STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS,
BUSINESS & PROFESSIONAL LICENSING

DRAFT

BOARD OF PHARMACY
MINUTES OF MEETING
August 10-11, 2017

By authority of AS 08.01.070(2) and in compliance with the provisions of Article 6 of AS 44.62, a scheduled meeting of the Board of Pharmacy was held August 10-11, 2017 at the Atwood Building 550 W7th, Suite 1270.

These minutes were prepared by the staff of the Division of Corporations, Business and Professional Licensing. The minutes have not been reviewed or approved by the Board of Pharmacy.

The meeting was called to order by Chair, Leif Holm at 9:15 a.m.

Call to Order/Roll Call

Board Members Present constituting a quorum:

Leif Holm, PharmD, North Pole – Chair
Richard Holt, PharmD, Eagle River – Vice Chair
Phil Sanders, RPh, Soldotna
Lana Bell, RPh, Anchorage
James Henderson, RPh, Soldotna
Anne Gruening, Public Member, Juneau - Secretary

Attending from the Division of Corporations, Business and Professional Licensing were:

Donna Bellino, Licensing Examiner – Juneau
Brian Howes, Investigator – Anchorage - Telephonically
Sara Chambers, Deputy Director, Juneau – Telephonically

There were no visitors present.

Agenda Item 1- Review Agenda

The board reviewed the agenda for Thursday, August 10, 2017.

On a motion duly made by Ms. Gruening, seconded by Ms. Bell and approved unanimously, it was

RESOLVED to approve the agenda for Thursday, August 10, 2017.

Agenda Item 2- Review/Adopt Meeting Minutes

The Board reviewed final minutes from the May 4-5, 2017 meeting with one correction noted.

On a motion duly made by Ms. Bell, seconded by Ms. Gruening and approved unanimously, it was

RESOLVED to approve the minutes from May 4-5, 2017, Board meeting with correction.

Agenda Item 3- Ethics

Mr. Holm called for any ethics disclosures to be made. No ethics violations to report by board or staff.

Agenda Item 4 – Investigative Report – Investigator Howes

Investigator Howes joined the meeting telephonically, and presented to the Board the Investigative Report for the period of April 15, 2017 through July 31, 2017. Including cases, complaints, and intake matters, since the last report, the Division opened fifteen (15) files and closed nineteen (19) Pharmacy Board matters. A total of seven (7) matters remain on-going and under active investigation or are pending litigation.

Investigator Howes advised the Board that he has spoken with Safeway regarding the increase in the receipt of DEA form 106 Report of Theft/Loss forms sent in from Safeway Pharmacies.

Safeway advised that the increase was due to new policies and procedures that have been implemented from the Drug Enforcement Administration (DEA) investigation that resulted in disciplinary action to Safeway in the form of a fine. Additionally,

Safeway has implemented supplementary compliance measures, including enhanced training for pharmacy team members, a formal disciplinary structure for failure to timely report controlled substance theft or loss, and annual internal audits on significant loss/theft reporting. These additional measures will supplement the compliance program Albertsons Companies already has in place and will reinforce the company's commitment to compliance.

Investigator Howes also provided a brief update regarding the PDMP. There are currently 4,600 registered users and increased by almost by 2000 new registrations for the month of July. Seven thousand is the goal for complete compliance and are close to achieving that. Regarding PDMP Delegate registration, there have been 41 Pharmacy and 162 prescriber delegates that have registered.

There has also been an increase in patient requests to the PDMP. A patient request is when a patient's name is entered into the PDMP database. The month of June there were 23,000 patient requests and increased to 34,000 in July. This trend should continue to increase for the next couple months. Investigator Howes advised that providers are going to push for Certified Medical Assistants to be able to register as a delegate. Currently as written only employees that have a state license like a pharmacy technician or a nursing licensing can register as a delegate for access to the PDMP. CMA's are not licensed through the state and therefore are restricted from becoming a delegate with access to the PDMP.

Anne Gruening left room at 9:51 a.m.
Returned at 9:56 a.m.

The Board was ahead of schedule for the Budget Review so Ms. Bell provided a brief update from CSAC (Controlled Substance Advisory Council) meeting she recently attended. The Commissioner from the Department of Corrections attended the meeting and is seeking assistance from the council regarding MAT (medication assisted therapy) in helping get inmates off of opioids and developing an aftercare program when released. Another meeting of the council has been planned and this discussion will continue on how the council can help. Ms. Bell will continue to provide updates to the Board.

Break:
Off the record at 9:51 a.m.
On the record at 10:11 a.m.

Agenda Item 5 – Budget Review

Sara Chambers, Deputy Director for the division joined the meeting telephonically. Ms. Chambers reminded the Board that the Revenue & Expenditures reports for: FY 17 4th Quarter are not available until October. Ms. Chambers briefly reviewed Revenue & Expenditure Report for FY '17 1st-3rd quarters that were discussed at the May board meeting. Chair Holm requested confirmation that an Information and Technology expense for $49,783 was a charge for the PMDP. Ms. Chambers advised that she will verify that and get back to the board on Friday.

Deputy Director Chambers sent an email on Friday August 11, 2017 advising the $49, 793 was indeed for the vendor PDMP services and that the amount has already been backed out of the licensing program's expenses and applied to the PDMP grant. This update will be reflected in the 4th Quarter report that the Board will review at the November BOP meeting.

The Deputy Director touched base with the board on SB74 and the additional requirements that went into effect July 17, 2017. HB159 just signed into law by the Governor on July 25th, 2017 has components that take effect immediately, and in the next year.

The Division worked with HSS on a mailer sent out to all Pharmacists/practitioners who prescribe, administer, dispense schedule II, III, or IV, must now register with the PDMP (AS 17.30.200(o)). A second mailer is currently in the works to continue to proactively get the word out about the changes/requirements to SB74 to assist in easing any concerns or confusion. Deputy Director Chambers thanked both Chair Holm and Vice Chair Holt for their availability and responsiveness in assisting with providing input and edits to content ensuring what is communicated is accurate and easy to follow for all licensees that are impacted. The Board of Pharmacy has the heaviest lifting on developing regulations and ensuring they are clear and enforceable to the pharmacists and prescribers who are required to register with the PDMP.

An update was provided to the Board as to the status of the PDMP/Pharmacy Program Manager position. After three failed recruitment attempts at a Range 17, Deputy Director Chambers and Director Hovenden discussed at length what would be the best way to proceed. From those conversations, Deputy Director Chambers advised the Board of two options to move forward. The first option would be to go back to classifications and continue to work with them to help understand that the duties and responsibilities as currently written for a Range 17 are more in line with the duties and responsibilities of an Executive Administrator at a higher range.

The second option was to work with classification to modify the duties and responsibilities down to a Range 16 the same classification as the current Records and Licensing Supervisor for the pharmacy program. The upside to this option would allow a Records and Licensing Supervisor to take on the amended PDMP duties along with exclusive supervision of the pharmacy program including licensing and board responsibilities. The Deputy Director would continue to work closely with the person in this new position, and still remain involved with the oversite of fiscal and programmatic responsibilities. There is a Records and Licensing Supervisor who is currently working on a Master's degree in Public Health interested in pursuing this opportunity. Deputy Director Chambers is working to finalize. This option would have less of an impact to the Board's quest for an Executive Administrator for Pharmacy. The Board has been seeking through legislation the authority to hire an EA. The Board will continue work to champion the bill in which this authority is attached, and along with the Division are hopeful the bill will pass in the upcoming legislative session.

The Board thanked Ms. Chambers for her time and information provided to the Board.

Agenda Item 6 – Tabled Applications

There were several out-of-state pharmacy applications tabled from a previous mail ballot where the hours of operation had changed and there were questions if these pharmacies are still in compliance with the statute. Vice-Chair Holt requested interpretation/clarification of **Sec.08.80.158 REGISTRATION OF PHARMACIES OUTSIDE OF THE STATE.**

Ms. Bellino had Records and Licensing Supervisor, Sher Zinn review the statute. Ms. Zinn provided her interpretation and there was disagreement from Vice-Chair, Holt. Regulation Specialist, Jun Maiquis reviewed the statute and was in agreement with Vice-Chair Holt. It was decided to have an AAG review and provide interpretation of this statute. As requested, AAG Greider provided interpretation of "during its regular hours of operations". The Board reviewed and discussed the AG interpretation and will work to better clarify "during its regular hours of operations" through regulation.

Break for lunch:
Off the record at 12:01 p.m.
On the record at 1:15 p.m.

Agenda Item 6 – Tabled Applications Cont'd

The Board went into Executive Session to review/discuss items that had required investigative review.

On a motion duly made by Ms. Gruening, seconded by Ms. Bell and approved unanimously, it was

> **RESOLVED to go into Executive Session in accordance with AS44.62.301(c) for the purposes of discussing two confidential applications.**

Board staff to remain

Off the record at 1:18 p.m.
On the record at 1:51 p.m.

Board reviewed "yes" answer Pharmacist application.

On a motion duly made by Ms. Gruening, seconded by Ms. Bell and approved unanimously, it was

> **RESOLVED to table Pharmacist application with "yes" answer application pending further guidance and information.**

Board reviewed 2016-2018 pharmacy technician renewal application.

On a motion duly made by Ms. Gruening, seconded by Ms. Bell, approved via a roll call vote, it was

> **RESOLVED to recommend imposition of civil fine of $500/$250 suspended for failure to disclose a previous conviction on initial application in 2013 for Pharmacy Technician Donna Bolton.**

Roll Call Vote:
Lana Bell – Yes
Anne Gruening – Yes
Leif Holm – Yes,
James Henderson – Yes,
Rich Holt, - Abstain
Phil Sanders – Abstain

Agenda Item 7 –Regulations

The Board spent the remainder of the afternoon discussing and reviewing several regulations pertaining to pharmacy technicians to determine the best way to proceed as the role of pharmacy technician in a pharmacy is rapidly changing. The Board began this discussion at the May board meeting and continued to sort through various options, opinions to determine what changes are needed.

2:20 p.m. Adam Chesler, PharmD, Director, Regulatory Affairs/Cardinal Health joined the meeting telephonically.

Brief recap of some of the discussion, but has not yet been finalized:

1) Adding an Affidavit of Good Moral Character requirement to the pharmacy technician application.
2) Amending regulation to include a homeschooling certificate or college/University degree as acceptable graduating institutions licensure. Current requirement is a high school diploma or its equivalent.
3) Created definition of Nationally Certified Pharmacy Technician:
   A pharmacy technician who obtains and maintains an active national certification through PTCB or ICPT.
4) There was a spirited discussion on what functions a Nationally Certified Technician would be allowed to perform. Idaho regulations were looked at as a guide for this discussion. More discussion and definitive details on this will continue at the November meeting.
5) National Certification will not be mandatory nor require a separate license.

Break:

Off the record at 3:04 p.m.
Back on the record at 3:15 p.m.

James Henderson left the meeting for day at 4:18 p.m.

On a motion duly made by Mr. Sanders, seconded by Ms. Gruening and approved unanimously, it was

RESOLVED to recess the meeting until Friday morning, August 11th at 9:00 a.m.

Off the record at 4:38 p.m.

Friday May 5, 2017

The meeting was called to order by Leif Holm, Board Chair, at 9:15 a.m.

Call to Order/Roll Call

Those present, constituting a quorum of the board, were:

Leif Holm, Pharm D, North Pole- Chair
Rich Holt, Pharm D, Eagle River – Vice Chair
Anne Gruening Public Member, Juneau – Secretary
Phil Sanders RPh, Soldotna
James Henderson, RPh, Soldotna
Lana Bell, RPh, Anchorage

In attendance from the Division of Corporations, Business & Professional Licensing, Department of Commerce, Community and Economic Development were:

Donna Bellino, Licensing Examiner – Juneau

Visitors Present –

Adam Chesler, PharmD - Director, Regulatory Affairs/CardinalHealth - Telephonically
Molly Gray, Executive Director, AkPhA (Alaska Pharmacist Association)

Agenda Item 1 Review Agenda –

The Board reviewed the agenda for Friday, August 11, 2017.

On a motion duly made by Ms. Bell, seconded by Mr. Holt and approved unanimously, it was

RESOLVED to approve the agenda as is for Friday August 11th.

AGENDA ITEM 1 – Public Comment –

Chair Holm called for public comment at 9:18 a.m. No callers, nor anyone present for public comment.

Agenda Item 2 – Recap NABP 113th Annual Meeting

Ms. Bell reviewed her written report to the Board regarding her attendance at the NABP 113th Annual Meeting that was held in San Diego, CA in May. Ms. Bell advised she attended educational opportunities, group discussions, and was allowed to vote on issues brought up at the NABP business meetings. Business meeting included the election of officers and executive committee members for next year, and discussed and voted on Amendments to the constitution and bylaws.

Educational Opportunities included classes on:

- Expanded Scopes of Pharmacy Practice – pharmacists and technicians
- Telehealth
- Specialty Pharmacy
- USP 800 Hazardous Drugs

Some of the topics for group discussions attended:

- Effective role (and education/training) of support personnel to allow pharmacist as provider
- Mandating staff ratios
- Texting prescriptions
- How to ensure regulatory compliance with out-of-state licenses

Ms. Bell advised she learned a lot from attending this meeting and was informative on just how NABP supports Boards of Pharmacy. For every $1 spent by a board, the value of the return from NABP is $1600. Ms. Bell also learned about important issues to a Board of Pharmacy, and how best to contribute as a member of a board.

Agenda Item 3 – New/Old Business

The Board reviewed dates for 2018 Board of Pharmacy meetings and was in agreement the first quarter 2018 meeting will be held in Juneau. The Board would like to coordinate with AkPhA's legislative fly-in. The following dates were chosen:

February 28 – March 2nd – Juneau (coordinate with Legislative Fly-In)
May 17-18, 2018 – Teleconference
August 16-17, 2018 (1st FY 2019 meeting in person)
November 2018 dates TBD

Mr. Holt was invited back to give a presentation at the AkPhA February 2018 convention. The Board was in agreement of Mr. Holt again representing the Board

and his participation at the convention providing an update to any changes in regulation in the past year.

NABP District 6,7,8 meeting is being held in San Antonio, TX October 8-11, 2017. The Board discussed attendance of this meeting. Phil Sanders will check his calendar to see if he is available to attend.

MPJE State Item Pool Review –
Mr. Holt updated the Board that the questions written at the March MPJE Item Writing Workshop attended by Mr. Holt and Ms. Bellino last March now has to be reviewed. Questions for review not only include what Mr. Holt and Ms. Bellino wrote in March, but includes all other items written by the other states and is typically over 1,000 questions. You mark which items you want to use to be put into the state exam from what was written, or you can review and use items written by other states if they apply, and add those into Alaska's state MPJE exam. The Board discussed the best way to accomplish this requirement. This is the one time of year when NABP also includes all questions that are currently in pre-test or actively being scored to see if they fit or remove. Mr. Holt next week will begin going through items that were worked on in March into the exam, and then have some of the concrete ones that are not correct removed.

Molly Gray, Executive Director AkPhA interjected that one of the things that the Association's board would like to develop is a study guide for this exam. The Association would like to utilize the UAA pharmacy students to assist with the guide and work with the Board of Pharmacy on its development.

Ms. Bell volunteered to meet with Mr. Holt to assist with the item question review since she and Mr. Holt live locally. The Board was in agreement this subcommittee would be the best way to proceed with what is needed. Ms. Bellino will forward the NABP Statement on Conflict of Interest and Confidentiality to Ms. Bell. Ms. Bell will provide Mr. Holt dates she is available to meet.

2016-2018 Renewal CE Audits –
Pharmacist and pharmacy technician renewal applications randomly chosen for the 2016-2018 CE audit are ready for Board review. There are approximately 300 applications between the two licensing categories. Leif Holm, Phil Sanders, and James Henderson will be the CE Audit reviewing members for the Board. Renewal applications ready for review will be divided between the three reviewing members.

FY 2017 Annual Report –
The Board reviewed the final version submitted for the Annual Report for Fiscal Year 2017.

Wall Certificates were given to Chair Holm for signature.

Break:
Off the record at 10:27 a.m.
On the record at 10:38 a.m.

Ms. Bellino sought clarification from the Board on their interpretation of Sponsorship of a pharmacy intern versus supervising pharmacist of pharmacy intern. Recently there has been some confusion with the terminology, and if they are one in the same. The Board reviewed the current Declaration of Sponsorship and the Intern Affidavit of Experience forms. The Declaration of Sponsorship form has both sponsor and supervising pharmacist on it, and the Affidavit of Intern Experience form only has supervising pharmacist. The Board clarified that the sponsoring pharmacist and supervising pharmacist in most cases are not the same, and can see how the current forms could cause confusion. The Board revised both forms to only have sponsor/sponsoring pharmacist on both forms. Supervisor/supervising pharmacist was also removed from the forms. Ms. Bellino will have the forms amended to reflect these changes.

Agenda Item 4 – Correspondence/Report of Theft or Loss Reports

The Board reviewed correspondence and one Theft/Loss report received since the March meeting.

Break:
Off the record at 12:05 p.m.
Back on the record at 12:15 p.m.

Agenda Item 5 – Regulations

The Board spent the remainder of the meeting discussing and reviewing regulations. Resulting from the discussion the following changes, additions were approved.

On a motion duly made by Mr. Holt, seconded by Mr. Sanders and approved unanimously, it was

RESOLVED to approve the following regulations changes for submission to the Regulation Specialist:

Chapter 52. Board of Pharmacy.

Board of Pharmacy Proposed Regulatory Language:

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

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

12 AAC 52.120 LICENSE REQUIREMENTS FOR INDIVIDUAL PHARMACISTS

WORKING FOR TRIBAL HEALTH PROGRAMS. (a) a pharmacist who engages in the practice of pharmacy in a tribal health program in this state must be licensed by the board unless they notify the board that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 14 days after employment at a tribal health program in this state, and must include

(1) a completed Alaska State Pharmacist License Exemption form provided by thE Department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(3) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25

U.S.C. 450-458ddd-2 (Indian Self-Determination and Education Assistance Act).

(A) if the out-of-state pharmacist is employed with the tribal health program as an independent contractor then the pharmacist must also provide a copy of the contract.

(b) a pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) the licensing exemption only applies during time spent working for the tribal health program and does not extend to "moonlighting". An out-of-state licensed pharmacist working outside of their contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80. (Eff. ___/___/____, Register ____)

Authority: AS 08.80.003 AS 08.80.005 AS 08.80.030

12 AAC 52.240 PHARMACIST COLLABORATIVE PRACTICE AUTHORITY (b) is amended to read:

(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;

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement. (Eff. 11/10/2001, Register 160; am 2/11/2004, Register 169; am 11/16/2012, Register 204, Eff. ___/___/____, Register ____)

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.920 DISCIPLINARY GUIDELINES (a) is amended to read:

(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, **sexual orientation, gender identity** 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; [OR]

(21) violating AS 08.80.261(a)(3); **or**

(22) failing to meet continuing education requirements will result in a $100 civil fine per missing continuing education credit hour for pharmacists and a $25 civil fine per missing continuing education credit hour for technicians. (Eff. 1/16/98, Register 145, Eff. ___/___/____, Register ____)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315
AS 08.80.005 AS 08.80.261

12 AAC 52.423 REMOTE PHARMACY LICENSE (c) is amended to read:

(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.] (Eff. 9/17/2011, Register 199, Eff. ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425 TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY is amended to read:

(a) Only a **pharmacist employed by a** central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist **located in this state**. The pharmacist-in-charge of a [CENTRAL] **remote** pharmacy may supervise one or more remote pharmacies.

(b) Before a **pharmacist employed by a** central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising

pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

(1) still image capture;

(2) real time link;

(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and

(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy [ONLY] from the central pharmacy **or a wholesale distributor.** Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped. [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 have access to the records of the prescriptions dispensed by the remote pharmacy.** [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] **dispensed** by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the [CENTRAL] **remote** pharmacy. [AND DISTRIBUTED BY THE REMOTE PHARMACY] A prescription drug may not be [DISTRIBUTED] **dispensed** by a remote pharmacy until a-[LICENSED] pharmacist [AT] **employed by** the central pharmacy has verified the finished prescription product through the telepharmacy system.

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

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

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

(j) **Repeal __/__/___.** [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.] (Eff. 2/15/2006, Register 177, Eff. ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.530(a) is amended to read:

(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 if

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or

(2) the medication was recalled by the manufacturer or FDA; and

(3) it is segregated from the normal pharmacy inventory and may not be dispensed. (Eff. 1/16/98, Register 145, Eff. ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

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

12 AAC 52.465 CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS. (a) A prescription drug order for a Schedule II controlled substance may be partially filled if prescribed for

(A) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 CFR §1306.13; or

(B) a patient who is not terminally ill or residing in a long term care facility if;

(i) the partial fill is requested by the patient or the practitioner that wrote the prescription;

(ii) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;

(iii) each partial fill is electronically documented in the patient record;

(iv) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and

(v) it only occurs at the pharmacy where the original prescription order is on file. (Eff. ___/___/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.345

The meeting concluded.

On a motion duly made by Ms. Bell, seconded by Ms. Gruening, and approved unanimously, it was

RESOLVED to adjourn the meeting.

The board adjourned at 1:31 p.m.

Respectfully Submitted:

Donna Bellino

Donna Bellino
Licensing Examiner

Approved:

Leif Holm, PharmD., Chair
Date: 12/18/17