Kevin Meyer Lieutenant Governor State Capitol Juneau, Alaska 99811 907.465.3520 WWW.LTGOV.ALASKA.GOV



530 West 7th Ave, Suite 1700 Anchorage, Alaska 99501 907.269.7460 LT.GOVERNOR@ALASKA.GOV

OFFICE OF THE LIEUTENANT GOVERNOR ALASKA

MEMORANDUM

- **TO:**Glenn HoskinsonDepartment of Commerce, Community, and Economic Development
- FROM: April Simpson, Office of the Lieutenant Governor 465.4081
- **DATE:** February 15, 2022
- RE: Filed Permanent Regulations: Board of Pharmacy

Department of Commerce, Community, and Economic Development; Board of Pharmacy regulations re: PDMP database registration, renewal, and dispensing status notice requirements (12 AAC 52)

Attorney General File:	2021200355
Regulation Filed:	2/15/2022
Effective Date:	3/17/2022
Print:	241, April 2022

cc with enclosures:

Joseph Felkl, Department of Law Judy Herndon, LexisNexis Jun Maiquis, Regulations Specialist

ORDER CERTIFYING THE CHANGES TO **REGULATIONS OF THE BOARD OF PHARMACY**

The attached three pages of regulations, dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its November 18, 2021 teleconference meeting, under the authority of AS 08.80.005, AS 08.80.030, 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:

Digitally signed by Laura Laura Carrillo Date: 2021,12.07 Laura Carrillo, Executive Administrator Alaska Board of Pharmacy

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that , 2027 at 2:57 Rm., I on February 15 filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

in Meyer, Lieutenant Governor

Effective: Register: 24

Register 241, April 2022 PROFESSIONAL REGULATIONS

Chapter 52. Board of Pharmacy.

12 AAC 52.855(c) is amended to read:

(c) Except as provided in (a) of this section, 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 by providing [WEBSITE; AND]



(2) pay the fee established in 12 AAC 02.107.

12 AAC 52.855(d) is amended to read:

(d) After completing the registration requirements, a pharmacist or practitioner required PDMP designation (Los 102) to register with the PDMP will be issued a registration number [USER ACCOUNT, LOGIN NAME, AND PASSWORD BY THE DEPARTMENT].

12 AAC 52.855(e) is amended to read:

(e) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the <u>credentials identified in (c)(1)(A) and (B) of this section</u> [USER ACCOUNT, LOGIN NAME, AND PASSWORD ISSUED BY THE DEPARTMENT].

DOL File#202120

1

Register 241, April 2022 PROFESSIONAL REGULATIONS

(Eff. 12/29/2011, Register 200; am 6/7/2018, Register 226; am 5/6/2021, Register 238; am

3 / 17 / Zozz, Register 241)

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 52.856. PDMP registration renewal. (a) A PDMP registration will expire on the same date as the pharmacist's or practitioner's corresponding professional license. (b) To renew a PDMP registration, a licensee required to register must submit the fee established in 12 AAC 02.107 on or before the expiration date. (Eff. 3 / 17 / 2022, Register 241)

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 52.857. Change in dispensing or distributing of controlled substances. (a) A pharmacist registered with the PDMP under 12 AAC 52.855 must notify the board on a form

provided by the department when the pharmacist no longer dispenses controlled substances in

this state within 10 days of the change in dispensing status.

(b) A pharmacist who is not required to register with the PDMP and who has met the

requirements in 12 AAC 52.855(b) must comply with the requirements in 12 AAC 52.855(c)

within 10 days of any change in practice that requires the pharmacist to register with the PDMP.

(c) A pharmacy required to report to the PDMP that no longer dispenses or distributes

controlled substances in or to this state must notify the board on a form provided by the

department within 10 days of the change in dispensing or distributing status.

(d) A pharmacy that obtains a DEA registration after its license or registration is initially

DOL File#202120035

Register 241, April 2022 PROFESSIONAL REGULATIONS granted by the board must notify the board on a form provided by the department within 10 days of its intent to dispense or distribute controlled substances (Eff. 3 /17 /2022, Register

241)

AS 08.80.005 Authority:

AS 08.80.030

AS 17.30.200



MEMORANDUM

- To: The Honorable Kevin Meyer Lieutenant Governor
- From: Rebecca C. Polizzotto Chief Assistant Attorney General and Regulations Attorney Legislation, Regulations, and Legislative Research Section

State of Alaska Department of Law

Date: February 7, 2022
File No.: 2021200355
Tel. No.: 907-465-3600
Re: Department of Commerce, Community, and Economic Development; Board of Pharmacy:

amendment to 12 AAC 52; PDMP database registration, renewal, and dispensing status notice requirements

The Department of Law has reviewed the attached regulations of the Department of Commerce, Community, and Economic Development against the statutory standards of the Administrative Procedure Act. Based upon our review, we find no legal problems. This memorandum constitutes the written statement of approval under AS 44.62.060(b) and (c) that authorizes your office to file the attached regulations.

The Board of Pharmacy adopted the regulations after the close of the public comment period on December 7, 2021. The regulations amend 12 AAC 52 to update requirements concerning Alaska's prescription drug monitoring program (PDMP), as they relate to registration and renewal. Additionally, these regulations add a new section to 12 AAC 52 requiring that a pharmacist or pharmacy that has a change in PDMP status prohibiting that pharmacist or pharmacy from dispensing controlled substances be required to report that change in status to the department.

A number of technical edits are suggested to these regulations in order to clarify and keep consistent the language throughout 12 AAC 52 and to comport with the standards of the Drafting Manual for Administrative Regulations. None of these edits are substantive in nature.

The August 15, 2021 public notice states that this action is not expected to require an increased appropriation. Therefore, a fiscal note under AS 44.62.195 is not required.

RCP:bws

Honorable Kevin Meyer, Lieutenant Governor File No. 2021200355 February 7, 2022 Page 2 of 2

cc w/ enclosures:Jun Maiquis, Regulations ContactDivision of Corporations, Business, and Professional Licensing
Department of Commerce, Community & Economic Development

Harriet Milks, Senior Assistant Attorney General Department of Law

NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF THE ALASKA BOARD OF PHARMACY

BRIEF DESCRIPTION: The Board of Pharmacy proposes to update regulations relating to registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, and to establish PDMP registration renewal and change in dispensing or distributing of controlled substances.

The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

- 1. 12 AAC 52.855. Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, is proposed to amend the registration process with the PDMP.
- 2. 12 AAC 52.856. PDMP registration renewal, is a proposed new section that establishes PDMP biennial registration renewal requirements.
- 3. 12 AAC 52.857. Change in dispensing or distributing of controlled substances, is a proposed new section that establishes requirements for pharmacists who no longer dispenses or distributes controlled substances in Alaska to notify the board of the change in practice.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 465-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska.gov/203411, and using the comment link. The comments must be received not later than 4:30 p.m. on September 16, 2021. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806 or by e-mail at RegulationsAndPublicComment@alaska.gov. The questions must be received at least 10 days before the end of the public comment period. The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov not later than September 9, 2021 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/PHA-0821.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected. Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.80.005; AS 08.80.030; AS 17.30.200 **Statutes Being Implemented, Interpreted, or Made Specific:** AS 08.80.005; AS 08.80.030; AS 17.30.200

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 8/13/21

Jun Majquis, Regulations Specialist

Jun Maiquis, Regulations Specialist Division of Corporations, Business and Professional Licensing

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving notices), and the occupational area in which you are interested.

ADDITIONAL REGULATION NOTICE INFORMATION (AS 44.62.190(d))

- 1. Adopting agency: Board of Pharmacy Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing.
- 2. General subject of regulation: Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances.
- 3. Citation of regulation: 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857.
- 4. Department of Law file number: To be assigned.
- 5. Reason for the proposed action: Update and clarification of current regulations; compliance with state statute.
- 6. Appropriation/Allocation: Corporations, Business and Professional Licensing #2360.
- Estimated annual cost to comply with the proposed action to: A private person: \$25 PDMP biennial registration renewal fee. Another state agency: None known. A municipality: None known.
- 8. Cost of implementation to the state agency and available funding (in thousands of dollars): No costs are expected in FY 2022 or in subsequent years.
- The name of the contact person for the regulation: Laura Carrillo, Executive Administrator Alaska Board of Pharmacy Division of Corporations, Business and Professional Licensing Department of Commerce, Community, and Economic Development Telephone: (907) 465-1073 E-mail: laura.carrillo@alaska.gov
- 10. The origin of the proposed action: Board of Pharmacy.

8/13/21 11. Date:

Prepared by:

Jun Maiquis Regulations Specialist

AFFIDAVIT OF NOTICE OF PROPOSED REGULATION AND FURNISHING OF ADDITIONAL INFORMATION

I, Jun Maiquis, Regulations Specialist, of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being sworn, state the following:

As required by AS 44.62.190, notice of the proposed adoption of changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857, dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances, has been given by being

- 1. published in a newspaper or trade publication;
- 2. furnished to every person who has filed a request for notice of proposed action with the state agency;
- 3. furnished to appropriate state officials;
- 4. furnished to interested persons;
- 5. furnished to the Department of Law, along with a copy of the proposed regulation;
- 6. furnished electronically to incumbent State of Alaska legislators;
- 7. posted on the Alaska Online Public Notice System as required by AS 44.62.175(a)(1) and (b) and 44.62.190(a)(1).

As required by AS 44.62.190, additional regulation notice information regarding the proposed adoption of the regulation changes described above has been furnished to interested persons and those in (2), (4), and (6) of the list above. The additional regulation notice information also has been posted on the Alaska Online Public Notice System.

DATE: 12

Jun Maiquis, Regulations Specialist

day of T

SUBSCRIBED AND SWORN TO before me this _9

mber____, 2021.

Notary Public in and for the State of Alaska My commission expires:



AFFIDAVIT OF AGENCY RECORD OF PUBLIC COMMENT

I, Jun Maiquis, Regulations Specialist for the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, being duly sworn, state the following:

In compliance with AS 44.62.215, the Board of Pharmacy has kept a record of its use or rejection of factual or other substantive information that was submitted in writing as public comment and that was relevant to the accuracy, coverage, or other aspect of the Board of Pharmacy regulations on dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances.

DATE: _12/9/21

Jun Maiquis, Regulations Specialist

SUBSCRIBED AND SWORN TO before me this _ day of _ December___, 2021.



Notary Public in and for the State of Alaska My commission expires: w office

ANCHORAGE DAILY NEWS AFFIDAVIT OF PUBLICATION

Account #: 105545 ST OF AK/DEC/OCCU Attention To: ATTN TO: JUN MAIQUIS PO BOX 110806, JUNEAU, AK 99811

Order #: W0024503

Cost: \$478.12

Division of Corporations, Busines

Juneau

AUG 2 3 2021

STATE OF ALASKA THIRD JUDICIAL DISTRICT

Adam Garrigus being first duly sworn on oath deposes and says that she is a representative of the Anchorage Daily News, a daily newspaper. That said newspaper has been approved by the Third Judicial Court, Anchorage, Alaska, and it now and has been published in the English language continually as a daily newspaper in Anchorage, Alaska, and it is now and during all said time was printed in an office maintained at the aforesaid place of publication of said newspaper. That the annexed is a copy of an advertisement as it was published in regular issues (and not in supplemental form) of said newspaper on

08/15/2021

and that such newspaper was regularly distributed to its subscribers during all of said period. That the full amount of the fee charged for the foregoing publication is not in excess of the rate

charged private individuals. us Signed

Subscribed and sworn to before me this 16th day of August 2021.

Notary Public in and for

The State of Alaska. Third Division Anchorage, Alaska

MY COMMISSION EXPIRES 4/2024

NOTICE OF PROPOSED CHANGES IN THE REGULATIONS OF THE ALASKA BOARD OF PHARMACY The Board of Pharmacy (Board) proposes to adopt regulation changes in Title 12, Chapter 52 of the Alaska Administrative Code including the following:

1. 12 AAC 52.855. Registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, is proposed to amend the registration process with the PDMP.

PDMP. 2. 12 AAC 52.856. PDMP registration renewal, is a proposed new section that establishes PDMP biennial registration renewal requirements.

new section that establishes PDMP biennial registration renewal requirements. 3. 12 AAC 52.857. Change in dispensing or distributing of controlled substances, is a proposed new section that establishes requirements for pharmacists who no longer dispenses or distributes controlled substances in Alaska to notify the board of the change in practice.

You may comment on the proposed regulation changes, including the potential costs to private persons of complying with the proposed changes, by submitting written comments to Jun Malquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 99811-0806. Additionally, the Board will accept comments by facsimile at (907) 455-2974 and by electronic mail at RegulationsAndPublicComment@alaska.gov. Comments may also be submitted through the Alaska Online Public Notice System by accessing this notice on the system at http://notice.alaska. gov/203411, and using the comment link. The comments must be received not later than 4:30 p.m. on September 16, 2021. Comments received after this deadline will not be considered by the Board.

You may submit written questions relevant to the proposed action to Jun Maiquis, Regulations Specialist, Division of Corporations, Business and Professional Licensing, P.O. Box 110806, Juneau, AK 9981-10806 or by e-mail at RegulationsAndPublicComment@ alaska.gov, The questions must be received at least 10 days before the end of the public comment period. The Board will aggregate its response to substantially similar questions and make the questions and responses available on the Alaska Online Public Notice System and on the Board's website at https://www.commerce.alaska. gov/web/cbpl/ProfessionalLicensing/BoardofPharmacy.aspx. The Board may, but is not required to, answer written questions received after the 10-day cut-off date and before the end of the comment period.

If you are a person with a disability who needs a special accommodation in order to participate in this process, please contact Jun Maiquis at (907) 465-2537 or RegulationsAndPublicComment® alaska.gov not later than September 9, 2021 to ensure that any necessary accommodation can be provided.

A copy of the proposed regulation changes is available on the Alaska Online Public Notice System and by contacting Jun Malquis at (907) 465-2537 or RegulationsAndPublicComment@alaska.gov, or go to https://www.commerce.alaska.gov/web/portals/5/pub/ PHA-0821.pdf.

After the public comment period ends, the Board will either adopt the proposed regulation changes or other provisions dealing with the same subject, without further notice, or decide to take no action. The language of the final regulation may be different from that of the proposed regulation. You should comment during the time allowed if your interests could be affected. Written comments and questions received are public records and are subject to public inspection.

Statutory Authority: AS 08.80.005; AS 08.80.030; AS 17.30.200 Statutes Being Implemented, Interpreted, or Made Specific: AS 08.80.005; AS 08.80.030; AS 17.30.200

Fiscal Information: The proposed regulation changes are not expected to require an increased appropriation.

DATE: 8/13/2021 /s/ Jun Maiquis, Regulations Specialist Division of Corporations, Business and Professional Licensing

JADA L. NOWLING STATE OF ALASKA MY COMMISSION EXPIRES JULY 14, 2024

For each occupation regulated under the Division of Corporations, Business and Professional Licensing, the Division keeps a list of individuals or organizations who are interested in the regulations of that occupation. The Division automatically sends a Notice of Proposed Regulations to the parties on the appropriate list each time there is a proposed change in an occupation's regulations in Title 12 of the Alaska Administrative Code. If you would like your address added to or removed from such a list, send your request to the Division at the address above, giving your name, either your e-mail address or mailing address (as you prefer for receiving hotices), and the occupational area in which you are interested.

AFFIDAVIT OF BOARD ACTION

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, being duly sworn, state the following:

The attached motion dealing with registration with the prescription drug monitoring program (PDMP) controlled substance prescription database, PDMP registration renewal, and change in dispensing or distributing of controlled substances was passed by the Board of Pharmacy during its November 18, 2021 teleconference meeting.

Laura Carrillo Digitally signed by Laura Carrillo Date: 2021.12.07 14:54:21 -09'00'

Date: _____

Laura Carrillo, Executive Administrator

Excerpt from the Draft Minutes of the November 18, 2021 Teleconference Meeting of the Alaska Board of Pharmacy

The board reviewed the proposed changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 as publicly noticed and included in the board packet.

On a motion duly made by James Henderson to adopt the changes to 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857 as proposed and publicly noticed, seconded by Tammy Lindemuth, and approved unanimously, it was:

	APPROVE	DENY	ABSTAIN	ABSENT
Justin Ruffridge	Х			
Lana Bell	Х			
Tammy Lindemuth	Х			
James Henderson	X			
Ashley Schaber	х			
Leif Holm				X
Sharon Long	X			

RESOLVED to adopt 12 AAC 52.855, 12 AAC 52.856, and 12 AAC 52.857.

The motion passed with no further discussion.