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

# BOARD OF PHARMACY
# MINUTES OF THE TELECONFERENCE
# July 25, 2017

**By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled teleconference of the Board of Pharmacy was held at the State Office Building, 333 Willoughby Avenue, Tuesday July 25, 2017 beginning at 1:30 p.m. The meeting was held in the Conference Room A, 9th Floor Juneau, Alaska.**

## Agenda Item 1 Call to Order/Roll Call

The meeting was called to order by Chair, Leif Holm at 1:31 pm

Board Members present, constituting a quorum:

Anne Gruening, Public Member – Juneau
Phil Sanders, RPh – Soldotna
James Henderson, RPh – Soldotna
Rich Holt, Pharm.D, Vice-Chair – Wasilla
Leif Holm, Pharm.D, -North Pole

Not in attendance:

Anne Gruening, Public Member - Juneau

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

Donna Bellino, Licensing Examiner
Brian Howes, Investigator – Telephonically

## Agenda Item 2 Review Agenda

The Board reviewed the teleconference agenda for July 25th 2017.

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

**RESOLVED to accept the agenda as written.**

**Agenda Item 3 Ethics**

The Board had no ethics disclosures to report.

**Agenda Item 4 Review of SB74 Regulation Edits From DOL:**

The Board reviewed and discussed the edits received from Department of Law regarding changes to PDMP regulations submitted from the Board that resulted in changes to the following regulations:

**12 AAC 52.855 Registration with the controlled substance prescription database**
**12 AAC 52.860 Access to and conditions for use of the database**
**12 AAC 52.865 Requirements for pharmacists and practitioners**
**12 AAC 52.870 Waiver of electronic submission requirements by pharmacist or practitioner**
**12 AAC 52.875 Solicited requests for information from non-registered persons**
**12 AAC 52.880 Reports**
**12 AAC 52.885 Purge database records**
**12 AAC 52.890 Termination of access: grounds for discipline**

Lana Bell, RPh joined the teleconference at 1:45 pm

The Board had questions and needed to clarify some information from Investigator Howes. The Board called Investigator Howes who joined the teleconference discussion telephonically at 2:33 pm.

Investigator Howes completed his participation in the teleconference at 3: 26 pm.

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

**RESOLVED to approve the following regulation revisions for submission to Regulation Specialist in preparation for public comment:**

**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 52.855 is repealed and readopted to read:

**12 AAC 52.855. Registration with the controlled substance prescription database.**

(a) The following shall register with the controlled substance prescription database

(1) a pharmacist, before dispensing a schedule II, III, or IV controlled substance under federal law; or

(2) a practitioner, before prescribing, administering, or directly dispensing a schedule II, III, or IV controlled substance under federal law.

(b) An individual required to register with the controlled substance prescription database shall

(1) submit a completed application on a form prescribed by the board; and

(2) pay the fee set out in 2 AAC 02.310.

(c) The department shall issue an individual registered under this section a user account, login name, and password. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.860 is repealed and readopted to read:

**12 AAC 52.860. Access to and conditions for use of the database.**

(a) The following shall have access to the controlled substance prescription database as specified

(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; if delegating to an agent or employee

(i) the agent or employee must be licensed or registered under AS 08;

(ii) the practitioner must identify the agent or employee by name and license number; and

(iii) the practitioner is responsible for maintaining and terminating the agent or employee's access to the database.

(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; if delegating to an agent or employee

(i) the agent or employee must be licensed or registered under AS 08;

(ii) the pharmacist must identify the agent or employee by name and license number; and

(iii) the pharmacist is responsible for maintaining and terminating the agent or employee's access to the database.

(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.

(b) An individual permitted to receive information from the controlled substance prescription database under this section may not share user account information, login names, or passwords with any person, regardless of whether that person is also an authorized user of the controlled substance prescription database except as specified above;

(c) The database and information obtained from the controlled substance prescription database

(1) are confidential;

(2) are not public records;

(3) are not subject to public disclosure;

(4) may not be shared with the federal government; and

(5) shall be kept confidential in accordance with the confidentiality requirements of P.L. 104-191 (Health Insurance Portability and Accountability Act of 1996 (HIPAA)), 42 C.F.R. Part 2, and 45 C.F.R. Parts 160, 162, and 164. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865 is repealed and readopted to read:

**12 AAC 52.865. Requirements for pharmacists and practitioners.**

(a) The information required under AS 17.30.200(b) must be submitted by

(1) a pharmacist-in-charge of a licensed or registered pharmacy;

(2) a pharmacist, if the pharmacist-in-charge is not present; and

(3) a practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law.

(b) At least weekly, an individual required to submit information under AS 17.30.200(b) shall report to the Alaska Prescription Drug Monitoring Program (AKPDMP) the controlled substance dispensing information concerning controlled substances dispensed since the previous submission date. The requirement in 12 AAC 02.920(b) for time computation applies to a submission of information under this section.

(c) If notified by the board or the department of an error in transmitting the information required under AS 17.30.200(b), the individual shall correct the error no later than 10 days after the date of the notification.

(d) Except as provided under 12 AAC 52.870, an individual shall submit the information required under AS 17.30.200(b) to the AKPDMP through the use of the website provided for that purpose by the board.

(e) Except pharmacists, before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to a patient, a practitioner shall review the information in the database to check a patient's prescription records.

(f) The requirement to review information in the database under subsection (e) does not apply to a practitioner before dispensing, prescribing, or administering

(1) a controlled substance to a person who is receiving treatment

(A) in an inpatient setting;

(B) at the scene of an emergency or in an ambulance; in this sub-paragraph, "ambulance" has the meaning given in AS 18.08.200;

(C) in an emergency room;

(D) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(E) in a hospice or nursing home that has an in-house pharmacy; or

(2) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870 is amended to read:

**12 AAC 52.870. Waiver of electronic submission requirement by pharmacist or practitioner [DISPENSER].** (a) The department shall waive the electronic submission requirements of 12 AAC 52.865**(e)** [(B)] for good cause. The **pharmacist or practitioner** [DISPENSER] 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** [DISPENSER] must submit an application and sworn statement showing that

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

(2) the **pharmacist or practitioner** [DISPENSER] 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) **repealed ___/___/____** [THE DISPENSER WILL DISPENSE NINE OR FEWER PRESCRIPTIONS OF CONTROLLED SUBSTANCES A MONTH];

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

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

(c) The department may not grant a waiver under this section unless the **pharmacist or practitioner** [DISPENSER] first agrees in writing that, if the waiver is granted, the **pharmacist or practitioner** [DISPENSER] 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 weekly basis** 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.

(d) A request for a waiver under this section must be in writing using an application form prescribed 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** [DISPENSER] 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** [DISPENSER] shall inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

Article 9 is amended by adding a new section to read:

**12 AAC 52.885. Purge database records.** The patients name, street name and number, patient identification number, month and day of birth, and prescriber and dispenser information shall be purged from the database after two years have elapsed from the date the prescription was dispensed. The board may provide information to public or private entities that has not been purged for statistical research or educational purposes. The board will receive yearly certification from the software vendor that the database has been purged. (Eff. ___/___/____, Register ____).

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880 is amended to read:

**12 AAC 52.880. Reports** (a) The board will maintain a register for patient profile requests solicited under [12 AAC 52.855(B) or] 12 AAC 52.875. The register includes the following information:

…

(Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890 is amended to read:

**12 AAC 52.890. Termination of access; grounds for discipline** A violation of 12 AAC 52.855 - 12 AAC 52.890 **constitutes** [MAY BE] grounds for suspension, revocation, or restriction of the practitioner's or pharmacist's authorization to access the controlled substance prescription database and for **disciplinary sanctions** [DISCIPLINE OF THE PRACTITIONER OR PHARMACIST] and the imposition of penalties under **AS 08.01.075,** AS 08.80, and AS 17.30.200. (Eff. 12/29/2011, Register 200; am ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 17.30.200

**12 AAC 52.920 Disciplinary Guidelines** is amended by adding a new section to read:

(22) violating AS 17.30.200 or a regulation adopted thereunder dealing with the AKPDMP;

(Eff. 1/16/98, Register 145; am ___/___/____, Register ____)

**Authority:** AS 08.01.075 AS 08.80.005 AS 08.80.030
AS 08.80.261 AS 08.80.315 AS 08.80.460
AS 17.30.200

**12 AAC 52.995 Definitions is amended** by adding a new section to read:

(36) "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 to

otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in the state.

(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 ___/___/____, Register ____)

**Authority:** AS 08.80.005 AS 08.80.030 AS 08.80.157
AS 11.71.900 **AS 17.30.200**

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

**RESOLVED to adjourn the teleconference meeting.**

Off the record at 4:32 pm

Respectfully submitted:

Donna Bellino
Licensing Examiner

Approved:

Leif Holm, PharmD., Chair

Date: 12/18/17