appearance at the meeting on behalf of a Drug Room Location Change application. The only question the board had for Dr. Kim was when James Henderson asked about the controlled substances question on the inspection report not being complete, Dr. Kim confirmed that the Drug Room does not have a DEA license, therefore it does not handle controlled substances.

Due to the sheer number of applications, the Licensing Examiner (Andy Khmelev) made the ballots be open through 12/10/18. The board agreed with the large number of ballots, with the exception of the State of Alaska – Division of Public Health Drug room application, the remaining ballots will be voted on after the meeting, prior to the close date.

Task 3
The board must vote on the open ballots prior to close date (*the original close date is 12/10/18, however due to the earthquake the struck Anchorage on 11/30/18, the ballot close dates may be postponed*).

The meeting went into recess for lunch.

Off the record for lunch at 11:55 a.m.
Back on the record at 1:17 p.m.

Agenda Item 8 <u>Budget Report/Division Updates</u>

Acting Deputy Director Charles Ward and Accountant III Marylene Wales joined the meeting via teleconference to discuss the budget report and the division updates. No questions from the board regarding the budget report. Miss Wales then went over the FY18 Division Indirect Expenses which was $259,690. Board members did not have follow up questions. Pharmacy board currently has a surplus of $507,993 at the end of FY18. No further discussion on budget.

Agenda Item 9 <u>New Business</u>

Task 4
The board briefly reviewed the State of Alaska Opioid Epidemic Plan that was issued by the

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Department of Health and Social Services. The plan did not require discussion by the board, rather it was added into the agenda by Acting Director Sara Chambers for information purposes.

Task 5

Cheryl Mandala, a judge from the Office of Administrative Hearings joined the meeting in person, and Marilyn Zimmerman, the Division Paralegal II joined via teleconference, to discuss a consent agreement that required an executive session.

On a motion duly made by Leif Holm and seconded by Tammy Lindemuth in accordance with AS 44.62.310(c)(4), the board unanimously moved to enter executive session for the purpose of discussing matters involving consideration of government records that by law are not subject to public disclosure.

Staff members Andy Khmelev, Renee Hoffard, Marilyn Zimmerman, Brian Howes, and Cheryl Mandala were authorized to remain in the room.

Off record for executive session at 1:40 p.m.
Back on the record at 2:23 p.m.

No motions were made during the executive session.

On a motion duly made by Leif Holm, seconded by James Henderson, and approved unanimously, it was

> **RESOLVED to accept the consent agreement proposed for OAH 18-0850-PHA.**

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

The motion did not pass. There was no further discussion on this matter.

On a motion duly made by Leif Holm, seconded by James Henderson, and approved unanimously, it was

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RESOLVED to accept the consent agreement proposed for 2017-00048

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

Motion passed with no further discussion.

Agenda Item 10 <u>Old Business</u>

There was no old business to discuss. Board members requested a short break prior to public comment.

Off record at 2:28 p.m.
On record at 2:45 p.m.

Agenda Item 11 <u>Public Comment</u>

Molly Gray was present during public comment. She reminded the board members of the Annual Convention in February at the Sheraton in Anchorage. There were no further appearances or discussions during the public comment period.

On a motion duly made by Tammy Lindemuth, seconded by Leif Holm, and approved unanimously, it was

RESOLVED to close public comment at 2:50 p.m.

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

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Lana Bell				x

Motion passed with no further discussion.

On a motion duly made by Tammy Lindemuth, seconded by James Henderson, and approved unanimously, it was

RESOLVED to send Rich Holt and Leif Holm as the board delegates to the annual conference on February 8-10th.

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

Motion passed with no further discussion.

Public comment officially closed at 2:50 p.m.

Agenda Item 12 <u>Correspondence</u>

Molly Gray, from the Alaska Pharmacists Association, came to give a presentation on pharmacy tech immunizations. She described how the state of Washington allows pharmacy technicians administer immunizations as a way of delegation of administration. The state of Arizona has implemented it as well. A Pharmacist certified for immunizations would delegate the task to a tech who has gone through the certification program. Delegation of authority would happen under the supervision of the pharmacist. It opens the possibility of technical tasks to be done by the technicians which would open more for pharmacists to work on other projects and have more time for counseling the person that comes in for an immunization. Leif holm asked what the supervision would look like. Molly gray suggested that the board discuss how this would play out with a certified technician. Leif Holm is on board for it if the training is there, and the liability will remain on the pharmacist. Chair Holt brought up that a pharmacist could have concern about the proximity and how close the pharmacist would be to the technician administering immunizations. In regulation the direct supervision definition and personal supervision definition allows for a proximity, and not physically having to be there. It makes no sense to allow this practice, but still require the pharmacist to be present for the administration. Chair Holt also pointed out that there is

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currently a regulation project for pharmacy technicians, and this topic could continue to be discussed on day 2 of the meeting when the regulation project will be up for discussion.

Moving onto next topic of correspondence was "How can a pharmacy dispense a prescription medication to a facility (not a patient) outside of their corporation?" Comes from an email from a bible camp in Unalakleet. Chair Holt mentioned regulation 12 AAC 52.590 about prescribing drugs to a practitioner or a patient.

12 AAC 52.590. PREPACKAGING OF DRUGS. For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

(1) the name, address, and telephone number of the pharmacy;
(2) the name, strength, and quantity of the drug;
(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;
(4) cautionary information required for patient safety and information; and
(5) the initials of the pharmacist.

Tammy Lindemuth expressed concerns if the child that's at a remote camp doesn't know about what kind of allergies they have or how to take their medication. The question on hand is whether or not a prepackaged drug is for a provider, or if it's for the person its prescribed to specifically. Chair Holt interprets the regulation as a prescription is specifically for a person. Leif Holm expressed concern of the fact that in a situation where a child is at a remote camp, and medication is dispensed incorrectly which could result in the death of a child, the liability could end up with the doctor who prescribed the medication, or the pharmacist who provided it. In order to prevent a child dying, Sharon Long stated that there should be a way for it to be allowed for dispensing medication at a remote site with no medical professional standing by. Chair Holt is worried that an untrained professional administering drugs could be a huge liability for the pharmacist. The determination was that a prescription is for a specific person, and that the provider responsible for actions. The patient will have to be referred to the statutory definition of a prescription which is for an individual person. The other option would be to refer them to 12 AAC 52.590, where prepackaged drugs get sent to a prescribing practitioner.

Next topic was an email from the NABP, which had the subject, "Licensure Transfer Program Referenced in FTC Report of Expedited Pharmacist License Portability." The note discusses the concept of mutual recognition of licensure and expedited licensure. Chair Holt determined that the note was more for information purposes. No further discussions on this matter.

Next topic was an email from Ryan Ruggles, the pharmacy director for Anchorage Neighborhood Health Center, was asking if a pharmacist can administer injectable medications. Examples of injectable medications are vitamins, hormones, etc. The board

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agreed that yes a pharmacist can do that with their scope of practice. No further discussions on this matter.

Next topic of discussion was an email from Ian Thomson, the Seattle District State Liaison for the FDA, who on the board of pharmacy would be the best contact regarding compounding pharmacies. Chair Holt mentioned that it sounds like the FDA wants to inspect compounding pharmacies, and they need a local coordinator. Renee Hoffard suggested they contact the investigator so that the board maintains their neutrality. Board agrees that Brian Howes be the contact for the FDA for compounding pharmacies.

Agenda Item 13 **<u>Review Reports of Lost/Stolen Rx</u>**

There were two DEA forms submitted by Safeway for losses of medications. The board determined that there was nothing outside the scope of normal practice loss. The loss reports are from Safeway, and Safeway has a policy to report all losses, regardless of how minor the loss is. Leif Holm states that they are going above and beyond the scope of reporting losses. Tammy Lindemuth commented that CARRS Pharmacy #2628 in Anchorage has not had a loss or theft in two years until this report came in, so it may be in the boards interests to keep an eye on that particular pharmacy.

Agenda Item 14 **<u>Administrative Business</u>**

Board Chair Rich Holt signed the wall certificates, and Renee Hoffard informed him that the complete minutes for signature will be prepped and given to him the following day. Board members also discussed hotel/parking issues that they have had when it comes to reimbursements from the state.

The board concluded with their agenda items for day one and went into recess until the following day.

Off the record for recess until the following day at 3:51 p.m.

Due to the earthquake that occurred at 8:30 am on Friday, November 30th, 2018, in Anchorage, Alaska, the board was unable to resume its meeting. Therefore the meeting was officially adjourned as of 3:51 pm on Thursday, November 29th 2018.

_____

Andy Khmelev, Licensing Examiner Date

_____

Rich Holt, Board of Pharmacy Chair Date

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

1. Request for draft regulation changes initiated by the board during a properly noticed public meeting.

2. Reason for the proposed action: 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 – board must provide in the meeting minutes an estimated costs in the aggregate to comply with the proposed action to:

- **Private Persons**
- **Other State Agencies**
- **Municipalities**

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

- **Private Persons: (i.e. licensee or a nongovernmental entity, such as a partnership or corporation) $50 annually to comply with the proposed action**
- **Other State Agencies: None**
- **Municipalities: None**

4. Board staff transmits the board minutes or an excerpt of the minutes and draft language or proposals for proposed regulation changes requested by the board to the Regulations Specialist.

5. Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.

6. Regulations Specialist prepares draft of regulation changes working with the 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. Board reviews final draft, amends if needed and requests that draft be finalized and public noticed. Determine if board 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.

8. Board or staff needs to complete the Proposed Regulation Recommendation Form (PRRF) – see attached. This form, along with the draft copy of the proposed regulation changes, will be submitted to the director, then commissioner's special assistant, and then governor's staff for consideration/approval to go out for public comment.

9. Regulations Specialist sends notice to the Anchorage Daily News (or other newspapers if warranted) for publication, all interested parties, and licensees if warranted. The Regulations Specialist also posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent (and newly elected) legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, the Administrative Regulation Review Committee, Legislative Council, Lt. Governor, Governor, and Dept. of Law.

10. The Regulations Specialist or board staff shall make a good faith effort to answer a relevant question received at least 10 days before the end of the public comment period. Questions must be in writing or asked at a public meeting. The Regulations Specialist or board staff shall answer the question in writing and make the question and answer available to the public. The Regulations Specialist or board staff may, but is 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 copied by the Regulations Specialist and given to the board staff to include in the board packets for the next meeting for the board to consider 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.

12. Board has few options at its next meeting. It can adopt the proposed regulation changes as written, amend and adopt them, or choose to take no action on them. If the board adopts the regulation changes, the chair signs an

adoption order, and the board staff signs an affidavit of board action and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

13. In addition to making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received on the record and considered the cost to private persons of the regulatory action being taken.

14. Regulations Specialist prepares project for transmittal to Dept. of Law, which includes the adopted regulations, certain affidavits, and other appropriate documents.

15. Dept. of Law reviews and occasionally will 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, and to the chair and all members of Administrative Regulation Review Committee (ARRC), together with any fiscal note, if required. The ARRC chair has 10 days to submit to the governor comments on the regulations.

16. Unless returned by the governor, when the governor, the ARRC, 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.

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

18. 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 Dept. of Law with the final project.

Statutes and Regulations
Pharmacy

February 2019

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

*DIVISION OF CORPORATIONS, BUSINESS
AND PROFESSIONAL LICENSING*

NOTE: The official version of the statutes in this document is printed in the Alaska Statutes, copyrighted by the State of Alaska. The official version of the regulations in this document is published in the Alaska Administrative Code, copyrighted by the State of Alaska. If any discrepancies are found between this document and the official versions, the official versions will apply.

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CHAPTER 80. PHARMACISTS AND PHARMACIES.

Article

1. **The Board of Pharmacy (§§ 08.80.003 - 08.80.105)**
2. **Licensing and Registration (§§ 08.80.110 - 08.80.270)**
3. **Duties of Licensed Pharmacists (§§ 08.80.294 - 08.80.335)**
4. **Unlawful Acts (§§ 08.80.390 - 08.80.460)**
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ARTICLE 1. THE BOARD OF PHARMACY.

Section

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(16) **[Effective July 1, 2019]** license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

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

(d) **[Effective July 1, 2019]** The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

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

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

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

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

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

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

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

ARTICLE 2. LICENSING AND REGISTRATION.

Section

110. Qualifications for licensure by examination
116. Internship and other training programs
120. Grading and content of examination
145. Reciprocity; license transfer
147. Renewal of licensure
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157. Licensing of facilities
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159. Licensing and inspection of facilities outside of state [Effective July 1, 2019]
160. Fees
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168. Administration of vaccines and related emergency medications
261. Disciplinary sanctions
270. Executive administrator of the board

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

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

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

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

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

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

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

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

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

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

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

(2) is at least 18 years of age;

(3) is of good moral character;

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

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

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

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

(8) pays all required fees.

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

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

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

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

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

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

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

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

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

(g) A licensed facility shall report to the board

(1) permanent closing;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(k) **[Effective July 1, 2019]** This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

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

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

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

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

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

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

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

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

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

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

AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

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

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. [Effective July 1, 2019] (a) Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;

(2) appoint an agent on whom process can be served in the state; and

(3) authorize inspection of the facility by a designee of the board under (c) of this section.

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

(1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

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

(1) require an inspection of the applicant's facility located outside the state; and

(2) approve a designee to conduct the inspection.

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

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

(1) examination;

(2) reexamination;

(3) investigation for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) registration or licensure of a facility classified under AS 08.80.157(b).

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

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

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

(b) 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.

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

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

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

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

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

(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or a drug that impairs the applicant's or licensee's ability to practice safely;

(D) physical or mental disability; or

(E) other factors determined by the board;

(8) engaged in conduct involving moral turpitude or gross immorality;

(9) made a controlled substance available to a person except upon prescription issued by a person licensed to prescribe controlled substances;

(10) was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(12) failed to report relevant information to the board about a pharmacist or pharmacy intern that the applicant or licensee knew or suspected was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(13) aided another person to engage in the practice of pharmacy or to use the title of "pharmacist" or "pharmacy intern" without a license; or

(14) engaged in unprofessional conduct, as defined in regulations of the board.

(b) The board may place under seal all drugs that are owned by or in the possession, custody, or control of a licensee at the time a license is suspended or revoked or at the time the board refuses to renew a license. Except for perishable items, the drugs may not be disposed of until the licensee has exhausted administrative and judicial remedies relating to the licensing action. Perishable items may be sold upon order of the court with the proceeds to be deposited with the court. The board shall notify the Department of Health and Social Services about drugs placed under seal under this subsection.

Sec. 08.80.270. EXECUTIVE ADMINISTRATOR OF THE BOARD. (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

ARTICLE 3. DUTIES OF LICENSED PHARMACISTS.

Section

294. Information about equivalent generic drugs and interchangeable biological products
295. Substitution of equivalent drug products or interchangeable biological products
297. Prescription prices and less costly alternatives
315. Confidentiality of records
330. Licensed pharmacist appointed as "pharmacist-in-charge"
335. Prescription for an opioid; voluntary request for lesser quantity

Sec. 08.80.294. INFORMATION ABOUT EQUIVALENT GENERIC DRUGS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed;

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS OR INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) Unless the prescription indicates that it is to be dispensed only as written, the

pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product.

(b) A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing practitioner through

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

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

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

(c) **[Effective July 1, 2019]** 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) **[Effective July 1, 2019]** 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. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained by a pharmacist in the patient’s records or that is communicated to the patient as part of patient counseling is confidential and may be released only to

(1) the patient or as the patient directs;

(2) a practitioner or pharmacist when, in the pharmacist’s professional judgment, release is necessary to protect the patient’s health and well-being; and

(3) other persons or governmental agencies authorized by law to receive confidential information.

Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS “PHARMACIST-IN-CHARGE”. (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

Sec. 08.80.335. PRESCRIPTION FOR AN OPIOID; VOLUNTARY REQUEST FOR LESSER QUANTITY. (a) A pharmacist filling a prescription for an opioid that is a schedule II or III controlled substance under federal law may, at the request of the individual for whom the prescription is written, dispense the prescribed opioid in a lesser quantity than prescribed.

(b) Nothing in this section shall be construed to prevent substitution of an equivalent drug under AS 08.80.295.

ARTICLE 4. UNLAWFUL ACTS.

Section

390. Pharmacists required in hospitals and clinics
400. Other licensees not affected
410. Use of term "pharmacist" prohibited
420. Certain advertising prohibited
430. Use of pharmacy symbols prohibited
450. Disciplinary action
460. Penalties

Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that dispenses drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

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

Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

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

(b) *Repealed 1980.*

Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED. A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

Sec. 08.80.460. PENALTIES. (a) Except for a violation of AS 08.80.297, a person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) **[Delayed amendment, effective July 1, 2019]** A person who violates the provisions of AS 08.80.295 **<u>or 08.80.297 may be punished</u>** [IS PUNISHABLE] by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

ARTICLE 5. GENERAL PROVISIONS.

Section

470. Construction
475. Federal facilities not affected

480. Definitions
490. Short title

Sec. 08.80.470. CONSTRUCTION. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.30, or AS 17.20 (the Alaska Food, Drug and Cosmetic Act).

Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

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

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(3) "board" means the Board of Pharmacy;

(4) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(5) "controlled substance" has the meaning given in AS 11.71.900;

(6) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(7) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(9) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(10) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(11) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;
(B) rational therapy-contraindications;
(C) reasonable dose and route of administration;
(D) reasonable directions for use;
(E) duplication of therapy;
(F) drug-drug, drug-food, and drug-disease interactions;
(G) adverse drug reactions; and
(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

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

(13) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(14) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(15) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor or a nonprescription drug or commercially packed legend drug or device;

(16) "legend drug" means a prescription drug;

(17) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(18) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(19) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(20) **[Effective July 1, 2019]** "outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location;

(21) "owner" means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(22) "patient counseling" means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(23) "person" has the meaning given in AS 01.10.060 and also includes a governmental agency;

(24) "pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(25) "pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy;

(26) "pharmacist-in-charge" means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy's personnel;

(27) "pharmacy" means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157(b);

(28) "pharmacy located outside of the state" means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(29) "pharmacy technician" means a supportive staff member who works under the immediate supervision of a pharmacist;

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

(31) "practitioner" means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(32) "preceptor" means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(33) "prescription drug" means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) "Caution: Federal law prohibits dispensing without prescription"; (B) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(34) "prescription drug order" means a lawful order of a practitioner for a drug or device for a specific patient;

(35) "prospective drug use review" means a review of the patient's drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(36) "significant adverse drug reaction" means a drug-related incident that may result in serious harm, injury, or death to the patient;

(37) "substitute" means to dispense, without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug; or

(B) an interchangeable biological product in place of the prescribed biological product;

(38) **[Effective July 1, 2019]** "third-party logistics provider" means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

(39) "wholesale" means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

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

Sec. 08.80.490. Short title. This chapter may be known as the Pharmacy Act.

CHAPTER 52.
BOARD OF PHARMACY.

Article

1. **Licensing, Registration, and Permit Requirements (12 AAC 52.010 – 12 AAC 52.140)**
2. **Personnel (12 AAC 52.200 – 12 AAC 52.250)**
3. **License Renewal and Continuing Education Requirements (12 AAC 52.300 – 12 AAC 52.350)**
4. **Guidelines for Pharmacies and Pharmacists (12 AAC 52.400 – 12 AAC 52.445)**
5. **Pharmacy Practice Standards (12 AAC 52.450 – 12 AAC 52.590)**
6. **Wholesale Drug Distributors and Facilities (12 AAC 52.610 – 12 AAC 52.695)**
7. **Institutional Pharmacies (12 AAC 52.700 – 12 AAC 52.730)**
8. **Drug Rooms and Facilities Without a Pharmacy (12 AAC 52.800 – 12 AAC 52.850)**
9. **Controlled Substance Prescription Database (12 AAC 52.855 – 12 AAC 52.895)**
10. **Disciplinary Guidelines (12 AAC 52.900 – 12 AAC 52.980)**
11. **General Provisions (12 AAC 52.990 – 12 AAC 52.995)**

ARTICLE 1.
LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

Section

10. Classifications of licensure
20. Facility license
30. Change of pharmacy location or name
40. Change of pharmacy ownership
50. Closed pharmacies
60. Fire or other disaster
70. Application for pharmacist license by examination
75. Good moral character
80. Internship requirements for a pharmacist license
90. Examination requirements and registration
92. Approval to sit for examination
95. Application for pharmacist license by reciprocity
100. Temporary pharmacist license
110. Emergency pharmacist permit
120. Review of pharmacist intern license application
130. Registration of pharmacies located outside of the state
140. Pharmacy technician license

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE. (a) The board will issue the following categories of licenses or permits to a qualified individual:

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

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

(1) pharmacy license;
(2) repealed 2/26/2000;
(3) wholesale drug distributor license;
(4) drug room license;
(5) registration of a pharmacy located outside of the state;
(6) remote pharmacy license.

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158

AS 08.80.030 AS 08.80.155 AS 08.80.390
AS 08.80.116 AS 08.80.157

12 AAC 52.020. FACILITY LICENSE. (a) An applicant for a facility license shall submit

(1) the fees required in 12 AAC 02.310;

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

(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and

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

(b) Repealed 1/17/2007.

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

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

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (a) The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall

(1) submit a new, completed application for a pharmacy license; and

(2) pay the duplicate license fee required in 12 AAC 02.105;

(3) repealed 1/17/2007.

(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (a) Repealed 1/17/2007.

(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.050. CLOSED PHARMACIES. (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall

(1) submit to the board a written notice of the cessation of pharmacy operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the pharmacy ceased operations;

(B) a statement signed by the pharmacist-in-charge attesting that an inventory of all controlled substances on hand has been conducted; and

(C) a statement signed by the pharmacist-in-charge attesting to the manner of disposition for all prescription drugs possessed by the pharmacy;

(2) arrange for the transfer of prescription drug orders or computer prescription records to another pharmacy to facilitate continuous patient care; and

(3) provide for the maintenance and availability of prescription drug orders or hard copies of computer prescription records in accordance with 12 AAC 52.450(a) that are not transferred to another pharmacy;

(4) repealed 1/17/2007.

(b) In the absence of a pharmacist-in-charge, the owner of the pharmacy shall meet all requirements of this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.060. FIRE OR OTHER DISASTER. (a) If a pharmacy has a fire or other disaster, the pharmacist-in-charge of the pharmacy shall

(1) within 10 days, report to the board the date of a fire or any disaster that may affect the strength, purity, or labeling of drugs, devices, or other materials used in the practice of the pharmacy;

(2) provide the board with a copy of a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances," reporting the loss or destruction of controlled substances or DEA order forms; if the extent of the loss of controlled substances cannot be determined, the pharmacist-in-charge shall submit to the board a complete inventory of all remaining controlled substances and a statement, signed by the pharmacist-in-charge, attesting to the accuracy of the inventory; and

(3) notify the board in writing within 10 days after any change in the pharmacy's address, including a move to a temporary location or a return to the pharmacy's permanent location.

(b) If a pharmacy maintains a temporary location for more than 90 days, the pharmacist-in-charge of the pharmacy shall apply for a new and separate facility license as required in 12 AAC 52.030.

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (a) The board will issue a pharmacist license by examination to an applicant who meets the requirements of AS 08.80.110, 08.80.116, and this section.

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

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

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

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

(4) either

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

(B) a certified copy of

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

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

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

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

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

12 AAC 52.075. GOOD MORAL CHARACTER. As used in AS 08.80, "good moral character" includes not having been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

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

(c) Repealed 4/16/2016.

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

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION. (a) In addition to the requirements in AS 08.80.110, an applicant for a pharmacist license shall pass the

(1) North American Pharmacy licensing examination (NAPLEX) administered by the National Association of Boards of Pharmacy with a NAPLEX scaled score of 75 or above; and

(2) Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(b) An applicant for a temporary pharmacist license shall pass the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(c) An applicant for a pharmacist license that has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of examination scores directly to the department.

(d) An applicant for licensure by examination must submit an application under 12 AAC 52.070 and be approved under 12 AAC 52.092 before sitting for examination under this section.

(e) An applicant who has failed the Alaska pharmacy jurisprudence examination specified in (f) of this section may not retake the examination for at least 30 days.

(f) The Multistate Pharmacy Jurisprudence Examination administered by the national Association of Boards of Pharmacy (NABP) is the examination adopted by the board as the Alaska pharmacy jurisprudence examination. An applicant shall satisfy all other license requirements within one year after passing the Alaska pharmacy jurisprudence examination or retake the examination.

(g) An applicant applying for a pharmacy license by examination shall make application within one year of successfully passing the NAPLEX. An applicant applying more than one year after passing the NAPLEX shall retake the NAPLEX or apply for a pharmacy license under AS 08.80.145.

Authority: AS 08.01.065 AS 08.80.110 AS 08.80.150
AS 08.80.005 AS 08.80.120 AS 08.80.160
AS 08.80.030

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.

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

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

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

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

(4) either

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

(B) a certified copy of

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

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

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

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (a) The board will issue a pharmacist license by reciprocity to an applicant who meets the requirements of AS 08.80.145 and this section.

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

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

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

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

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

(4) either

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

(B) a certified copy of

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

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

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

(6) either

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

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) verification that the applicant is currently licensed as a pharmacist in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy;

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

(d) An applicant for licensure under this section who has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (c)(1) – (6) and (8) – (10) of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.100. TEMPORARY PHARMACIST LICENSE. (a) The board will issue a temporary pharmacist license to an applicant for licensure if the applicant

(1) submits a completed application for licensure;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) repealed 2/26/2000;

(4) provides for the National Association of Boards of Pharmacy (NABP) to notify the board that the applicant has submitted a preliminary application to NABP for license transfer;

(5) pays the application fee, pharmacist license fee, and temporary license fee required in 12 AAC 02.310;

(6) passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above;

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

(8) submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

(b) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, the board will extend the temporary license for an additional period not to exceed 60 days.

(d) A temporary license is not renewable.

(e) An individual may not receive more than one temporary license.

Authority: AS 08.80.005 AS 08.80.145 AS 08.80.150
AS 08.80.030

12 AAC 52.110. EMERGENCY PHARMACIST PERMIT. (a) If the board determines that an emergency exists, the board will issue an emergency pharmacist permit for the purpose of providing coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, to an applicant who

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

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

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

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

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

(1) applies on a form provided by the department;
(2) pays the application fee and the pharmacist intern license fee established in 12 AAC 02.310;
(3) has
(A) enrolled in a college of pharmacy accredited by the ACPE; or
(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;
(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;
(5) submits a Declaration of Sponsorship of Pharmacy Intern form completed by the applicant's sponsor pharmacist at each work location for which the applicant is to work;
(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;
(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act); and
(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) - (2) and (5) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state. The pharmacist intern license is valid for only those work locations for which the individual previously submitted sponsorship declarations in accordance with (b)(5) of this section. Before the individual may work at an additional work location, the individual must

(1) submit a sponsorship declaration for that location in accordance with (b)(5) of this section; and
(2) have a revised license issued to the individual.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an out-of-state pharmacy registration. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive an out-of-state pharmacy registration will not be issued a registration unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that registration.

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

(1) applies on an application provided by the department that includes
(A) the company name and owner name;

(B) the pharmacy name;
(C) the location of the facility;
(D) a mailing address and telephone number;
(E) a toll free number accessible by patients in this state;
(F) the federal employer identification number;
(G) the names of all partners or corporate officers;
(H) the name, address, and telephone number for pharmacist-in-charge;
(I) the names of all pharmacists working in the facility;
(J) completion of the professional fitness section of the application; and
(K) the name of the appointed registered agent;

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

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

(4) submits an inspection report or self-inspection report completed within the last two years.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140. PHARMACY TECHNICIAN LICENSE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacy technician license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacy technician license.

(b) The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including
(A) the applicant's name, mailing address, and telephone number; and
(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310.

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

Authority: AS 08.80.005 AS 08.80.030

ARTICLE 2.
PERSONNEL.

Section

200. Pharmacist-in-charge
210. Pharmacist duties
220. Pharmacist interns
230. Pharmacy technicians
240. Pharmacist collaborative practice authority
250. Job shadowing in pharmacy

12 AAC 52.200. PHARMACIST-IN-CHARGE. (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

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

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

(2) training of all pharmacy personnel;

(3) establishing policies and procedures for pharmacy operations;

(4) maintaining required records;
(5) storage of all materials, including drugs and chemicals;
(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and
(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

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

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

12 AAC 52.210. PHARMACIST DUTIES. Except as provided in 12 AAC 52.220, the following duties may be performed only by a pharmacist:
(1) receiving an oral prescription drug order;
(2) consulting with a prescriber regarding a patient or prescription;
(3) interpreting a prescription drug order;
(4) determining the product required for a prescription;
(5) interpreting data in a patient medication record system;
(6) making a final check on all aspects of a completed prescription and assuming the responsibility for a filled prescription, including the accuracy of the drug prescribed and of the prescribed drug's strength, labeling, and proper container; and
(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.220. PHARMACIST INTERNS. (a) A pharmacist intern may not represent that the pharmacist intern is a pharmacist. Only a person licensed by the board as a pharmacist intern may take, use, or exhibit the title of pharmacist intern or any other similar term.

(b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist under the direct supervision of a pharmacist.

(c) A pharmacist intern may not sign or initial any document that is required to be signed or initialed by a pharmacist unless the supervising pharmacist also signs or initials the document.

(d) A pharmacist intern shall file with the board a report of work experience on a form provided by the department within 30 days of completion or termination of an internship in the practice of pharmacy required under 12 AAC 52.080.

(e) A pharmacist supervising a pharmacist intern
(1) must be licensed as a pharmacist and be in good standing with the board;
(2) shall provide direct supervision to an intern during professional activities throughout the entire period of the internship;
(3) shall physically review prescription drug orders and the dispensed product before delivery of a product to the patient or the patient's agent;
(4) is responsible for the work of the pharmacist intern;
(5) may supervise more than one pharmacist intern; more than one pharmacist intern may not dispense simultaneously under the direct supervision of the same supervising pharmacist.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410
AS 08.80.030 AS 08.80.116

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

(b) A pharmacy technician shall work under the direct supervision of a person who is licensed as a pharmacist.

(c) A pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

(d) An individual working as a pharmacy technician shall wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.

(e) Before an individual may regularly perform the tasks of a pharmacy technician, the individual shall complete training required by the pharmacist-in-charge. Duties performed by the pharmacy technician must be consistent with the training the pharmacy technician has received.

(f) If a pharmacy technician will assist in the preparation of sterile pharmaceuticals, including parenteral medications, the pharmacy technician must have completed a minimum of 40 hours of on-the-job training in the

preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform those tasks.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

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

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

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

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

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

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

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months; and

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

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

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

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

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

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

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

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.250. JOB SHADOWING IN PHARMACY. (a) A pharmacist-in-charge or job shadowing preceptor of a pharmacy may allow job shadowing by a student in the pharmacy only as specified in this section.

(b) Before a student begins a job shadowing program under this section, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board, which includes the names of the pharmacy, the participating student, and the pharmacist-in-charge or job shadowing preceptor. The student and the pharmacist-in-charge or preceptor shall sign the form. The parent or guardian of the student shall also sign the form if the student is less than 18 years of age.

(c) The pharmacist-in-charge or, if applicable, the job shadowing preceptor shall familiarize the student with the confidentiality requirements of 45 C.F.R., Parts 160 and 164 (HIPAA) and ensure compliance with this section and the relevant sections of AS 08.80 and this chapter.

(d) A pharmacist-in-charge or job shadowing preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than 50 hours;

(C) perform any functions reserved for licensed, certified, or registered pharmacy personnel;

(2) a ratio of job shadowing student to pharmacist-in-charge or job shadowing preceptor other than one to one.

(e) After completion of the job shadowing program by a student, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board where the pharmacist-in-charge or job shadowing preceptor provides the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The job shadowing documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed by that student.

(f) In this section,

(1) "job shadowing" means for educational purposes and through observation only, the observation by a student of the functions and duties of a pharmacy and pharmacy staff with the intended purpose of giving the student an opportunity to observe career possibilities available in the field of pharmacy;

(2) "job shadowing preceptor" means a licensed pharmacist, other than the pharmacist-in-charge, designated by the pharmacist-in-charge to supervise a student while that student is job shadowing;

(3) "student" means a person currently enrolled in a high school or post-secondary education program.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

Editor's note: The job shadowing documentation form required by 12 AAC 52.250 may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, P.O. Box 110806, Juneau, AK 99811-0806; phone: (907) 465-2589; or the division's website at http://www.commerce.state.ak.us/occ/ppha.htm.

ARTICLE 3.
LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS.

Section

300. License renewal
310. Reinstatement of an expired pharmacist or pharmacy technician license
320. Continuing education requirements for pharmacists
325. Continuing education requirements for pharmacy technicians
330. Alternative continuing education schedule
340. Approved programs
350. Audit of records by the board

12 AAC 52.300. LICENSE RENEWAL. (a) Pharmacy, wholesale drug distributor, and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license shall submit

(1) a completed renewal application;

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

(3) a completed self-inspection of the premises questionnaire on a form provided by the department.

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

(1) a completed renewal application;

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

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) 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.

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

12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE. (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

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

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated.

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

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacy technician license shall certify that, during the concluding licensing period, the applicant

(1) completed 10 contact hours of continuing education accepted by the board under 12 AAC 52.340; or

(2) obtained initial certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB).

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) Instead of complying with the continuing education requirements in (a) of this section, an applicant for renewal of a pharmacy technician license for the first time may

(1) verify in an affidavit, on an application for renewal, that the applicant has read the state statutes and regulations compiled by the board; and

(2) submit an affidavit, signed by the pharmacist-in-charge, verifying the applicant's pharmacy technician training in accordance with 12 AAC 52.230.

(d) An applicant for reinstatement of a pharmacy technician license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005

Editor's note: Information regarding certification with the Pharmacy Technician Certification Board described in 12 AAC 52.325 may be obtained from the Pharmacy Technician Certification Board, 1100 15th Street, NW, Suite 703, Washington, DC 20005-1707, phone: (202) 429-4120 or at PTCB's website at www.ptcb.org. The Alaska

Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE. An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.165

12 AAC 52.340 APPROVED PROGRAMS. (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section, the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

Authority: AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

ARTICLE 4.
GUIDELINES FOR PHARMACIES AND PHARMACISTS.

Section

400. General guidelines for pharmacies
410. Care of drug stocks and devices
420. Security
423. Remote pharmacy license
425. Telepharmacy system for a remote pharmacy
430. Guidelines relating to sterile pharmaceuticals
440. Guidelines relating to compounding practices
443. Approval for shared pharmacy services by pharmacy
444. Approval for shared pharmacy services by pharmacist
445. Shared pharmacy services

12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, "*Facility Standards for Pharmacies,*" dated November 2016, and incorporated by reference in this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES. (a) A drug or device that has exceeded its expiration date shall be removed from stock and quarantined until properly disposed of in accordance with 12 AAC 52.560.

(b) A pharmacist may not dispense a drug or device beyond the expiration date on the drug or device.

(c) All drugs and devices on shelves or display for sale shall be protected against contamination, deterioration, and adulteration.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.420. SECURITY. (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department security requirements.

(c) All drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

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

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) Prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

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

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

12 AAC 52.423. REMOTE PHARMACY LICENSE. (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;
(2) the applicable fees established in 12AAC 02.310; and
(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

(1) it is able to comply with the requirements of 12 AAC 52.425; and

(2) there is no access to a non-remote pharmacy within ten road miles of the proposed remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles.

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300. A remote pharmacy license may not be renewed if a non-remote pharmacy opens for business within ten road miles of the remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. (a) Only a 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. The pharmacist-in-charge of a central pharmacy may supervise one or more remote pharmacies.

(b) Before 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 only from the central pharmacy. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped. Itemized records of drugs shipped or received must be verified by the supervising pharmacist at both the central pharmacy and the remote pharmacy.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must also maintain a record of the prescriptions filled at the remote pharmacy. The records must distinguish prescriptions filled at the remote pharmacy from those filled at the central pharmacy and at other remote pharmacy locations.

(g) The prescription label of a prescription drug distributed 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 central pharmacy and distributed by the remote pharmacy. A prescription drug may not be distributed by a remote pharmacy until a pharmacist at the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and

(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

(j) The pharmacist-in-charge of the central pharmacy must ensure that the remote pharmacy is in compliance with all laws, including regulations, governing the activities of the pharmacy.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.430. GUIDELINES RELATING TO STERILE PHARMACEUTICALS. A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the guidelines established by the board in the pamphlet titled, "*Sterile Pharmaceuticals,"* dated February 2008, and incorporated by reference in this section.

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.430, *"Sterile Pharmaceuticals"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES. A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "*Compounding Practices,"* dated February 2008, and incorporated by reference in this section

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.440, *"Compounding Practices"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY. (a) A requesting pharmacy in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

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

(1) that the pharmacy has a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

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

(3) that the pharmacy either

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

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

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

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. (a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

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

(1) that the pharmacist

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

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

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

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

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.445. SHARED PHARMACY SERVICES. (a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.

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

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

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

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

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

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

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

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

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

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

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

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

(2) filling pharmacy, shall either

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

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

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

(1) outline the responsibilities of each participant;

(2) include a list that contains

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

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

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

(3) address

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

(B) the adequate protection of the confidentiality and integrity of patient information;

(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;

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

(E) compliance with federal and state laws; and

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

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

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

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

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

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

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

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.158
AS 08.80.030

ARTICLE 5.
PHARMACY PRACTICE STANDARDS.

Section

450. Prescription drug order records
460. Prescription drug order information
470. Refills
480. Labeling
490. Prescriptions by electronic transmission
500. Transfer of a prescription drug order
510. Substitution
520. Customized patient medication package (patient med-pak)
530. Return or exchange of drugs
540. Notification of theft or significant loss
550. Advertising
560. Destruction and disposal of drugs
570. Drug regimen review
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585. Mandatory patient counseling
590. Prepackaging of drugs

12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug orders by

(1) keeping the original hard copy prescription drug order presented by a patient;

(2) keeping a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal;

(3) keeping a prescription drug order put into writing either manually or electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION. (a) Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the following information:

(1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;

(2) address of the patient unless the prescription drug order is for a noncontrolled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;

(3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;

(4) name and strength of the drug prescribed;

(5) quantity prescribed;

(6) directions for use;

(7) date of issue;

(8) refills authorized, if any;

(9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;

(10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature; and

(11) if the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, a pharmacist shall add the following information to the prescription drug order:

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

(2) initials or identification code of the dispensing pharmacist;

(3) quantity dispensed, if different from the quantity prescribed;

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

(5) if the drug was prescribed by generic name or if an equivalent drug product other than the one prescribed was dispensed, for the drug product actually dispensed, at least one of the following:

(A) the name of the manufacturer or distributor;

(B) the national drug code number;

(C) the short name code; or

(D) the trade name.

(c) After oral consultation with the prescribing practitioner, a pharmacist may add the following information to schedule II controlled substance prescriptions:

(1) date of issue of the prescription;
(2) address of the patient;
(3) strength of the drug prescribed;
(4) drug dosage form;
(5) drug quantity prescribed;
(6) directions for use;
(7) DEA registration number.

(d) After oral consultation with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any modification to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribed.

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.470. REFILLS. (a) 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.

(b) 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.

(c) Each time a prescription drug order is dispensed, the pharmacist shall record the 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.

(d) If an original prescription drug order is prescribed as a 30-day supply, the pharmacist may dispense up to a 100-day supply on refills if the

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

(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.

Authority: AS 08.80.005 AS 08.80.030

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

(1) name, address, and phone number of the dispensing pharmacy;
(2) unique identification number of the prescription drug order;
(3) date the prescription drug order is dispensed;
(4) initials of the dispensing pharmacist;
(5) name of the prescribing practitioner;
(6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;
(7) directions for use;
(8) quantity dispensed;
(9) appropriate ancillary instructions or cautions;
(10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";
(11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner; and
(12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent.

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION. (a) Legend drug and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws.

A pharmacist may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

(1) name, address, and telephone number of the prescribing practitioner;

(2) electronic signature or manual signature of the prescribing practitioner;

(3) the information required in 12 AAC 52.460(a)(1) - (8); and

(4) any other information required by federal law.

(b) A pharmacist may dispense a prescription that has been received electronically.

(c) The system for electronic transmission of prescriptions must address the following:

(1) patient's choice of pharmacy; the system may not restrict the patient's choice of pharmacy;

(2) security of the system; the system must have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information; the system must include

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other applicable equipment from an unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control, and audit access to confidential patient information; and

(D) processes to prevent unauthorized access to the prescription information when transmitted electronically;

(3) confidentiality of patient information; the system must maintain the confidentiality of patient information consistent with state and federal laws;

(4) authentication; to be valid prescriptions transmitted by an authorized prescriber or the prescribing practitioner's authorized agent from computer to a facsimile machine or from computer to computer must use an electronic signature; the prescribing practitioner's system must authenticate the sender's authority and credentials to transmit a prescription to a pharmacy and

(A) the prescribing practitioner's system must provide an audit record of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(B) the right of the board to access the prescribing practitioner's electronically transmitted prescriptions for purposes of investigations;

(5) a prescribing practitioner's system that utilizes intermediaries in the electronic communication of prescriptions to pharmacies is responsible to ensure that the contracts with the intermediaries require security measures that are equal to or better than those provided by this section and prohibit the modification of a record of a prescription after it has been transmitted by the prescribing practitioner to the pharmacist;

(6) if a paper copy prescription that is generated by the pharmacist or pharmacy technician from the electronic prescription system is printed, an electronic signature may be substituted for a manual signature;

(7) the system must maintain the integrity and confidentiality of patient information transmitted electronically for its system as required by this chapter, other state law, and federal law.

(d) In this section,

(1) "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription;

(2) "electronic transmission of prescriptions" means the communication from an authorized prescribing practitioner or the prescribing practitioner's authorized agent to a pharmacy of the patient's choice, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with this section, other state law, and federal law;

(3) "security" means a system to maintain the confidentiality and integrity of prescription information, including

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other pertinent equipment from unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control and audit access to confidential patient information; and

(D) processes for its system to prevent unauthorized access to the prescription information when transmitted electronically.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER. (a) For the purpose of dispensing a refill of a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(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) if transferred verbally, the transfer shall be communicated directly between two licensed pharmacists;

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

(3) the pharmacist 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 receiving the prescription drug order information;

(C) the name of the pharmacist transferring the prescription drug order information; and

(D) the date of the transfer;

(4) the pharmacist 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 number of refills authorized on the original prescription drug order;

(C) the number of valid refills 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 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 number of authorized refills is not exceeded.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.510. SUBSTITUTION. (a) A pharmacist may dispense an equivalent drug 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) the equivalent drug product costs the patient less than the prescribed drug product; and

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

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

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the term "equivalent drug product" is defined in AS 08.80.480.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK). (a) Instead of dispensing one or more prescribed drug products in separate containers, a pharmacist may, with the written consent of the patient, patient's caregiver, or prescribing practitioner, provide a customized patient medication package or patient med-pak.

(b) A patient med-pak is a series of containers prepared by a pharmacist for a specific patient containing one or more prescribed solid oral dosage forms and designed or labeled to indicate the day and time, or period of time, when the contents within each container are to be taken.

(c) The pharmacist shall prepare a label for a patient med-pak that includes

(1) the name of the patient;

(2) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for the drug products in the patient med-pak;

(3) the name, strength, physical description or identification, and total quantity of each drug product in the patient med-pak;

(4) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product in the patient med-pak;

(5) any other information, statements, or warnings required or appropriate for any of the drug products in the patient med-pak;

(6) the name of the prescribing practitioner of each drug product in the patient med-pak;

(7) the date of preparation of the patient med-pak and the expiration date assigned to the patient med-pak; the expiration date may not be more than 60 days from the date of preparation of the patient med-pak;

(8) the name, address, and telephone number of the pharmacy; and

(9) the initials of the dispensing pharmacist.

(d) If the patient med-pak allows for the removal or separation of the intact containers from the patient med-pak, the pharmacist shall label each individual container of the patient med-pak to identify each of the drug products contained in the patient med-pak.

(e) When preparing a patient med-pak, the dispensing pharmacist shall take into account any applicable compendium requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container in the med-pak and any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(f) In addition to any individual prescription filing requirements, the pharmacist shall make and file a record of each patient med-pak. Each record must contain

(1) the name and address of the patient;

(2) a unique identification number for the patient med-pak itself and a separate, unique, identification number for each of the prescription drug orders for each drug product contained in the patient med-pak;

(3) information identifying or describing the design, characteristics, or specifications of the patient med-pak that is sufficient to prepare an identical patient med-pak for the patient;

(4) the date of preparation of the patient med-pak and the expiration date assigned;

(5) any special labeling instructions; and

(6) the name or initials of the pharmacist who prepared the patient med-pak.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.530. RETURN OR EXCHANGE OF DRUGS. (a) Except as provided in (b) of this section, a pharmacy or pharmacist may not accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed.

(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

(1) the pharmacist can readily determine that there has been no entry or attempt at entry to the unit dose package or blister card;

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the standards of the United States Pharmacopoeia (1995 revision) for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(3) the drug has not come into the physical possession of the person for whom it was prescribed, and control of the drug is known to the pharmacist to have been the responsibility of a person or persons licensed to prescribe, dispense, or administer drugs; and

(4) the drug labeling or packaging has not been altered or defaced, and the identity of the drug, its strength, lot number, and expiration date are retrievable.

Authority: AS 08.80.005 AS 08.80.030

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

12 AAC 52.540. NOTIFICATION OF THEFT OR SIGNIFICANT LOSS. If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.550. ADVERTISING. A pharmacy may advertise prescription drug prices if the advertisement contains all of the following information:

(1) proprietary, trade, or generic name of the drug product;

(2) name of the manufacturer or distributor of the drug product;

(3) dosage form and strength of the drug product;

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

(5) the hours that pharmaceutical services are available from the advertiser.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS. (a) A licensed pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a manner that makes the drugs unfit for human consumption.

(b) A drug that is a controlled substance shall be disposed of in accordance with federal statutes and regulations.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.570. DRUG REGIMEN REVIEW. (a) A pharmacist shall perform a drug regimen review, as defined in AS 08.80.480, for each prescription drug order.

(b) If a pharmacist identifies any of the items listed in AS 08.80.480 during the drug regimen review, the pharmacist shall avoid or resolve the problem by consulting with the prescribing practitioner, if necessary.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.580. DATA PROCESSING SYSTEMS. A pharmacy may use an automated data processing system to maintain the records required in AS 08.80 and this chapter if the system

(1) is capable of on-line retrieval of all information required in 12 AAC 52.460, 12 AAC 52.470, and 21 C.F.R. 1306.22, as amended as of February 6, 1997;

(2) is capable of producing an audit trail printout for all dispensing of any specified strength and dosage form of a drug; and

(3) has adequate safeguards to prevent loss of data and reasonable security to prevent unauthorized access to, modification of, or manipulation of patient records.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.585. MANDATORY PATIENT COUNSELING. (a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

(1) the name and description of the prescribed drug;

(2) the dosage and the dosage form;

(3) the method and route of administration;

(4) the duration of the prescribed drug therapy;

(5) any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;

(6) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;

(7) patient techniques for self-monitoring of the drug therapy;

(8) proper storage;

(9) prescription refill information; and

(10) the action to be taken in the event of a missed dose.

(b) A pharmacist shall counsel the patient or the patient’s agent face-to-face. If face-to-face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist’s own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopoeia Drug Information or comparable information.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient’s caregiver refuses the counseling.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.590. PREPACKAGING OF DRUGS. For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

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

(2) the name, strength, and quantity of the drug;

(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;

(4) cautionary information required for patient safety and information; and

(5) the initials of the pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

ARTICLE 6.
WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

Section

610. Wholesale drug distributor license
620. Wholesale drug facilities
625. Personnel requirements; grounds for denial or other disciplinary action
630. Drug storage
640. Written policies and procedures
645. Examination of drug shipments
650. Records and inventories
660. Returned, damaged, and outdated drugs
670. Drug recalls
680. Inspections
685. Prohibition against direct distribution
690. Salvage and reprocessing
695. Provisions not applicable

12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (a) An applicant for a wholesale drug distributor license shall

(1) apply on the form provided by the department;

(2) pay the fees required in 12 AAC 02.310;

(3) provide a list of the names and résumés of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provide the name and the résumé of the person who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submit a completed self-inspection of the premises questionnaire on a form provided by the department; and

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

(b) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (a) of this section; and

(2) be registered with the DEA.

(c) Within 30 days of a change in facility manager, the new facility manager must

(1) submit the completed change of pharmacy manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (a)(4) and (6) of this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.620. WHOLESALE DRUG FACILITIES. (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR OTHER DISCIPLINARY ACTION. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and

managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs.

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

12 AAC 52.630. DRUG STORAGE. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements or official United States Pharmacopoeia (USP), 1995 revision, compendium requirements, to help ensure that the identity, strength, quality, and purity of the products are not affected. If a temperature requirement is not listed for a drug, the drug may be stored at controlled room temperature as defined in the USP.

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

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

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

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES. A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs;

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;

(7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS. (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.650. RECORDS AND INVENTORIES. (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

(1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;

(2) the identity and quantity of the drug received, distributed, or disposed of; and

(3) the date of receipt and of distribution or other disposition.

(b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS. (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030

12 AAC 52.695. PROVISIONS NOT APPLICATIONS. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the

power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) any of the following transfers of a drug, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee during any 12-consecutive-month period:

(A) the sale of a drug by a retail pharmacy to another retail pharmacy or to a practitioner, or the offer by a retail pharmacy to sell a drug to another retail pharmacy or to a practitioner;

(B) the purchase of a drug by a retail pharmacy or by a practitioner from another retail pharmacy, or the offer by a retail pharmacy or by a practitioner to purchase a drug from another retail pharmacy;

(C) the trade of a drug by a retail pharmacy with another retail pharmacy, or the offer by a retail pharmacy to trade a drug with another retail pharmacy;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

ARTICLE 7.
INSTITUTIONAL PHARMACIES.

Section

700. (Repealed)
710. Absence of a pharmacist from an institutional pharmacy
720. Emergency room outpatient medications
730. Drug distribution and control

12 AAC 52.700. INSTITUTIONAL PHARMACIES. Repealed 2/26/2000.

12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY. (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;

(B) name, strength, and amount of the drug;

(C) date and time of removal; and

(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical to check the stock container or similar unit dose package of the drug removed ; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS. (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the

(A) name, address, and telephone number of the institutional facility;

(B) name, strength, and quantity of the drug;
(C) cautionary information required for patient safety and information;
(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and
(E) initials of the pharmacist;
(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and
(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the
(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.
(c) Prepackaged medications shall be kept in a secure place within the emergency room.
(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.
(e) This section does not apply to the administration of a single dose to a patient.
(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL. (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.
(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.
(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.
(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

ARTICLE 8.
DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

Section
800. Drug room license
810. Pharmacist required
820. Responsibilities of the consultant pharmacist
830. Emergency drug kits
840. First dose kits
850. Emergency distribution

12 AAC 52.800. DRUG ROOM LICENSE. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.
(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.810. PHARMACIST REQUIRED. An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST. A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.840. FIRST DOSE KITS. (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.850. EMERGENCY DISTRIBUTION. In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

ARTICLE 9.
CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

855. Registration with the prescription drug monitoring program controlled substance prescription database
860. Access to and conditions for use of the prescription drug monitoring program database
865. Reporting and reviewing PDMP information
870. Waiver of electronic submission requirement by pharmacist or practitioner
875. Solicited requests for information from non-registered persons
880. Reports
885. Purged database records
890. Grounds for discipline
895. Correcting information in database

12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE. (a) A licensed pharmacist shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) before dispensing a schedule II, III, or IV controlled substance under federal law.

(b) Before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

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

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

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

(e) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.860. ACCESS TO AND CONDITIONS FOR USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM DATABASE. (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes in AS 17.30.200(d)(1) of an inquiry under a search warrant, subpoena, or order issued by an administrative law judge or a court,

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

(2) "personnel of another board or agency" means an employee of this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(c) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(1) employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy and providing PDMP data storage or data management services; or

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

(d) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an agent or employee to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(e) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom that department's commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(u), a pharmacist must submit information required under AS 17.30.200(b), if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(u), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily as of the previous submission date.

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

(d) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(f) Unless excused from reporting under AS 17.30.200(u), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(g) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a pharmacist or practitioner must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

(c) The department may not grant a waiver under this section unless the pharmacist or practitioner first agrees in writing that, if the waiver is granted, the pharmacist or practitioner will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board on at least a daily basis using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the pharmacist or practitioner files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A pharmacist or practitioner must inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS. (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a $10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880. REPORTS. (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

(1) the date on which the request was received;

(2) the name of the patient and the patient's date of birth;

(3) the name, title, and address of the individual requesting the profile;

(4) the date on which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.885. PURGED DATABASE RECORDS. The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890. GROUNDS FOR DISCIPLINE. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a practitioner not licensed by this board shall be reported to the practitioner's licensing board.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.895. CORRECTING INFORMATION IN DATABASE. (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

(1) on a form or in a format prescribed by the board,

(A) a description of the information asserted to be incorrect, and the correction requested;

(B) the mailing and physical address and telephone number of the requester; and

(C) a signed, sworn statement attesting to the truth of the corrected information;

(2) documentation to support the correction requested; and

(3) proof of the requester's identity.

(b) If the board determines that it

(1) has sufficient information to make a determination, the board will

(A) notify the requester that the request is granted; or

(B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;

(2) lacks sufficient information to grant or deny the request, the board

(A) will request additional information from the requester; and

(B) will not act on the request until after the additional information is received.

(c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

Authority: AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

ARTICLE 10.
DISCIPLINARY GUIDELINES.

Section

900. Purpose of disciplinary guidelines
910. Violations
920. Disciplinary guidelines
930. Terms of probation
940. Use of alcohol or controlled substances
950. Probation terms for professional incompetence
960. Mental or physical disabilities
970. Reinstatement of a suspended license
980. Reinstatement of a revoked license

12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES. The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board's disciplinary policies are known and are administered consistently and fairly.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.910. VIOLATIONS. (a) A person who is licensed under AS 08.80 and this chapter who, after a hearing under AS 44.62 (Administrative Procedure Act), is found to have violated a provision of AS 08.80 or this chapter is subject to the disciplinary penalties listed in AS 08.01.075, including public notice of the violation and penalty in appropriate publications.

(b) Nothing in the guidelines set out in 12 AAC 52.920 prohibits the board from imposing greater or lesser penalties than those described in 12 AAC 52.920 or restricting the practice of a licensee depending upon the circumstances of a particular case.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.920. DISCIPLINARY GUIDELINES. (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;

(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making a false or fraudulent claim concerning a drug;

(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;

(12) violating the provisions of a board order or memorandum of agreement;

(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;

(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;

(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;

(18) violating AS 08.80.315 dealing with the confidentiality of records;

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;

(20) offering, giving, soliciting, or receiving compensation for referral of a patient;

(21) violating AS 08.80.261(a)(3); or

(22) violating AS 17.30.200 or a regulation adopted under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.

(b) The board will, in its discretion, revoke a license if the licensee

(1) commits a violation that is a second offense;

(2) violates the terms of probation from a previous offense;

(3) violates AS 08.80.261(a)(1) or (4);

(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;

(5) is professionally incompetent if the incompetence results in risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee

(1) wilfully or repeatedly violates AS 08.80 or this chapter; or

(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

Authority:	AS 08.01.075	AS 08.80.261	AS 08.80.460
	AS 08.80.005	AS 08.80.315	AS 17.30.200
	AS 08.80.030		

12 AAC 52.930. TERMS OF PROBATION. The board will, in its, discretion, subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:

(1) obey all laws pertaining to the practice of pharmacy in this state;

(2) fully comply with the probation program established by the board and cooperate with representatives of the board;

(3) notify the board in writing of the dates of departure and return if the licensee leaves the state to reside or practice pharmacy outside the state;

(4) report in person at meetings of the board or to its designated representatives during the period of probation, as directed by the board;

(5) submit written reports and verification of actions as required by the board during the period of probation;

(6) if employed in the practice of pharmacy at any time during the period of probation, have the employer submit to the board verification that the employer understands the conditions of probation;

(7) be employed as a pharmacist only in a setting in which full supervision is provided and not personally act as a supervisor.

Authority:	AS 08.01.075	AS 08.80.030	AS 08.80.261
	AS 08.80.005		

12 AAC 52.940. USE OF ALCOHOL OR CONTROLLED SUBSTANCES. (a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for the habitual abuse of alcohol or illegal use of controlled substances may also be subject to one or more of the following:

(1) physical and mental health examinations as determined by the board to evaluate the licensee's ability to perform the professional duties of a pharmacist;

(2) as determined by the board, participation until completion in an ongoing program of rehabilitative counseling, Alcoholics Anonymous, Narcotics Anonymous, or an impaired practitioner group that includes progress reports from the care provider when requested by the board;

(3) abstaining from the personal use of alcohol or controlled substances in any form except when lawfully prescribed by a practitioner licensed to practice in Alaska;

(4) submitting to tests and samples required for the detection of alcohol or controlled substances at the request of the board or the board's representative.

(b) Access to a controlled substance in the work setting will, in the board's discretion, be restricted.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.950. PROBATION TERMS FOR PROFESSIONAL INCOMPETENCE. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation after being found professionally incompetent may be subject to one or more of the following terms of probation:

(1) successful completion of an appropriate course or courses in pharmacy, as determined by the board, before the end of the probationary period; or

(2) participation in 15 contact hours of appropriate continuing education in pharmacy.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.960. MENTAL OR PHYSICAL DISABILITIES. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for practicing or attempting to practice pharmacy while afflicted with a physical or mental illness, deterioration, or disability that interferes with the licensee's performance of pharmacy may be subject to a physical or mental health examination to evaluate the licensee's ability to perform the professional duties of a pharmacist and if medically determined to be necessary may be required to participate in and complete a recommended treatment program that includes written progress reports from the care provider when requested by the board.

Authority: AS 08.01.075 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.970. REINSTATEMENT OF A SUSPENDED LICENSE. The board may reinstate a suspended license only if the requirements of the suspension order have been met.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.980. REINSTATEMENT OF A REVOKED LICENSE. (a) One year after revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

(b) The applicant for reinstatement shall appear before the board.

(c) The board will, in its discretion, impose restrictions upon the pharmacist or pharmacy when reinstating a license.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

ARTICLE 11.
GENERAL PROVISIONS.

Section

990. Display of license certificate
991. Disciplinary decision or conviction reporting requirement
992. Independent administration of vaccines and related emergency medications
994. Independent dispensing of opioid overdose drugs by pharmacists
995. Definitions

12 AAC 52.990. DISPLAY OF LICENSE CERTIFICATE. A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee shall display the department's Internet web site posting confirming licensure. The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: The current posting confirming licensure can be found at the Internet web site of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing: www.commerce.state.ak.us/occ/search3.htm.

12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT. (a) A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony

or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee not later than 30 days after the date of the disciplinary decision or conviction.

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility.

Authority:	AS 08.01.075	AS 08.80.030	AS 08.80.315
	AS 08.80.005	AS 08.80.261	AS 08.80.460

12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;

(B) diseases that may be prevented by vaccination or immunization;

(C) current CDC immunization schedules;

(D) vaccine storage and management;

(E) informed consent;

(F) physiology and techniques for administration of immunizations;

(G) pre-immunization and post-immunization assessment and counseling;

(H) immunization reporting and records management; and

(I) identifying, responding to, documenting, and reporting adverse responses;

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;

(3) who has not administered a vaccine during the past 10 years must complete a course as described in (1) of this subsection before administering a vaccine; and

(4) must adhere to 12 AAC 52.320, including continuing education requirements under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory, and that is carried by the pharmacist if providing off-site immunizations:

(A) oral and injectable diphenhydramine; and

(B) adult and pediatric auto-inject epinephrine devices, or injectable epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed; the manual must

(A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;

(B) document that the policy and procedures manual has been reviewed and updated annually;

(C) address how vaccine related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);

(D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;

(E) address proper disposal of used or contaminated supplies;

(F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions, including the administration of related emergency medications; and

(G) detail how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern must

(1) have completed an ACPE-accredited immunization course or other comparable course that meets the requirements of (a)(1) of this section;

(2) maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training; and

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

(d) A pharmacist administering a vaccine must provide the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

(f) For purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if

(1) the pharmacist meets the requirements of this chapter and is the prescriber and administrator of the vaccine; or

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

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.

(h) In this section,

(1) "CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;

(2) "FDA" means the United States Food and Drug Administration.

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

12 AAC 52.994. INDEPENDENT DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS. (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall

(1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;

(2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and

(3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.

(b) A pharmacist may

(1) supply an opioid overdose drug as

(A) an intramuscular injection;

(B) an intranasal spray;

(C) an auto-injector; or

(D) any other product forms approved by the United States Food and Drug Administration; and

(2) recommend other optional items when appropriate, including

(A) alcohol pads;

(B) rescue breathing masks; or

(C) rubber gloves.

(c) When dispensing an opioid overdose drug

(1) the pharmacist shall

(A) label the drug in accordance with 12 AAC 52.480;

(B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";

(C) ensure that the label includes directions to call 911 or other available emergency services; and

(D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450;

(2) the pharmacist may

(A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including

(i) dosing;

(ii) administration;

(iii) effectiveness;

(iv) adverse effects;

(v) storage conditions;

(vi) shelf life; and

(vii) safety;

(B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.

(d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or 12 AAC 52.490.

(e) In this section,

(1) "opioid overdose drug"

(A) has the meaning given in AS 08.80.168;

(B) includes naloxone hydrochloride;

(2) "recipient" means the person to whom an opioid overdose drug is furnished.

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480

12 AAC 52.995. DEFINITIONS. (a) In this chapter, unless the context requires otherwise,

(1) "ACPE" means Accreditation Council for Pharmacy Education;

(2) "approved program" means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved or accredited provider;

(3) "approved provider" means an individual, institution, organization, association, corporation, or agency offering an approved program under 12 AAC 52.340 and is not an accredited provider;

(4) "authorized inspector" means a member of the board or an investigator with the division assigned occupational licensing functions in the department;

(5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(6) "blood component" means that part of blood separated by physical or mechanical means;

(7) "board" means the Alaska Board of Pharmacy;

(8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;

(9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;

(10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;

(11) "DEA" means the United States Drug Enforcement Administration;

(12) "department" means the Department of Commerce, Community, and Economic Development;

(13) "direct supervision" means supervision that insures adequate safety controls either by personal supervision or through a telepharmacy system;

(14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;

(15) "institutional facility" means a

(A) hospital;

(B) long-term care facility, including a nursing home, convalescent home, or other related facility;

(C) mental health facility;

(D) rehabilitation center;

(E) psychiatric center;

(F) developmental disability center;

(G) drug abuse treatment center;

(H) family planning clinic;

(I) penal institution;

(J) hospice; or

(K) public health facility;

(16) "institutional pharmacy" means a pharmacy located in an institutional facility;

(17) "licensee" means a person who is licensed under AS 08.80 and this chapter;

(18) "live program" means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;

(19) "sterile pharmaceutical" means a drug dosage form free from living microorganisms (aseptic);

(20) "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in 12 AAC 52.695;

(21) "central pharmacy" means a pharmacy providing remote pharmacy services through a telepharmacy system;

(22) "personal supervision" means supervision that includes visual or physical proximity to ensure adequate safety controls;

(23) "pharmacy" includes a central pharmacy and a remote pharmacy;

(24) "remote pharmacy" means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

(25) "still image capture" means a specific image captured electronically from a video or other image capture device;

(26) "store and forward" means a video or still image record that is saved electronically for future review;

(27) "telepharmacy system" means a system under the direct supervision of a licensed pharmacist that monitors the dispensing and distribution of prescription drugs and provides for related drug use review and patient counseling services through a computer link and a video link with sound;

(28) "accredited provider" means an individual, institution, organization, association, corporation, or agency that is recognized by the ACPE as able to provide quality continuing education programs;

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

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

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

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

(33) "shared pharmacy services" means a system allowing the processing by a participating pharmacist or a pharmacy of a request from another participating pharmacist or pharmacy to process or fill a prescription drug order, including dispensing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, and institutional order review;

(34) "dispenser" means a practitioner who delivers a controlled substance to an ultimate user or research subject under the lawful order of a practitioner; in this paragraph, "delivers" includes the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery;

(35) "profile" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance;

(36) "PDMP" means the prescription drug monitoring program's controlled substance prescription database.

(b) In AS 08.80.315(3), "other persons or governmental agencies" include investigators for the department who are assigned to conduct investigations under AS 08.

(c) In AS 08.80.030(b)(7), "monitoring of drug therapy" means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitoring of drug therapy" includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

(d) In AS 17.30.200 and 12 AAC 52.855 – 12 AAC 52.895, "practitioner" has the meaning given in AS 11.71.900.

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

CHAPTER 30.
CONTROLLED SUBSTANCES.

Article

1. **Regulation of Manufacture, Distribution, Prescription, and Dispensing of Controlled Substances (§§ 17.30.020 – 17.30.090)**
2. **Enforcement and Forfeiture (§§ 17.30.100 – 17.30.126)**
3. **Education and Research (§§ 17.30.140)**
4. **Information (§§ 17.30.150, 17.30.155)**
5. **Controlled Substance Prescription Database (§§ 17.30.200)**
6. **General Provisions (§§ 17.30.900)**

ARTICLE 1.
REGULATION OF MANUFACTURE, DISTRIBUTION, PRESCRIPTION, AND DISPENSING OF CONTROLLED SUBSTANCES.

Section

20. Registration requirements; inspections
60. Records of registrants
70. Order forms; prescriptions
80. Unlawful administration, prescriptions, and dispensation of controlled substances
90. Sale or purchase of certain listed chemicals

Sec. 17.30.020. Registration requirements; inspections. (a) A person who manufactures, distributes, dispenses, or conducts research with a controlled substance in the state or who proposes to manufacture, distribute, or dispense a controlled substance in the state, shall comply with the registration requirements of 21 U.S.C. 811 - 830 (Controlled Substances Act), and the regulations adopted under those sections.

(b) A person registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances in the state may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by the person's registration and in conformity with the other provisions of this chapter.

(c) [Repealed, § 22 ch 146 SLA 1986.]

(d) [Repealed, § 22 ch 146 SLA 1986.]

(e) [Repealed, § 22 ch 146 SLA 1986.]

(f) A peace officer may enter a registrant's premises at reasonable times and in a reasonable manner to inspect the premises and records required to be maintained under federal law. An inspection may not extend to financial data, pricing data, or sales data, other than shipment data, unless the owner, operator, or agent in charge of the premises consents

(g) Upon request from a peace officer, a person who manufactures, distributes, dispenses, or conducts research with a controlled substance in the state shall provide evidence of current registration under 21 U.S.C. 811 - 830 (Controlled Substances Act) and the regulations adopted under those sections.

Sec. 17.30.060. Records of registrants. A person registered under federal law to manufacture, distribute, dispense, or conduct research with controlled substances in the state shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law.

Sec. 17.30.070. Order forms; prescriptions. (a) A controlled substance may be distributed by one registrant to another registrant only if the distribution is in accordance with federal requirements for order forms.

(b) A controlled substance may not be dispensed by a practitioner other than in accordance with federal requirements regarding prescriptions for controlled substances.

(c) If the classification of a controlled substance in a schedule set out in AS 11.71.140 - 11.71.190 is different from its corresponding classification under federal law, the requirements of (a) and (b) of this section are determined by the classification of the substance under federal law.

Sec. 17.30.080. Unlawful administration, prescription, and dispensation of controlled substances. (a) A controlled substance classified under federal law or in a schedule set out in AS 11.71.140 - 11.71.190 may not be administered, prescribed, dispensed, or distributed other than for a medical purpose.

(b) A person who violates (a) of this section, or who otherwise manufactures, distributes, dispenses, or conducts research with a controlled substance in the state without fully complying with 21 U.S.C. 811 - 830 (Controlled Substances Act), and regulations adopted under those sections, is guilty of misconduct involving a controlled substance under AS 11.71.010 - 11.71.060 in the degree appropriate to the circumstances as described in those sections. Upon filing a complaint, information, presentment, or indictment charging a medical assistance provider with misconduct involving a controlled substance under AS 11.71.140 - 11.71.190, the attorney general shall, in writing, notify the commissioner of health and social services of the filing.

(c) Upon receiving a notice from the attorney general under (b) of this section, the commissioner of health and social services shall immediately undertake a review of all unpaid claims or requests for reimbursements attributable to services claimed to have been provided by the person charged.

(d) In this section,

(1) "claims" has the meaning given in AS 47.05.290;

(2) "medical assistance provider" has the meaning given in AS 47.05.290;

(3) "medical purpose" means a purpose that is solely medical as opposed to any other purpose, that is reasonably necessary for treatment of a person's illness, injury, or physical or mental health, and that is provided by a practitioner while acting within the usual course of professional practice or research and in accordance with a standard of care generally recognized and accepted within the medical profession in the United States;

(4) "practitioner" has the meaning given in AS 11.71.900.

Sec. 17.30.090. Sale or purchase of certain listed chemicals. (a) A seller, retailer, or vendor may not sell for personal use and a person may not purchase for personal use ephedrine base, pseudoephedrine base, or phenylpropanolamine base, as those terms are used in P.L. 109-177, 120 Stat. 192, unless that sale or purchase complies with and meets the requirements of P.L. 109-177, 120 Stat. 192, with regard to amounts, identification required, storage, access and availability, and logbooks. A seller, retailer, or vendor shall maintain the logbook for the period required under P.L. 109-177, 120 Stat. 192, and shall allow law enforcement officers access to the logbook. Each seller, retailer, and vendor shall provide training to the seller's, retailer's, or vendor's employees and agents in the requirements of this section. The Department of Public Safety shall provide assistance and information to sellers, retailers, and vendors to meet the requirements of this section.

(b) A seller, retailer, or vendor may not sell to a person under 16 years of age and a person under 16 years of age may not purchase a product or substance identified in (a) of this section.

(c) Nothing in this section limits the authority of a seller, retailer, or vendor regulated by this section to report to a law enforcement agency or officer suspicious purchases of a chemical, product, or substance. A seller, retailer, or vendor is not liable in a civil action for release of information to a law enforcement agency concerning matters related to this section.

(d) A seller, retailer, or vendor does not violate this section if the seller, retailer, or vendor proves by a preponderance of the evidence that the seller, retailer, or vendor

(1) exercised the degree of care of a reasonable employer to ensure compliance with (a) - (c) of this section; and

(2) determined that the employees and agents of the seller, retailer, or vendor had been notified of the requirements of this section by

(A) securing each employee's or agent's written acknowledgment of notification of those requirements; or

(B) making another appropriate determination.

(e) A person who violates this section shall forfeit and pay to the state a civil penalty of not more than $10,000 for each violation.

ARTICLE 2.
ENFORCEMENT AND FORFEITURE.

Section

100. Powers of the department of Public Safety
110. Items subject to forfeiture
112. Proceedings resulting in forfeiture
114. Seizure and custody of property
116. Procedure for forfeiture action
118. Petition for release of seized items
120. Petition for sale of seized item
122. State disposal of forfeited property
124. Remittance of claimant
126. Forfeiture of controlled substances

Sec. 17.30.100. Powers of the Department of Public Safety. (a) The commissioner of public safety shall enforce this chapter and shall cooperate with other state and federal agencies in the discharge of their responsibilities pertaining to illicit traffic in controlled substances and in suppressing the abuse of controlled substances. Under this section, the powers of the commissioner of public safety include but are not limited to the following:

(1) arranging for the exchange of information among government officials concerning illicit traffic in and abuse of controlled substances;

(2) coordinating training programs pertaining to controlled substances at both local and state levels;

(3) cooperating with the Drug Enforcement Administration of the United States Department of Justice by establishing a centralized unit to accept, catalog, file, and collect statistics, including records of persons who have violated the provisions of this chapter or AS 11.71 in the state and making the information available for federal, state, and local law enforcement purposes; and

(4) instituting in the superior court, actions for injunctions against continued manufacture, distribution, dispensation, or research with a controlled substance in the state by a person who violates 21 U.S.C. 811—830 (Controlled Substances Act) or the regulations adopted under those sections.

(b) The commissioner of public safety may not furnish the name or identity of a patient or research subject whose identity could not be obtained under AS 17.30.155.

(c) The Department of Public Safety, in accordance with AS 37.07 (the Executive Budget Act), may apply for and accept money necessary to exchange information concerning narcotics trafficking between the states, or otherwise related to the enforcement of AS 11.71 or AS 11.73.

(d) The Department of Public Safety or a local law enforcement agency may accept from the United States Attorney General property, including money, that is forfeited under 21 U.S.C. 881 (the Controlled Substances Act). The Department of Public Safety and local law enforcement agencies shall, in accordance with 21 U.S.C. 881 (e) and regulations and policies adopted under that section, use property and the proceeds of property obtained under this subsection in the enforcement of this chapter, AS 11.71, and municipal ordinances substantially similar to this chapter and AS 11.71.

Sec. 17.30.110. Items subject to forfeiture. The following may be forfeited to the state:

(1) a controlled substance which has been manufactured, distributed, dispensed, acquired, or possessed in violation of this chapter or AS 11.71;

(2) raw materials, products, and equipment which are used or intended for use in manufacturing, distributing, compounding, processing, delivering, importing, or exporting a controlled substance which is a felony under this chapter or AS 11.71;

(3) property which is used or intended for use as a container for property described in (1) or (2) of this section;

(4) a conveyance, including but not limited to aircraft, vehicles or vessels, which has been used or is intended for use in transporting or in any manner in facilitating the transportation, sale, receipt, possession, or concealment of property described in (1) or (2) of this section in violation of a felony offense under this chapter or AS 11.71; however,

(A) a conveyance may not be forfeited under this paragraph if the owner of the conveyance establishes, by a preponderance of the evidence, at a hearing before the court as the trier of fact, that use of the conveyance in violation of this chapter or AS 11.71 was committed by another person and that the owner was neither a consenting party nor privy to the violation;

(B) a forfeiture of a conveyance encumbered by a valid security interest at the time of seizure is subject to the interest of the secured party if the secured party establishes, by a preponderance of the evidence, at a hearing before the court as the trier of fact, that use of the conveyance in violation of this chapter or AS 11.71 was committed by another person and that the secured party was neither a consenting party nor privy to the violation;

(5) books, records, and research products and materials, including formulas, microfilm, tapes, and data, which are used in violation of this chapter or AS 11.71;

(6) money, securities, negotiable instruments, or other things of value used in financial transactions derived from activity prohibited by this chapter or AS 11.71; and

(7) a firearm which is visible, carried during, or used in furtherance of a violation of this chapter or AS 11.71.

Sec. 17.30.112. Proceedings resulting in forfeiture. (a) Property listing in AS 17.30.110 may be forfeited to the state either upon conviction of the defendant of a violation of this chapter or AS 11.71, or upon judgment of a court in a separate civil proceeding in rem. The court may order a forfeiture in the in rem pro proceeding if it finds that an item specified in AS 17.30.110 was used during or in aid of a violation of this chapter or AS 11.71.

(b) It is not a defense in an in rem proceeding brought under this section that a criminal proceeding has resulted in a conviction or conviction of a lesser offense for a violation of this chapter or AS 11.71.

(c) When forfeiting property under (a) of this section, a court may award to a municipal law enforcement agency that participated in the arrest or conviction of the defendant, the seizure of property, or the identification of property for seizure, (1) the property if the property is worth $5,000 or less and is not money or some other thing that is divisible, (2) up to 75 percent of the property or the value of the property if the property is worth more than $5,000 or is money or some other thing that is divisible. In determining the percentage a municipal law enforcement agency may receive under this subsection, the court shall consider the municipal law enforcement agency's total involvement in the case relative to the involvement of the state.

Sec. 17.30.114. Seizure and custody of property. (a) Property listed in AS 17.30.110 may be seized by a peace officer upon an order issued by a court having jurisdiction over the property upon under AS 17.30.110. Seizure without a court order may be made if

(1) the seizure is incident to a valid arrest or a search under a valid search warrant;

(2) the property subject to seizure has been the subject of an earlier judgment in favor of the state in a criminal proceeding or civil proceeding in rem under this chapter or AS 11.71; or

(3) there is probable cause that the property was used, is being used, or is intended for use, in violation of this chapter or AS 11.71 and the property is easily movable; property seized under this paragraph may not be held for more than 48 hours without a court order obtained to continue its detention.

(b) Property taken or detained under (a) of this section shall be held in the custody of either the commissioner of public safety or a municipal law enforcement agency authorized by the commissioner of public safety to retain custody of property listed in AS 17.30.110 subject only to the orders and decrees of the court having jurisdiction over any forfeiture proceedings. If property is seized under this chapter, the commissioner of public safety or an authorized municipal law enforcement agency may

(1) place the property under seal;

(2) remove the property to a place designated by the court; or

(3) take custody of the property and remove it to an appropriate location for disposition in accordance with law; or

(4) with court approval, transfer the property to another state or federal law enforcement agency for forfeiture proceedings by that agency; the court having jurisdiction shall grant the approval under this paragraph if the property

(A) will be retained within the jurisdiction of the court by the agency to which the property is being transferred; or

(B) is

(i) not needed as evidence; or

(ii) needed as evidence, and the property is fungible or the property's evidentiary value can otherwise be preserved without retaining the property within the jurisdiction of the court.

(c) Within 10 days after a seizure under AS 17.30.110-17.30.126, the commissioner of public safety shall make an inventory of any property seized, including controlled substances, and shall appraise the value of any items seized other than controlled substances.

Sec. 17.30.116. Procedure for forfeiture action. (a) Within 20 days after a seizure under AS 17.30.110-17.30.126, the commissioner of public safety shall, by certified mail, notify any person known to have an interest in an item with an appraised value of $500 or more, or who is ascertainable from official registration numbers, licenses, or other state, federal or municipal numbers on the item, of the pending forfeiture action. Additionally, the commissioner of public safety shall publish notice of forfeiture action of an item valued at $500 or more in a newspaper of general circulation in the judicial district in which the seizure was made, or if no newspaper is published in that judicial district, in a newspaper published in the state and distributed in that judicial district. The notice shall be published once each week during four consecutive calendar weeks. The requirements of this subsection do not apply to the forfeiture of controlled substances which have been manufactured, distributed, dispensed, or possessed in violation of this chapter or AS 11.71, regardless of their value.

(b) Upon service or publication of notice of commencement of a forfeiture action under this section, a person claiming interest in the property shall file within 30 days after the service or publication, a notice of claim setting out the nature of the interest, the date it was acquired, the consideration paid, and an answer to the state's allegations. If a claim and answer is not filed within the time specified, the property described in the state's allegation must be ordered forfeited to the state without further proceedings or showings.

(c) Questions of fact or law raised by a notice of forfeiture action and answer of a claimant in an action commenced under this section must be determined by the court sitting without jury. This proceeding may be held in abeyance until conclusion of any pen ding criminal charges against the claimant under this chapter or AS 11.71.

Sec. 17.30.118. Petition for release of seized items. (a) A claimant under AS 17.30.116(b) may at any time petition for release of a seized item as follows:

(1) to a court in which a warrant for seizure has been issued;

(2) to a court in which a criminal or civil action alleging forfeiture of the item has been filed; or

(3) before an action is filed, or if no seizure warrant was issued, to a court, in the judicial district in which the violation took place.

(b) An item may not be released by the court under (a) of this section unless the claimant gives adequate assurance that the item will remain subject to the court's jurisdiction and

(1) the court finds that the release is in the best interests of the state; or

(2) the claimant provides a bond or other valid and equivalent security equal to twice the assessed value of the item.

Sec. 17.30.120. Petition for sale of seized item. A claimant may petition the court for sale of an item before final disposition of court proceedings. The court shall grant a petition for sale upon a finding that the sale is in the best interests of the state and the preservation and maintenance of the item seized. Proceeds from the sale plus interest to the date of final disposition of the court proceedings become the subject of the forfeiture action.

Sec. 17.30.122. State disposal of forfeited property. Property forfeited under AS 17.30.110—17.30.126 other than controlled substances and firearms shall be disposed of by the commissioner of administration in accordance with applicable law. Firearms shall be disposed of as provided in AS 18.65.340. As to property other than firearms or controlled substances, the commissioner of administration may

(1) destroy property harmful to the public;

(2) sell the property and use the proceeds for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, custody, and court costs;

(3) take custody of the property and authorize its use in the enforcement of this chapter or AS 11.71, or transfer it to another agency of the state or a political subdivision of the state for a use in furtherance of the administration of justice;

(4) take custody of the property and remove it for disposition in accordance with law;

(5) forward it to the Drug Enforcement Administration of the United States Department of Justice for disposition; or

(6) transfer ownership of an aircraft to the Alaska Wing, Civil Air Patrol.

Sec. 17.30.124. Remittance to claimant. (a) Upon a showing that a claimant is entitled to remittance under AS 17.30.110-17.30.126, the court shall order that

(1) if the claimant is entitled to the item, it shall be delivered to the claimant immediately;

(2) if the claimant is entitled to remittance of some value less than the total value of the item, the claimant is entitled, at the claimant's choice, to receive either the value of the claimant's interest or, upon receipt of payment of the difference in value by the claimant, the entire item.

(b) An offender who used an item subject to remission in violation of this chapter or AS 11.71 shall be assessed a fine which may not be less than the cost of any lien payment or remittance made by the state plus the reasonable costs of the seizure.

Sec. 17.30.126. Forfeiture of controlled substances. (a) A controlled substance manufactured, possessed, transferred, sold, or offered for sale in violation of this chapter or AS 11.71 is contraband and must be seized and summarily forfeited to the state. The commissioner of public safety or the commissioner's designee, including a municipal law enforcement agency authorized under AS 17.30.114(b) of this section to retain custody of controlled substances, is responsible for the disposal of controlled substances which have been forfeited. The controlled substances shall be disposed of in accordance with procedures and requirements prescribed by the commissioner.

(b) Plants from which controlled substances may be derived and which have been planted or cultivated in violation of this chapter or AS 11.71, or which are grown in the wild, may be seized and summarily forfeited to the state.

ARTICLE 3.
EDUCATION AND RESEARCH.

Section

140. Education and research

Sec. 17.30.140. Education and research. (a) The commissioner of health and social services shall provide for educational programs designed to prevent and deter the abuse of controlled substances. In connection with these programs, the commissioner may

(1) assist the regulated industry and interested groups and organizations in contributing to the reduction of abuse of controlled substances;

(2) promote better recognition of the problems surrounding abuse of controlled substances within the regulated industry and among interested groups and organizations;

(3) consult with interested groups and organizations to aid them in solving administrative and organizational problems;

(4) evaluate procedures, projects and techniques conducted or proposed as part of educational programs on abuse of controlled substances;

(5) disseminate the results of research on abuse of controlled substances to promote a better public understanding of the problems which exist and their solutions; and

(6) with the cooperation of the Department of Law, assist in the education and training of state and local law enforcement officials in their efforts to prevent illicit traffic in and abuse of controlled substances.

(b) The commissioner of health and social services shall encourage research on controlled substances and may

(1) establish methods to assess the effects of controlled substances and identify and characterize those with potential for abuse;

(2) make studies and undertake research to

(A) develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of this chapter;

(B) determine patterns of abuse of controlled substances and their social effects; and

(C) improve methods for preventing, predicting, and understanding the abuse of controlled substances;

(3) enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for conducting research, demonstrations, or special projects which bear directly on abuse of controlled substances and for related research and educational activities.

ARTICLE 4.
INFORMATION.

Section
150. Reliance on Drug Enforcement Administration
155. Confidentiality of certain information

Sec. 17.30.150. Reliance on Drug Enforcement Administration. Results, information, and evidence received from the Drug Enforcement Administration of the United States Department of Justice relating to the enforcement functions of this chapter, including results of inspections conducted by it, may be relied on and acted on by the Department of Public Safety in the exercise of its enforcement functions under this chapter.

Sec. 17.30.155. Confidentiality of certain information. A practitioner engaged in medical practice or research may not disclose the name or identity of a patient or research subject that the practitioner is required to keep confidential unless ordered by a court to disclose it within the context of a criminal investigation or proceeding.

ARTICLE 5.
CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section
200. Controlled substance prescription database

Sec. 17.30.200. Controlled substance prescription database. (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (u) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (u) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the

information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner’s licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;
(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;
(v) in a hospice or nursing home that has an in-house pharmacy; or
(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.
(*l*) A person
(1) with authority to access the database under (d) of this section who knowingly
(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;
(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;
(C) allows another person who is not authorized to access the database to access the database commits a class C felony;
(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.
(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures
(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to
(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;
(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;
(C) increase coordination among prescription drug monitoring program partners;
(D) involve stakeholders in the planning process;
(2) shall include information related to the
(A) security of the database; and
(B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.
(n) In this section,
(1) "board" means the Board of Pharmacy;
(2) "database" means the controlled substance prescription database established in this section;
(3) "knowingly" has the meaning given in AS 11.81.900;
(4) "pharmacist-in-charge" has the meaning given in AS 08.80.480;
(5) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160.
(o) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.
(p) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (o) of this section.
(q) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section
(1) must be provided to the practitioner;
(2) is confidential;
(3) may not disclose information that is confidential under this section;
(4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.
(r) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.
(s) The Department of Commerce, Community, and Economic Development shall
(1) assist the board and provide necessary staff and equipment to implement this section; and
(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (o) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall
(A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and
(B) consult with the board to establish the fees under this paragraph.
(t) Notwithstanding (q) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a

practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

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

(1) administered to a patient at

(A) a health care facility; or

(B) a correctional facility;

(2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(A) inpatient pharmacy; or

(B) emergency department.

ARTICLE 6.
GENERAL PROVISIONS.

Section

900. Definitions

Sec. 17.30.900. Definitions. (a) Unless the context clearly requires otherwise, the definitions set out in AS 11.71.900 apply to this chapter.

(b) [Repealed, 22 ch 146 SLA 1986.]

General Requirements.

(a) Each pharmacy is of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparation of prescription drug orders.

(b) There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

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

(d) Each pharmacy has a sink with hot and cold running water within the pharmacy and maintained in a sanitary condition.

(e) There are refrigeration facilities with a thermometer in the prescription department for the proper storage of drugs requiring refrigeration. Temperatures in the refrigerator are maintained within United States Pharmacopeia standards.

(f) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.

Equipment and Supplies.

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

(b) All equipment is kept in a clean and orderly manner. Equipment used in the compounding or preparation of prescription drug orders (counting, weighing, measuring, mixing, stirring, and molding equipment) is clean and in good repair.

Library. A reference library is maintained which includes the following:

(1) A current copy (hard-copy or electronic media access) of the Alaska Pharmacy Statutes and Regulations.

(2) At least one current or updated reference (hard-copy or electronic media access) from each of the following categories:

(A) Patient information – examples are;

(i) USP Dispensing Information; or

(ii) Patient Drug Facts; or

(iii) reference text or information leaflets which provide patient information.

(B) General information – examples are;

(i) Facts and Comparisons; or

(ii) USP Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or

(iii) Remington's Pharmaceutical Sciences.

(C) Clinical Information – examples are;

(i) AHFS Drug Information; or

(ii) Micromedex; or

(iii) Clinical Pharmacology; or

(iv) reference material pertinent to the practice setting.

(3) The telephone number of the nearest poison control center is readily available.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines on facilities, reference materials, equipment, supplies and other matters. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.400.

STERILE PHARMACEUTICALS
February 2008

Scope and Purpose.

The purpose of this pamphlet is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (eg. home, hospital, extended care facility, hospice, practitioner's office).

Definitions.

(a) "Biological Safety Cabinet" – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(b) "Class 100 Environment" – an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209D.

(c) "Cytotoxic" – a pharmaceutical that has the capability of killing living cells.

(d) "Parenteral" – a sterile preparation of drugs for injection through one or more layers of the skin.

(e) "Sterile Pharmaceutical" – dosage form free from living micro-organisms (aseptic).

Policy and Procedure Manual.

(a) A policy and procedure manual is prepared and maintained for the compounding, dispensing, and delivery of sterile pharmaceutical drug orders. The manual is reviewed and revised as necessary on an annual basis by the pharmacist-in-charge and is available for inspection at the pharmacy.

(b) The manual includes policies and procedures, as applicable, for:

(1) Clinical services;
(2) Sterile product handling, preparation, dating, storage and disposal;
(3) Major and minor spills of cytotoxic agents;
(4) Disposal of unused supplies and medications;
(5) Drug destruction and returns;
(6) Drug dispensing;
(7) Drug labeling;
(8) Duties and qualifications for professional and nonprofessional staff;
(9) Equipment use and maintenance;
(10) Handling of infectious waste pertaining to drug administration;
(11) Infusion devices and drug delivery systems;
(12) Training and orientation of professional and non-professional staff commensurate with the services provided;
(13) Dispensing of investigational medications;
(14) Quality control and quality assurance;
(15) Recall procedures;
(16) Infection control;
(17) Suspected contamination of sterile products;
(18) Orientation of employees to sterile technique;
(19) Sanitation;
(20) Security; and
(21) Transportation.

Physical Requirements.

(a) The pharmacy designates an area for the preparation of sterile products that is functionally separate from areas for the preparation of non-sterile products and is constructed to minimize traffic and airflow disturbances. It is used only for the preparation of these specialty products. It is of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy preparing parenteral products has:

(1) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environments during normal activity;

(2) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biological safety cabinets;

(3) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand washing prior to compounding;

(4) The designated area shall have hard cleanable surfaces, walls, floors and ceilings;

(5) Appropriate disposal containers for used needles, syringes, etc. and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patient's homes;

(6) Refrigerator/freezer with thermometer;

(7) Temperature controlled delivery container, if appropriate;

(8) Infusion devises, if appropriate;

(9) Supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(c) Laminar flow hood certification (or clean room certification, if applicable) are conducted at least every six months by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports are maintained for at least two years. In addition, prefilters are replaced on a regular basis and the replacement date documented.

(d) The pharmacy has current reference materials related to sterile products. These reference materials will contain information on stability, incompatibilities, preparation guidelines, and the handling of chemotherapy drug products.

Personnel.

(a) All personnel participating in the preparation and/or dispensing of compounded sterile pharmaceuticals are trained in this specialized function, including the principles of aseptic technique. All duties and responsibilities of personnel are consistent with their training and experience.

(b) Pharmacies providing parenteral products to non-hospitalized patients have a pharmacist accessible twenty-four hours per day to respond to patient's and other health professional's questions and needs.

Drug Distribution and Control.

(a) In addition to labeling required for all dispensed prescription drug orders, the labeled container of a sterile pharmaceutical bears the expiration date of the preparation based upon published data.

(b) Delivery Service. The pharmacist-in-charge assures the environmental control of all products shipped. Therefore, any compounded sterile pharmaceutical is shipped or delivered to a patient in appropriate temperature controlled (as defined by United States Pharmacopeia Standards) delivery containers and stored appropriately in the patient's home or outpatient location.

(c) Disposal of Infectious/Hazardous Waste. The pharmacist-in-charge is responsible for assuring there is a system for the disposal of cytotoxic waste and infectious waste in a manner so as not to endanger the public health.

(d) Emergency Kit. When sterile pharmaceuticals are provided to home care patients, the pharmacy may supply the licensed nurse with emergency drugs, if the prescribing practitioner has authorized the use of these drugs by a protocol for use in an emergency situation (e.g. anaphylactic shock).

Cytotoxic Drugs.

The following additional requirements are necessary for those pharmacies that prepare cytotoxic drugs to assure the protection of the personnel involved:

(a) All cytotoxic drugs are compounded within a vertical flow, Class II, Biological Safety Cabinet. Policy and procedures are developed for the cleaning of the laminar airflow hood between compounding cytotoxic drugs and other parenteral products, if applicable.

(b) Protective apparel is worn by personnel compounding cytotoxic drugs. This includes disposable gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs are used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents are developed and included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Patient Training.

If appropriate, the Pharmacist demonstrates or documents the patient's training and competency in managing the type of therapy provided by the Pharmacist to the patient in the home environment. A pharmacist is involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The Pharmacist is responsible for seeing the patient's competency in the above areas is reassessed on an ongoing basis.

Quality Control and Quality Assurance Procedures.

(a) Quality Control. There is a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures are in place to assure the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures include, but are not limited to, the following:

(1) recall procedures;

(2) storage and dating;

(3) documentation of appropriate functioning of refrigerator, freezer, and other equipment;

(4) documentation of aseptic environmental control device certification and the regular replacement of prefilters;

(5) a process to evaluate and confirm the quality of the prepared pharmaceutical product; and

(6) if bulk compounding of parenteral solutions is performed utilizing non-sterile chemicals, extensive end product testing is documented prior to the release of the product from quarantine. This process includes appropriate tests for particulate matter and pyrogens.

(b) Quality Assurance.

(1) There is a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure efficient drug delivery, patient safety, and positive patient outcomes.

(2) There is documentation of quality assurance audits at regular, planned intervals which may include infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions, and drug therapy appropriateness.

(3) A plan for corrective action of problems identified by quality assurance audits is developed which includes procedures for the documentation of identified problems and action taken.

(4) A periodic evaluation of the effectiveness of the quality assurance activities is completed and documented.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.430.

(a) A pharmacist may compound drugs in limited quantities before receiving a valid prescription drug order if the pharmacist has a historical basis of valid prescription drug orders generated solely within an established relationship between the pharmacist, a patient, and a prescribing practitioner for the amount of drugs compounded. Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

(b) Compounding includes the preparation

(1) according to a prescription drug order of drugs or devices that are not commercially available;

(2) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

(c) When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription drug order or in the computerized patient medication record. The prescribing practitioner's authorization is in addition to signing to permit substitution on a prescription drug order or advising verbally that substitution is permitted. The reconstitution of commercially available products according to the manufacturer's guidelines is permissible without notice to the prescribing practitioner.

(d) A pharmacist may not offer compounded drug products to prescribing practitioners, pharmacists, or pharmacies for resale except in the course of professional practice for a prescribing practitioner to administer to an individual patient. The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is considered manufacturing.

(e) A pharmacist may receive, store, and use drug substances for compounding prescriptions that meet official compendia requirements. A pharmacist shall use the pharmacist's professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia.

PERSONNEL

A pharmacist engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.

COMPOUNDING FACILITIES

(a) A pharmacy engaging in compounding shall have a specifically designated and adequate area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area of the pharmacy must be provided. The facilities must include hot and cold water, soap or detergent, and air-driers or single use towels.

(d) The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse must be disposed of in a safe and sanitary manner.

(e) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous

cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be used in order to prevent cross-contamination.

RECORDS AND REPORTS

(a) A pharmacist shall keep records of all compounded products for two years. The records must be readily available for authorized inspection at the pharmacy.

(b) A pharmacist shall ensure that there are formulas maintained electronically or manually. A formula must include ingredients, amounts, methodology and equipment, if needed, and special information regarding sterile compounding.

(c) A pharmacy engaging in compounding must have written procedures for the compounding of drugs to assure that the finished products have the identity, strength, quality, and purity they are represented to possess. The procedures must include a listing of the components, their amounts in weight or volume, the order of component mixing, and a description of the compounding process. The procedures must list all equipment and utensils and the container or closure system relevant to the sterility and stability of the intended use of the drug. The procedures must be followed in the execution of the drug compounding procedure.

(d) A pharmacist shall accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist shall check these operations at each stage of the compounding process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another container, the new container must be identified with the component name and the weight or measure.

(e) To assure the reasonable uniformity and integrity of compounded drug products, written procedures must be established and followed that describe the tests or examinations to be conducted on the product compounded. The control procedures must be established to monitor the output and to validate the performance of those compounding processes that include the following when appropriate:

(1) capsule weight variation;

(2) adequacy of mixing to assure uniformity and homogeneity;

(3) clarity, completeness, or pH of solutions;

(f) A pharmacy engaging in compounding shall establish and follow appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile. The procedures must include validation of any sterilization process.

(g) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include

(1) the date of preparation;

(2) the lot numbers – the lot numbers may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If a lot number is assigned by the pharmacy, the pharmacy shall record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components;

(3) the expiration date of the finished product. This date may not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber or to be stored in until dispensing. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist;

(4) the signature or initials of the pharmacist performing the compounding;

(5) initials of the person preparing each process;

(6) initials of the pharmacist supervising each process;

(7) a formula for the compounded product maintained in a readily retrievable form;

(8) the name of the manufacturer of the raw materials;

(9) the quantity in units of finished products or grams of raw materials; and

(10) the package size and the number of units prepared.

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

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist on compounding practices. Professional conduct by a licensee includes adherence to these guidelines.
See 12 AAC 52.440.

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 52.010 is amended to read:

12 AAC 52.010. Classifications of licensure. (a) The board will issue the following categories of licenses or permits to a qualified individual:

(1) pharmacist license;

(2) temporary pharmacist license;

(3) emergency permit to practice pharmacy;

(4) pharmacist intern license;

(5) pharmacy technician license.

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

(1) pharmacy license;

(2) repealed 2/26/2000;

(3) wholesale drug distributor license;

(4) drug room license;

(5) registration of a pharmacy located outside of the state; [AND]

(6) remote pharmacy license**;**

(7) third-party logistics viders;

(8) outsourcing lities;

(9) license of a wholesale drug distributor located outside of the state. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 2/15/2006, Register 177; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158

AS 08.80.030 AS 08.80.155 **AS 08.80.159**

AS 08.80.116 AS 08.80.157 AS 08.80.390

12 AAC 52.110 is amended to read:

12 AAC 52.110. Emergency pharmacist permit. (a) If the board **or two licensed pharmacist board members** determines that an emergency exists, the board will issue an emergency pharmacist permit for the purpose of providing coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, to an applicant who

(1) submits a completed application for a pharmacist license;

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

(3) submits a certified true copy of a current pharmacist license in good standing in another state;

(4) **repealed ____/____/_____** [PASSES THE ALASKA PHARMACY JURISPRUDENCE EXAMINATION WITH A SCALED SCORE OF 75 OR ABOVE]; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

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

(c) An applicant may not receive more than one emergency permit. An emergency permit is not renewable. (Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 8/12/2007, Register 183; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.510 is amended to read:

12 AAC 52.510. Substitution. (a) A pharmacist may dispense an equivalent drug product **or interchangeable biological product** instead of the prescribed drug if

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

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

(3) **repealed / /** [THE EQUIVALENT DRUG PRODUCT COSTS THE PATIENT LESS THAN THE PRESCRIBED DRUG PRODUCT]; and

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

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

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the **terms** [TERM] "equivalent drug product" **or "interchangeable biological product" are** [IS] defined in AS 08.80.480. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.610 is amended to read:

12 AAC 52.610. Wholesale drug distributor license. (a) **The following checklist is established by the board for review of an application** [AN APPLICANT] for a wholesale drug distributor license**. A wholesale drug distributor license will be issued to an applicant who** [SHALL]

(1) **submits a completed, notarized application** [APPLY] on **a** [THE] form provided by the department;

(2) **pays** [PAY] the fees required in 12 AAC 02.310;

(3) **provides** [PROVIDE] a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) **provides** [PROVIDE] the name and the resume of the **facility manager** [PERSON] who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) **submits** [SUBMIT]

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; **or** [AND]

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) **submits** [SUBMIT] completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety**; and**

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located for non-resident wholesale drug distributors.

(b) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (a) of this section; and

(2) be registered with the **DEA** [(DEA)].

(c) Within 30 days of a change in **location, ownership, or** facility manager, the new facility manager must

(1) submit the completed change of **facility** [PHARMACY] manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (a)(4) and (6) of this section.

(d) When a wholesale distributor ceases operations, the facility manager of the wholesale distributor shall notify the board on a form provided by the department the cessation of operations; the form must be submitted within 10 days after the cessation of operations. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am ____/____/_____, Register _____)

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

The authority citation of 12 AAC 52.620 is changed to read:

12 AAC 52.620. Wholesale drug facilities.

. . .

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

12 AAC 52.625 is amended to read:

12 AAC 52.625. Personnel requirements; grounds for denial or other disciplinary action. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and

managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated **facility** manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs. (Eff. 1/16/98, Register 145; am ____/____/_____, Register _____)

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

12 AAC 52.630 is amended to read:

12 AAC 52.630. Drug storage. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements or official United States Pharmacopoeia (USP), 1995 revision, compendium requirements, to help ensure that the identity, strength, quality, and purity of the products are not affected. If a temperature requirement is not listed for a drug, the drug may be stored at controlled room temperature as defined in the USP.

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

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored. (Eff. 1/16/98, Register 145; am ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

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

The authority citation of 12 AAC 52.640 is changed to read:

12 AAC 52.640. Written policies and procedures.

. . .

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.645 is changed to read:

12 AAC 52.645. Examination of drug shipments.

. . .

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.650 is changed to read:

12 AAC 52.650. Records and inventories.

. . .

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.660 is changed to read:

12 AAC 52.660. Returned, damaged, and outdated drugs.

. . .

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

The authority citation of 12 AAC 52.670 is changed to read:

12 AAC 52.670. Drug recalls.

. . .

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

The authority citation of 12 AAC 52.680 is changed to read:

12 AAC 52.680. Inspections.

. . .

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

The authority citation of 12 AAC 52.685 is changed to read:

12 AAC 52.685. Prohibition against direct distribution.

. . .

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

The authority citation of 12 AAC 52.690 is changed to read:

12 AAC 52.690. Salvage and reprocessing.

. . .

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

The authority citation of 12 AAC 52.695 is changed to read:

12 AAC 52.695. Provisions not applicable.

. . .

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

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

12 AAC 52.696. Outsourcing facilities. (a) An applicant who meets the requirements on checklist set out in (b) of this section has demonstrated the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The following checklist is established by the board for review of an application for an outsourcing facility license; an outsourcing facility license will be issued to an applicant who

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

department;

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

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

(4) provides the name and the résumé of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

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

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA).

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

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

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

(f) When an outsourcing facility ceases operations, the facility manager shall

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the outsourcing facility ceased operations;

(B) arrange for the records of the outsourcing facility to be retained for two years.

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

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

(i) The outsourcing facility shall be registered with the Food and Drug Administration as a 503b outsourcing facility. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

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

12 AAC 52.697. Third-party logistics providers. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

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

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

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

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

(4) provides the name and the résumé of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

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

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

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

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

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

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the third-party logistics provider ceased operations;

(B) arrange for the records of the third-party logistics provider to be

retained for two years.

(g) A third-party logistics provider shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

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

12 AAC 52.993. Executive administrator. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance are to be reviewed by a board member;

(2) attend state or national meetings or conferences on behalf of the board;

(3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;

(4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;

(5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board; and

(6) in consultation with two licensed pharmacist board members, review and approve emergency pharmacist permit required under 12 AAC 52.110. (Eff. ____/____/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

12 AAC 52.995 is amended by adding a new subsection to read:

(e) In 12 AAC 52.610 – 12 AAC 52.697, "facility manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations. (Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am ____/____/_____, Register _____)

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: Auth, Robert Charles (LAW)
To: Carrillo, Laura N (CED)
Cc: Maiquis, Jun C (CED)
Subject: RE: Board of Pharmacy proposed regs law pre-review
Date: Wednesday, February 13, 2019 2:45:14 PM
Attachments: DraftingManual-AdminRegs.pdf

Laura, based on my review of the attached Drafting Manual for Administrative Regulations (August 2018), I do not think the board can do that. The problem is that the Alaska Supreme Court has never addressed the issue of whether standards adopted by reference may include all future amendments. Manual at p. 102. Because this type of adoption raises unresolved constitutional issues, the Department of Law recommends that any future amendments be made by formal adoption of the amended version in a new regulations project, unless the simplified process in AS 44.62.245 is available. Id.

AS 44.62.245 allows the agency to adopt by reference future amended versions of material only if that material is of a particular type, either: 1) a regulation of another state agency or 2) material for which adoption by reference of future amended versions is explicitly authorized by another statute. Id at p. 84. Since neither of these situations apply with regard to the USP, the new regulation must clearly state that a particular dated version of the material is being adopted by reference. Id. at p. 81.

Bob

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Tuesday, February 12, 2019 1:49 PM
To: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Thanks, Bob! I've forwarded this onto our board chair.

We have a question under section 12 AAC 52.630 relating to drug storage. The board wants to update the USP standard (currently references the 1995 version); however, the most updated version is nearly impossible to pin down because it's constantly being updated. Moreover, there are several USP standards, all with varying published dates. What's your take on allowing the board to say something to the effect of, "the most current versions…"?

I'm aware that LAW has previously informed us that a specific date needs to be indicated so that the public can give specific comments. Is this still a barrier to adopting most recent versions without explicitly mentioning the published date?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy

Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Auth, Robert Charles (LAW)
Sent: Wednesday, February 6, 2019 3:47 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Laura, here are my comments in the format you requested. Bob

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Friday, February 01, 2019 1:57 PM
To: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Hi Bob,

Thank you for your thorough feedback on this project. The board is accustomed to reviewing the cursory review by LAW in Word and marked by track changes—could you please reference your comments to the specific sections this way? I anticipate the board will be requesting the review to be in that format. I've attached previous regulations reviewed by Megyn, which will be a part of this project (they're complete but just attached for your reference).

Thank you in advance,

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

From: Maiquis, Jun C (CED)
Sent: Friday, February 1, 2019 9:53 AM
To: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Cc: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Thank you, Bob. I will forward your review and comments to the board and staff. Have a great weekend!

Jun

From: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Sent: Thursday, January 31, 2019 2:54 PM
To: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Jun, I have reviewed the draft regulations and I have the following comments:

1. 12 AAC 52.010 (b). All of the current facility licenses, and the draft paragraph (9)("license of a wholesale drug distributor located outside of the state") are described in the singular and include the word "license" or "registration." So, I think that draft paragraph (7)("third party logistics provider") should add the word "license" at the end and draft paragraph (8) ("outsourcing facilities") should be changed to "outsourcing facility license."

2. 12 AAC 52.110(a) and 12 AAC 52.993(6). Both of these draft regulations authorize someone other than the full board to grant emergency permits: a) two board members (12 AAC 52.110(a)) and b) the executive administrator, in consultation with two board members (12 AAC 52.993(6). In the first place, these regulations conflict with each other and with current 12 AAC 52.010(a)(3), which provides that the board will issue emergency permits. So, depending on which regulation you read, either the board has sole authority to issue emergency permits, or that authority is shared with two board members, or the executive administrator, in consultation with two board members, has that authority.

   The second problem is that there is no explicit legislative authority for a delegation of licensing authority to the executive administrator or to two board members. The board is solely responsible for the control and regulation of the practice of pharmacy. AS 08.80.030(a). To that end, it issues licenses to applicants who are qualified to engage in the practice of pharmacy. AS 08.80.030(b)(2). One of those licenses is an emergency permit to practice pharmacy. AS 08.80.155.

Therefore, while the recent legislation authorized the board to delegate authority to the executive administrator "that is necessary to conduct board business" (AS 08.80.030(b)(15)), I do not believe that is sufficient to delegate authority to issue an emergency permit, or any other license to practice pharmacy. If something as important as issuing a license were considered to be mere "board business," then virtually every function of the board could fall under that category and could therefore be delegated to the executive administrator. In contrast, the legislature explicitly authorized the executive administrator of the State Medical Board (or a board member) to issue temporary permits to practice medicine. AS 08.64.270(a).

3. 12 AAC 52.610(a). This draft regulation makes the issuance of an instate or out of state

wholesale drug distributor license mandatory if the 7 checklist items are met. This is in contrast with draft 12 AAC 52.696(a)(outsourcing facility license) and draft 12 AAC 52.697(a) (third party logistics providers license), as well as with current 12 AAC 52.130(a)(out of state pharmacy registration), which all include additional language to the effect that an applicant who does not meet the requirements of the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a license will not be issued one unless the board reviews the application and determines that the applicant is qualified. Presumably this language has been put in these regulations because of AS 08.80.157(d), which authorizes the board to deny an application for a facility license if it determines that granting the license would not be in the public interest. I cannot see any reason for not including this same language in the drug distributor license regulation as well.

Bob

From: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Sent: Thursday, December 27, 2018 9:08 AM
To: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

That's correct. Thank you. Jun

From: Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Sent: Friday, December 21, 2018 11:11 AM
To: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Subject: FW: Board of Pharmacy proposed regs law pre-review

Jun, am I correct in assuming that there is no Prolaw matter open on this project? Thanks, Bob

---

From: Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>
Sent: Thursday, December 20, 2018 5:28 PM
To: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Cc: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>; Auth, Robert Charles (LAW) <robert.auth@alaska.gov>
Subject: RE: Board of Pharmacy proposed regs law pre-review

Hi Jun,
Bob Auth can help the Board of Pharmacy. Please let us know if there is anything else we can do for you.
Thank you,
Rebecca

From: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Sent: Monday, December 17, 2018 5:20 PM
To: Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>

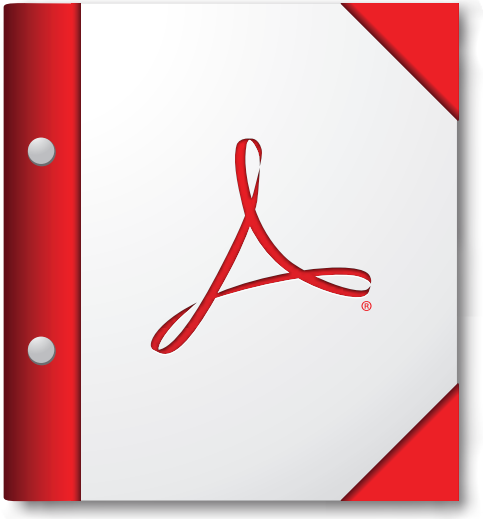
Cc: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Board of Pharmacy proposed regs law pre-review

Hello Rebecca,

The Board of Pharmacy is requesting that Dept. of Law do a pre-review of the attached draft of the proposed regs project. We have not worked with Law on this project. The attached proposed regs deals with various regulations including licensing of certain entities, facilities, wholesale drug distributor license, creating duties for executive administrator, etc., to implement changes to AS 08.80 enacted under Chapter 66, SLA 2018 (SB 37), also attached in .pdf. When you get the chance, please assign and have an AAG do a pre-review of the attached draft proposed regs project.

Thank you,

Jun Maiquis
Regulations Specialist
Division of Corporations, Business and Professional Licensing
Department of Commerce, Community, and Economic Development
(907) 465-2537
jun.maiquis@alaska.gov



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From:	Richard Holt
To:	Carrillo, Laura N (CED)
Subject:	Re: License Verification
Date:	Saturday, February 2, 2019 7:55:05 AM
Attachments:	image001.png

Very interesting. I suppose if we don't have anything like that a wholesaler could potentially sell to anybody?

Probably a good idea for us to discuss about adding if everybody feels that way. Let's put it on the wholesale topic for the agenda.

Thanks!

Richard Holt, BS Pharm, PharmD, MBA
Chair, Alaska Board of Pharmacy

Any and all statements provided herein shall not be construed as an official policy, position, opinion or statement of the Alaska Board of Pharmacy. Alaska Board of Pharmacy staff cannot and do not provide legal advice. Alaska Board of Pharmacy staff provide assistance to the public by providing reference to the Alaska Board of Pharmacy statutes and regulations; however, any such assistance provided by Alaska Board of Pharmacy staff shall not be construed as legal advice for any particular situation, nor shall any such assistance be construed to communicate all applicable laws and regulations governing any particular situation or occupation. Please consult an attorney regarding any legal questions related to state or federal laws and regulations, including the interpretation and application of the laws and regulations governing the Alaska Board of Pharmacy.

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From: "Carrillo, Laura N (CED)" <laura.carrillo@alaska.gov>
Date: Wednesday, January 30, 2019 at 11:14 AM
To: Richard Holt <dokholt@mac.com>
Subject: FW: License Verification

Hi Rich,

I was talking to Mr. Goldman on the phone, who is doing research on wholesale drug distributor requirements, particularly wanting to know whether Alaska requires that wholesale drug distributors first verify the identify of the purchaser. I looked in all the sections relating to wholesale drug distributors, but didn't find that this is a requirement. If we did have that type of requirement, it would seem fitting to fall under 12 AAC 52.620(b) or 12 AAC 52.650 (records and inventories).

I asked him if other states have this requirement, and he sent me language Arizona has: "A full service wholesale permittee may furnish prescription-only drugs only to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit." Ariz. Rev. Stat. § 32-1983(B).

Since we're making changes to these regulations anyway, what are your thoughts on adding this?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
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Fax: 907-465-2974

From: Scott I. Goldman [mailto:SGoldman@hpm.com]
Sent: Wednesday, January 30, 2019 10:09 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: License Verification

A full service wholesale permittee may furnish prescription-only drugs only to a pharmacy or medical practitioner. The full service wholesale permittee must first verify that person holds a valid license or permit.
Ariz. Rev. Stat. § 32-1983(B).

Scott Goldman
Legal Assistant
Hyman, Phelps & McNamara, P.C.
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From: Richard Holt
To: Carrillo, Laura N (CED)
Subject: Re: PHA fingerprinting
Date: Monday, February 11, 2019 2:50:14 PM

Agreed. I know I didn't realize that it was Alaska specific only so I'm not sure the other board members know that. However, since the regulations for WD was the same for out of state and in state it would require us to separate them. Good point to address when we review the regs sent back to us.

Sent from my iPhone

On Feb 4, 2019, at 1:48 PM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

> I reached out to public safety, and they said that we didn't need explicit statutory authority because AS 12.62.160(b)(8) "is a catchall statute that covers everything". If that's the case, I wonder why the other programs the division regulates got authority in their own statutes. I do know that this statute only provides us with state information rather than national background information, so maybe that's the difference. If the board does plan to subject out-of-state wholesale applicants to the same fingerprinting requirements, I wonder how useful getting a state-level check would be. Wouldn't the board be interested in background information from elsewhere? I suppose that's where we'd need the statutory authority. Thoughts?
>
> Thank you,
>
> **Laura Carrillo, MPH**
> Executive Administrator
> Alaska Board of Pharmacy
> Prescription Drug Monitoring Program
> State of Alaska – DCCED – CBPL
> Direct: 907-465-1073
> PDMP: 907-269-8404
> PDMP email: akpdmp@alaska.gov
> Fax: 907-465-2974
>
> ---
>
> **From:** Richard Holt [mailto:dokholt@mac.com]
> **Sent:** Monday, February 4, 2019 10:40 AM
> **To:** Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
> **Subject:** Re: PHA fingerprinting
>
> Hmmmmm. Strange that it was ever approved with that. I'll also take a look but I'm not sure I'll find anything different
>
> Sent from my iPhone

On Feb 4, 2019, at 10:28 AM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Hi Rich,

FYI, I was looking at the wholesale drug distributor regulations this morning and noticed that we don't have the corresponding statutory authority to request fingerprint cards as we do in 12 AAC 52.610(a)(6). All programs/departments that have the authority to ask for these have it in statute. I also looked on the Department of Public Safety's website and wasn't able to find our authority there, either.
https://dps.alaska.gov/Statewide/R-I/Background/Statutes

Unless I'm missing something, it looks like we need to repeal this section. I'll add this to our meeting for discussion.

Thank you,

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

From: Carrillo, Laura N (CED)
Sent: Monday, February 4, 2019 10:24 AM
To: Chambers, Sara C (CED) <sara.chambers@alaska.gov>
Subject: PHA fingerprinting

Hi Sara,

I circled back with Sher and Andy on this. Andy's never processed a wholesale drug distributor application, but the last time one was issued was in May by Donna. She did send the fingerprints to DPS for processing, and we received notice back from them about the results. Sher indicated that we do have authority in the public safety statutes to request fingerprint cards for wholesale drug distributors only, but I was unable to find in their statutes or ours that we do:
https://dps.alaska.gov/Statewide/R-I/Background/Statutes

Colleen and I are working on refunding the fingerprint cards we've received and I'll be updating the application to no longer request this. I'll let the board know we need to strike it from our regulations, too.

Thank you,

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

A growing number of licensed Pharmacy Interns are also seeking or have received licensure as a Pharmacy Technician in the state. Although this practice is not expressly prohibited by statute or regulation, the Board views this practice as an unreasonable interpretation of regulation that is redundant, costly, and confusing to patient care teams and employers in which these people may be working or training. Although this has been allowed in the recent past, the Board will no longer allow a licensed Pharmacy Intern to also be licensed as a Pharmacy Technician.
Those Interns currently holding both licenses should consider their Pharmacy Technician license expired. Likewise, the Board will not allow a properly licensed Pharmacist to also be licensed as a Pharmacy Intern or Pharmacy Technician. Any Pharmacist who holds either of these licenses should consider those licenses expired.

This clarification does not exclude a licensed Pharmacy Intern or Pharmacist from performing Pharmacy Technician duties spelled out in 12 AAC 52.230. A properly licensed Pharmacy Intern or Pharmacist may perform any/all Pharmacy Technician duties without restriction and in accordance with their corresponding duties. .

PHARMACIST INTERN LICENSURE REQUIRMENTS REGULATED BY THE BOARD OF PHARMACY: PROPOSED ADMENDMENT

(AAC 52.140(c))

1. **Adopting agency:** Department of Commerce, Community, and Economic Development – Division of Corporations, Business and Professional Licensing.
2. **General subject of regulation:** Pharmacist Technician license expiration
3. **Citation of regulation:** 12 AAC 52.140
4. **Department of Law file number:** To be assigned.
5. **Reason for the proposed action:** With the establishment of a school of pharmacy in Alaska, a growing number of licensed Pharmacy Interns are also seeking or have received licensure as a Pharmacy Technician in the state. The Board of Pharmacy views this practice as an unreasonable interpretation of regulation that is redundant, costly, and confusing to patient care teams and employers in which these people may be working or training. The proposed action explicitly prohibits a licensed Pharmacy Intern or licensed Pharmacist to also be licensed as a Pharmacy Technician in the State of Alaska
6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing - #???
7. **Estimated costs in the aggregate to comply with proposed action to:**
   a. Private Persons: None known
   b. Other State Agencies: None known
   c. Municipalities: None known
8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**
   No costs are expected in FY 2018 or in subsequent years.
9. **The name of the contact person for the regulations:**
   Sara Chambers, Professional Licensing Operations Manager
   Division of Corporations, Business and Professional Licensing
   Department of Commerce, Community, and Economic Development
10. **The origin of the proposed action:** Division of Corporations, Business and Professional Licensing
11. **Date:**_____08/31/18_____ Prepared by: _____

Chapter 52 Licensing, Registration, and Permit Requirements.

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

12 AAC 52.140, is amended to read:

12 AAC 52.140. PHARMACY TECHNICIAN LICENSE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacy technician license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacy technician license.

(b)The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including

(A) the applicant's name, mailing address, and telephone number; and

(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2)certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310.

(c) A pharmacy technician license expires

(1) on June 30 of even-numbered years and may be renewed

(2) upon licensure as a Pharmacy Intern or Pharmacist and may not be renewed

Authority: AS 08.80.005 AS 08.80.030

PHARMACIST INTERN LICENSURE REQUIRMENTS REGULATED BY THE BOARD OF PHARMACY: PROPOSED ADMENDMENT

(AAC 52.120(b)(5))

1. **Adopting agency:** Department of Commerce, Community, and Economic Development – Division of Corporations, Business and Professional Licensing.
2. **General subject of regulation:** Pharmacist intern licensure requirements.

3. **Citation of regulation:** 12 AAC 52.120

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

5. **Reasoned for the proposed action:** This regulation change eliminates the Declaration of Sponsorship requirements for licensing of Pharmacy Interns. With the establishment of a pharmacy school in Alaska, the Declaration of Sponsorship requirement adds significant workload to the licensing process with little benefit in oversite and hinders the licensed Pharmacy Intern from fully participating in accreditation required curricular activities. The proposed action eliminates improves efficiency in the licensing process and facilitates full participation of Pharmacy Interns in required educational activities.

6. **Appropriation/Allocation:** Corporations, Business and Professional Licensing - #???

7. **Estimated costs in the aggregate to comply with proposed action to:**

   a. Private Persons: None known

   b. Other State Agencies: None known

   c. Municipalities: None known

8. **Cost of implementation to the state agency and available funding (in thousands of dollars):**

   No costs are expected in FY 2018 or in subsequent years.

9. **The name of the contact person for the regulations:**

   Sara Chambers, Professional Licensing Operations Manager

   Division of Corporations, Business and Professional Licensing

   Department of Commerce, Community, and Economic Development

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

11. Date:_____08/31/18_____ Prepared by: _____

Register_____,_____2018 **PROFESSIONAL REGULATIONS**

Chapter 52 Licensing, Registration, and Permit Requirements.

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

12 AAC 52.120, is amended to read:

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

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

(1) applies on a form provided by the department;

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

(3) has

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

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

(4) certifies that the applicant has not been convicted of a felony or another crime

that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) [SUBMITS A DECLARATION OF SPONSORSHIP OF PHARMACY INTERN FORM COMPLETED BY THE APPLICANT'S SPONSOR PHARMACIST FOR EACH WORK LOCATION FOR WHICH THE APPLICANT IS TO WORK;]

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

(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act); and

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

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) - (2) and (5) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state. [THE PHARMACIST INTERN LICENSE IS VALID FOR ONLY THOSE WORK LOCATIONS FOR WHICH THE INDIVIDUAL PREVIOUSLY SUBMITTED SPONSORSHIP DECLARATIONS IN ACCORDANCE WITH (b)(5) OF THIS SECTION. BEFORE THE INDIVIDUAL MAY WORK AT AN ADDITIONAL WORK LOCATION, THE INDIVIDUAL MUST (1) SUBMIT A SPONSORSHIP DECLARATION FOR THAT LOCATION IN ACCORDANCE WITH (b)(5) OF THIS SECTION; AND (2) HAVE A REVISED LICENSE ISSUED TO THE INDIVIDUAL.]

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

TASK LIST

- Board staff will follow-up with Director McCullough and/or Melissa Dumas on the proposed fees for the new license categories
- Laura Carrillo will continue to look into the mandatory use compliance manual feature provided by Appriss Health to improve universal registration and use
- Ms. Carrillo will continue to work with Deputy Director, Sara Chambers, Admin Officer, 369 Melissa Dumas, and Appriss Health to submit a change order for the Clinical Alerts feature
- Ms. Carrillo will add to the board's ongoing regulation project the following language: "12 AAC 956 52.860(f): A dispenser or practitioner not licensed or registered under AS 08 may receive information from the database through multi-state agreements signed and executed by the department"
- Laura Carrillo will receive draft language from Thomas Wadsworth regarding a position statement on holding dual licenses. Ms. Carrillo will forward this to the board via OnBoard for voting