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

BOARD OF PHARMACY
MINUTES OF MEETING
March 2-3, 2017

By authority of AS 08.01.070(2) and in compliance with the provisions of Article 6 of AS 44.62, a scheduled teleconference meeting of the Board of Pharmacy was held via WebEx Teleconference March 2-3, 2017 at the State Office Building 333 Willoughby Ave., 9th Floor Conference room B.

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 9:08 a.m.

Call to Order/Roll Call

Board Members Present constituting a quorum:

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

Not in Attendance:
Taryl Giessel, Public Member, Eagle River

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

Donna Bellino, Licensing Examiner – Juneau
Janey Hovenden, Director - Juneau
Brian Howes, Investigator – Anchorage

Visitors Present via teleconference –
Greg Estep, PharmD – Walgreens
Adam Chesler, PharmD – Director, Regulatory Affairs/Cardinal Health

Agend a Item 1- Review Agenda

The board reviewed the agenda for Thursday, March 2, 2017.

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

RESOLVED to approve the agenda for Thursday, March 2, 2017.

Agenda Item 2- Review/Adopt Meeting Minutes

The Board reviewed the minutes from the November 17-18, 2016 meeting

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

RESOLVED to approve the minutes from November meeting with one minor 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 presented the Investigative Report for the period of November 16, 2016 through February 15, 2017. Including cases, complaints, and intake matters, since the last report, the Division opened nine (9) files and closed ten (10) Pharmacy Board matters. A total of fifteen (15) matters remain on-going and under active investigation or are pending litigation.

Agenda Item 5 – Budget Review

Martha Hewlett, Administrative Officer II was not available due to illness and Director Hovenden had another meeting she needed to attend. The Board reviewed the Revenue & Expenditures reports for:

FY 16 4th Quarter
FY 17 1st and 2nd Quarters

Upon the Board's review there were questions regarding direct expenditures that the Board would like further clarification on.

As the Board was ending their review of the Revenue and Expenditures Director Hovenden entered the meeting and the Board was able to address their indirect expenditure questions to the Director.

Director Hovenden was able to answer the Board's questions, but there are two items that will require her to research and clarify. Director Hovenden will forward the information to the Board when known.

Director Hovenden and Board reviewed and discussed **HB90 "An Act relating to occupational licensing fees; relating to an occupational investigation surcharge; and providing for an effective date."** This bill would create a pro rata investigation surcharge for all professional licensees. If the bill were to pass it will create an investigative fund and individual boards would no longer pay for investigative costs. There would be a reduction in personal services and contractual direct expenditures to the Boards as investigative costs would come out of the new investigative pool of funds. The Director encouraged the board to weigh in on this bill and get their opinions known.

Agenda Item 6 – Marny Rivera, PH.D Associate Professor Justice Center, UAA

Professor Rivera introduced herself and addressed the Board regarding a grant the state of Alaska received from the CDC. This is a Prescription Drug Overdose: Data-Driven Prevention Initiative (DPPI) grant.

Generally the grant is designed to provide funding to examine the heroin and prescription drug problem in Alaska, and to provide strategies for improving the problem here. Ms. Rivera is leading the UAA evaluation team conducting a policy analysis of statutes and regulations designed to prevent opioid misuse, abuse and overdose.

The goal of this policy analysis would be to gather information in Alaska and other states and to take a look at rates of use, overdose, and overdose deaths in Alaska and other states to identify some promising practices that they might consider for use in Alaska. The evaluation team considers the Board of Pharmacy a stake holder in this grant and in the process, and Ms. Rivera wanted to let the Board know they are doing this work and provide an opportunity for the Board to provide input regarding this policy analysis.

Specifically, if the BOP already has ideas on laws or regulations involving PDMP, Naloxone access, pain clinics or other relevant legislation the Board believes would be affective that the evaluation team should be researching and possibly implementing in Alaska. It would be great for the board to have a way to share that information with Ms. Rivera so it can be included in the policy analysis. Ms. Rivera also advised the evaluation team could provide periodic updates to the Board about the process and results.

Mr. Holt had a question for Ms. Rivera. Mr. Holt is interested in keeping abreast of assessing the impact of legislation in Alaska versus other states. Many other states have specific controlled substance regulations of their own which tend to be more stringent than federal regulations that Alaska strictly follows. Mr. Holt would like to know if there is a correlation between other states that have controlled substance regulations of their own which are more stringent, versus the federal regulations that Alaska tends to follow. If so, is there is a correlation between more direct state control of CS regulations, and is that something that the Board needs to look at for Alaska? Ms. Rivera made note of Mr. Holt's question.

Mr. Holm asked Ms. Rivera what is the time frame when an update would be available? Ms. Rivera could provide updates quarterly, perhaps monthly. Ms. Rivera advised that her report is due at the end of August. The Board will have already met by then, so the next opportunity for Ms. Rivera to update the Board will be at the November 30th and December 1st BOP meeting. The Board will invite Ms. Rivera to the November meeting when she can present to the Board the outcome from the evaluation team. The Board thanked Ms. Rivera for her time and look forward to speaking with her at the November meeting.

Break:
Off the record at 10:42 a.m.
Back on the record at 10:50 a.m.

Agenda Item 7 – Correspondence/Report of Theft of Loss

The Board reviewed correspondence and Theft of Loss reports received between the November 2016 and March 2017 meeting.

The Board reviewed the report of theft of loss reports received from Safeway. There is concern from the Board that the DEA 106 reports are being reported later than the twenty-four (24) hours of discovering a potential loss that is required. There is also concern for the one Safeway pharmacy that submitted more than one report.

The Board requested that the investigator for the Board of Pharmacy reach out to Kelly Nelson who is the corporate person who is responsible for Alaska to find out exactly what is their corporate policy. The investigator will also inquire as to why multiple pharmacies are reporting loss.

Ms. Bellino will forward copies of the DEA forms to the investigator with the Board's request.

Agenda Item 8 – Tabled Applications

The Board reviewed six (6) applications that were tabled from the January/February mail ballots.

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

> **RESOLVED to approve the tabled pharmacy technician applications for Melissa Brittain, Timothy Brown, and Adam Bohman.**

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

> **RESOLVED to table the approval of the pharmacy technician application for Melissa Lause until receipt of additional details of circumstances not provided in the letter of explanation.**

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

> **RESOLVED to approve the application for out-of-state pharmacy for Bluegrass of Lexington.**

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

> **RESOLVED to approve the application for out-of-state pharmacy LDI Pharmacy pending receipt of requested self-inspection report and approval from the Board member who tabled the application.**

Agenda Item 9 New/Old Business

The Board reviewed and updated a letter of support for SB37 and HB9. Both bills are Board of Pharmacy bills seeking statutory authority to license out-of-state wholesale drug distributors, third party distributors, and 503B outsourcing facilities. Both bills also include the creation of an executive administrator for the Board of Pharmacy.

Letters will be sent to Senator Giessel for SB37 and Representative Saddler for HB9 Senate and House sponsors of the bills.

The Board also reviewed a letter Chair Holm drafted in opposition for **SB32: An Act relating to biologic products.**

Lastly the Board reviewed a letter of support Chair Holm drafted in support of **SB38: Pharmacy Benefit Managers and Auditing of Pharmacy records.**

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

RESOLVED to approve letters of support for SB37, SB38 and HB9.

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

RESOLVED to approve the letter of Non-support for SB32: An Act relating to biologic products.

12:34 p.m. Ms. Bell had to leave the meeting to attend the CSAC meeting beginning at 1:00 p.m.

The Board briefly discussed if they should consider state regulations for Controlled substances. Other states do have their own CS regulations in addition to federal regulations. Mr. Holt brought this up in the earlier discussion with Ms. Rivera from UAA. The Board will revisit this subject at the November meeting when the Board receives the report from Ms. Rivera with the outcome of her research.

Travel to the upcoming NABP 113th Annual meeting May 20-23 in Orlando, Florida was discussed. Ms. Bell expressed interest in attending this meeting. The Board of Pharmacy does budget for attending this meeting and NABP does offer a travel grant

up to $1,500 in travel fee to defray expenses such as airfare, hotel, meals and taxis, parking, and tips.

The Board is in support of Ms. Bell submitting for approval to attend the annual meeting.

Mr. Holt and Ms. Bellino will be attending NABP's MPJE Item workshop March 14-16 being held in Northbrook, IL.

Mr. Holt will discuss with NABP the best process to how to have exam questions updated when there are regulation changes. This is important to understand and follow as the Board is working on many new and updated regulations.

Due to the short time left for the Thursday's meeting, Chair Holm moved the agenda item reviewing the Board's Project Tracking Spreadsheet to Friday's agenda.

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

> **RESOLVED to move review of Project Tracking Spreadsheet to the Friday March 3rd agenda.**

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

> **RESOLVED to recess the meeting until Friday Morning March 3rd at 9:00 a.m.**

Off the record at 1:03 p.m.

Friday March 3, 2017

Due to technical difficulties with WebEx the meeting was called to order by Leif Holm, Board Chair, at 9:33 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, Wasilla – Vice Chair
Anne Gruening Public Member, Juneau – Secretary
Phil Sanders RPh, Soldotna
Lana Bell, RPh, Anchorage
James Henderson, RPh, Soldotna

Not in attendance:
Taryl Giessel Public Member, Eagle River

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 –
Greg Estep, PharmD – Walgreens
Adam Chesler, PharmD - Telepharm.com

Agenda Item 1 Review Agenda –

The board reviewed the agenda and added time for the project tracking spreadsheet. Ms. Bell advised that she had some follow up items from the CSAC meeting that she would like to share with the Board. Due to the late start, Mr. Holm advised he would try to leave time at the end of the meeting for the update.

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

RESOLVED to approve the amended agenda with changes for Friday March 3rd.

AGENDA ITEM 1 – Regulation Review –

The Board reviewed written public comments received for changes to the following pharmacy regulations sent out for public comment:

12 AAC 52.120 Review of pharmacist intern license application
12 AAC 52.210 Pharmacist Duties
12 AAC 52.320 CE Requirements for Pharmacists
12 AAC 52.400 General Guidelines for pharmacists
12 AAC 52.450 Prescription drug orders
12 AAC 52.460 Prescription drug order information
12 AAC 52.500 Transfer of prescription drug order
12 AAC 52.585 Mandatory patient counseling
12AAC 52.992 Independent administration of vaccines and related emergency medications

After review and discussion from the comments received for the 9 regulations the board:

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

> **RESOLVED based on the review of public comment from proposed regulations the Board adopted:**
>
> **12 AAC 52.120 Review of a pharmacist intern license application (3) (b) (A) is adopted and is amended to read: enrolled in a college of pharmacy accredited by ACPE**
>
> **12 AAC 52.210 Pharmacist duties (1) adopted and amended to read:**
> **(1) Receiving an oral prescription drug order**
>
> **12 AAC 52. 320 Continuing Education Requirements for Pharmacists is adopted and amended by adding:**
> **(e) A pharmacist administering vaccines or related emergency medications under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations, vaccines, or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.**

12 AAC 52.400 General Guidelines for Pharmacies is adopted and amended to read: *"Facility Standards for Pharmacies," dated* November 2016

12 AAC 52. 450 Prescription Drug Order Records is adopted and amended to read (b) 1-4

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

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

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

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

12 AAC 52.585 Mandatory patient counseling (A) – The introductory language of 12 AAC 52.585 is repealed and readopted to read:

(a) Before dispensing a prescription for the first time for a new patient of the pharmacy, or 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 must personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgement. The counseling may include

12 AAC 52.460 Prescription Drug Order information (a)
The Board would like to re-amend and resend out for public comment if deemed necessary to include changes to:

(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 it must include the name of the prescribing practitioner.

12 AAC 52. 500 Transfer of a Prescription Drug Order is adopted and re-amend (d) #5 that it is not to be repealed and add back in [When a prescription drug order is transferred, the transferring pharmacy may not issue any further refills].

12 AAC 992 Independent administration of vaccines and related emergency medications is adopted and would like to re-amend (a)

(1) (D) to read vaccine storage and management, and (I) to read identifying, responding to, documenting, and reporting adverse responses

(2) *add* in maintain certification and *keep documentation* in adult and pediatric cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training; and

(3) *a pharmacist who has not administered a vaccine within the past 10 years must complete a course as described in (a)(1) of this section before administering a vaccine.*

add* (4) Referral - *Pharmacist must adhere to 12 AAC 52.320 Continuing Education Requirements.

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section.

(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.

SB 74 REGULATIONS –

The Board reviewed and discussed the preliminary draft of SB74 regulations. The discussion began with the Board reviewing the definition of what a dispenser is versus what a practitioner is, and the need for a pharmacist to monitor the PDMP for each CII & CIII prescription dispensed.

This is not what the Board intended and per guidance Mr. Holm received from AAG Greider who advised that the Board should write the regulations as they would like for them to be and if there is a problem with what is submitted they will let the Board know.

The definition of Practitioner is in statute and cannot be changed so when practitioner is used the definition can be referred to. The Board's desire would not be to include pharmacists.

Mr. Holt made the point that when working on the SB74 FAQ it was presented that the pharmacist did not have to check the PDMP and the FAQ once vetted and reviewed from the Division was returned that pharmacists do have to check.

Mr. Holm believes that this could be incorrect based on his discussion with the Department of law. The Board proceeded to review the draft of the regulation changes:

Current Regulation reads:
12 AAC 52.855 REGISTRATION BY DISPENSER AND ACCESS REQUIREMENTS FOR CONTOLLED SUBSTANCE PRESCRIPTION DATABASE.

Amended Regulation:
12 AAC 52.855 REGISTRATION BY [DISPENSER] ***PHARMACISTS, PRACTITIONERS OR AUTHORIZED DELEGATES*** AND ACCESS REQUIREMENTS FOR CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

(a) Currently reads:

To receive information from the controlled substance prescription database, a dispenser must register with the Board by submitting a completed application on a form prescribed by the board, and must agree in writing to comply with the conditions set out in **12 AAC 52.860**. The department shall issue a dispenser registered under this section a user account, login name, and password.

Will be changed to:

To receive information from the controlled substance prescription database, a ***pharmacist, practitioner or authorized delegate*** must register with the Board by submitting a completed application [ON A FORM PRESCRIBED] ***provided*** by the board, ***pay any applicable fees*** and must agree in writing to comply with the conditions set out in **12 ACC 52.860**. The department shall issue a ***pharmacist, practitioner or authorized delegate*** registered under this section a user account, login name, and password.

(b) Currently reads:

A pharmacist or practitioner not registered under this section may request a patient profile from the board if the pharmacist or practitioner

(1) has a valid license to practice in this state or in another jurisdiction with licensure standards that are substantially similar to the licensure in this state;

(2) submits the request on a form prescribed by the board and
(A) mails it to the board; or
(B) sends it to the board by facsimile transmission;
(3) signs the request and includes the business name and address of the pharmacist or practitioner;
(4) includes in the request the patient's name and date of birth, the purpose of the request, and the date range for the patient profile; and
(5) includes evidence establishing the requester has, with the subject of the requested information,
(A) a pharmacist-patient relationship as required under AS 17.30.200(d)(4); for purposes of this subparagraph, a pharmacist-patient relationship exists if the subject of the requested information is a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; or
(B) a practitioner-patient relationship as required under AS 17.30.200(d)(3).

Amended Regulation:
(B) A pharmacist or practitioner not registered under this section may request a patient profile from the [BOARD] **Alaska Prescription Drug Monitoring Program (AKPDMP)** if the pharmacist or practitioner
(1) has a valid license to practice in this state or in another jurisdiction with licensure standards that are substantially similar to the licensure standards in this state;
(2) submits the request on a form prescribed by the [BOARD] ***AKPDMP*** and
(A) mails it to the[BOARD] **AKPDMP**; or
(B) sends it to the **AKPDMP** by facsimile transmission
(3) – (5) stay the same as above

(c)Currently reads:
A patient profile generated by the board under (b) of this section shall be
Amended to:
A patient profile generated by the ***AKPDMP*** under (b) of this section
(d) Is repealed:
Nothing in this section requires a pharmacist or practitioner to receive information from the controlled substance prescription database or to request a patient profile from the Board
(e) **Amended to add new subsection:**

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 within 30 days of obtaining a license or registration.

(f) Amended to add new subsection:

The Department of Commerce, Community and Economic Development shall assist the board and provide necessary staff and equipment and establish fees for registration with the database by a pharmacist or practitioner required to register under AS 17.30.200(o) 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

(1) Set fee for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and

(2) Consult with the board to establish fees under this paragraph.

(g) Amended to add new subsection:

(1) "delegate" is defined as an agent or employee of a practitioner or pharmacist who has been authorized to access the database on behalf of the practitioner or pharmacist and must be licensed or registered under AS 08;

(2) "Practitioner" is defined as:

(A) a physician, dentist, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer or use in teaching or chemical analysis a controlled substance in the course of professional practice or research in the state;

(B) a Pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice of research in this state.

Current Regulation reads:

12 AAC 52. 860 CONDITIONS FOR ACCESS TO AND USE OF DATABASE

(a) A dispenser registered under 12 AAC 52.855(a) to receive information from the controlled substance prescription database may not

(1) & (2) remain the same

(b) remains the same

Amended Regulation would read:

12 AAC 52.860 CONDITIONS FOR ACCESS AND USE OF DATABASE

(a) ***pharmacist, practitioner or authorized delegate*** *under 12 AAC 52. 855 (a) to receive information from the controlled substance prescription database may not*

(1) & (2) remain the same

(b) remains the same

(c) ***Amended to add new subsection:***

Delegates shall only access the data base to the extent the information relates specifically to a current patient of the practitioner or pharmacist to whom is being prescribed or dispensed or considering prescribing or dispensing a controlled substance.

(1) ***a pharmacist or practitioner who elects to utilize a delegate is responsible for maintaining their delegate access and terminating access of any delegate to the database that should be no longer have delegate privileges.***

(d) ***Amended to add new subsection:***

The database and the information contained within the database are

(1) Confidential;

(2) Not public records;

(3) not subject to public disclosure; and

(4) may not be shared with federal government

(e) ***Amended to add new subsection:***

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)state and local law enforcement authorities may receive printouts of information contained in the database under a search warrant, subpoena, 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. Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(f) ***Amended to add new subsection:***
the board shall
(1) provide that prescription information in the database be purged from the database after two years have elapsed from the date the prescription was dispensed;
(2) undertake to ensure the security and confidentiality of the database and the information contained within the database.

Amended to add new subsection:

(g) ***An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted information.***

Amended to add new subsection:

(h) ***Pharmacists, practitioners or authorized delegates may not be held civilly liable for damages for assessing or failing to access the information in the database.***

Current Regulation Reads:
12 AAC 52.865 REQUIREMENT FOR DISPENSERS

Amended Regulation would read:

12 AAC 52. 865 REQUIREMENT FOR [DISPENSERS] **PHARMACISTS, PRACTITIONERS OR AUTHORIZED DELEGATES.**

(a) A **pharmacist, practitioner or authorized delegate** must acquire and maintain a National Provider Identifier (NPI) number under 45 C.F.R. 162.404-162.414 issued to the dispensing pharmacy.

(b) Except as provided under 12 AAC 52.870, a **pharmacist, practitioner or authorized delegate** shall submit information required under AS 17.30.200(b) through the use of

(1) the American Society for Automation in Pharmacy's Standard for Prescription Monitoring Programs, 2009, Version 4.1: or

(2) the website provided for that purpose by the board.

(c) *[NO LATER THAN THE FIFTH DAY OF EACH MONTH, A DISPENSER]* ***On at least a weekly basis, 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 administered to a patient at a health care facility*** *shall* ***submit*** *to the* ***AKPDMP, by a procedure and in a format established by the board,*** *the* ***following*** *controlled substance dispensing information*

(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 the 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.

The requirement in **12 AAC 02.920(b)** for time computation applies to a report made under this section.

(d) No changes

(e) A **pharmacy** that is not required to report under AS 17.30.200 shall **have the pharmacist-in-charge sign and** submit a sworn statement at the end of each calendar year certifying that **no** pharmacists **working at the pharmacy have** dispensed any controlled substances listed in that section during the previous 12 months and does not intend to dispense the controlled substances listed in that section.

Current Regulation reads:

12 AAC 52.870 WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY DISPENSER

Amended Regulation would read:

12 AAC 52.870 WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST, PRACTITIONER OR AUTHORIZED DELEGATE

(a) The department shall waive the electronic submission requirements of 12 AAC 52.865(b) for good cause. The[DISPENSER]**pharmacist, practitioner or authorized delegate** requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purpose of this section a[DISPENSER]**pharmacist, practitioner or authorized delegate** must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the [DISPENSER] **pharmacist, practitioner or authorized delegate** prevents the [DISPENSER] **pharmacist, practitioner or authorized delegate** from complying with 12 AAC 52.865(b);

(2) the [DISPENSER] **pharmacist, practitioner or authorized delegate** 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) REPEAL [THE DISPENSER WILL DISPENSE NINE OR FEWER PRESCRIPTIONS OF CONTROLLED SUBSTANCES A MONTH.]

(4) The [DISPENSER] **pharmacist, practitioner or authorized delegate's** business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(b); or

(5) the [DISPENSER] **pharmacist, practitioner or authorized delegate** will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(b).

(c) The department may not grant a waiver under this section unless the [DISPENSER] **pharmacist, practitioner or authorized delegate** first agrees in writing that, if the waiver is granted, the [DISPENSER] ***pharmacist, practitioner or authorized delegate*** will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board using

(1) the pharmacy universal claims form of the National Council for Prescription Drug Programs; or

(2) an alternative form approved by the board as providing substantially the same information as the form described in (1) of this subsection.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) Amended to add new subsection:

A [DISPENSER] ***pharmacist, practitioner or authorized delegate*** shall inform the board within 30 days if the basis for the waiver of electronic reporting no longer exits.

Current Regulation reads:

12 AAC 52.880. REPORTS

(a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.865(b) or 12 AAC 52.875. The register includes the following:

(1) he date on which the request was received;

(2) the name of the patient and the patient's date of birth;

(3) the name, title, business, and address of the individuals requesting profile and, if the individual is a practitioner, the practitioner's current federal Drug Enforcement Administration registration number;

(4) the date of which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may be only accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52. 855 – 12 AAC 52.890.

Amended to add new subsection:

(c) New subsection:

The board is authorized to provide unsolicited notification to a pharmacist or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with frequency inconsistent with generally recognized standards of safe practice.

Current Regulation reads:
12 AAC 52.890 TERMINATION OF ACCESS; GROUNDS FOR DISCIPLINE

Amended Regulation would read:
12 AAC 52. 890[TERMINATION OF ACCESS;] **GROUNDS FOR DISCIPLINE** [A VIOLATION OF] **Failure to comply with** 12 AAC 52.855- 12 AAC 52.890 [MAY BE GROUNDS FOR SUSPENSION, REVOCATION, OR RESTRICTION OF THE PRACTITIONER'S OR PHARMACIST'S AUTHORIZATION TO ACCESS THE CONTROLLED SUBSTANCE PRESCRIPTION DATATBASE AND FOR DISCIPLINE OF THE PRACTITIONER OR PHARMACIST] **constitutes unprofessional conduct** and **is the basis for** the imposition of **disciplinary sanctions under AS 08.01.075** [PENALITES UNDER AS 08.80] and 17.30.200.

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

RESOLVED to submit draft of AKPDMP regulation changes due to SB74 for regulations 12 AAC 52.855-12 AAC 52.890 reviewed on March 3, 2017 as a regulation project in preparation for being sent out for public comment.

Agenda Item 2 – Public Comment –

Chair Holm called from public comment a 1:21 p.m. There were no callers for public comment.

The Board reviewed the other two groups of regulations, Compounding and Pharmacy Technicians that the Board has on the agenda and are in need of review, discussion, and updating.

Chair Holm discussed with the Board dividing and conquering the next group of regulations. Chair Holm will work with Mr. Henderson on compounding regulations and Mr. Holt will work with Mr. Sanders on pharmacy technician regulations. The goal to these pairings is to assist in research and drafting changes as deemed necessary.

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

RESOLVED to adjourn the meeting.

The board adjourned at 1:34 p.m.

Respectfully Submitted:

Donna Bellino

Donna Bellino
Licensing Examiner

Approved:

Leif Holm, PharmD., Chair
Date: 5/4/17