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OFFICE OF THE LIEUTENANT GOVERNOR
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MEMORANDUM

TO: Jun Maiquis
Department of Commerce, Community & Economic Development

FROM: Scott Meriwether, Office of the Lieutenant Governor
465.4081

DATE: May 9, 2018

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy regulations re: prescription drug monitoring program (PDMP) controlled substance prescription database (12 AAC 52.855 - 12 AAC 52.890; 12 AAC 52.920(a)(22); 12 AAC 52.995)

Attorney General File:	2018200042
Regulation Filed:	5/8/2018
Effective Date:	6/7/2018
Print:	226, July 2018

cc with enclosures: Linda Miller, Department of Law
Judy Herndon, LexisNexis

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached eight pages of regulations, dealing with prescription drug monitoring program (PDMP) controlled substance prescription database, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its February 28 – March 1–2, 2018 meeting, under the authority of AS 08.01.075, AS 08.80.005, AS 08.80.030, AS 08.80.157, AS 08.80.261, AS 08.80.315, AS 08.80.460, AS 11.71.900, and AS 17.30.200 and after compliance with the Administrative Procedure Act (AS 44.62), specifically including notice under AS 44.62.190 and 44.62.200 and opportunity for public comment under AS 44.62.210.

This action is not expected to require an increased appropriation.

On the record, in considering public comments, the Board of Pharmacy paid special attention to the cost to private persons of the regulatory action being taken.

The regulation changes described in this order take effect on the 30th day after they have been filed by the lieutenant governor, as provided in AS 44.62.180.

DATE: 03/02/2018
Juneau, Alaska

Leif Holm, PharmD., Chair
Board of Pharmacy

FILING CERTIFICATION

I, Byron Mallott, Lieutenant Governor for the State of Alaska, certify that on May 8, 2018 at 8304 .m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

Byron Mallott, Lieutenant Governor

Effective: June 7, 2018.

Register: 226, July 2018.

Chapter 52. Board of Pharmacy.

12 AAC 52.855 is repealed and readopted to read:

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. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226)

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 prescription drug monitoring program database. (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes ~~of~~ 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 ~~this~~ 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 ~~the~~ this state ~~of~~ ~~Alaska~~ who is assigned to a board or agency that requires ~~licensees~~ a practioner to register with the PDMP ~~or an agency~~ ~~identified in a search warrant, subpoena, or order issued by an administrative law judge or a court.~~

(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 ~~state~~ 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~~ 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 ~~the DHSS~~ commissioner or commissioner's official designee has requested access in writing to the board before ~~prior to~~ the release of information. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226)

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. Reporting and reviewing PDMP information. (a) Unless excused from reporting under AS 17.30.200(u), information required under AS 17.30.200(b) ~~must be submitted by a pharmacist,~~ a pharmacist must submit 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 ~~Alaska Prescription Drug Monitoring Program~~ (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)(8), "other appropriate identifier" and "other appropriate identifying information" means the state-issued license number of the prescribing practitioner and the dispensing pharmacist or practitioner.

(e) ~~Within~~ Not later than 72 hours ~~of~~ 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. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226)

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(c)** [12 AAC 52.865(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(c)** [12 AAC 52.865(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'S] business is located in an area that lacks access to the telecommunication services needed to comply with

12 AAC 52.865(e) [12 AAC 52.865(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)** [12 AAC 52.865(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 daily basis** using **a form approved by the board**

[(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 **provided** [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 must** [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 6/7/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

The introductory language of 12 AAC 52.880(a) is amended to read:

(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:

. . .

12 AAC 52.880(a)(3) is amended to read:

(3) the name, title, [BUSINESS,] and address of the individual requesting the profile [AND, IF THE INDIVIDUAL IS A PRACTITIONER, THE PRACTITIONER'S CURRENT FEDERAL DRUG ENFORCEMENT ADMINISTRATION REGISTRATION NUMBER];

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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

12 AAC 52.885. Purge 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. (Eff. 6/7/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890 is repealed and readopted to read:

12 AAC 52.890. Grounds for discipline. A violation of 12 AAC 52.855 – 12 AAC ~~52.890~~ 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 ~~52.890~~ 52.885 by a practitioner not licensed by this board shall be reported to the practitioner's licensing board. (Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226)

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.920(a) is amended by adding a new paragraph to read:

(22) violating AS 17.30.200 or a regulation adopted ~~thereunder~~ under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.

(Eff. 1/16/98, Register 145; am 6/7/2018, Register 226)

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 52.995 is amended by adding a new subsection to read:

(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. (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)

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

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

(36) "PDMP" means the prescription drug monitoring program's controlled substance prescription database.