

August 28, 2020 - Alaska Board of Pharmacy Meeting - Day 2

Aug 28, 2020 9:00 AM - Aug 28, 2020 4:30 PM AKDT

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STATE OF ALASKA

**Department of Commerce, Community, and Economic Development
Professional Licensing**

ALASKA BOARD OF PHARMACY



August 27 - 28, 2020

Teleconference/Videoconference

Board Packet

PUBLIC PACKET



ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

AUGUST 28, 2020 – DAY 2

Call-in Number: 1-253-215-8782
Pin: 96325810118#, Code: 730209

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*
(Vice Chair)

James Henderson,
RPh

Lana Bell, *RPh*
(Secretary)

Justin Ruffridge,
(PharmD)

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

Staff:

Laura Carrillo,
Executive
Administrator

Lisa Sherrell, *PDMP*
Program
Coordinator

Heather Noe,
Occupational
Licensing Examiner

Upcoming Zoom Meetings:

November 5 – 6.

Meeting Details

Meeting Name: August 28, 2020 - Alaska Board of Pharmacy Meeting - Day 2

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 08/28/2020

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 08/28/2020

Meeting Location: Videoconference via Zoom

Meeting Registration Link: <https://zoom.us/meeting/register/tJludEYgrzsrG9ym9m-XMMfwDtv7eG4V0Ehb>

Agenda

- I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Holt)
- II. Agenda Item #2 – 9:05 a.m. Review/Approve Agenda (Chair Holt)
- III. Agenda Item #3 – 9:10 a.m. Ethics Disclosures (Chair Holt)
- IV. Agenda Item #4 – 9:15 a.m. Legal Opinion Reviews (Laura Carrillo)
 - A. PDMP MOUs (*July 31, 2020*)
 - B. PDMP multiple accounts (*pending*)
 - C. PDMP timeframe to register (*July 29, 2020*)
 - D. Zero reporting to PDMP (*May 20, 2020*)

Board Members:

Richard Holt,
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Sharon Long, *Public*
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Occupational
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Meetings:

November 5 – 6

E. Remote order entry (*pending*)

F. Extending CE and inspection report due dates (*July 1, 2020*)

G. Automated drug kiosk (*pending*)

V. Agenda Item #5 – 9:30 a.m. Regulations (Chair Holt)

A. Regulations workflow

B. Emergency regulations to permanent recap (*eff. August 30, 2020*)

C. PDMP regulations

D. Other regulations

VI. Agenda Item #6 – 12:00 p.m. Lunch

VII. Agenda Item #7 – 1:00 p.m. Return to Regulations (Chair Holt)

VIII. Agenda Item #8 – 2:30 p.m. Potential Statute Changes (Chair Holt)

IX. Agenda Item #9 – 4:30 p.m. Adjourn

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
 - Administrative Services Division
 - Division of Program Development
 - Information Systems and Services Division
 - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.



Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.



Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than \$150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than \$150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.



The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.



Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.



Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.



Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.



Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*



John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.



The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation. A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.



Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.



The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.



Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.* If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to \$5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our [Executive Branch Ethics web site](#) or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the [2019 Designated Ethics Supervisors Handbook](#) (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
 1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the [Department of Law ethics web site](#). If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
 1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

From: [Carrillo, Laura N \(CED\)](#)
To: [Sherrell, Lisa D \(CED\)](#); [Walsh, Sharon J \(CED\)](#)
Subject: FW: Request for assistance with PDMP/PHA Board statutes
Date: Wednesday, May 20, 2020 4:47:00 PM

Hello,

Here is Megyn's response regarding MOU access. She clarifies that we indeed need to still check to make sure every provider working at a clinic, hospital, etc., is actively licensed, registered with the PDMP, and up to date on all their PDMP fees before approving an integration. Unless we get a statute change, we have to continue our current process, which means there is no room for expediting these requests. I will follow-up with our pending requestors on this.

I think it is time we address the medical director credential access in the MOU, but it will also need to be a regulation change.

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Weigand, Megyn A (LAW)
Sent: Wednesday, May 20, 2020 4:31 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: RE: Request for assistance with PDMP/PHA Board statutes

Hi Laura,
Please see my responses in red below. Thanks!

Megyn Weigand
Assistant Attorney General

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Friday, May 15, 2020 4:34 PM
To: Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>
Subject: RE: Request for assistance with PDMP/PHA Board statutes

Hi Megyn,

Thanks for reviewing! It would be our PDMP system integrating into their EHR system rather than non-state HER systems being placed into the PDMP. This integration allows providers who are already accessing their clinic system to click on a PDMP tab to query prescription history instead of opening a separate browser and logging in.

If I'm understanding you correctly, we should not be integrating with other systems since it is not in statute? **Probably not, I suspect the MOUs require the party to keep the information from the database confidential, not allow access by someone who is not registered, and not share it, etc.?** I looked back at the first integration we approved, which was back in 2016 for a pain clinic in Wasilla. I don't know what the exact screening and approval

process entailed at that time, but currently we do check to make sure all providers in the clinic have a professional license, are registered with the PDMP, and up to date on fees. We aren't notified of new employees or when employees leave though, but we do engage in ongoing monitoring of these issues separately as part of our licensing functions. Does this mean that all integrations we've approved have to now be revoked until a statute change can be made, and does this nullify our existing MOUs with the state health information exchange, healthConnect, and subcontractor for emergency department integrations, Collective Medical? **No. The MOU system is one step the board is taking "to ensure the security and confidentiality of the database and information contained within the database," under AS 17.30.200, checking the license and registration status of everyone in the clinic / hospital is another. But until there is a statutory amendment allowing information sharing outside the PDMP, or shifting the oversight responsibility from the Board, the Board can't remove those steps from the approval process. A detailed record of the administrative burden (cost, time, effect on care, etc.) tracking MOAs and registration creates will help the Board make their case to the legislature that an amendment is needed.**

To your questions: it depends; for integrations with clinics and hospitals who have connected through healthConnect, the board cannot readily see who looked at patient information because they query using their medical directors' credentials. The same is true for delegates. This is in our MOU and was an initial concern, but the collective thought was that an audit trail would give us the information we need to see who is performing those searches. The medical director access actually limits the effectiveness of a mandatory compliance module feature we purchased to help us track compliance, since it misidentifies providers as not having reviewed Rx history when perhaps they did via their director. **Does this need to be changed in the MOUs?** Re: HB242, removing the language to not share with the federal government was something we had discussed as making sense to repeal because we do already share information with the federal government when we get a subpoena, e.g.: from the DEA. The bill does propose to remove the purging language because in practice, we often have subpoenas requesting information earlier than two years, and DHSS cannot effectively monitor public health trends (AS 17.30.200(d)(10)) with just two years of data. I don't see anything in HB 89 that would affect integrations.

Please let me know if you have any other questions!

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Weigand, Megyn A (LAW)
Sent: Friday, May 15, 2020 3:48 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Fw: Request for assistance with PDMP/PHA Board statutes

Hi Laura and thanks!

Under AS 17.30.200(d) it is not just the PDMP database, but the information itself which the Board has an obligation to keep confidential. I don't fully understand what is meant by "integrations," so I'll set out a couple examples, and if I'm wrong about what integration means, please correct me. Is the data in a non-state entity's EHR going to be placed in the PDMP? If so, once in the PDMP, that data will not be available to anyone other than those listed in AS 17.30.200(d). And any prescription information imported into the PDMP must be purged after two years. Or, is information from the PDMP going to be populated in a non-

state entity's EHR? If so, the same rules apply - the entity must agree that only those defined in AS 17.30.200(d) can access the information, the information must be purged after 2 years, the federal government cannot access the PDMP information through the entity's EHR, etc.

AS 17.30.200 defines those who can access the information and excludes all others, so integration will not solve the approval process. Individuals employed at a clinic or hospital who review the PDMP information, even when that information is integrated into another system, must still be licensed and registered and up to date on PDMP fees.

Easing access to this information by allowing the information to be placed in another database (EHR) will require a statutory amendment.

I had a couple other questions: 1) If the PDMP information is integrated into another EHR system, will the Board be able to see which licensee accesses a patient's information? 2) Have you reviewed HB 242 and HB 89 which are currently pending in the legislature? If enacted, would either of these bills create additional barriers to the board's desire to streamline access?

Thanks,

Megyn

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Monday, May 11, 2020 11:17 AM
To: Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>
Subject: RE: More efficient PDMP - Gateway approval process - MOUs still needed?

Hi Megyn,

[REDACTED] We've been deliberating whether there is sufficient authority under AS 17.30.200 or AS 08.80 for the board to approve intrastate PDMP integrations with clinic or hospital electronic health record systems. Below, I provided an example from Arizona—they have statutory language regarding this, whereas we don't (or at least it's not apparent to me). We've been executing MOUs with the EHR vendors (I think because we don't have the authority?) but am wondering whether this is even needed. Our goal is to streamline the approval process, which currently takes months because we have to make sure the individuals employed at the clinic/hospital is properly licensed per AS 17.30.200(d)(3)(4) and are up-to-date on their PDMP registration fees (most of the time, there's issues there).

There's several EHR vendors out there, so having separate MOUs for each vendor is becoming time consuming and difficult to manage for us. Currently, Providence Hospital is wanting to integrate PDMP data with their system using vendor, Epic.

Thank you,

Laura Carrillo, MPH

Executive Administrator

Alaska Board of Pharmacy

Prescription Drug Monitoring Program

State of Alaska – DCCED – CBPL

Direct: 907-465-1073

PDMP: 907-269-8404

PDMP email: akpdmp@alaska.gov

Fax: 907-465-2974

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Friday, March 20, 2020 1:03 PM
To: Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>
Cc: Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: Re: More efficient PDMP - Gateway approval process - MOUs still needed?

Hi Sharon,

After looking at [Arizona's statutes](#), A.R.S. 36-2606, I'm concerned we would need to have explicit statutory authority for integrations, which may be why the previous chief said we had to do MOUs. Read subsections (F) and (I):

<https://www.azleg.gov/viewDocument/?docName=http://www.azleg.gov/ars/36/02606.htm>

F. Beginning the later of October 1, 2017 or sixty days after the statewide health information exchange has integrated the controlled substances prescription monitoring program data into the exchange, a medical practitioner, before prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III or IV for a patient, shall obtain a patient utilization report regarding the patient for the preceding twelve months from the controlled substances prescription monitoring program's central database tracking system at the beginning of each new course of treatment and at least quarterly while that prescription remains a part of the treatment. Each medical practitioner regulatory board shall notify the medical practitioners licensed by that board of the applicable date. A medical practitioner may be granted a one-year waiver from the requirement in this subsection due to technological limitations that are not reasonably within the control of the practitioner or other exceptional circumstances demonstrated by the practitioner, pursuant to a process established by rule by the Arizona state board of pharmacy...

I. If a medical practitioner or dispenser uses electronic medical records that integrate data from the controlled substances prescription monitoring program, a review of the electronic medical records with the integrated data shall be deemed compliant with the review of the program's central database tracking system as required in subsection F of this section.

Here's a document I found describing AZ's integration requests. Something I'm thinking we can model after. Do we need a legal opinion for clarifying whether explicit statutory authority, like in AZ, is required for interstate datasharing? We don't have this authority in the controlled substance act, AS 17.30.200. Language for the health information exchange is under DHSS - Chapter 166 (Health Information Exchange; AS 18.23.300 and 07 AAC 166.010-990.): <http://www.akleg.gov/basis/aac.asp#7.166.010>

Here's AZ's integration request link:

https://pharmacymp.az.gov/sites/default/files/PMP%20Gateway%20Integration_06252018.pdf

Thank you,

Laura Carrillo, MPH

Executive Administrator

Alaska Board of Pharmacy

State of Alaska – DCCED – CBPL

Direct: 907-465-1073

PDMP: 907-269-8404

PDMP email: akpdmp@alaska.gov

Fax: 907-465-2974

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>

Sent: Friday, March 20, 2020 12:42 PM

To: Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>

Subject: Re: More efficient PDMP - Gateway approval process - MOUs still needed?

Thank you, Sharon! FYI: all the providers should all have access to the PDMP already if they have a license; the integration piece will just be a convenience value added, so at least for us, it's not too time sensitive and won't force them out of compliance. Providence wants to go live by April 14th, so I'll work with Lisa on getting statute language from AZ and will get back to you

on moving forward.

Thank you,

Laura Carrillo, MPH

Executive Administrator

Alaska Board of Pharmacy

State of Alaska – DCCED – CBPL

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[Redacted]

[Redacted]

[Redacted]

[Redacted]



Thank you,

Laura Carrillo, MPH

Executive Administrator

Alaska Board of Pharmacy

State of Alaska – DCCED – CBPL

Direct: 907-465-1073

PDMP: 907-269-8404

PDMP email: akpdmp@alaska.gov

Fax: 907-465-2974

From: Carrillo, Laura N (CED)

Sent: Wednesday, January 9, 2019 9:16 AM

To: Chambers, Sara C (CED) <sara.chambers@alaska.gov>; Ward, Charles W (CED) <charles.ward@alaska.gov>

Cc: Howes, Brian K (CED) <brian.howes@alaska.gov>; Francois, Greg A (CED) <greg.francois@alaska.gov>

Subject: PDMP Gateway Approvals

Good morning,

One of my goals for this year is to establish a more clear and efficient process to review and approve datasharing requests. We receive a number of approval requests from various health entities through our Gateway portal. It's sometimes difficult to determine what type of entity is requesting the access and whether their intent is within the parameters of our statutes. Arizona's PDMP laws are similar to ours and have a great process to field these requests.

Questions:

Can we create a web-based integration interest form similar to theirs? <https://pharmacypmp.az.gov/integration-interest-form>

If yes, I'd like to move forward with creating a terms and condition document like this one-

https://pharmacypmp.az.gov/sites/default/files/2018%20Gateway%20Terms%20and%20Conditions_REV062718.pdf.

What are your thoughts?

I've asked AZ's administrator for more information on their review process.

Thank you,

Laura Carrillo, MPH

Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
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Direct: 907-465-1073
PDMP: 907-269-8404
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Fax: 907-465-2974

[REDACTED]

[REDACTED]

[REDACTED]

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Carrillo, Laura N (CED)
Sent: Wednesday, January 9, 2019 9:16 AM
To: Chambers, Sara C (CED) <sara.chambers@alaska.gov>; Ward, Charles W (CED) <charles.ward@alaska.gov>
Cc: Howes, Brian K (CED) <brian.howes@alaska.gov>; Francois, Greg A (CED) <greg.francois@alaska.gov>
Subject: PDMP Gateway Approvals

Good morning,

One of my goals for this year is to establish a more clear and efficient process to review and approve datasharing requests. We receive a number of approval requests from various health entities through our Gateway portal. It's sometimes difficult to determine what type of entity is requesting the access and whether their intent is within the parameters of our statutes. Arizona's PDMP laws are similar to ours and have a great process to field these requests.

Questions:

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If yes, I'd like to move forward with creating a terms and condition document like this one-

https://pharmacypmp.az.gov/sites/default/files/2018%20Gateway%20Terms%20and%20Conditions_REV062718.pdf.

What are your thoughts?

From: [Weigand, Megyn A \(LAW\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Cc: [Dinegar, Harriet C \(LAW\)](#); [Maiquis, Jun C \(CED\)](#); [Sherrell, Lisa D \(CED\)](#); [Walsh, Sharon J \(CED\)](#); [Jones, Alysia D \(CED\)](#); [Murray, Marianne \(CED\)](#); [Bonnell, Joseph K \(CED\)](#)
Subject: Re: Timeframe to register with the PDMP
Date: Thursday, July 30, 2020 9:17:02 AM

This is good.

On Jul 29, 2020, at 9:36 PM, Carrillo, Laura N (CED)
<laura.carrillo@alaska.gov> wrote:

Hi Megyn,

I believe it will be something to the effect of: a provider must register within 30 days after the date of initial licensure under AS 08 and the date of obtaining a DEA registration, whichever date is later. I'm not sure yet about a timeframe to renew, but the renewal piece will be somewhat automated as long as we receive their PDMP renewal payment along with their license renewal payment.

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Weigand, Megyn A (LAW)
Sent: Wednesday, July 29, 2020 3:31 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>; Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>; Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Jones, Alysia D (CED) <alysia.jones@alaska.gov>; Murray, Marianne (CED) <marianne.murray@alaska.gov>; Bonnell, Joseph K (CED) <joseph.bonnell@alaska.gov>
Subject: Re: Timeframe to register with the PDMP

Thanks, Laura. As long as the BOP is satisfied it has conducted due diligence in reaching out to the professional boards impacted by its decision, that is sufficient. This email thread also serves to keep folks in the loop as I see the EAs are cc'd.

Are all the boards' regulations based on the same event? For example: within X number of days after getting a DEA number, or within X number of days after getting a license, or within X number of days after renewing a license, etc.

Megyn

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Wednesday, July 29, 2020 3:22 PM
To: Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>; Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>; Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Jones, Alysia D (CED) <alysia.jones@alaska.gov>; Murray, Marianne (CED) <marianne.murray@alaska.gov>; Bonnell, Joseph K (CED) <joseph.bonnell@alaska.gov>
Subject: RE: Timeframe to register with the PDMP

Thank you, Megyn!

We've discussed grace periods at board meetings during our PDMP update, but we haven't had a formal request for feedback sent to each board. The board of pharmacy did model this 30-day timeframe after the optometry board adopted this in April 2017 and when the medical board similarly adopted this grace period at their May 2019 meeting. The dental board also adopted a 30-day timeframe during their December 2019 meeting, so I suppose pharmacy is proposing what the majority of the other boards have established thus far. Nursing and veterinary have a 120 and 180-day grace period, respectively, though we have discussed a 30-day grace period with these boards/staff previously and Dr. Murray plans to discuss this with her nursing board at their upcoming August meeting.

Is this sufficient consultation, or would you recommend the board of pharmacy request feedback from each affected board?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Weigand, Megyn A (LAW)

Sent: Wednesday, July 29, 2020 1:15 PM

To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>; Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>

Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>; Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Jones, Alysia D (CED) <alysia.jones@alaska.gov>; Murray, Marianne (CED) <marianne.murray@alaska.gov>; Bonnell, Joseph K (CED) <joseph.bonnell@alaska.gov>

Subject: Re: Timeframe to register with the PDMP

Hi Laura,

Yes, this could create a conflict - and at a minimum confusion - about the deadline to register with the PDMP. Has the Board of Pharmacy consulted with the boards that will be impacted by the new deadline? If not yet, it is advisable that they do.

Thanks,
Megyn

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>

Sent: Wednesday, July 29, 2020 10:34 AM

To: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>; Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>

Cc: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>; Walsh, Sharon J (CED) <sharon.walsh@alaska.gov>; Jones, Alysia D (CED) <alysia.jones@alaska.gov>; Murray, Marianne (CED) <marianne.murray@alaska.gov>; Bonnell, Joseph K (CED) <joseph.bonnell@alaska.gov>

Subject: Timeframe to register with the PDMP

Hi Harriet and Megyn,

Since AS 17.30.200(k) requires the board of pharmacy to set the timeframe to register with the PDMP, which they intend to set as a 30-day timeframe, my understanding was that timeframes previously adopted on record or proposed in regulations would conflict with this statute—is this an accurate reading? The board of pharmacy plans to discuss this at their meeting on August 28th, and I know MED and NUR are meeting that month and may discuss this, too.

(k) In the regulations adopted under this section, the board shall provide

- (1) that prescription information in the database be purged from the database after two years have elapsed from the date the prescription was dispensed;
- (2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;
- (3) a procedure and time frame for registration with the database;

(s) In this section,

(1) "board" means the Board of Pharmacy;

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: [Weaver, Steven C \(LAW\)](#)
To: [Dinegar, Harriet C \(LAW\)](#); [Carrillo, Laura N \(CED\)](#)
Cc: [Pollard, Susan R \(LAW\)](#); [Maiquis, Jun C \(CED\)](#); [Sherrell, Lisa D \(CED\)](#)
Subject: RE: PHA-0120 HM edits.2
Date: Wednesday, May 20, 2020 10:41:27 AM
Attachments: [image001.png](#)

Okay, I must have seen an earlier draft. Here are my thoughts on this draft:

I recommend an active voice sentence as follows:

“The information submitted daily must reflect all prescriptions for Schedule II, III, or IV controlled substances under federal law that were dispensed on the previous day. If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled substances **on the previous day, the pharmacist or practitioner must indicate this on the form.**”

Please let me know if you have any questions,

Steven C. Weaver

Senior Assistant Attorney General
Legislation and Regulations Section
Alaska Department of Law
123 4th Street, Suite 600
P.O. Box 110300
Juneau, AK 99811-0300
907-465-3600

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From: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
Sent: Wednesday, May 20, 2020 10:02 AM
To: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>; Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Pollard, Susan R (LAW) <susan.pollard@alaska.gov>; Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: Re: PHA-0120 HM edits.2

Steve, this is the language that I think I suggested on 1/30:

(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 PDMP daily on a form provided by the board. The information submitted daily must reflect all prescriptions for Schedule II, III, or IV controlled substances under federal law that were dispensed on the previous day; **where no such prescriptions were dispensed on the previous day, the practitioner must so**

indicate on the form.

Won't that work?

From: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>
Sent: Wednesday, May 20, 2020 9:47 AM
To: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>; Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Pollard, Susan R (LAW) <susan.pollard@alaska.gov>; Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: FW: PHA-0120 HM edits.2

Harriet and Laura: I believe that a "zero reporting" requirement would be within the reach of the statute. My only concern would be technical: I looked at some of the text that circulated around January, and that language said something along the lines of "the pharmacist-in-charge shall do daily reporting, including zero reporting, . . ." Using "zero reporting" alone leaves the reader guessing about what "zero reporting" is. I would advise fleshing out the non-intuitive language, if it has been unchanged since January.

Susan: Do you have any concerns? If we talked about this, it would have been around the end of January.

Steven C. Weaver
Senior Assistant Attorney General
Legislation and Regulations Section
Alaska Department of Law
123 4th Street, Suite 600
P.O. Box 110300
Juneau, AK 99811-0300
907-465-3600

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From: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
Sent: Wednesday, May 20, 2020 9:18 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>; Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Cc: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: Re: PHA-0120 HM edits.2

Yes. I think we concluded that the quantity of zero could reasonably be included in the board's reading of AS 17.30.200(b)(6), which requires the pharmacist-in-charge to submit, daily, the

quantity and strength of controlled substances dispensed. It's a little bit of a stretch, but it is certainly not inconsistent with legislative intent to track prescriptions. And there could be an argument that whatever the math (is "zero" a quantity?), requiring licensees to enter a zero at least will eliminate any question about whether the licensee simply forgot or neglected to fill that box in.

If Steve disagrees, I know he'll speak up.

Thanks for checking in, Laura.

Harriet Milks

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Tuesday, May 19, 2020 4:38 PM
To: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>; Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Cc: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: RE: PHA-0120 HM edits.2

Hi Harriet, sorry, this slipped off my radar. Any determination on whether we can require zero reporting in regulation?

Thank you,

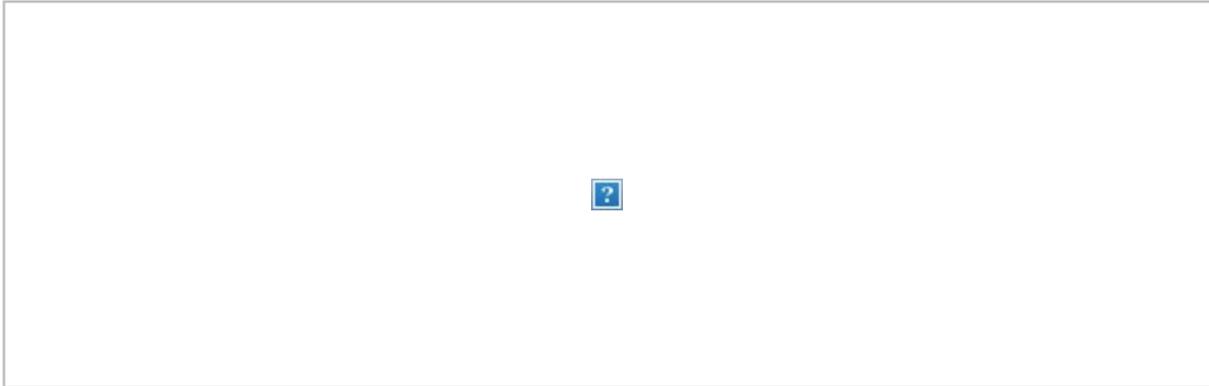
Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
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PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Carrillo, Laura N (CED)
Sent: Friday, January 31, 2020 2:54 PM
To: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>; Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>
Cc: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>; Sherrell, Lisa D (CED) <lisa.sherrell@alaska.gov>
Subject: RE: PHA-0120 HM edits.2

Thank you, Harriet! I'm including our new PDMP manager, Lisa Sherrell, for her knowledge.

Some background on zero reporting: Since the term, "zero reporting" isn't in AS 08 or AS 17.30.200,

it leaves the potential for pharmacies to appear non-compliant with the daily reporting requirement in 12 AAC 52.865(b), even if no prescriptions are dispensed for the day but not reported. The PDMP manager has to perform pharmacy analyses to determine whether pharmacies are non-compliant, which involves identifying the number and specific days on which no prescriptions were reported (see image below; we don't know for certain whether these missing days are because no prescriptions were dispensed or if the pharmacy forgot to report).



The previous PDMP administrator used to require a Certification of No Controlled Substances Dispensed form for pharmacies not dispensing. We were told sometime in late 2017/early 2018 by Megyn Greider that the board didn't have the authority to require this form and that it was obsolete now that mandatory reporting was in effect. Further interpretation was that the reporting requirement only applied if pharmacies dispensed/distributed controlled substances at all, even once a year, including zero reports, whereas for pharmacies never dispensing/distributing, the reporting requirement doesn't apply. Is this still an accurate read?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Dinegar, Harriet C (LAW)
Sent: Thursday, January 30, 2020 12:44 PM
To: Maiquis, Jun C (CED) <jun.maiquis@alaska.gov>; Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Weaver, Steven C (LAW) <steve.weaver@alaska.gov>
Subject: PHA-0120 HM edits.2

Here is another edit for your consideration. The only edit is on page 7. Steve and Susan think there is sufficient – albeit indirect – statutory authority. It may need further tweaking, but we are getting

closer.

From: [Carrillo, Laura N \(CED\)](#)
To: [Walsh, Sharon J \(CED\)](#)
Subject: FW: Guidance request [Legal Opinion Request: Remote Order Entry]
Date: Monday, August 17, 2020 2:06:00 PM
Attachments: [Remote order entry by out-of-state organization 05-08-2020.docx](#)

Hi Sharon,

Here is a legal opinion request from the board on remote order entry for PHA, unrelated to PDMP.

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Carrillo, Laura N (CED)
Sent: Monday, May 11, 2020 8:22 AM
To: jruffridge@icloud.com
Subject: FW: Guidance request

Hi Justin,

Please see the revised legal opinion request around shared pharmacy services from Rich. Please let me know if you have any additional comments/feedback before I send to Dept. of Law!

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Richard Holt [<mailto:dokholt@mac.com>]
Sent: Sunday, May 10, 2020 4:13 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Re: Guidance request

I def think we need some guidance from Pipeline on what services they are offering.

Looking at the definitions of telepharmacy vs. shared pharmacy services i think there's a definite difference. It sounds like the applicant is doing more of shared pharmacy services (entering prescriptions, etc).

Does this more accurately what we are looking to distinguish? See if this makes sense to Justin.

Thanks.

On May 8, 2020, at 7:48 AM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Hi Rich, please see the attached draft from Justin and let me know your thoughts!

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Carrillo, Laura N (CED)
Sent: Friday, May 8, 2020 7:44 AM
To: Justin Ruffridge <jruffridge@icloud.com>
Subject: RE: Guidance request

Thanks, Justin. This looks great! See attached with my comments. I'll forward onto Rich for his feedback.

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Justin Ruffridge [<mailto:jruffridge@icloud.com>]
Sent: Thursday, May 7, 2020 4:33 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Guidance request

Laura,

Can you see if I am on the right track here?

Justin

<Remote order entry by out-of-state organization 05-08-2020.docx>

The Board of Pharmacy would respectfully request legal guidance regarding current statutes and regulations as they pertain to remote pharmacies and telepharmacy. Working from a specific example, it would be helpful if we could clarify the following:

If a pharmacist, employed through an out of state organization that provides remote pharmacy services described in 12 AAC 52.995(a)(24), but is not located in the state, is providing order entry, verification of prescriptions, clinical consultations, and other telepharmacy services, is that permitted under our current regulations? Based on recent developments, there is potential for out of state remote pharmacists employed by out of state companies to have contracted with health care organizations within our state and are providing pharmacist services remotely. Specifically, in the following statute it seems that action is prohibited.

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. (a) Only a pharmacist employed by a central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state. The pharmacist-in-charge of a remote pharmacy may supervise one or more remote pharmacies.

12 AAC 52.995(a)(24). "remote pharmacy" means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

In addition, if this practice is allowable, would that out of state pharmacist and organization need licensure by the Board of Pharmacy to provide these services? If so, what type of license would best fit the services being provided if not located in the state?

We have deliberated on this subject in recent board meetings and have not been able to reach a definitive conclusion as to the scope and intent of our current regulations. Specifically, the validity of an out of state organization providing remote pharmacist services within the State of Alaska and if that is allowable what recourse we have to require licensure.

Commented [CLN(1)]: PipelineRx is registered as an out-of-state pharmacy and is located in Rosemont, IL. I don't know if this is the same out-of-state pharmacy the applicant is employed by. Should we specify that it's an out-of-state pharmacy that doesn't meet the definition of a remote pharmacy? I've added this in as placeholder language.

Deleted: remote

From: [Dinegar, Harriet C \(LAW\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Cc: [Walsh, Sharon J \(CED\)](#); [Chambers, Sara C \(CED\)](#); [Cain, Rebecca \(LAW\)](#)
Subject: RE: Extending CE completion date for pharmacy
Date: Wednesday, July 1, 2020 9:22:32 AM

Laura, thank you for asking.

The Director's order implicitly extends the time to complete CE. The reason for this is the same as that for extending the time to renew – present circumstances have required licensees to focus on care delivery. The same likely goes for providers of the required training and education courses.

I think similar reasoning supports accepting inspection reports as far back as June, 2018. Licensees may have obtained inspections not anticipating a COVID delay; requiring them to get new inspections within the adjusted two-year timeframe would (a) likely run up against the same kind of COVID-related delay that has required these adjustments in the first place, and (b) penalize them for getting their inspection reports in early or at least, inconvenience and disadvantage them for no reason that serves the public interest.

If Sara or Sharon disagree, they are welcome to chime in!

From: Carrillo, Laura N (CED)
Sent: Wednesday, July 1, 2020 9:10 AM
To: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>
Subject: Extending CE completion date for pharmacy

Hi Harriet, I spoke with Sharon about this this morning and she recommended following up with you. The board of pharmacy extended their license renewal from June 30 to September 30 via a director's order, but the order doesn't mention extending completion of continuing education to this date. Would there be any issues in interpreting this to also mean CE is extended?

Also, several pharmacy license categories require inspection reports to completed within the last two years. Since renewal is extended, I believe we take that to mean we can only accept renewal with inspection reports completed between September 30, 2018 and this September, and not accept inspections from June 30, 2018, is that correct?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: [Dinegar, Harriet C. \(LAW\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Cc: [Cain, Rebecca \(LAW\)](#); [Weigand, Megyn A \(LAW\)](#)
Subject: Drug Kiosk initial review with hm redline
Date: Tuesday, August 18, 2020 11:49:39 AM
Attachments: [Drug Kiosk initial review with hm redline.docx](#)

Laura, here is my very preliminary take on this proposal. It is eminently doable, but as my comments indicate, some more thought is needed about where these things will be located and who, exactly, is responsible for them. Also, it doesn't seem like they are remote pharmacies, but perhaps some reference should be made to that section in the regulations?

There may need to be a specific definition of premises as applies to these kiosks. For example, there isn't much need for them if they are right by the cashier in the pharmacy, but what if they are just outside the pharmacy so they can be accessed after hours? Can they be like automatic tellers located in an anteroom of the licensed establishment, or are they going to be outside Fred Myer? If so, maybe the board will want to have authority to approve the location so it can deny an application if they think would attract bad actors. Drug addicts are known to steal antibiotics, for example. Note that physical facilities for storage and dispensing drugs must comply with the 2013 federal Drug Supply Chain Security Act (AS 08.80.030(b)(7) and (d)). The board should look at that and see if it needs to be more specific about security.

I don't see a PDMP issue because there are no controlled substances. And Dr. Holt is right; any thought about licensing drug kiosks will need statutory support in the form of an amendment.

Megyn may have more to add.

12 AAC 52.415 AUTOMATED DRUG KIOSKS

(a) A pharmacy in this state may install and use automated drug kiosks which are accessible to the patient or the patient's agent for the purpose of purchasing their completed prescription drug orders if

(1) prior to a prescription drug order being distributed from the machine the pharmacist has counseled the patient in accordance with 12 AAC 52.230;

(2) no state or federal control substances are placed in the unit and there is a conspicuously posted sign near the machine which states "this machine does not contain controlled substances"; and

(3) all containers stored in the units are packaged, labeled, and stored in accordance with AS 08 and federal laws.

(b) the pharmacist must

(1) assign, discontinue, or change access to the system;

(2) ensure that access to the medications comply with state and federal regulations; and

(3) ensure that the automated prescription drug dispensing units are filled or stocked accurately;

(c) This section does not apply to prescription drug dispensing machines used in institutional facilities.

(d) In AS 08.80, "automated drug kiosks" means a vending machine that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of drugs, and which collect, control and maintain all transaction information.

Commented [HCD1]: Where? On the pharmacy premises? If not, see 12 AAC 52.420(c) (some drugs need to be kept in the pharmacy) and consider issues of maintenance (by a licensed pharmacist?) and security (who is responsible for ensuring that location is secure and not an attractant for trouble).

Commented [HCD2]: Or do you mean "to" – because the counseling would have to happen before the recipient of the prescription approaches the machine to purchase the drug, and it can't necessarily be known when the prescription will be picked up and thus distributed "from" the machine.

Commented [HCD3]: Consider saying: "no drug that is a controlled substance as defined by state or federal law."

Commented [HCD4]: This should probably be "on" and the board may consider being more specific about what it thinks is conspicuous – contrasting color, large font, all caps, etc.

Commented [HCD5]: Is this the pharmacist in charge?

Deleted: shall have the responsibility to

Commented [HCD6]: This needs work. I think there is a better – and likely longer – way to lay out what the pharmacist must do, to set up the machine. Among other things, this should address the pharmacist's obligation to record transactions and link them to the pharmacy's database as required, keep prescription records, and maintain security of access to the machine.

Deleted: or mechanical system

Commented [HCD8]: This sounds more like a robot than a vending machine. Consider saying the vending machine "stores, packages, and dispenses prescription drugs, and maintains a record of transactions initiated or completed."

From: [Weigand, Megyn A \(LAW\)](#)
To: [Dinegar, Harriet C \(LAW\)](#); [Carrillo, Laura N \(CED\)](#)
Cc: [Cain, Rebecca \(LAW\)](#)
Subject: Re: Drug Kiosk initial review with hm redline
Date: Tuesday, August 18, 2020 3:43:00 PM
Attachments: [Screen Shot 2020-08-18 at 3.12.12 PM.png](#)
[Screen Shot 2020-08-18 at 3.13.55 PM.png](#)
[Screen Shot 2020-08-18 at 3.14.45 PM.png](#)

Does the proposed use of kiosks conflict with 12 AAC 52.420(f) which states 'Prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent'?

Under AS 08.80.480(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient. Are these kiosks "dispensing" the drug? Or is the pharmacist dispensing the drug when he or she puts it into the machine?

Megyn

To avoid:





From: Dinegar, Harriet C (LAW) <harriet.dinegar@alaska.gov>

Sent: Tuesday, August 18, 2020 11:49 AM

To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>

Cc: Cain, Rebecca (LAW) <rebecca.cain@alaska.gov>; Weigand, Megyn A (LAW) <megyn.weigand@alaska.gov>

Subject: Drug Kiosk initial review with hm redline

Laura, here is my very preliminary take on this proposal. It is eminently doable, but as my comments indicate, some more thought is needed about where these things will be located and who, exactly, is responsible for them. Also, it doesn't seem like they are remote pharmacies, but perhaps some reference should be made to that section in the regulations?

There may need to be a specific definition of premises as applies to these kiosks. For example, there isn't much need for them if they are right by the cashier in the pharmacy, but what if they are just outside the pharmacy so they can be accessed after hours? Can they be like automatic tellers located in an anteroom of the licensed establishment, or are they going to be outside Fred Myer? If so, maybe the board will want to have authority to approve the location so it can deny an application if they think would attract bad actors. Drug addicts are known to steal antibiotics, for example. Note that physical facilities for storage and dispensing drugs must comply with the 2013 federal Drug Supply Chain Security Act (AS 08.80.030(b)(7) and (d)). The board should look at that and see if it needs to be more specific about security.

I don't see a PDMP issue because there are no controlled substances. And Dr. Holt is right; any thought about licensing drug kiosks will need statutory support in the form of an amendment.

Megyn may have more to add.

Steps in the Board Regulation Adoption Process

<i>Day 1</i>	<p>1 At an open meeting, the board votes on language to change regulations. This motion is forwarded to the Division Regulations Specialist for drafting.</p>	<i>Day 65</i>	<p>7 Division Regulations Specialist compiles answers to questions and posts FAQ on the program web page.</p>	<p><i>Once Regulations Are Effective</i></p>	
<i>Day 30</i>	<p>2 Once drafting is complete, the board holds another public meeting to edit or approve draft for public notice.</p>	<i>Day 75</i>	<p>8 Regulations Specialist compiles public comments for distribution to board.</p>		<p>14a Agency posts summary on Alaska Online Public Notice System</p>
	<p>3 Approved language is reviewed by Division attorney.</p>	<i>Day 90</i>	<p>9 Board holds an open meeting to review public comments, make minor changes, and adopt regulations. Substantive changes may require additional drafting and public notice (Step 2).</p>		<p>14b Regulation published in Alaska Administrative Code</p>
	<p>4 Department of Law opens file.</p>		<p>10 Division submits final regulation package to Department of Law for review and approval, and to the Governor's office.</p>	<p>14c Forms & FAQ updated on program web page</p>	
<i>Day 45</i>	<p>5 Division publishes and distributes public notice, additional regulation notice information, and proposed regulation to all licensees and interested parties. Public notice posted in newspaper and on Alaska Online Public Notice System</p>		<p>11 Agency attorney reviews regulation</p>		
	<p>6 Public comment period and/or hearing (if applicable).</p>	<i>Day 110</i>	<p>12 Regulations attorney reviews and either approves or disapproves regulation</p>		
		<i>Day 150</i>	<p>13 Unless returned by the Governor, Lt. Governor's office files approved regulation; regulations become effective in 30 days</p>		

All timeframes are estimated, dependent upon staff and attorney workflow and board scheduling.

Steps in the Regulation Process for a Board and Commission (board)¹

Beginning the Process

1. At an open meeting, the board initiates and votes on proposed regulation changes.
2. **Reason:** Identify the reason for the proposed action, such as compliance with new or changed state law. If applicable, identify the law, order, decision, or other action of the federal government, or federal or state court, if that is the basis for the proposed action. The description need only be a sentence or two.
3. **Cost information:** In the meeting minutes there must be estimated costs in the aggregate to comply with the proposed action to:
 - A private person
 - Another state agency
 - A municipality

Cost information is described simply as an estimate of annual costs within the board's ability to determine due to its familiarity with the regulated community.

Example: The Board of Chiropractic Examiners is proposing to add three CE credits to their continuing competency requirements for a biennial license renewal. The proposal may cost

- A private person: \$50 per applicant/licensee
 - Another state agency: None known
 - A municipality: None known
4. Within 10 days of the meeting, board staff must transmit board minutes² or an excerpt of the minutes, draft language or proposals, and a completed Regulations FAQ Worksheet for the proposed regulation changes requested by the board to the Regulations Specialist.

What comes next: Regulations Specialist

5. The Regulations Specialist determines if there is authority in statute to adopt the proposed regulation changes.
6. The Regulations Specialist prepares a draft of regulation changes, using the Department of Law's *Drafting Manual for Administrative Regulations* for conformity and style, and works with board staff before submitting the final draft to the board for review/approval. In some instances the draft regulation changes will be reviewed by an AAG before the final draft is submitted to the board for review/approval.
7. Once completed, the draft proposed regulation changes are presented to the board at its next public meeting to review and approve the final draft, amends if needed, and requests that the approved draft be finalized and public noticed.

Public Notice

8. NOTE: The board must **always** provide an opportunity for submission of written comments in the regulation-adoption process. Also, the board should determine if it wants to hold a public hearing on the proposed regulation changes at its next meeting. If it does, the location, date and time of the hearing needs to be included in the public notice. Public hearings are usually held in conjunction with a regularly-scheduled meeting of the board and are always recorded. Oral public hearing is optional; however, answering the following questions will help the board determine if an oral public hearing is needed:
 - Are the regulations controversial and is there likely to be substantial public interest in them?
 - Would those most affected by the regulations be better able to participate if an oral hearing were held?
 - Would the board benefit from a face-to-face or teleconferenced opportunity to receive comments on the proposed regulations from interested persons?
9. Regulations Specialist sends notice to Alaska Dispatch News (or other newspapers if warranted) for publication, all interested parties, and licensees, if warranted. The Regulations Specialist posts the notice on the Alaska Online Public Notice System, electronically transmits a copy of the notice and proposed regulation changes to all incumbent legislators and the Legislative Affairs Agency, House & Senate Labor & Commerce Committees, Legislative Council, Lt. Governor, Governor, and Department of Law (Law). It is also emailed to board members and affected staff, including the commissioner's office. Public notice will be posted on the board's webpage.

Comment Period

10. The Regulations Specialist or board staff shall make a good faith effort to answer relevant questions received at least 10 days before the end of the public comment period. Questions must be in writing or asked at the legally noticed public meeting. The Regulations Specialist or board staff shall answer questions in writing and make the questions and answers available on the Alaska Online Public Notice System and the board's webpage. FAQs will be posted on the board's webpage and updated when relevant questions are answered. The Regulations Specialist or board staff may, but are not required to, answer written questions received after the 10-day cutoff date.
11. After the comment deadline (at least 30 days in duration), comments received on proposed regulation changes are compiled and copied by the Regulations Specialist and given to board staff to include in the board packets for the next open board meeting to be considered prior to adopting. Comments received after the deadline should not be forwarded to the board and comments should not be taken at the board meeting from the public prior to adoption unless a hearing was noticed and the comments are heard by the board during the comment period.

Adoption

12. The board's options regarding the proposed regulation changes at its next meeting are:

- a. It can adopt the proposed regulation changes as written/publicly noticed, amend, and adopt them; or
 - b. Choose to take no action on them.
 - c. Substantive changes may require additional drafting and public notice (see Step 7 above).
13. When making a motion to adopt the regulations, the board is required to state on the record that it has reviewed any comments received, and considered the cost to private persons of the regulatory action being taken.
14. When regulation changes are adopted:
 - a. The chair signs the adoption/certification order; and
 - b. The board staff signs an affidavit of board action and/or affidavit of oral hearing (if applicable) and attaches it to the relevant minutes or an excerpt of the minutes and forwards to the Regulations Specialist.

Finalizing the regulation change process

15. Regulations Specialist prepares the final regulation package for transmittal to Department of Law for final review/approval, which includes the adopted regulations, certain affidavits, and other appropriate documents.
16. Assigned agency attorney reviews the regulations.
17. Regulations attorney reviews and either approves or disapproves regulation changes. Law reviews and will occasionally make edits. (On rare occasions, this may require the edited version to be re-adopted by the board at a subsequent meeting.) At the same time, the adopted regulations are submitted to the governor for review. The governor has 30 days to review the regulations under AS 44.62.040(c), and return the regulation for specified reasons.
18. Unless returned by the governor, when the governor and Law's review are complete, the adopted regulations are forwarded to the Lt. Governor for filing. Regulation changes are effective 30 days after filing unless a later effective date is specified in the adoption order.

Once regulations are effective

19. Agency posts summary of approved regulation changes on Alaska Online Public Notice System.
20. Agency updates statutes and regulations board webpage.
21. Regulation published in Alaska Administrative Code.

¹ The process may take six months to a year or longer to complete. It may be expedited if a board meets often or holds a teleconference following the written comment period to adopt the final regulations. Department of Law workload also plays a big part in the timeframe.

² Board minutes reflecting concisely what the project entails plays an important part in getting a project rolling. This is true for the initial stages and the final motion adopting the regulations following the public comment period due to the relevant minutes or an excerpt of the minutes being forwarded to the Department of Law with the final project.

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: Amy Demboski
Department of Commerce Community and Economic Development

FROM: April Simpson, Office of the Lieutenant Governor 
465.4081

DATE: July 31, 2020

RE: Filed Permanent Regulations: Board of Pharmacy

Board of Pharmacy emergency regulations made permanent re: expedited handling of prescriptions in response to the COVID-19 pandemic and future disasters (12 AAC 52)

Attorney General File:	2020200314
Regulation Filed:	4/3/2020 & 7/31/2020
Effective Date:	8/30/2020
Print:	235, October 2020

cc with enclosures: Harry Hale, Department of Law
Judy Herndon, LexisNexis
Jun Maiquis, Regulations Specialist

ORDER CERTIFYING THE CHANGES TO
REGULATIONS OF THE BOARD OF PHARMACY

The attached fourteen pages of permanent amended emergency regulations, relating to the practice of pharmacy, including pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions, are hereby certified to be a correct copy of the regulation changes that the Board of Pharmacy adopted at its May 28, 2020 teleconference meeting, under the authority of AS 08.01.075, AS 08.01.100, AS 08.80.005, AS 08.80.030, AS 08.80.110, AS 08.80.116, AS 08.80.147, AS 08.80.157, AS 08.80.159, AS 08.80.165, AS 08.80.168, AS 08.80.261, AS 08.80.295, AS 08.80.330, AS 08.80.410, AS 08.80.480, AS 11.71.900, AS 17.30.200, and AS 17.30.900, 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: 06/03/2020
Juneau, Alaska

Laura Carrillo
Laura Carrillo, Executive Administrator
Board of Pharmacy

April Simpson for

FILING CERTIFICATION

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on July 31, 2020 at 1:13 p.m., I filed the attached regulations according to the provisions of AS 44.62.040 – 44.62.120.

April Simpson
for Kevin Meyer, Lieutenant Governor

Effective: August 30, 2020.

Register: 235, October 2020

CERTIFICATION OF COMPLIANCE

I, Laura Carrillo, Executive Administrator for the Board of Pharmacy, certify that, as required by AS 44.62.260 in order to make the attached fourteen pages of regulations permanent, as of this date a legal opinion of the Department of Law has been requested under AS 44.62.060, a notice conforming to AS 44.62.200 was issued in compliance with AS 44.62.190, and an opportunity for public comment was provided under AS 44.62.210, for the following emergency regulation:

12 AAC 52.060 – 12 AAC 52.995, relating to the practice of pharmacy under the authority of AS 08.80 and 12 AAC 52, including pharmacist duties, pharmacy interns, pharmacy technicians, pharmacy technician with national certification, license renewal, shared pharmacy services during emergency, refills, labeling, prescriptions by electronic transmission, transfer of a prescription drug order, substitution, emergency preparedness, independent administration of vaccines and related emergency medications, and definitions.

This regulation originally was filed as an emergency regulation on April 3, 2020.

This action is not expected to require an increased appropriation.

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

DATE: 06/03/2020
Juneau, Alaska

Laura Carrillo
Laura Carrillo, Executive Administrator
Board of Pharmacy

FILING CERTIFICATION

April Simpson for

I, Kevin Meyer, Lieutenant Governor for the State of Alaska, certify that on July 31, 2020 at 1:14 p.m., I filed the attached regulation according to the provisions of AS 44.62.

for April Simpson
Kevin Meyer, Lieutenant Governor

Register: 235, October 2020

FOR DELEGATION OF THE LIEUTENANT GOVERNOR'S AUTHORITY

I, KEVIN MEYER, LIEUTENANT GOVERNOR OF THE STATE OF ALASKA, designate the following state employees to perform the Administrative Procedures Act filing functions of the Office of the Lieutenant Governor:

**Josh Applebee, Chief of Staff
Kady Levale, Notary Administrator
April Simpson, Regulations and Initiatives Specialist**

IN TESTIMONY WHEREOF, I have signed and affixed the Seal of the State of Alaska, in Juneau, on December 11th, 2018.



Kevin Meyer

**KEVIN MEYER
LIEUTENANT GOVERNOR**

~~EMERGENCY REGULATION~~

Register 235, October 2020 PROFESSIONAL REGULATIONS

Chapter 52. Board of Pharmacy.

(and that subsection is further amended)

The emergency adoption of 12 AAC 52.060(d) is made permanent to read: *(that)*

(d) In this section, "other disaster" includes any disaster situation *[which]* causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory. (Eff. 1/16/98, Register 145; am 4/3/2020, Register 234)

am 8/30/2020, Register 235

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

The emergency amendment of the introductory language of 12 AAC 52.210 is made permanent to read:

12 AAC 52.210. Pharmacist duties. Except as provided in 12 AAC 52.220 and 12 AAC 52.235, the following duties may be performed only by a pharmacist:
...

The emergency amendment of 12 AAC 52.210(1) is made permanent to read:

(1) receiving an oral prescription drug order from a practitioner or authorized agent of a practitioner;

The emergency adoption of 12 AAC 52.210(8) is made permanent and that paragraph is further amended to read:

The emergency amendment of 12 AAC 52.210(6), *(7)*, and *(8)* are made permanent to read:

(6) assuming the responsibility for a filled prescription;

The emergency amendment of 12 AAC 52.210(7) is made permanent to read:

(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and

(8) *(administering)* administer a prescription drug order in accordance with *the practitioner's* prescriber's order.

~~EMERGENCY REGULATION~~

Register 235, October 2020 PROFESSIONAL REGULATIONS

2; am 8/30/2020,
Register 235

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

The emergency repeal of 12 AAC 52.220(e)(3) is made permanent to read:

(3) repealed 4/3/2020;

(Eff. 1/16/98, Register 145; am 1/17/2007, Register 181; am 10/31/2019, Register 232; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410

AS 08.80.030 AS 08.80.116

12 AAC 52.230(c) is amended to read:
(c) Except as provided in 12 AAC 52.235, a [A] pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

The emergency amendment of 12 AAC 52.230(a)(2) is made permanent to read:

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.

(Eff. 1/16/98, Register 145; am 4/4/2002, Register 162; am 1/23/2003, Register 165; am 4/3/2020, Register 234)

am 8/30/2020
Register 235

Authority: AS 08.80.030 AS 08.80.480

The emergency adoption of 12 AAC 52.235 is made permanent and that section is further amended to read:

12 AAC 52.235. Pharmacy technician with national certification. (a) A pharmacy technician who holds a national certification [AND WHO WORKS UNDER THE DIRECT (and under the direct supervision of that pharmacist) SUPERVISION OF A PHARMACIST] may, at the direction of the pharmacist on duty,

(1) perform a final check (of) and distribute a non-controlled substance prescription if

~~EMERGENCY REGULATION~~

Register 235, October 2020 PROFESSIONAL REGULATIONS

(A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination ^{of} substitution;

that (B) the pharmacy uses a bar code scanning and verification system that confirms the drug selected to fill the prescription is the same as indicated on the prescription label;

(C) [(B)] the pharmacy uses software that displays the image or graphical description of the correct drug being verified; ^{however,} provided that if there is any distributed deviation ^{between} [from] the image or graphical description ^{the} and actual product being [dispensed], a pharmacist must review and dispense the order; and

(D) [(C)] each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500; ^{or}

(3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.

(b) Prescription drug order information clarifications ^{(a)(3) of} under this ^{section} subsection must have the following information documented on the prescription drug order ^{section}

(1) the result of the clarification;

practitioner (2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the prescriber or authorized agent ^{that the pharmacy technician} [they] spoke to; and technician

(4) the date [AND TIME] of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

~~EMERGENCY REGULATION~~

Register 235, October 2020 PROFESSIONAL REGULATIONS

(d) In this section, ^{that} [a] "bar code scanning and verification system" means any technology ^{that} [which] scans the bar code on a manufacturer drug container to ensure ^{inputted} the product being distributed matches the expectation of what was prescribed and ^{input} into the dispensing software. (Eff. 4/3/2020, Register 234; am 8/30/2020, Register 235)

Authority: AS 08.80.005 AS 08.80.030

and is further amended

CC Publisher: To reflect the repeal of 12 AAC 52.300(c)(4), please insert an "and" connector at the end of 12 AAC 52.300(c)(2).))

The emergency amendment of 12 AAC 52.300(c)(3) is made permanent to read:

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; **[AND]**

The emergency repeal of 12 AAC 52.300(c)(4) is made permanent to read:

(4) repealed 4/3/2020. (Eff. 1/16/98, Register 145; am 2/26/2000, Register 153; am 5/5/2000, Register 154; am 5/26/2006, Register 178; am 4/3/2020, Register 234)

is am 8/30/2020 Register 235

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

and that section is further amended

The emergency adoption of 12 AAC 52.446 is made permanent to read:

12 AAC 52.446. Shared pharmacy services during emergency. (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy

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services [as defined in 12 AAC 52.995(33)] without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient's agent, (or filling [,]) the filling pharmacy, pharmacist, ([,]) or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled or dispensed

(1) (A) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) (B) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services (that) (which) distributes prescription under 12 AAC 52.235 drug orders using a pharmacy technician who holds (2) national certification shall maintain manual or electronic records identifying, individually for each order processed, filled or distributed

(1) the name, initials, or identification code of each pharmacy technician
← who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

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(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order. (Eff. 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

is am 8/30/2020,
Register 235

The emergency repeal of 12 AAC 52.470(a) is made permanent to read:

(a) Repealed 4/3/2020.

The emergency repeal of 12 AAC 52.470(b) is made permanent to read:

(b) Repealed 4/3/2020.

The emergency amendment of 12 AAC 52.470(c) is made permanent to read:

(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.

The emergency amendment of 12 AAC 52.470(d) is made permanent to read:

(d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the

(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; and

(2) drug is not a federal or state scheduled controlled substance.

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The emergency adoption of 12 AAC 52.470(g) is made permanent to read:

(g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,

(1) “existing” means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;

(2) “chronic” means a drug that the patient takes regularly, for greater than three months.

The emergency adoption of 12 AAC 52.470(h) is made permanent to read:

(h) Under (g) of this section, the pharmacist must

(1) reduce the patient’s prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;

(2) document “continuation of therapy”, “COT”, or words of similar meaning on the prescription drug order; and

(3) file and maintain the prescription in accordance with 12 AAC 52.450.

12 AAC 52.470 is amended by adding a new subsection to read:

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order. (Eff.

1/16/98, Register 145; am 6/29/2018, Register 226; am 4/3/2020, Register 234; am

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8 / 30 / 2020, Register 235)

Authority: AS 08.80.005 AS 08.80.030

The emergency amendment of 12 AAC 52.480(4) is made permanent to read:

(4) initials, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(Eff. 1/16/98, Register 145; am 1/14/2004, Register 169; am 2/15/2006, Register 177; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

The emergency amendment of the introductory language of 12 AAC 52.490(a) is made permanent to read:

(a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

• • •
(Eff. 1/16/98, Register 145; am 11/10/2001, Register 160; am 8/12/2007, Register 183; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

The emergency repeal of 12 AAC 52.500(d)(1) is made permanent to read:

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(1) repealed 4/3/2020;

(and that paragraph is further amended)

The emergency amendment of 12 AAC 52.500(d)(3) is made permanent to read:

(3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:

(A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;

(B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds national certification receiving the prescription drug order information;

(C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds national certification transferring the prescription drug order information; and

(D) the date of the transfer;

The emergency amendment of 12 AAC 52.500(d)(4) is made permanent to read:

(4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:

(A) the original date of issue;

(B) the original unique identification number of the prescription;

(C) the quantity of drug or device remaining;

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(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

The emergency amendment of 12 AAC 52.500(d)(5) is made permanent to read:

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

The emergency amendment of 12 AAC 52.500(f)(2) is made permanent to read:

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am 10/31/2019, Register 232; am 4/3/2020, Register 234) ; am 8/30/2020, Register 235

Authority: AS 08.80.005 AS 08.80.030

The emergency amendment of the introductory language of 12 AAC 52.510(a) is made permanent to read:

(a) A pharmacist or pharmacist intern may dispense an equivalent drug product or interchangeable biological product instead of the prescribed drug if

(and that paragraph is further amended)

The emergency amendment of 12 AAC 52.510(a)(1) is made permanent to read:

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(1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording indicating ^{that} the practitioner does not want it substituted;

and that subsection is further amended

The emergency adoption of 12 AAC 52.510(c) is made permanent to read:

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product ^{if} so long as there is nothing on the prescription drug order from ^{prescribing practitioner that indicates that the practitioner wants} the prescriber that would indicate they want only the substituted product dispensed. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am 10/31/2019, Register 232; am 4/3/2020, Register 234) *am 8/30/2020, Register 235*

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

and that subsection is further amended

The emergency amendment of 12 AAC 52.985(a) is made permanent to read:

(a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor ^{that} under AS 26.23.020 which results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

The emergency amendment of 12 AAC 52.985(b) is made permanent to read:

(b) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription,

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the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

The emergency repeal of 12 AAC 52.985(c) is made permanent to read:

(c) Repealed 4/3/2020.

The emergency repeal of 12 AAC 52.985(d) is made permanent to read:

(d) Repealed 4/3/2020.

and that subsection is further amended

The emergency adoption of 12 AAC 52.985(f) is made permanent to read:

(f) During a disaster emergency declared by the governor of this state

(1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;

(2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the *that* date *ends* the governor determines the disaster emergency *no longer exists*;

(3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized. (Eff. 10/31/2019, Register 232; am 4/3/2020, Register 234)

Authority: AS 08.80.005 AS 08.80.030

am 8/31/2020, Register 235

The emergency amendment of 12 AAC 52.992(d) is made permanent to read:

(d) A pharmacist or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each

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vaccine administered.

(Eff. 7/9/2017, Register 223; am 4/3/2020, Register 234)

Authority: AS 08.01.075 AS 08.80.168 AS 08.80.480
AS 08.80.030 AS 08.80.261

The emergency amendment of 12 AAC 52.995(a)(33) is made permanent to read:

(33) "shared pharmacy services" means a system allowing the processing by a participating pharmacist, ~~pharmacist intern, or pharmacy technician who holds a national certification~~ or a pharmacy of a request from another participating pharmacist, ~~pharmacist intern, or pharmacy technician who holds a national certification~~ or pharmacy to enter or review a prescription drug order ^{or} process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

Struck out text is disapproved. AC 26 7/27/2020

paragraph

The emergency adoption of 12 AAC 52.995(a)(38) is made permanent and that ~~section~~ is further amended to read:

(38) "pharmacy technician who holds a national certification" means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA) [INSTITUTE FOR THE CERTIFICATION OF PHARMACY TECHNICIANS (ICPT)].

(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

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9/11/2010, Register 195; am 12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am 10/31/2019, Register 232; am 4/3/2020, Register 234; am 8 / 30 / 2020, Register 235)

Authority: AS 08.80.005 AS 08.80.159 AS 17.30.200
AS 08.80.030 AS 11.71.900 AS 17.30.900
AS 08.80.157

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.840. FIRST DOSE KITS. (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.850. EMERGENCY DISTRIBUTION. In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

ARTICLE 9. CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

855. Registration with the prescription drug monitoring program controlled substance prescription database

860. Access to and conditions for use of the prescription drug monitoring program database

865. Reporting and reviewing PDMP information

870. Waiver of electronic submission requirement by pharmacist or practitioner

875. Solicited requests for information from non-registered persons

880. Reports

885. Purged database records

890. Grounds for discipline

895. Correcting information in database

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.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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 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 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 this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(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 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 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 commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(u), a pharmacist must submit information required under AS 17.30.200(b), 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 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)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours 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.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner 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 must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner 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) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

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

(d) A request for a waiver under this section must be in writing using an application form provided 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 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 inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS. (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a \$10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880. REPORTS. (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

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

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

(3) the name, title, and address of the individual requesting the profile;

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

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.885. PURGED 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.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890. GROUNDS FOR DISCIPLINE. A violation of 12 AAC 52.855 – 12 AAC 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 52.885 by a practitioner not licensed by this board shall be reported to the practitioner’s licensing board.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.895. CORRECTING INFORMATION IN DATABASE. (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

- (1) on a form or in a format prescribed by the board,
 - (A) a description of the information asserted to be incorrect, and the correction requested;
 - (B) the mailing and physical address and telephone number of the requester; and
 - (C) a signed, sworn statement attesting to the truth of the corrected information;
- (2) documentation to support the correction requested; and
- (3) proof of the requester's identity.
- (b) If the board determines that it
 - (1) has sufficient information to make a determination, the board will
 - (A) notify the requester that the request is granted; or
 - (B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;
 - (2) lacks sufficient information to grant or deny the request, the board
 - (A) will request additional information from the requester; and
 - (B) will not act on the request until after the additional information is received.
- (c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

Authority: AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

ARTICLE 10. DISCIPLINARY GUIDELINES.

Section

- 900. Purpose of disciplinary guidelines**
- 910. Violations**
- 920. Disciplinary guidelines**
- 925. Grounds for denial or discipline for criminal history**
- 930. Terms of probation**
- 940. Use of alcohol or controlled substances**
- 950. Probation terms for professional incompetence**
- 960. Mental or physical disabilities**
- 970. Reinstatement of a suspended license**
- 980. Reinstatement of a revoked license**

12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES. The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board’s disciplinary policies are known and are administered consistently and fairly.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

Sec. 17.30.150. Reliance on Drug Enforcement Administration. Results, information, and evidence received from the Drug Enforcement Administration of the United States Department of Justice relating to the enforcement functions of this chapter, including results of inspections conducted by it, may be relied on and acted on by the Department of Public Safety in the exercise of its enforcement functions under this chapter.

Sec. 17.30.155. Confidentiality of certain information. A practitioner engaged in medical practice or research may not disclose the name or identity of a patient or research subject that the practitioner is required to keep confidential unless ordered by a court to disclose it within the context of a criminal investigation or proceeding.

ARTICLE 5. CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

200. Controlled substance prescription database

Sec. 17.30.200. Controlled substance prescription database. (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (u) of this section.

(b) 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 dispensed or administered under the circumstances described in (u) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

(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 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.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. 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) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant 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.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

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

(i) in an inpatient setting;

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

(iii) in an emergency room;

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

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

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(l) A person

- (1) with authority to access the database under (d) of this section who knowingly
 - (A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;
 - (B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;
 - (C) allows another person who is not authorized to access the database to access the database commits a class C felony;
- (2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.
- (m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures
 - (1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to
 - (A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;
 - (B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;
 - (C) increase coordination among prescription drug monitoring program partners;
 - (D) involve stakeholders in the planning process;
 - (2) shall include information related to the
 - (A) security of the database; and
 - (B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.
- (n) 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 by a procedure and in a format established by the board.
- (o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (o) of this section.
- (p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section
 - (1) must be provided to the practitioner;
 - (2) is confidential;
 - (3) may not disclose information that is confidential under this section;
 - (4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.
- (q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.
- (r) The Department of Commerce, Community, and Economic Development shall
 - (1) assist the board and provide necessary staff and equipment to implement this section; and
 - (2) establish fees for registration with the database by a pharmacist or practitioner required to register under (o) of this section 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
 - (A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and
 - (B) consult with the board to establish the fees under this paragraph.
- (s) In this section,
 - (1) "board" means the Board of Pharmacy;
 - (2) "database" means the controlled substance prescription database established in this section;
 - (3) "knowingly" has the meaning given in AS 11.81.900;
 - (4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;
 - (5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.
- (t) Notwithstanding (q) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.
- (u) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is
 - (1) administered to a patient at

- (A) a health care facility; or
- (B) a correctional facility;
- (2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital
 - (A) inpatient pharmacy; or
 - (B) emergency department.

**ARTICLE 6.
GENERAL PROVISIONS.**

Section

900. Definitions

Sec. 17.30.900. Definitions. (a) Unless the context clearly requires otherwise, the definitions set out in AS 11.71.900 apply to this chapter.

(b) [Repealed, 22 ch 146 SLA 1986.]

PDMP Regs Change Suggestions

12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE. (a) A licensed pharmacist physically present in the state shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP). Registration must be completed within 30 days of initial licensure if employment will involve dispensing a schedule II, III, or IV controlled substance under federal law. A prescriber shall register within 30 days after the date of initial licensure under AS 08 and the date of obtaining a DEA registration, whichever date is later.

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(1) If not dispensing in the state, a pharmacist must submit a PDMP dispensation exemption form provided by the board within 30 days of initial licensure.

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(2) If a pharmacist who submitted a dispensation exemption form but will have a change in dispensing status must register before dispensing.

(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 by providing

(1) a unique and secure email-based login;

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(2) password;

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(3) user role;

(4) healthcare specialty;

(5) the drug enforcement administration (DEA) number issue to the prescriber or, if a pharmacist, the employer's DEA

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(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 PDMP registration number by the department.

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(d) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using

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(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.

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(f) To maintain the registration, a pharmacist or practitioner required to register with the PDMP must

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(1) renew the registration by submitting the fee established in 12 AAC 02.107 at the time coinciding with professional license renewal

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(2) promptly notify the department of any change in employment that requires a change in the email login

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(3) promptly notify the department of any change in DEA registration number or status

(4) update the password every 180 days

(g) if a pharmacist or practitioner required to register with the PDMP has approved a delegate to access the database on the provider's behalf, it is the responsibility of the provider to deactivate the delegate if

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(1) the delegate is no longer employed at the same practice as the provider; or

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(2) is still employed but no longer assisting the provider in a supportive capacity for the specific patient.

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Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

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 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,

Deleted: assigned to a board or agency that requires a practitioner to register with the PDMP.

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

Commented [CLN(1)]: Per communication with Harriet Milks on 05/14/2020. This includes investigators assigned to prescribing board as well as investigators from other state depts., e.g.: Dept. of Public Safety or Dept. of Corrections. This would not require a statute change.

(2) "personnel of another board or agency" means an employee of this state who is accessing the database for investigational purposes.

(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, (management, or analysis services); or

Commented [CLN(2)]: If different from storage services, what does data management services include? Compiling, analyzing?

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

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(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 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 commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(u), a pharmacist must submit information required under AS 17.30.200(b), 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 PDMP daily as of the previous submission date. The information submitted daily must reflect all prescriptions for Schedule II, III, or IV controlled substances under federal law that were dispensed on the previous day. If the pharmacist or practitioner did not dispense any Schedule II, III, or IV controlled substances on the previous day, the pharmacist or practitioner must indicate this on the form.

(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)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours 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. 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.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner 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 must submit a sworn statement on the form provided by the board showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner 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) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

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

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

Commented [CLN(3): Per Steve Weaver suggestion on 05-20-2020

Commented [CLN(4): I don't believe this is reported since it's not an ASAP field. If it was reported, we should be able to search this, but license#s never show up in data submissions. It would certainly be helpful—do pharmacy or reporting systems even have the field to report this?

Deleted: to the PDMP administrator

Deleted: an application and sworn statement showing that

Commented [CLN(5): Do need this? This reads as an AND to (b)(1)

Commented [CLN(6): This seems redundant to (b)

(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 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 inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Commented [CLN(7)]: What about just the duration of the disaster or emergency, consistent with other emergency regs?

Commented [SLD(8R7)]: I think we want to leave this as is. If the board decides to make the emergency regs permanent, wouldn't it effectively make this permanent? I think it would be best to make them re-apply for the waiver to certify the necessity of the waiver still exists.

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall

- (1) be fluent in the reading, writing, and speaking of the English language;
- ~~(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;~~
- (3) be a graduate of a college in a degree program approved by the board;
- (4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
- (5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

- (1) submits a written application to the board on a form required by the board;
- (2) is at least 18 years of age;
- ~~(3) is of good moral character;~~
- (4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
- (5) has engaged in the practice of pharmacy for at least one year ~~or has met the internship requirements of this state~~ within the one-year period immediately before applying for a license under this section;
- (6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;
- (7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and (8) pays all required fees.

Sec. 08.80.158 REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. REPEAL

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs ~~or devices~~ to a

(A) licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

- (1) obtain a license under AS 08.80.157;
- (2) appoint an agent on whom process can be served in the state; and
- (3) authorize inspection of the facility by a designee of the board under (c) of this section ~~or~~

(B) consumer in this state, a pharmacy located outside of the state shall

- (1) obtain a license under AS 08.80.157; and
- (2) appoint an agent on whom process can be served in the state.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

- (1) register as an outsourcing facility with the United States Food and Drug Administration; and (2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

- (1) require an inspection of the applicant's facility located outside the state; and
- (2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

- (1) examination;
- (2) reexamination;
- (3) investigation for licensing by license transfer; (4) pharmacist license;
- (5) temporary license;
- (6) pharmacy technician license;
- (7) pharmacy intern license;
- (8) emergency permit;
- (9) license amendment or replacement;
- (10) ~~registration or~~ licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF DRUGS VACCINES AND RELATED EMERGENCY MEDICATIONS.~~

- (a) ~~A pharmacist may independently prescribe~~
- (1) ~~and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).~~
 - (2) ~~and dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).~~
 - (3) ~~and dispense dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;~~
 - (4) ~~and dispense epinephrine auto-injectors;~~
 - (5) ~~and dispense drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:~~
 - (A) ~~do not require a new diagnosis;~~
 - (B) ~~are minor and generally self-limiting;~~
 - (C) ~~have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or~~
 - (D) ~~in the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.~~
 - (6) ~~In this section,~~
 - (1) ~~"opioid overdose drug" has the meaning given in AS 17.20.085;~~
 - (2) ~~"related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.~~
- (b) ~~The board shall not adopt any regulations authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.~~

Commented [RH1]: We are already allowed to do this: 12 AAC 52.992 and 12 AAC 52.994

Commented [RH2]: This is taken from Idaho laws: <https://legislature.idaho.gov/statutesrules/idstat/Title54/T54CH17/SECT54-1704/>

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist or person acting at the direction of a pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) “health care plan” means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

- (A) a health care insurance plan as defined under AS 21.54.500;
- (B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);
- (C) a plan offered under AS 39.30.090 or 39.30.091;
- (D) a federal governmental plan as defined under AS 21.54.500;
- (E) the Medicaid or Medicare program; or
- (F) a self-insured employer benefit plan;

(2) “pharmacy benefits manager” has the meaning given in AS 21.27.955.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person’s license.

(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.

(c) In this section, “regularly” means to dispense more than a 3-day supply to a patient.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title “pharmacist,” “assistant pharmacist,” or “druggist,” or the descriptive term “pharmacy,” “drug store,” “drug sundries,” “~~apothecary~~”, or other similar title or term containing the word “drug,” in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,

(12) “equivalent drug product” means a drug product that has the same established name, active ingredients, strength or concentration, ~~dosage form~~, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(30) “practice of pharmacy” means the interpretation, evaluation, and dispensing of prescription drug orders in the patient’s best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the ~~independent prescribing, dispensing and administration of vaccines and related emergency medication; the independent dispensing of opioid overdose~~ drugs and devices in accordance with AS 08.80.168; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

E-Prescribing

The Centers for Medicare & Medicaid (CMS) has released a Request for Information (RFI) for Electronic Prescribing of Controlled Substances in Medicare Part D. The RFI seeks input from stakeholders around implementation of Section 2003 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) which generally requires that prescriptions for controlled substances covered under a Medicare Part D prescription drug plan be transmitted by a health care practitioner electronically.

The RFI is available at

<https://www.federalregister.gov/documents/2020/08/04/2020-16897/medicare-program-electronic-prescribing-of-controlled-substances-request-for-information>. Comments are due by October 5, 2020.

E-Prescribing is a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care - is an important element in improving the quality of patient care. The inclusion of electronic prescribing in the Medicare Modernization Act (MMA) of 2003 gave momentum to the movement, and the July 2006 Institute of Medicine report on the role of e-prescribing in reducing medication errors received widespread publicity, helping to build awareness of e-prescribing's role in enhancing patient safety. Adopting the standards to facilitate e-prescribing is one of the key action items in the governments plan to expedite the adoption of electronic medical records and build a national electronic health information infrastructure in the United States.

The MMA created a new voluntary prescription drug benefit under Medicare Part D. Although e-prescribing will be optional for physicians and pharmacies, Medicare Part D will require drug plans participating in the new prescription benefit to support electronic prescribing.

Standards Timeline

- On November 7, 2005, CMS published the first set of adopted standards known as the foundation standards. The foundation standards became effective on January 1, 2006. These standards apply to all electronic prescribing done under Part D of the MMA.

- MMA required CMS to implement pilot projects to test additional standards. These additional standards were pilot tested in 2006.
- On June 23, 2006 CMS published an interim final rule with comment to adopt NCPDP SCRIPT Standard version 8.1 on a voluntary basis to be used for e-prescribing.
- The results of the pilot test were announced in a report to Congress in April 2007 and were the basis for an NPRM proposing additional standards that was published on November 16, 2007.
- The final e-prescribing rule was published at the Federal Register on April 7, 2008. In this final rule CMS adopted 3 additional standards for use in e-prescribing under part D.
- On January 2009 CMS published a final rule, In this reg the Medicare Part D e-Prescribing foundation standards were updated to include:
 - The National Council for Prescription Drug Programs Telecommunication Standard Specification, Version D, Release 0 for eligibility queries between dispensers and Part D sponsors.
 - The Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010; For eligibility and benefits queries and responses between prescribers and Part D sponsors.
- On November 18, 2008 CMS Published the 2009 Physician Fee Schedule Payment Final Rule. In that payment reg CMS lifted the exemption to the Computer Generated Fax (CGF) exemption. CMS listed a date of January 1, 2012 for the elimination of the CGF exemption.
- On July 01, 2010 CMS published an interim final rule with comment to adopt NCPDP SCRIPT Standard version 10.6 on a voluntary basis to be used for e-prescribing.
- 2013 the PFS final rule adopted the Script Version 10.6 standard effective (10/1/13)
 - Retires Version 8.1
 - Lifted the Long Term Care Exemption effective(10/1/14)
- 2014 the PFS final rule adopted a newer version of the NCPDP Formulary and Benefits 3.0 transaction effective 2/28/15 and it also retires NCPDP Formulary and Benefits version 1.0 on 3/1/15.
- On April 16, 2018 CMS published a final rule (CMS-4182-F) to adopt a new NCPDP SCRIPT Standard Version 2017071(2017071) and retirement of current NCPDP SCRIPT Version 10.6 (10.6) for use in the Medicare Prescription Drug Benefit Program (Part D) program effective January 1, 2020.
- On May 23, 2019, CMS published a final rule (CMS-4180-F) requiring that Part D plans adopt one or more real time benefit tools (RTBTs) capable of giving prescribers clinically appropriate patient-

specific real-time formulary and benefit information. This mandate is effective January 1, 2021.

Related Links

[Electronic Prescribing \(eRx\) Incentive Program](#)

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From: [Richard Holt](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: Re: Physical exam prior to dispensing?
Date: Saturday, June 20, 2020 10:16:05 AM

We can definitely discuss and see if the board is interested in adding it.

Sent from my iPhone

On Jun 16, 2020, at 12:13 PM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Maybe something to add to future statute changes?

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
Direct: 907-465-1073
PDMP: 907-269-8404
PDMP email: akpdmp@alaska.gov
Fax: 907-465-2974

From: Richard Holt [mailto:rholtpharmd@icloud.com]
Sent: Tuesday, June 16, 2020 11:47 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Re: Physical exam prior to dispensing?

Would be nice but We don't have an internet Pharmacy licensing category - just out of state.

Sent from my iPhone

On Jun 16, 2020, at 11:44 AM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

It looks like the Ryan Haight Act and is permanent in the context of Internet pharmacies. Should we be licensing internet pharmacies under that specific category, or maybe just putting in regulation that they have to indicate whether they are an internet pharmacy?

<https://www.justice.gov/archive/olp/pdf/hr-6353-enrolled-bill.pdf>

<https://www.deadiversion.usdoj.gov/21cfr/21usc/829.htm>

Thank you,

Laura Carrillo, MPH
Executive Administrator
Alaska Board of Pharmacy
Prescription Drug Monitoring Program
State of Alaska – DCCED – CBPL
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PDMP: 907-269-8404
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Fax: 907-465-2974

From: Richard Holt [<mailto:rholtpharmd@icloud.com>]
Sent: Tuesday, June 16, 2020 9:26 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Re: Physical exam prior to dispensing?

Yes. I can find it tonight; however, the DEA did release this in March so I don't know if it's permanent or temporary which is what I will have to research.

<https://www.dea.gov/press-releases/2020/03/20/deas-response-covid-19>

Does that help?

Thanks,
Rich

Sent from my iPhone

On Jun 16, 2020, at 9:02 AM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Is there a federal requirement to conduct a physical exam prior to dispensing? The VET board is working on a regulations project and is wanting the citation for this. I couldn't find any federal law; the CDC says exams before dispensing or prescribing is a state-by-state law.

Thank you,

Laura Carrillo, MPH
Executive Administrator
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