

(Public Board Packet)

November - Alaska Board of Pharmacy Meeting - Day 1

Nov 14, 2019 9:00 AM AKST

Table of Contents

1. Agenda Item #1 - 9:00 a.m. Roll Call/Call to Order.....	3
2. Agenda Item #2 - 9:05 a.m. Review/Approve Agenda.....	8
3. Agenda Item #3 - 9:09 a.m. Ethics Disclosures.....	11
4. Agenda Item #4 - 9:10 a.m. Review/Approve Minutes.....	24
A. March 7-8, 2019 draft.....	69
B. June 27, 2019 draft.....	93
5. Agenda Item #5 - 9:20 a.m. PDMP Update (Laura Carrillo).....	114
A. PDMP Board Report.....	114
i. June 2019.....	114
ii. October 2019.....	123
B. Grants/Enhancements and Activities.....	133
i. BJA Grant.....	133
a. NarxCare.....	134
b. License Integration.....	180
c. Compliance Module.....	184
ii. DDPI Grant.....	185
a. Clinical Alerts.....	216
b. Awareness and Feedback Questionnaire (feedback).....	224
C. Overdose to Action "OD2A" Grant.....	264
i. RxCheck.....	267
D. Military Health System PDMP (MHS PMP).....	269
6. Agenda Item #6 - 10:00 a.m. Investigative Update (Carl Jacobs).....	272
A. May 21, 2019 Report.....	272
B. October 31, 2019 Report.....	275
C. Hallandale Pharmacy (civil fine).....	277
D. Southside Pharmacy 3 (civil fine).....	282
E. Distinguished Pharmaceuticals (voluntary surrender).....	285
7. Agenda Item #7 - 10:30 a.m. Consent Agreements (Marilyn Zimmerman).....	289
A. Outstanding.....	289
i. Joan Bittner.....	289
B. Review Previously Approved CE Audits.....	307
i. Dorothy Luchansky.....	309
ii. Merry Gregg.....	316
C. License Actions.....	325
i. Arielle Vargas (default and revocation).....	325
ii. Kao Saelee (voluntary surrender).....	341
8. Agenda Item #8 - 11:00 a.m. New Business.....	347
A. NABP Presentation (Bill Cover).....	347
B. Additional Resources.....	372
i. Clearing House (disciplinary).....	372
ii. Durable Medical Equipment Accreditation.....	373
iii. Pre-NAPLEX Program.....	375
iv. Verified Internet Pharmacy Practice Sites (VIPSS).....	376
v. Verified Pharmacy Program (VPP).....	407
vi. Virtual Wholesalers - Manufacturers.....	408

C. FDA Requirements - 3PLs - Wholesalers.....	493
9. Agenda Item #9 - 12:30 p.m. Old Business.....	495
A. Automated Dispensing.....	495
i. Follow-up from Kevin Rew w/ examples.....	495
ii. Automated Dispensing (telepharmacy).....	530
B. IHS Legal Opinion - PIC Licensure.....	531
C. Board of Pharmacy Newsletter.....	539
D. "Apothecary".....	540
E. Position Statements.....	542
i. Example from the Chiropractic Board.....	542
ii. Apothecary.....	545
iii. Virtual Wholesalers/Manufacturers.....	545
iv. Durable Medical Equipment.....	545
v. Automated Dispensing Cabinets.....	545
vi. Kiosks.....	545
10. Agenda #10 - 4:30 p.m. Recess until Friday, November 15th.....	546

STATE OF ALASKA

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

ALASKA BOARD OF PHARMACY



November 14, 2019

Teleconference/Videoconference

Robert Atwood Building Suite 1550 (Anchorage)
State Office Building, 9th Floor, Conf. Room A (Juneau)

Board Packet

(Public Packet)

2019 STATE HOLIDAY CALENDAR

JANUARY

S	M	T	W	R	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
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27	28	29	30	31		

FEBRUARY

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MARCH

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31						

APRIL

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JUNE

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JULY

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AUGUST

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SEPTEMBER

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29	30					

OCTOBER

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NOVEMBER

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DECEMBER

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29	30	31				

State Holidays

Date	Holiday
01/01	New Year's Day
01/21	MLK Jr.'s Birthday
02/18	Presidents' Day
03/25	Seward's Day
05/27	Memorial Day
07/04	Independence Day

 Holiday

State calendar maintained by the Division of Finance, Department of Administration
<http://doa.alaska.gov/calendars.html>

Biweekly employees please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

State Holidays

Date	Holiday
09/02	Labor Day
10/18	Alaska Day
11/11	Veterans' Day
11/28	Thanksgiving Day
12/25	Christmas Day

Board or Commission: _____

Meeting Date: _____

Agenda Item # _____

Tab # _____

Topic: _____

Primary Motion

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

Subsidiary Motion or Amendment

Motion:

Board Member	Motion	2nd		Yes Vote	No Vote	Abstain	Recuse	Comments

EXECUTIVE SESSION MOTION

Sec. 44.62.310. Government meetings public.

(c) The following subject may be considered in an executive session:

- (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity;
- (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion;
- (3) matters which by law, municipal charter, or ordinance are required to be confidential;
- (4) matters involving consideration of government records that by law are not subject to public disclosure.

MOTION WORDING:

“In accordance with the provisions of Alaska Statute 44.62.310 (c), I move to go into executive session for the purpose of discussing (select the appropriate statutory citation for the situation):

- (1) matters, the immediate knowledge of which would clearly have an adverse effect upon the finances of the public entity; *OR***
- (2) subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion; *OR***
- (3) matters which by law, municipal charter, or ordinance are required to be confidential; *OR***
- (4) matters involving consideration of government records that by law are not subject to public disclosure.**

**Board staff is requested to remain during the session *OR*
Board only to remain during session.”**

Staff will then state **“The board is off the record at _____(time).”**

Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Richard Holt, PharmD, MBA (Chair)	03/01/2016		03/01/2020
Leif Holm, PharmD (Vice Chair)	03/01/2015	01/08/2019	03/01/2019
Lana Bell, RPh	05/31/2016	03/01/2018	03/01/2022
Phil Sanders, RPh	03/01/2016		03/01/2020
James Henderson, RPh	03/01/2017		03/01/2021
Tammy Lindemuth, Public Member	01/24/2018		03/01/2021
Sharon Long, Public Member	03/01/2018		03/01/2022



ALASKA BOARD OF PHARMACY MEETING TENTATIVE AGENDA

NOVEMBER 14, 2019 (DAY 1)

Teleconference: 1-800-315-6338
Access Code: 52550

Discussion of the following topics may require executive session. The executive session phone number has not been provided for the public.

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*

James Henderson,
RPh (Vice Chair)

Lana Bell, *RPh*
(Secretary)

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

Upcoming Meetings:

TBD

Alternative dial-in:
1-408-638-0968

Meeting ID:
975 839 590

Meeting Details

Meeting Name: June - Alaska Board of Pharmacy Meeting - Day 1

Meeting Start Time: 9:00 AM Alaskan Daylight Time

Meeting Start Date: 11/14/2019

Meeting End Time: 4:30 PM Alaskan Daylight Time

Meeting End Date: 11/14/2019

Meeting Location: Robert Atwood Building, 550 W 7th Ave, Suite 1550

Agenda

- I. Agenda Item #1 - 9:00 a.m. Roll Call/Call to Order
- II. Agenda Item #2 - 9:05 a.m. Review/Approve Agenda
- III. Agenda Item #3 – 9:09 a.m. Ethics Disclosures
- IV. Agenda Item #4 - 9:10 a.m. Review/Approve Meeting Minutes
 - A. March 7-8, 2019 draft
 - B. June 27, 2019 draft
- V. Agenda Item #5 - 9:20 a.m. PDMP Update (Laura Carrillo)
 - A. PDMP Board Report
 - B. Grants/Enhancements and Activities

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*

James Henderson,
RPh (Vice Chair)

Lana Bell, *RPh*
(Secretary)

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

Upcoming Meetings:

TBD

1. BJA Grant
 - a. NarxCare
 - b. License Integration
 - c. Compliance Module
 2. DDPI Grant
 - a. Clinical Alerts
 - b. Awareness and Feedback Questionnaire
 3. Overdose to Action “OD2A” Grant
 - a. RxCheck
 4. Military Health System PDMP
- VI. Agenda Item #6 - 10:00 a.m. Investigative Update (Carl Jacobs)
- A. May
 - B. October
 - C. Hallandale Pharmacy
 - D. Southside Pharmacy 3
 - E. Distinguished Pharmaceuticals
- VII. Agenda Item #7 - 10:30 a.m. Consent Agreements (Marilyn Zimmerman)
- A. Outstanding
 1. Joan Bittner
 - B. Review Previously Approved Audits
 1. Dorothy Luchansky
 2. Merry Gregg
 - C. License Actions
- VIII. Agenda Item #8 - 11:00 a.m. New Business
- A. NABP (Bill Cover)
 1. Disciplinary Clearing House
 2. Durable Medical Equipment Accreditation
 3. Pre-NAPLEX Program
 4. Verified Internet Pharmacy Practice Sites (VIPSS)
 5. Verified Pharmacy Program (VPP)
 6. Virtual Wholesalers - Manufacturers

B. FDA Requirements - 3PLs - Wholesalers

LUNCH – 12:30 p.m. – 1:30 p.m.

IX. Agenda Item #9 – 1:30 p.m. Old Business

- A. Automated Dispensing
- B. IHS Legal Opinion – PIC Licensure
- C. Board of Pharmacy News Letter
- D. “Apothecary”
- E. Position Statements
 - 1. Example from Chiropractic Board
 - 2. Apothecary
 - 3. Virtual Wholesalers/Manufacturers
 - 4. Durable Medical Equipment
 - 5. Automated Dispensing Cabinets
 - 6. Kiosks

X. Agenda #10 - 4:30 p.m. Recess until November 15th

MEMORANDUM

State of Alaska
Department of Law

TO: _____ DATE: _____
FILE NO.: _____
TEL. NO.: _____
FROM: Angie White
Litigation Assistant
Department of Law
Opinions, Appeals, & Ethics Section
FAX: _____
SUBJECT: Executive Branch Ethics Act, AS
39.52 Quarterly Report
[INSERT QUARTERLY DATE
RANGE]

******SAMPLE LANGUAGE – PLEASE COPY ONLY THE PARTS THAT APPLY
ONTO YOUR BOARD OR COMMISSION’S LETTERHEAD ******

As designated ethics supervisor and chair [executive director] for the _____, I wish to advise you that I have received no notifications of potential violations or requests for ethics determinations under the Ethics Act (AS 39.52) and have made no written determinations for this quarter.

OR

As designated ethics supervisor and chair [executive director] for the _____, I have received ___ notification(s) of a potential violation and ___ requests for ethics determinations under the Ethics Act (AS 39.52) I have attached a copy of the notices and requests along with my written determination(s) for review by the attorney general. I did [did not] receive an advisory opinion from the Attorney General.

AND

Except as addressed above, no other [board member] [commissioner] disclosed a potential conflict of interest at a recorded public meeting during this quarter.

OR

In addition to the above, at the [date] meeting, [Board member] [Commissioner] _____ disclosed a potential conflict with respect to _____ [insert brief description]_____. *Insert disposition:* [S/He refrained from participation.] or [I determined s/he could [could not] participate.] or [The Board [Commission] members voted to permit [not to permit] participation.]

State of Alaska Department of Law

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 Guy Bell, 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 Guy Bell, 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 Guy Bell, 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: Leslie Ridle, Deputy Commissioner

Commerce, Community & Economic Development: Jon Bittner, Deputy Commissioner

Corrections: April Wilkerson, Director of Administrative Services

Education & Early Development: Les Morse, Deputy Commissioner

Environmental Conservation: Tom Cherian, Director of Administrative Services

Fish & Game: Kevin Brooks, Deputy Commissioner

Health & Social Services: Dallas Hargrave, Human Resource Manager

Labor & Workforce Development: Michael Monagle, Director, Division of Workers Compensation

Law: Jonathan Woodman, Assistant Attorney General

Military & Veterans Affairs: Marty Meyer, Special Assistant to Commissioner

Natural Resources: John Crowther, Inter-Governmental Coordinator

Public Safety: Terry Vrabec, Deputy Commissioner

Revenue: Dan DeBartolo, Administrative Services Director

Transportation & Public Facilities:

- Highways & Public Facilities: Steve Hatter, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Rob Campbell, Regional Director
- Northern Region: Rob Campbell, Acting Regional Director
- Southcoast Region: Acting Regional Director
- Alaska Marine Highway System: Michael Neussl, Deputy Commissioner
- Headquarters: Mary Siroky, Administrative Services Director

Updated April 2015

Department of Law attorney.general@alaska.gov P.O. Box 110300, Juneau, AK 99811-0300
Phone: 907-465-3600 Fax: 907-465-2075 TTY: 907-258-9161
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State of Alaska

Department of Law

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

Department of Law attorney.general@alaska.gov P.O. Box 110300, Juneau, AK 99811-0300
Phone: 907-465-3600 Fax: 907-465-2075 TTY: 907-258-9161
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State of Alaska

Department of Law

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 Manual for Designated Ethics Supervisors (April 2008), 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 269-7195.
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 Kim Halstead, Litigation Assistant, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-279-2834.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Jon Woodman, at 269-5100 or jonathan.woodman@alaska.gov. Please direct questions about reporting procedures to Kim Halstead at 269-7195 or kimberly.halstead@alaska.gov.

6/14

Department of Law attorney.general@alaska.gov P.O. Box 110300, Juneau, AK 99811-0300
Phone: 907-465-3600 Fax: 907-465-2075 TTY: 907-258-9161
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1 State of Alaska
2 Department of Commerce, Community and Economic Development
3 Division of Corporations, Business and Professional Licensing
4

5 Alaska Board of Pharmacy
6

7 DRAFT MINUTES OF THE MEETING
8

9 March 7, 2019 In-Person and Teleconference via OnBoard
10

11 By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62,
12 Article 6, a scheduled meeting of the Board of Pharmacy was held in-person at the
13 Robert Atwood Building, Conference Room ACC in Anchorage, Alaska and at the
14 State Office Building, 9th Floor, Commissioner's Conference Room in Juneau,
15 Alaska on March 7th and 8th, 2019.
16

17 These are draft minutes that have not yet been approved by the board.
18

19 Agenda Item 1 Call to Order/Roll Call Time: 9:05 a.m.
20

21 The March 7, 2019 meeting day was called to order by Chair, Rich Holt at 9:05 a.m.
22

23 Board members present, constituting a quorum:
24

25 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
26 Leif Holm, PharmD #PHAP1606
27 Phil Sanders, RPh #PHAP776
28 James Henderson, RPh #PHAP1683 (Absent)
29 Lana Bell, RPh #PHAP893
30 Tammy Lindemuth, Public Member
31 Sharon Long, Public Member (Absent)
32

33 Division staff present:
34

35 Norman Thompson, Occupational Licensing Examiner
36 Allan Alcancia, Occupational Licensing Examiner
37 Laura Carrillo, Executive Administrator
38 Chelsea Childress, Records & Licensing Supervisor
39 Brian Howes, Investigator
40 Greg Francois, Chief Investigator
41 Melissa Dumas, Administrative Officer
42 Marylene Wales, Accountant

43 Members from the public present:

44

45 Catherine Kowalski, #PHAP926 (Petersburg Rexall Drug)

46 Mackenzie Peeler, #PHAC2981 (Petersburg Rexall Drug)

47 Dirk White, #PHAP811 (Harry Race Pharmacy)

48 Adele Davis, (Alaska Pharmacy Association, SEARHC)

49 Scott Watts, #PHAP899 (Ron's Apothecary Shoppe)

50 Molly Gray, (Alaska Pharmacy Association)

51 Kane Olson, #PHAP1875 (via phone from Anchorage)

52 Daniel Nelson, #PHAP1413 (via phone from Fairbanks)

53 Karen Miller, #PHAP1109 (via phone from Fairbanks)

54 Andrew Jaconette, #MEDS5328 (via Anchorage)

55 Jordan Hussey, #123640 (via Anchorage)

56 Nancy Kavan, #PHAP1069

57 Joann Nelson (pharmacist)

58

59 Other members present:

60

61 Chris Kennedy, Administrative Law Judge

62 Kenneth Bressers, OMRO

63

64 **Agenda Item 2 Review/Approve Agenda**

Time: 9:09 a.m.

65

66 The board reviewed the agenda.

67

68 **On a motion duly made by Tammy Lindemuth, seconded by Lana Bell, and approved**
69 **unanimously, it was**

70

71 **RESOLVED to accept the March 7, 2019 agenda as written.**

72

	APPROVE	DENY	ABSTAIN	ABSENT
73				
74	Leif Holm	x		
75	Richard Holt	x		
76	Phil Sanders	x		
77	Lana Bell	x		
78	Tammy Lindemuth	x		
79	James Henderson			x
80	Sharon Long			x

81

82 The motion passed with no further discussion.

83

84

85 **Agenda Item 3** **Ethics** **Time: 9:09 a.m.**

86
87 The board then moved on to addressing ethics disclosures. In anticipation of discussing licensee’s
88 feedback on the Board of Pharmacy’s letter released on January 23, 2019 written by Chair Holt,
89 Mr. Holt clarified for the record that he will be addressing the matter as a board member. He
90 further clarified that when addressing the letter, it will have no bearing towards any particular
91 company or pharmacist, including any pharmacists whom he currently employs.
92

93 **Agenda Item 4** **Public Comment** **Time: 9:15 a.m.**

94
95 Federal Legislation and Employer Directives

96 Dirk White commented that as of January 1, 2020, there will be federal legislation requiring
97 pharmacists to review the Prescription Drug Monitoring Program (PDMP) prior to dispensing a
98 controlled substance. Through Chair Holt, Ms. Carrillo commented that each state has their own
99 registration, reviewing, and reporting requirements, and that licensees in Alaska are not required to
100 comply with this national directive. Chair Holt affirmed, stating pharmacists are not required to
101 review prior to dispensing under current state statute or regulation, and that he was not aware of
102 this requirement at this time, but was interested in researching this. Adele Davis commented that
103 corporations may be issuing mandates to its pharmacists requiring them to review before
104 dispensing.
105

106 **TASK 1**

107 Chair Holt and Laura Carrillo will look into the federal reviewing mandate that will go into effect
108 for pharmacists on January 1, 2020.
109 *(Completed on 03/11/19; Ms. Carrillo found an amendment to the Social Security Act/ Medicaid Partnership*
110 *Act from the 115 Congress [2017-2018 legislature] addressing an upcoming mandate. The mandate would require*
111 *states to notify the Centers for Medicaid and Medicare Services (CMS) by January 1, 2023 as to whether or not*
112 *they have state law requiring pharmacists to check the PDMP, not that reviewing by pharmacists will be required).*
113

114 Veterinary Patients and PDMP Patient Fields

115 Katherine Kowalski inquired about reviewing patient prescription history. Through Chair Holt,
116 Ms. Carrillo commented that both the Board of Veterinary Examiners and the Board of Pharmacy
117 sought legal advice on whether veterinarians can review the patient prescription history of the
118 animal’s owner, as the ability to do so was not clear in the veterinary statutes and regulations. Ms.
119 Carrillo informed the public that law ultimately opined that veterinarians can and should review
120 the animal owner’s patient prescription history since the potential to divert the controlled
121 substance lies with the human owner and not with the animal. Ms. Carrillo also stated that it was
122 up to the Board of Veterinary Examiners to come to establish standards for entering patient
123 information, i.e.: human owner’s date of birth rather than animal’s date of birth.
124
125
126
127

128 **TASK 2**

129 Laura Carrillo will follow-up with the veterinary board through its staff, Chelsea Childress and
130 Dawn Hannasch, on PDMP reviewing and reporting standards and patient identification criteria,
131 and the guidance the board has for its licensees, if any.
132 *(Completed on 03/11/19; Ms. Carrillo forwarded the legal opinion regarding this issue dated 09/12/2018 to the*
133 *Board of Veterinary Examiners staff and sent a template created on 08/02/2018 for the veterinary board to*
134 *facilitate the discussion on standards for entering information in patient fields).*

135
136 Transfer of unfilled controlled substances
137 Katherine Kowalski commented on transferring of unfilled controlled substances, stating that
138 there might be situations in which more than one controlled substance prescription is issued by
139 the same prescriber due to inability to transfer unfilled prescriptions, and inquired to the board
140 who would be responsible for the subsequent or duplicate prescription. Ms. Kowalski stated that,
141 for example, if a prescriber writes a prescription in Ketchikan, the patient travels to Petersburg
142 where the prescription can't be transferred to, so writes another prescription to be picked up at a
143 pharmacy location in Petersburg: who is responsible for the new prescription?

144
145 Informal Complaints
146 Dirk White informed the board that the nutritional bar, "Rx Bar" is being sold by an out-of-state
147 company in coffee shops and pharmacies throughout Alaska, and inquired whether it is a violation
148 of AS 08.80.430, which prohibits the use of pharmacy symbols unless a license is obtained under
149 AS 08.80. Mr. White also commented that there is a nutritional store in Sitka referring to itself as
150 an apothecary, citing AS 08.80.420 as a potential violation of certain advertisements prohibited.

151
152 PDMP Processing Delays
153 Adele Davis commented on the PDMP processing delays, noting that it is taking 10 -12 weeks for
154 access to be approved. Several members from the public reiterated this concern, including Dirk
155 White, Katherina Kowalski, and Scott Watts, who stated that pharmacists are not able to comply
156 with the mandate to review patient prescription history and inquired whether pharmacists will be
157 able to defend potential violations for non-compliance. Through Chair Holt, Ms. Carrillo again
158 clarified that pharmacists are not required to review patient prescription history, but that
159 timeliness of registration will depend on the date the individual is licensed to the date a complete
160 application to access the PDMP is submitted rather than administratively approved. Ms. Carrillo
161 acknowledge the delay in processing PDMP applications, which she stated is directly related to the
162 position being vacant for three months due to the continuation of the state hiring freeze. Ms.
163 Carrillo informed the public that in the two months preceding the vacancy, she was on maternity
164 leave, but that the board's investigator, Brian Howes, dedicated his free time to processing these
165 whenever possible. Ms. Carrillo further informed the public that she, Norman Thompson, and
166 Charles Ward, the division's marine pilot coordinator, are allocating time to processing these in the
167 order received, but that there is no fully-dedicated staff person to process the 2,600 registrations
168 manually. For reference, Ms. Carrillo stated most states have 4 – 9 full-time PDMP staff.

169

170 In the interim of hiring a dedicated PDMP staff member, Ms. Carrillo informed the public that
171 pharmacists could register as a delegate under AS 17.30.200(d)(4) as these accounts can be
172 approved relatively more expeditiously since they don't require validation documents.
173

174 **TASK 3**

175 Ms. Carrillo will review and approve “pharmacist delegate – licensed” accounts daily and will
176 update the pharmacist’s user role from the delegate role to the pharmacist role once the licensee’s
177 form and payment is processed. PDMP registration issue dates in the licensing database will reflect
178 the actual date approval was given.
179

180 January 23rd, 2018 Letter to Pharmacists

181 Daniel Nelson commented that he has been a pharmacist for almost 17 years and has always felt
182 personal pride in being a pharmacist, and that as a profession are respected members of the
183 community where people invest a lot of trust in them, but feels for the first time that the rust and
184 perception of the profession was severely undermined as a result of the letter. Mr. Nelson further
185 commented that the letter was patronizing and tone deaf to the opioid epidemic, adding that he
186 understands the intent of the letter was to address how to approach refusing a prescription, but
187 that the tone of the letter was overwhelmingly threatening and negative towards the pharmacists.
188 Mr. Nelson stated that the Board of Pharmacy has a responsibility to address and answer
189 questions about the letter, stating that the root of the issue came from a particular pharmacy that
190 was no longer able to purchase controlled substances from a wholesaler, which consequently left
191 hundreds of patients without a pharmacy almost overnight. Mr. Nelson inquired what the board’s
192 responsibility is when a wholesaler ceases to supply to a pharmacy, what recourse a pharmacy can
193 take when a wholesaler has terminated its contract, and whether there is due process in
194 investigating the quantity of controlled substances being purchased when it is perceived to be in
195 an egregious and alarming amount prior to that wholesaler being able to revoke a purchasing
196 contract. It was further stated that the medical board should be weighing in on this issue,
197 particularly when it comes to dangerous opioid and benzodiazepine combinations.
198

199 In response to Mr. Nelson, Chair Holt stated that there were multiple complaints raised to
200 different agencies within the state, and that the board was looped into the issue and asked to
201 provide a response. Chair Holt clarified that there were specific and actual scenarios that were
202 relayed to the board, and the letter was a multi-factorial approach to give a sweeping generalization
203 to remind pharmacists that they do have a right to refuse, but that the approach in which one does
204 so should be professional. Chair Holt expressed appreciate for the feedback on the tone of the
205 letter, but was hopeful that explaining the circumstances under which the letter was created will
206 help provide the public and licensees with a better understanding behind its intent.
207

208 In response to Mr. Nelson’s comment on due process prior to wholesalers revoking a purchasing
209 contract, Chair Holt stated the board does not regulate business contracts or are otherwise
210 involved in limitations in purchase agreements between wholesalers and pharmacies.
211

212 Jordan Hussey from Walgreens commented that pharmacists are experiencing backlash from
213 prescribers who just bring up the letter to try reinforcing that pharmacists cannot refuse to fill
214 prescriptions. Chair Holt responded that the letter does state that pharmacists have the right to
215 refuse, and offered the reminder that pharmacists must approach refusals with professionalism.
216 Chair Holt also commented that a follow-up FAQ document was done in collaboration with the
217 Board of Nursing and the Medical Board, and that they are continuing to try working
218 collaboratively with these boards to come out with a joint statement as there should be
219 professional dialogue between affected professions.

220
221 Karen Miller commented that she's been a retail pharmacist for 25 years and did see a recent shift
222 of prescribing in quantities that she had not seen before. Ms. Miller added that she did see what
223 she perceived to be egregious prescribing, but that prescribers would not pick up the phone or
224 make efforts to communicate with the pharmacy about the prescription. Ms. Miller also stated that
225 she and her colleagues do their best to scrutinize prescriptions to determine whether they are
226 legitimate, but may refuse simply because they don't have the supply as they see a high number of
227 palliative, hospice, and cancer treatment patients. With regards to the letter, Ms. Miller stated it
228 made her and her colleagues nervous about refusing.

229
230 Ms. Carrillo commented to the public that if a pharmacist has a concern about a prescriber or
231 another pharmacist licensee, that the division cannot look into a complaint unless it is done so
232 through the proper investigative process. Ms. Carrillo, through the Chair, encouraged the public to
233 file complaints when they believe there is an issue of safety at hand, which she explained could be
234 accomplished by submitting a Request for Contact Form to the Investigations Section. Ms.
235 Carrillo stated that there was information on this process included on the FAQ document, and
236 Molly Gray commented that the complaint process could be published through the AKPHA.

237
238 Dr. Andy Jaconette commented that he is a physician with a focus in interventional pain and
239 addiction medicine, and that he is very concerned about patients not being able to have their
240 prescriptions filled all of a sudden. Dr. Jaconette added that he has been prescribing the same
241 medications in the same quantity for the last 10 years, and that the sudden refusal to fills is
242 harmful to patients. Dr. Jaconette then inquired to the board whether they were aware of active
243 prosecutions against pharmacists dispensing in dangerous or unsafe quantities, to which Chair
244 Holt stated there are, but that he was not aware of any that are currently happening in Alaska. Dr.
245 Jaconette expressed frustration that pharmacists are encroaching on the practice of medicine by
246 attempting to provide a diagnosis and altering medications, adding that he is having to call
247 pharmacists because they are not calling his office. Chair Holt commented that the Board of
248 Pharmacy has been actively attempting to work with other prescribing boards to release a joint
249 statement since December, but that efforts have not been successful. To Dr. Jaconette's comment
250 on scope of practice, Chair Holt stated that pharmacists are obligated and have the authority to
251 evaluate prescriptions. Chair Holt also stated that SB 74 mandated that representatives from all
252 board were to convene as a subcommittee to establish prescribing limits, and that the committee
253 [CBPL's Joint Committee on Prescriptive Guidelines] was required to submit the recommendation
254 to the legislature; however, the legislature did not do anything with the recommendations. Chair

255 Holt added that the recommendations could have been a foundation on which to provide better
256 guidance to prescribers. Lana Bell thanked Dr. Jaconette for advocating for more support, and
257 added that when the board makes recommendations, it still has to go through the legislature,
258 which can be a time-consuming process.

259
260 Dr. Jaconette continued to express concern over the lack of communication between prescribers
261 and pharmacists, and the harm that is being done to patients as a result of refused dispensing.
262 Lana Bell expressed appreciation for Dr. Jaconette coming o defend his profession, his patients,
263 and his practice, but reiterated that all pharmacists are doing their best to address these efforts.
264 Ms. Bell added that pharmacists are highly trained in pharmacology and are here to be a good tool
265 for the prescriber, but that in her practice, she always defers to the physician in making the
266 ultimate decision. Ms. Carrillo stated that she would be holding a PDMP touch-base meeting on
267 March 11th and that she would be addressing the topic of improved collaboration amongst
268 affected boards.

269
270 **TASK 4**

271 Ms. Carrillo will follow-up with the board after the CBPL touch-base meeting on PDMP topics,
272 including the need for increased collaboration between boards and the need to release a joint
273 statement.

274
275 *Catherine Kowalski, Mackenzie Peeler, and Dirk White left the room at 10:04 a.m.*

276 *Allan Alcancia left the room at 10:14 a.m.*

277 *Scott Watts and Molly Gray left the room at 10:32 a.m.*

278 *Adele Davis left the room at 10:45 a.m.*

279
280 *Allan Alcancia entered the room at 10:18 a.m.*

281
282 **Agenda Item 5 PDMP Update**

Time: 10:26 a.m.

283
284 Letter from Board to director, Sara Chambers

285 Chair Holt presented a draft letter from the board to division director, Sara Chambers, requesting
286 additional resources to process PDMP registration applications more timely, noting a significant
287 delay with over 2,600 pending registration applications to be processed. The board reviewed the
288 letter.

289
290 **On a motion duly made by Tammy Lindemuth, Seconded by Lana Bell and with**
291 **unanimous approval to forward the letter requesting additional staff resources for the**
292 **PDMP to director Chambers, it was:**

293
294 **RESOLVED to send the letter dated March 7, 2019 to division director, Sara**
295 **Chambers, addressing the need for staff to process pending PDMP registrations.**

296
297

	APPROVE	DENY	ABSTAIN	ABSENT
298				
299	Leif Holm	x		
300	Richard Holt	x		
301	Phil Sanders	x		
302	Lana Bell	x		
303	Tammy Lindemuth	x		
304	James Henderson			x
305	Sharon Long			x

306

307 The motion passed with no further discussion.

308

309 **TASK 5**

310 Ms. Carrillo will forward the letter to director Chambers and will provide an update to the board
311 once complete.

312 *(Completed on 03/11/19; Ms. Carrillo also notified the board that director Chambers received approval to*
313 *continue with the PDMP program coordinator recruitment).*

314

315 PDMP Board Report: Pharmacy

316 Hearing nothing further on public comment, Laura Carrillo addressed the Board of Pharmacy
317 report for the PDMP update, which included information up to January 31, 2019. For the Board
318 of Pharmacy, there were 1972 currently registered pharmacists, with registration compliance at
319 94%; the highest compliance rate among all boards with PDMP requirements. Ms. Carrillo then
320 reviewed the breakdown of registered users by related user roles, including IHS, VA, military
321 dispensers, and pharmacist delegates. Ms. Carrillo noted to the board that despite being the only
322 profession not required to login or review patient prescription history pharmacists have the
323 highest login and review rates compared to those professions mandated to do so, which
324 demonstrates pharmacist’s efforts to maximize the PDMP. For threshold reporting, Ms. Carrillo
325 informed the board that 21 patients appeared to meet or exceed the established threshold of
326 receiving more than five prescriptions from more than five pharmacies over a three-month period
327 (5-5-3 threshold), and that notifications will be sent to respective boards. For the record, Ms.
328 Carrillo clarified that these unsolicited notifications that are sent to the boards do not disclose the
329 name of the licensee who contributed to a patient meeting or exceeding this threshold, but that
330 the notification is authorized in statute. In responding to DEA subpoenas, Ms. Carrillo responded
331 that the response rate is at 100%, with the majority of subpoenas received in 2018 was for
332 patients, followed by prescribers, and then dispensers.

333

334 Ms. Carrillo then informed the board that as of January 31, 2019, there were 181 delinquent
335 pharmacies, meaning that these pharmacies either failed to report at least one time within a week
336 up until June 30, 2018, or did not submit daily from July 1, 2018 to January 1, 2019. Due the
337 continued vacancy, letters have not been sent to these pharmacies notifying them of their
338 delinquent reporting status; however, Ms. Carrillo stated it is a priority to get notices sent once the
339 PDMP Program Coordinator position is filled.

340 **TASK 6**

341 Delinquent reporting notices will be sent to the 181 pharmacies by the PDMP Program
342 Coordinator.

343 *(In-progress).*

344

345 PDMP Report to the 31st Legislature

346 Ms. Carrillo presented the draft of the legislature to the board, which included updated data on
347 registration, reviewing, and reporting measures and various PDMP related activities. The board
348 reviewed the report.

349

350 **On a motion duly made by Lana Bell, Seconded by Phil Sanders and with unanimous**
351 **approval to submit the PDMP legislative report, it was:**

352

353 **RESOLVED to submit to the 31st Legislature the Prescription Drug Monitoring**
354 **Program report as written.**

355

	APPROVE	DENY	ABSTAIN	ABSENT
356 Leif Holm	x			
357 Richard Holt	x			
358 Phil Sanders	x			
359 Lana Bell	x			
360 Tammy Lindemuth	x			
361 James Henderson				x
362 Sharon Long				x

363

364 The motion passed with no further discussion.

365

366 **TASK 7**

367 Ms. Carrillo will submit the legislative report via director, Sara Chambers.
368 *(Completed on 03/11/2019; pending submittal to legislature via Senator Cathy Giessel).*

369

370 Enhanced Programmatic Desk Review (EPDR) by BJA

371 Ms. Carrillo informed the board that they had an EPDR scheduled with the Bureau of Justice
372 Assistance (BJA), in which a series of questions were asked regarding financial, administrative, and
373 programmatic matters related to the PDMP. Ms. Carrillo stated that Andy Jones, previously with
374 the Alaska Department of Health and Social Services' (DHSS) Office of Substance Misuse and
375 Addiction Prevention (OSMAP) was primarily responsible for providing responses to the
376 questions. Updates provided by Ms. Carrillo included ongoing activities, including enhancement
377 features to the AWARe platform and collaboration efforts with DHSS.

378

379

380

381

382 Letter of Support for CDC’s Overdose Data to Action Grant “OD2A”
 383 The board reviewed a draft letter prepared in support of the Opioid Data to Action (CDC-RFA-
 384 CD19-1904) grant to assist DHSS’s Injury Surveillance Program in applying for grant funds. The
 385 funds would be used to advance and evaluate state-level interventions for the PDMP, ultimately
 386 requiring the continuation of multi-state department collaborative efforts between DHSS and the
 387 PDMP. If funding is awarded, the PDMP would have two deliverables to comply with: 1.)
 388 improving database functionality and expanding the PDMP through improved intra- and inter-
 389 state interoperability. Ms. Carrillo informed the board that while there may be existing grant funds
 390 to cover enhancement features to comply with the database functionality aspect, additional funds
 391 would be particularly helpful with expanding sharing of data among in-state entities and out-of-
 392 state entities.

393
 394 **TASK 8**

395 Ms. Carrillo will request more information on solutions to comply with improving database
 396 functionality and improving intra- and inter-state functionality, and will continue to collaborate
 397 with Appriss Health and DHSS on these advancements
 398 *(Completed on 03/12/19; Ms. Carrillo submitted an internal request to submit a proposal for ASTHO/CDC*
 399 *to highlight PDMP successes; Ms. Carrillo also requested a cost estimation sheet from Appriss for*
 400 *enhancements/applications to assist in complying with the OD2A Grant, including: OpenBeds and ERvive).*

401
 402 **On a motion duly made by Tammy Lindemuth, Seconded by Rich Holt and with**
 403 **unanimous approval for the letter of support for the Overdose Data to Action grant, it was:**
 404

405 **RESOLVED to approve the letter of support for inclusion into the application for**
 406 **the Overdose Data to Action grant to be submitted by the Alaska Department of Health**
 407 **and Social Services.**

	APPROVE	DENY	ABSTAIN	ABSENT
410 Leif Holm	x			
411 Richard Holt	x			
412 Phil Sanders	x			
413 Lana Bell	x			
414 Tammy Lindemuth	x			
415 James Henderson				x
416 Sharon Long				x

417
 418 The motion passed with no further discussion.

419
 420 Military Health System PDMP (“MHS PMP”)

421 Ms. Carrillo informed the board that the military recently launched their own prescription drug
 422 monitoring program and presented a draft MOU she prepared for the military and the state
 423 PDMP to connect to each other. Ms. Carrillo stated that the interoperability specifications are still

424 in the development stages, but that she would follow-up once the Department of Defense returns
425 the MOU to the department.

426

427 **TASK 9**

428 Ms. Carrillo will follow-up with the board on the status of the MHS PMP. (*On-going*).

429

430 Delayed PDMP Registration Protocol

431 The board addressed the protocol for assessing delayed registrations. Ms. Carrillo included in the
432 board packet a letter template the Board of Nursing uses when notifying licensees that they may
433 have registered late with the PDMP. Rich Holt inquired how the board would assess late
434 registrations given the current 2,600 registration backlog. Ms. Carrillo stated that a delayed
435 registration wouldn't be determined based on the date the account is approved and access is given,
436 but rather the date from when the pharmacist is issued an Alaska license to the date they submit a
437 complete PDMP registration, including creation and submission of online credentials through
438 AWAReE, as well as submission of the form and payment. Since the deadline to register for
439 existing licenses went into effect on July 17, 2017, the processing of late registrations would only
440 apply to newly licensed pharmacists. Chair Holt commented on the fact that not every pharmacist
441 is required to register, just those dispensing federally scheduled II – IV controlled substances in
442 Alaska. Ms. Carrillo inquired about when it is appropriate to gather the information on a
443 pharmacist's dispensing status. Investigator, Brian Howes, recommended that dispensing status
444 could be determined during the investigation of a complaint, at which time the discovery of non-
445 compliance with registration may be considered a secondary violation given there is a violation
446 found as a result of the initial complaint, and consequently a disciplinary action issued against the
447 pharmacist's license. Ms. Carrillo also suggested putting in an IT order for a dispensing
448 designation to be available for pharmacist license types.

449

450 The board also discussed delayed registrations, ultimately determining that they should be given 30
451 days to submit a complete PDMP registration application from the date they are issued an initial
452 pharmacist license. The courtesy letter will be modeled after the Board of Nursing letter and no
453 action will be taken since the letter will warn licensees that they must renew their PDMP
454 registration on time or may risk a disciplinary action against their license.

455

456 **On a motion duly made by Lana Bell, Seconded by Tammy Lindemuth and with**
457 **unanimous approval to set a grace period for registering with the PDMP, it was:**

458

459 **RESOLVED to set the registration window as 30-days of being issued an initial**
460 **pharmacist license to the date a complete PDMP application (including submission of**
461 **online credentials via alaska.pmpaware.net and the requisite form and payment, if**
462 **applicable) is submitted. A courtesy letter will be submitted to licensees reminding them**
463 **of their requirement to renew their registration timely.**

464

465

466

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			

467	Richard Holt	x	
468	Phil Sanders	x	
469	Lana Bell	x	
470	Tammy Lindemuth	x	
471	James Henderson		x
472	Sharon Long		x

473
474 The motion passed with no further discussion.

475
476 **TASK 10**

477 Ms. Carrillo will put in an IT work order to add the dispensation designation to the pharmacist
478 license category.
479 *(Completed 03/13/19; Ms. Carrillo put in the request via program coordinator, Colleen Kautz, who will request
480 this through IT).*

481
482 **TASK 11**

483 Chair Holt will draft a courtesy letter notifying newly licensed pharmacists that they have
484 potentially registered late based on the 30-day grace period.
485 *(Completed 03/10/19; Chair Holt drafted the letter and also suggested this be a good opportunity to assess
486 dispensation status; Ms. Carrillo drafted a form titled, 'PDMP Exemption Statement for Non-Dispensing
487 pharmacists on 03/12/19 and submitted to publications specialist, Hannah Hamburg for finalizing).*

488
489 Chair Holt called for break at 11:23 a.m.
490 *Off record at 11:23 a.m.*
491 *On record at 11:29 a.m.*

492
493 **Agenda Item 6 Conference and Meeting Updates Time: 11:30 a.m.**

494
495 Controlled Substance Advisory Committee (CSAC)

496 Lana Bell addressed the CSAC, first reminding the board that legislation from FY18 resulted in
497 the shift of the CSAC chair position from the Department of Law to the Board of Pharmacy or
498 the Board of Pharmacy's designee. Chair Holt designated this position to Lana Bell, who is the
499 current chair of the committee. Ms. Bell reiterated earlier concerns that due to the lack of clear
500 communication and direction into the continuation of administrative support to assist the new
501 chair in this capacity, it has been difficult to assert authority over the committee and schedule
502 subsequent meetings. Ms. Bell added that the committee is required to meet twice per year, but the
503 Department of Law has expressed that they would not be continuing to provide support, such as
504 publishing meeting dates, scheduling meetings, and writing meeting minutes. The authorizing
505 statute did not provide for the Board of Pharmacy staff to perform the necessary administrative
506 support to the CSAC, which makes being in the position of chair difficult to navigate. Ms. Bell
507 ultimately expressed she would like to consider that the chair appoint a new designee to this
508 position and further added the CSAC committee has great potential to mobilize resources to

509 address emerging issues requiring a multidisciplinary approach. Chair Holt agreed to entertain this
510 and recommended it be added to the March 8, 2019 agenda under Administrative Business,
511 Agenda Item #22.

512
513 Phil Sanders inquired as to whether the CSAC has accomplished any particular tasks, to which Ms.
514 Bell stated that they have; most recently, the CSAC addressed emergency scheduling with the
515 support and recommendation that unscheduled substance be scheduled on an emergency basis
516 when there is an immediate threat to public health and safety.

517
518 **Agenda Item 7 Investigative Report Time: 11:42 a.m.**

519
520 Investigator, Brian Howes was present in Anchorage to provide the board’s investigative report,
521 which included the opening of 22 matters and closing of 13. Mr. Howes also informed the board
522 that one was related to a licensing action and one that was related to PDMP registration, which he
523 recommended should be discussed under executive session.

524
525 **On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), the board**
526 **unanimously moved to enter executive session for the purpose of discussing subjects that**
527 **tend to prejudice the reputation and character of any person, provided the person may**
528 **request a public discussion.**

529
530 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

531
532 Staff members, Laura Carrillo, Norman Thompson, Allan Alcancia, and Brian Howes were
533 authorized to remain in the room.

534
535 *Off record for executive session at 11:45 a.m.*

536 *On record for public discussion at 12:08 p.m.*

537
538 Upon return from executive session, Chair Holt clarified for the record that no motions were
539 made under executive session.

540
541 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and with**
542 **unanimous approval to accept the voluntary surrender of Neil Holder, Alaska Pharmacist**
543 **License #PHAP1391, Case #2019-000186, it was:**

544
545 **RESOLVED to accept the voluntary license surrender of license # PHAP2124 by**
546 **Neil Holder. The voluntary surrender was based upon evidence of violations against AS**
547 **08.01.075, AS 08.80.261(a)(7), and AS 08.80.261(a)(8).**

548
549

	APPROVE	DENY	ABSTAIN	ABSENT
550 Leif Holm	x			
551 Richard Holt	x			

593 NABP to report to the NPDB, it would create a reciprocal relationship in which the board could
594 query the NPDB for applicants seeking initial licensure in Alaska.

595

596 **TASK 12**

597 Ms. Carrillo will follow-up with the NABP for more information on the pros of entering into this
598 agreement, including clarifying whether it would allow for the board to also query the NPDB for
599 applicants pursuing licensure in Alaska, and will also request which states have a current
600 agreement for adverse action reporting.

601 *(Initiated on 03/14/19; Ms. Carrillo sent an email to the NABP requesting additional information).*

602

603 Skilled Nursing Facilities

604 The board moved to discussion on skilled nursing facilities. Ms. Bell's impression was that the
605 questions being raised are most appropriate for medical directors of skilled nursing facilities, which
606 had to do with access to emergency medication kits and the use of automated drug cabinets. The
607 letter, initially sent by Matthew Keith, requested an opportunity to speak with the board directly
608 on this issue; however, Mr. Keith passed the baton to Piper Machamer, who was not present at
609 the meeting to address this with the board.

610

611 **TASK 13**

612 Ms. Carrillo will follow-up with Piper Machamer from Geneva Woods Pharmacy to request that
613 the questions related to emergency medication kits and automated drug cabinets be clarified.

614 *(Completed 03/18/19; Ms. Carrillo sent an email to Ms. Machamer requesting for specific questions on
615 03/14/19 and received a response on 03/18/19 indicating the interest/initiative is being withdrawn).*

616

617 Opioid Issue Feedback (Letter from Chair)

618 The board reviewed correspondence submitted by licensees expressing their opinions on the letter
619 released on January 23, 2019. Chair Holt reiterated that he supports pharmacists, their right to
620 refuse, their clinical judgment, and reminded the public that the intent of the letter was to address
621 the approach of refusing to fill a prescription. Tammy Lindemuth expressed how the letter was
622 received negatively by the pharmacy community and inquired whether there is any recourse the
623 board can take to remedy the relationship with its constituents. Lana Bell commented that the
624 board can continue to provide clarification as to the background and intent of the letter, but that
625 ultimately, it will require increased efforts between prescribing boards to provide better guidance.
626 Ms. Carrillo stated that she and Chair Holt created a draft joint statement that addressed the topic
627 of supporting prescribing and dispensing practices and the need to improve increased
628 communication and collaboration. Ms. Carrillo reminded the board that they would be holding a
629 meeting on March 11th with board staff, and Chair Holt recommended appointing delegates to
630 serve on a community for the purpose of giving input on this multidimensional issue.

631

632 **TASK 14**

633 Ms. Carrillo will follow-up with the board on the status of the PDMP touch-base meeting with
634 board staff affected by AS 17.30.200.

635 *(Initiated again on 03/14/19; Ms. Carrillo emailed Chair Holt with a status update on the meeting; the Medical*
 636 *Board EA indicated she would put the joint statement letter back on the board's radar, and Ms. Carrillo is active*
 637 *working with the Board of Dental Examiners appointed delegate, David Neilsen, to get his profession's perspective*
 638 *included in the letter).*

639
 640 IHS Pharmacist-in-Charge License Requirements

641 Norman Thompson included in the board packet correspondence from Robert Clark,
 642 President/CEO of Kakanak Hospital, which is a federal facility operating as Bristol Bay Area
 643 Health Corporation (BBAHC). BBAHC's pharmacy is currently licensed in Alaska but is a tribal
 644 health organization. Tribal organizations are exempt from state licensure requirements under the
 645 Indian Self-Determination and Education Assistance Act (ISDEAA) of 1975, however, the
 646 pharmacy pursued licensure in the state. Chair Holt commented to the board that BBAHC had
 647 inquired whether one of their pharmacists could serve as a pharmacist-in-charge without holding a
 648 pharmacist license in Alaska as the pharmacist holds an active license in another state. The initial
 649 interpretation was that because the pharmacy holds a license in Alaska, the pharmacy is ultimately
 650 subject to state law, including having a pharmacist-in-charge who holds a license under AS 08,
 651 which is a requirement under 12 AAC 52.200. This interpretation was relayed to BBAHC, to
 652 which Mr. Clark responded with reasoning justifying that the pharmacist-in-charge should not
 653 have to hold an Alaska pharmacist license due to the exemption under ISDEAA. The board
 654 ultimately decided that a legal opinion would need to be requested.

655
 656 **On a motion duly made by Lana bell, seconded by Phil Sanders, and approved**
 657 **unanimously, it was:**

658
 659 **RESOLVED to submit to the AAG a request to clarify whether Alaska-licensed**
 660 **pharmacies seeking exemptions to licensure requirements of its staff under ISDEAA can**
 661 **be granted for a pharmacist-in-charge.**

662

	APPROVE	DENY	ABSTAIN	ABSENT
663 Leif Holm	x			
664 Richard Holt	x			
665 Phil Sanders	x			
666 Lana Bell	x			
667 Tammy Lindemuth	x			
668 James Henderson				x
669 Sharon Long				x

670
 671 The motion passed with no further discussion.

672
 673 **TASK 15**

674 Ms. Carrillo will request a legal interpretation on whether a pharmacist for an Alaska-licensed IHS
 675 pharmacy can appoint a pharmacist-in-charge who does not hold a license under AS. Ms. Carrillo

676 will also follow-up with BBAHC/Kanakanak Hospital informing them that a legal opinion has
677 been requested.
678 *(Completed 05/01/2019; Ms. Carrillo requested a legal opinion through director Sara Chambers on 04/12/19.*
679 *Director Chambers cited AGO No. AN2009102500 on 05/01/18 indicating IHS individuals or entities with*
680 *an Alaska license under AS 08. must comply with all applicable laws. Follow-up provided to applicant.)*

681
682 Partial Fill for Schedule II Medications
683 Included in the board packet was a link to file comments regarding proposed federal legislation on
684 partial fills for schedule II controlled substances. The board did not discuss this in depth.
685

686 **Agenda Item 11 Budget Update Time: 1:30 p.m.**

687
688 *Melissa Dumas and Marylene Wales entered the room at 1:26 p.m.*
689 *Melissa Dumas and Marylene Wales left the room at 1:52 p.m.*

690
691 Administrative Officer, Melissa Dumas, and Marylene Wales, Accountant, were present to provide
692 the board with a budget update for the FY19 1st and 2nd Quarter, as well as the FY19 2nd Quarter
693 report for the PDMP. Ms. Wales commented that for the first quarter, the board had \$63,290 in
694 total revenue, \$47,677 in total direct expenditures, which includes personal services, travel,
695 contractual, supplies, and equipment, and \$112,597 in total expenses. The ending cumulative
696 surplus for this period was \$458,686. For the 2nd quarter, the board's ending cumulative surplus
697 was \$363,440.

698
699 For the PDMP 2nd quarter report, Ms. Dumas informed the board that there are currently two
700 revenue streams: the \$25.00 registration and renewal fee required per biennium and grant funds
701 received through reimbursable service agreements (RSAs), for which the board has collected
702 \$65,045 and expended \$82,641.04, respectively. Ms. Dumas clarified that the board has not spent
703 any revenue collected through the registration fee. Leif Holm commented that it was in statute, at
704 least initially, that the fee was not to exceed the cost to operate, and inquired whether this was
705 based on the theoretical cost or actual cost to operate. Mr. Holm further added that it's
706 convenience to be collecting a cushion, but it's also in the best interest to start spending money as
707 it will continue to cost more and more to comply with grant deliverables. Ms. Carrillo commented
708 that there are existing funds to cover enhancements they wish to pursue, including NarxCare and
709 the compliance module. Mr. Holm added that the board have discussed NarxCare in the past, but
710 that it's not necessarily a critical feature, to which Ms. Carrillo stated that there are limited options
711 to comply with grants and that NarxCare is one solution. Chair Holt commented that the
712 compliance module would be beneficial as it would allow us to more closely monitor compliance.
713 Ms. Dumas suggested that we need to give the revenue and expenditure streams about another
714 year to fully assess the registration fee's impact, after which time a fresh fee analysis can be
715 conducted to further assess whether the fee can be reduced.

716
717
718

719 **Agenda Item 8** **New Business**

Time: 1:02 p.m.

720
721 The board returned to discussion on correspondence items, beginning with regulations on partial
722 fills of schedule II medications.

723
724 Transfer of Unfilled Controlled Substances

725 Chair Holt commented that the NABP came out with a letter in 2017 regarding confusion over
726 federal regulations and transfers of prescriptions for schedule II controlled substances. The Drug
727 Enforcement Administration made an exception to title 21, code of federal regulations, Section
728 1306.25, such that a DEA-registered pharmacy that has filled an initial prescription could transfer
729 the original prescription to another DEA-registered pharmacy. This would allow the secondary
730 pharmacy to dispense any remaining refills permitted by the prescriber. Chair Holt commented
731 that the exception, however, did not outline guidance for verbal, faxed, or hardcopy orders, that
732 the only exception is for electronically prescribed controlled substance prescriptions. In addition,
733 Chair Holt added that the exception didn't provide guidance for the method in which to forward a
734 prescription, including documentation requirements. It is Chair Holt's understanding that at this
735 time, there is inconsistent practices over transferring of prescriptions because of the lack of clarity
736 in the guidance.

737
738 **Agenda Item 12** **Old Business**

Time: 2:00 p.m.

739
740 *Chris Kennedy, Administrative Law Judge, and Kenneth Bressers, representing OMRO pharmacy entered the*
741 *room at 2:00 p.m.*

742 *Chris Kennedy, Administrative Law Judge, and Kenneth Bressers, representing OMRO pharmacy left the room at*
743 *2:48 p.m.*

744
745 The board then addressed the OMRO case, which the board had denied registration to during
746 their May 10-11, 2018 meeting.

747
748 **On a motion duly made by Tammy Lindemuth in accordance with AS 44.62.310(c)(2), the**
749 **board unanimously moved to enter executive session for the purpose of discussing**
750 **subjects that tend to prejudice the reputation and character of any person, provided the**
751 **person may request a public discussion. It was:**

752
753 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

754
755 Staff members were not authorized to stay in the room.

756
757 *Off record for executive session at 2:02 a.m.*

758 *On record for public discussion at 2:48 p.m.*

759 Upon returning from executive session, Chair Holt commented that no motions were made under
760 executive session.

761

762 On a motion duly made by Tammy Lindemuth to adopt the ALJ's final decision to
 763 approve issuance of the out-of-state pharmacy registration, it was:

765 **RESOLVED** to accept the ALJ's final decision to issue the registration for OMRO
 766 Pharmacy.

	APPROVE	DENY	ABSTAIN	ABSENT
768 Leif Holm	x			
769 Richard Holt	x			
770 Phil Sanders	x			
771 Lana Bell	x			
772 Tammy Lindemuth	x			
773 James Henderson				x
774 Sharon Long				x

776
 777 The motion passed with no further discussion.

778
 779 **Agenda Item 8 New Business Time: 3:15 p.m.**

780
 781 The board returned to discussion on new business items, beginning with regulations on partial fills
 782 of schedule II medications.

783
 784 Transfer of Unfilled Controlled Substances

785 Chair Holt commented that the question boils down to whether a pharmacy can transfer a
 786 controlled substance prescription. Chair Holt prompted the board to determine whether the board
 787 should prepare a guidance statement. Ms. Lindemuth proposed drafting a position statement until
 788 further information could be obtained and Ms. Bell suggested the topic be tabled until the next
 789 meeting. The board discussed having the Department of Law review this issue, to which Mr.
 790 Sanders inquired what the specific ask would be. Ms. Bell stated that it would be to determine
 791 whether the board has the authority or if it is appropriate to weigh in on a federal rule.

792
 793 **On a motion duly made by Lana bell, seconded by Tammy Lindemuth, and approved**
 794 **unanimously, it was:**

795
 796 **RESOLVED** to submit to the AAG a request for input on whether the board can
 797 weigh in on a federal rule, particularly the issue concerning DEA guidance on transferring
 798 of controlled substance prescriptions.

	APPROVE	DENY	ABSTAIN	ABSENT
800 Leif Holm	x			
801 Richard Holt	x			

803	Phil Sanders	x	
804	Lana Bell	x	
805	Tammy Lindemuth	x	
806	James Henderson		x
807	Sharon Long		x

808

809 The motion passed with no further discussion.

810

811 **Agenda Item 10 Correspondence**

Time: 3:15 p.m.

812

813 NACDS – Lis Houchen (addressed earlier during public comment)

814

815 NABP Proposed Resolutions (reviewed)

816

817 NABP MPJE Workshop

818 Chair Holt commented he would be participating in this MPJE writing workshop remotely on
819 March 13-15, 2019 and that it requires review of over 2,000 items. The board discussed other
820 MPJE workshops, and Ms. Lindemuth noted to the board that the reviewing workshop is in the
821 fall. The board continued to discuss workshop events.

822

823 **TASK 17**

824 Ms. Carrillo will put in a travel request for Leif Holm to attend the NABP Annual Meeting using
825 grant funds.

826 *(Completed 03/08/19; Ms. Carrillo requested that the travel request be added for Leif Holm using NABP's*
827 *travel grant and for Ms. Carrillo's travel to be funded by federal grant funds through the RSA; Ms. Carrillo*
828 *confirmed on 03/19/19 with the NABP to transfer its travel grant to Mr. Holm).*

829

830 Automated Dispensing

831 The board reviewed questions from Kevin Rew who inquired about automated dispensing in two
832 settings: 1.) onsite at outpatient clinics in order to guarantee that the patient leaves the clinic with
833 the first prescription in hand (the primary interest); and 2.) on the pharmacy premises, for access
834 by patients who do not wish to wait in line for refills. Mr. Rew's specific questions were how the
835 board would consider approving a pilot project for automated dispensing and if the board would
836 be receptive to legislation changes requiring automated dispensing. In Mr. Rew's correspondence,
837 he indicated that California recently enacted rules to bring automated dispensing to outpatient
838 settings and was interested in whether Alaska was interested in pursuing this. Ms. Lindemuth
839 suggested requesting a copy of California's law and also recommended inquiring from Mr. Rew
840 how use of automated dispensing is monitored.

841

842 **TASK 18**

843 Ms. Carrillo will follow-up with Kevin Rew requesting a copy of California’s law on automated
844 dispensing and how the practice is being monitored. Ms. Carrillo will provide Mr. Rew’s responses
845 to the board for their next meeting.

846 *(Completed 03/14/19; Ms. Carrillo requested additional information from Mr. Rew; Mr. Rew provided requested*
847 *information to Ms. Carrillo on 03/15/19 for inclusion into the board’s next meeting packet).*

848
849 Unlicensed Practice

850 The board reviewed an article regarding an individual who posed as a pharmacist at a Walgreens in
851 California.

852
853 Prescription Adaptation

854 The board reviewed correspondence from Dennis McAllister from Express Scripts who inquired
855 whether the board would consider entertaining legislation enabling pharmacists to adapt
856 prescriptions as is done in Washington. Mr. Holm commented that it could improve relationships
857 with providers; however, Chair Holt commented dosage forms as written in Washington can’t be
858 changed in Alaska because it’s written in Alaska statutes. The board continued to discuss
859 prescription adaptation.

860
861 **TASK 19**

862 Phil Sanders will review existing statutes and regulations to propose the law based on Dennis
863 McAllister’s provided draft of Washington.

864
865 **TASK 20**

866 Ms. Carrillo will inform Dennis McAllister that the board will be looking into prescription
867 adaptation more closely and will address this again at their next meeting.
868 *(Completed 03/14/16; Ms. Carrillo informed Mr. McAllister of the status of the board’s attention to this*
869 *matter).*

870
871 **Agenda Item 12 Old Business Time: 3:42 p.m.**

872
873 The board returned to discussion of old business.

874
875 Continuing Education Audit

876 The board reviewed the outstanding continuing education audits for pharmacists for the renewal
877 period of July 1, 2016 to June 20, 2018. The hourly continuing education requirement for this
878 license type is 30 hours. Chair Holt inquired to Ms. Carrillo if the continuing education certificates
879 are screened in advance of board review, to which Ms. Carrillo affirmed.

880
881 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved**
882 **unanimously to accept the continuing education audits in compliance with 12 AAC 52.300-**
883 **350 for pharmacists: Christopher Sperry, Trevor Embry, Heidi Brainerd, Chad**
884 **Lamoureux, Jacob Mock, Dawn Erbeck, Dean Thorson, Dawn Hughes, Karen Nelson,**
885 **Robert Grogan, Mary Heaster, Beth Dobson, Mike Branson, William Altland, Lorraine**

886 Ball, Debra Spurlock, Marlene Perschbacker, Charlene Hampton, Preston Van Curen,
 887 Nichell Moore, Cynthia Lynn McCoy, Rodney Gordon, Adam Schwartz, Craig Eyer,
 888 Matthew Keith, Bridget Alem, Stephen Cole, Heidi Bernhoft, Rosalynda Uy, Sally
 889 Wilhelm, Mark De Zeeuw, Megan Wiegand, Sarah Schock, Justin Conrett, Joyce
 890 Durcanin-Robbins, Jessica Hinckley, Rachel Botson, James Bunch, Dharna Begich,
 891 Patrick Welch, Steven Miller, Dawn Shill, Rose Winkel, Janet Schwartz, Myra Flint-Smith,
 892 Leonard Bolog, John Evey, Donna Michaud, Richard Einhellig, Kristopher Swinney,
 893 Elizabeth Tressler, Renee Robinson, Young Oh, Theresa Castellanos, Katelyn Hilton,
 894 Benjamin Schultz, Erin Narus, Christine Latta, Cheri Cubbison, Medelina Richmond,
 895 Chelsea Dubbe, Michael Kristie, Shawna O'Shea, Grant Cleveland, Ericka Richards,
 896 Samantha Ervin, Stephanie Stolen, Enoch Ronduen, Dane Brubaker, Joel Phair, Angelina
 897 Lovell, Cory Collins, Peter Simonich, Amanda Hammila, Jeffery Moseley, Heidie Carlson,
 898 Richard Batson, Tina Horn, Johanna Ellerup Ann Stout, Ryan Trevithick, Douglas Chan,
 899 Warner Wolf, Laura Garza, Bryce Farrar, Brandon Boller, Cindy Tobias, Teresa Kriletich-
 900 Bruce, John McGilvray, Kendal Haihoi, John Bittner, Douglas Bartko, Molly Hull, Jerry
 901 Gottbe, and Kelly Smoot, it was:

902
 903 **RESOLVED** to accept the continuing education audits for the above mentioned
 904 pharmacists, who demonstrated compliance with the continuing education requirements
 905 under 12 AAC 52.300 – 12 AAC 52.350 for the 2016 – 2018 renewal period.
 906

	APPROVE	DENY	ABSTAIN	ABSENT
907 Leif Holm	x			
908 Richard Holt	x			
909 Phil Sanders	x			
910 Lana Bell	x			
911 Tammy Lindemuth	x			
912 James Henderson				x
913 Sharon Long				x

914
 915
 916 The motion passed with no further discussion.
 917

918 **TASK 21**

919 Ms. Carrillo and Mr. Thompson will send audit closed letters to the pharmacists whose continuing
 920 education audits were accepted. Audit flags will also be removed from these licensee's records and
 921 those who have not complied with the audit will be contacted by the paralegal.

922 *(Audit closed letters sent 03/19/19. Ms. Carrillo sent Marilyn Zimmerman an email regarding licensees who did*
 923 *not appear to comply with the continuing education requirement as of 03/14/19).*
 924

925 The board reviewed the outstanding continuing education audits for pharmacy technicians for the
 926 renewal period of July 1, 2016 to June 20, 2018. The hourly continuing education requirement for
 927 this license type is 10 hours.

928 On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved
 929 unanimously to accept the continuing education audits in compliance with 12 AAC 52.300-
 930 350 for pharmacy technicians: Katya Drobkov (Strul), Lorena Gebhardt, Kathryn Carleton,
 931 Susan Landreth, Ty Miller, Brittany Romans, Jaaliyah Alexander, Krista Yadao, Dorothy
 932 Luchansky, Yu Chung, Sherry Chambers, Linda Cossairt, Merry Gregg, Brenda Elmer,
 933 Alysia Johnson, Sherri Brown, Alysia Davis, Kathleen Karl, Gibran Sandine, Carolyn
 934 Tamanaha, Marylyn Peralta, James Lyle, Mailee Vue, Mackenzie Peeler, Mary Rardin,
 935 Lisa Severson, Shannon Riggs, Michelle Powell, Elba Escamilla, Kristi Sternitzke-Morton,
 936 Neil Kahl, Dana Cartwright, Albert Orenca, Nomi Smith, Racquel Green, Glaiza Kordus,
 937 Connie Coca, Christopher Harvey, Elisabeth Wood, Kiriakia Reutov, Sandra Taylor,
 938 Kristina Kolomeychuk, Lawrence Yuquimpo, Jennifer Vlasoff, Jessica Hulet, Maricel Tiu,
 939 Gaojer Yang, Virginia Ravina, James Driggers, Michelle Oakey, Amber Vanderlinden,
 940 Adam Maccabee, Ma Salao, Apolla Mojica, Constance Srebernak, Ashley Moitoso, Kelli
 941 Anderson, Bonny Holm, Agnes Velasco, it was:

942
 943 **RESOLVED** to accept the continuing education audits for the above mentioned
 944 pharmacy technicians, who demonstrated compliance with the continuing education
 945 requirements under 12 AAC 52.300 – 12 AAC 52.350 for the 2016 – 2018 renewal period.
 946

	APPROVE	DENY	ABSTAIN	ABSENT
947 Leif Holm	x			
948 Richard Holt	x			
949 Phil Sanders	x			
950 Lana Bell	x			
951 Tammy Lindemuth	x			
952 James Henderson				x
953 Sharon Long				x

954
 955
 956 The motion passed with no further discussion.
 957

958 **TASK 22**

959 Ms. Carrillo and Mr. Thompson will send audit closed letters to the pharmacists whose continuing
 960 education audits were accepted. Audit flags will also be removed from these licensee’s records and
 961 those who have not complied with the audit will be contacted by the paralegal.

962 *(In-process as of 03/14/19; Ms. Carrillo sent Marilyn Zimmerman an email regarding licensees who did not*
 963 *appear to comply with the continuing education requirement).*

964
 965 The board would be reviewing tabled applications on March 8th.
 966

967 Applications and Forms

968 Ms. Carrillo provided a spreadsheet on completed application updates and in-process updates for
 969 the board to review.

970 Annual Report

971 Chair Holt commented he would begin the initial draft of the annual report due June 1st.

972

973

974 **TASK 23**

975 Chair Holt will work on the annual report due June 1st.

976 *(In-progress).*

977

978 **Agenda Item 14 Review Lost/Stolen Rx**

Time: 3:56 p.m.

979

980 The board reviewed the DEA form for Safeway Pharmacy #1820 (license #120100). Chair Holt
981 noted this was the third report in the past 24 months. They also reviewed the initial notification
982 from Geneva Woods Mat-Su Pharmacy (PHAR414).

983

984 **TASK 24**

985 Ms. Carrillo will email Kristin Martin to inquire as to whether they submitted the DEA-106 report
986 to make sure they filed within the appropriate timeline according to federal regulation.

987 *(Completed 03/14/19; Ms. Carrillo sent a follow-up email to Kristin Martin).*

988

989 **Agenda Item 15 Adjourn**

Time: 4:04 p.m.

990

991 Tammy moved to adjourn the meeting at 4:04 p.m. and to recess until March 8th.

1 State of Alaska
2 DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
3 DIVISION OF CORPORATION, BUSINESS AND PROFESSIONAL LICENSING
4

5 Alaska Board of Pharmacy
6 Thursday, June 27, 2019
7 10:30 am
8

9 By the authority of AA 08.01.070(2) and AS 08.86.030, and in compliance with the provisions of AS
10 44.62, Article 6, a scheduled meeting of the Alaska Board of Pharmacy was held via
11 video/teleconference on Thursday, June 27th, 2019.
12

13 **These are DRAFT minutes prepared by the staff of the Division of Corporation, Business and**
14 **Professional Licensing. These minutes have not been reviewed or approved by the Board.**

15
16 **Written meeting minutes reflect a brief overview of the business conducted by the board during their**
17 **meeting. For a more detailed account, please request a copy of the meeting recording.**
18

19 **The Chair brought the meeting to order at 10:42 am**
20

21 **Agenda Item 1 - Roll Call**
22

23 **Board Members Present Constituting a Quorum:**

24 Dr. Richard Holt – Chair
25 Lana Bell
26 Phil Sanders
27 Sharon Long
28

29 **Board Members Absent:**

30 Dr. Leif Holm
31 James Henderson
32 Tammy Lindemuth
33

34 **Staff Members present:**

35 Dawn K Hannasch-Records and Licensing Supervisor
36

37 **Members of the Public Present:**

38 Jessica Adams
39 Dan Nielson
40 Jessica
41 Victor Kao
42 Adel Davis
43 Molly Gray
44 Justin Chung
45
46

47 **Agenda Item 2 - Review/Approve Agenda**

48

49 The Chair, Dr. Richard Holt brought the meeting to order and requested that each member review the
50 drafted agenda. Dr. Holt stated that there will not be a public comment period during this meeting
51 because the public comment period for this regulations project has closed.

52

53 **On a motion duly made by Lana Bell, seconded by Sharon Long, with unanimous consent it**
54 **was:**

55

56 **resolved to approve the agenda as drafted.**

57

58 **Agenda Item 3 – Ethics Disclosure**

59

60 Of the four board members present at the meeting, none had ethic concerns to disclose.

61

62 **Agenda Item 4 – Regulations**

63

64 Hearing nothing further, Dr. Holt brought the boards attention to their board packet, which contains all
65 the written public comments that were received regarding the current regulations project affecting 12
66 AAC 52.010 – 12 AAC 52.995. The public comment period closed on May 24, 2019. Dr. Holt read each
67 comment aloud for the benefit of the public.

68

69 One of the public comments offered a recommendation to the board for changes to 12 AAC 52.423(b).
70 Mr. Sanders stated that he would prefer to complete the current regulation project and then look at
71 other changes in the future. However, board members, Sharon Long and Lana Bell, would like to
72 proceed with the recommended changes now. Dr. Holt requested that staff add the subject to the next
73 meeting, and the board ultimately decided to table 12 AAC 52.470(d) for further review and discussion.

74

75 The board continued their review of each public comment.

76

77 **On a motion duly made by Lana Bell, seconded by Phil Sanders, with unanimous consent it**
78 **was:**

79

80 **resolved to approve the regulations as written and publicly noticed except for 12 AAC**
81 **52.470(d) relating to a 30-day supply.**

82

83 **Agenda Item 5 – Adjourn**

84

85 The board adjourned the meeting following discussion of regulations.

86

87 _____

88 Laura Carrillo for Dawn Hannasch Date

89

90

91 _____

92 Richard Holt, Chair Date

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12 AAC 52.500(a) is amended to read:

(a) For the purpose of dispensing [A REFILL OF] a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.510(a) is amended to read:

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

...

12 AAC 52.510(a)(3) is repealed:

(3) **repealed** ____/____/____ [THE EQUIVALENT DRUG PRODUCT COSTS THE PATIENT LESS THAN THE PRESCRIBED DRUG PRODUCT]; and

...

12 AAC 52.510(b) is amended to read:

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the **terms** [TERM] "equivalent drug product" **or "interchangeable biological product" are** [IS] defined in AS 08.80.480. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.530(a) is amended to read:

(a) **A** [EXCEPT AS PROVIDED IN (b) OF THIS SECTION, A] pharmacy or pharmacist may [NOT] accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed **if**

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or

(2) the medication was recalled by the manufacturer or FDA; and

(3) it is segregated from the normal pharmacy inventory and may not be dispensed.

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

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.610 is amended to read:

12 AAC 52.610. Wholesale drug distributor license. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary

qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The following checklist is established by the board for review of an application

[AN APPLICANT] for a wholesale drug distributor license. **A wholesale drug distributor license will be issued to an applicant who** [SHALL]

- (1) **submits a completed, notarized application** [APPLY] on **a** [THE] form provided by the department;
- (2) **pays** [PAY] the fees required in 12 AAC 02.310;
- (3) **provides** [PROVIDE] a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;
- (4) **provides** [PROVIDE] the name and the resume of the **facility manager** [PERSON] who will manage the wholesale distribution of drugs and the wholesale drug facility;
- (5) **submits** [SUBMIT]

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; **or** [AND]

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) **submits** [SUBMIT] completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; **and**

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located for non-resident wholesale drug

distributors.

(c) [(b)] An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

- (1) meet the requirements of **(b)** [(a)] of this section; and
- (2) be registered with the **DEA** [(DEA)].

(d) [(c)] Within 30 days of a change in **location, ownership, or** facility manager, the new facility manager must

- (1) submit the completed change of **facility** [PHARMACY] manager form provided by the department;
- (2) submit the applicable fees established in 12 AAC 02.105(3); and
- (3) meet the requirements of **(b)(4)** [(a)(4)] and (6) of this section.

(e) When a wholesale distributor ceases operations, the facility manager of the wholesale distributor shall notify the board on a form provided by the department the cessation of operations; the form must be submitted within 10 days after the cessation of operations. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

12 AAC 52.620 is amended by adding a new subsection to read:

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid license under AS 08. (Eff. 1/16/98, Register 145; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

12 AAC 52.625(b) is amended to read:

(b) The board will not approve an application for a wholesale drug distributor license unless the designated **facility** manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs. (Eff. 1/16/98,

Register 145; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
 AS 08.80.030 **AS 08.80.159** AS 08.80.480

12 AAC 52.630(a) is amended to read:

(a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements [OR OFFICIAL UNITED STATES PHARMACOPOEIA (USP), 1995 REVISION, COMPENDIUM REQUIREMENTS,] to help ensure that the identity, strength, quality, and purity of the products are not affected. [IF A TEMPERATURE REQUIREMENT IS NOT LISTED FOR A DRUG, THE DRUG MAY BE STORED AT CONTROLLED ROOM TEMPERATURE AS DEFINED IN THE USP.]

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
 AS 08.80.030 **AS 08.80.159**

[**EDITOR'S NOTE:** A COPY OF THE UNITED STATES PHARMACOPOEIA MAY BE OBTAINED FROM THE UNITED STATES PHARMACOPOEIAL CONVENTION, INC., P.O. BOX 560, WILLISTON, VT 05495.]

The authority citation of 12 AAC 52.640 is changed to read:

12 AAC 52.640. Written policies and procedures.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.645 is changed to read:

12 AAC 52.645. Examination of drug shipments.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.650 is changed to read:

12 AAC 52.650. Records and inventories.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.660 is changed to read:

12 AAC 52.660. Returned, damaged, and outdated drugs.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.670 is changed to read:

12 AAC 52.670. Drug recalls.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.680 is changed to read:

12 AAC 52.680. Inspections.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.685 is changed to read:

12 AAC 52.685. Prohibition against direct distribution.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.690 is changed to read:

12 AAC 52.690. Salvage and reprocessing.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.695 is changed to read:

12 AAC 52.695. Provisions not applicable.

• • •

Authority: AS 08.80.005 AS 08.80.157 **AS 08.80.159**
AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 6 to read:

12 AAC 52.696. Outsourcing facilities. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The following checklist is established by the board for review of an application for an outsourcing facility license; an outsourcing facility license will be issued to an applicant who

- (1) submits a complete, notarized application on a form provided by the department;
- (2) pays the fees required in 12 AAC 02.310;
- (3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;
- (4) provides the name and the resume of the designated facility manager;
- (5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA).

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address shall apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager shall

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the outsourcing facility ceased operations;

(B) arrange for the records of the outsourcing facility to be retained for two years.

(g) An outsourcing facility shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility shall be registered with the Food and Drug Administration as

a 503b outsourcing facility. (Eff. ____/____/____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 6 to read:

12 AAC 52.697. Third-party logistics providers. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The following checklist is established by the board for review of an application for a third-party logistics provider license; a third-party logistics provider license will be issued to an applicant who

- (1) submits a complete, notarized application on a form provided by the department;
- (2) pays the fees required in 12 AAC 02.310;
- (3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;
- (4) provides the name and the resume of the designated facility manager;
- (5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and
- (6) submits completed fingerprint cards of the facility manager for evaluation and

investigation by the Department of Public Safety.

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of a third-party logistics provider that has changed its name or physical address shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager shall

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the third-party logistics provider ceased operations;

(B) arrange for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures. (Eff. ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.920(a)(19) is amended to read:

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, **sexual orientation, gender identity**, or sex in the provision of a service that is part of the practice of pharmacy;

12 AAC 52.920 is amended by adding a new subsection to read:

(e) Failing to meet continuing education requirements will result in a \$100 civil fine per missing continuing education credit hour for pharmacists and a \$25 civil fine per missing continuing education credit hour for technicians. (Eff. 1/16/98, Register 145; am 6/7/2018, Register 226; am ___/___/_____, Register _____)

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

12 AAC 52 is amended by adding a new section to Article 10 to read:

12 AAC 52.925. Grounds for denial or discipline for criminal history. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant’s or licensee’s ability to practice competently and safely include

- (1) murder;
- (2) manslaughter;
- (3) criminally negligent homicide;
- (4) assault;
- (5) sexual assault;
- (6) sexual abuse of a minor;

(7) unlawful exploitation of a minor, including possession or distribution of child pornography;

(8) incest;

(9) indecent exposure;

(10) robbery;

(11) extortion;

(12) stalking;

(13) kidnapping;

(14) theft;

(15) burglary;

(16) forgery;

(17) endangering the welfare of a child;

(18) endangering the welfare of a vulnerable adult;

(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;

(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely. (Eff. ___/___/____, Register _____)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.985 Emergency Preparedness. (a) If, as a consequence of a natural disaster or terrorist attack, a state of emergency is declared by the governor 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.

(b) If, as a consequence of a natural disaster or terrorist attack, a state of 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, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) When a state of emergency has been declared, a pharmacist in the area of the declared emergency may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication if

(1) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and

(2) the pharmacist makes a good faith effort to reduce the patients prescription drug information to a written prescription marked "emergency prescription" and then files and maintains the prescription in accordance with 12 AAC 52.450.

(d) If a declared state of emergency continues for more than 21-days after a pharmacist dispenses an emergency prescription under (c) of this section, the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110. (Eff. ___/___/____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.993. Executive administrator. The executive administrator may

- (1) review and approve continuing education competency audits; audits that are not in compliance are to be reviewed by a board member;
- (2) attend state or national meetings or conferences on behalf of the board;
- (3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;
- (4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;
- (5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board. (Eff. ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

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

- (37) "moral turpitude" includes conduct that is considered contrary to community standards of justice, honesty, or good morals.

12 AAC 52.995 is amended by adding a new subsection to read:

- (e) In 12 AAC 52.610 – 12 AAC 52.697, "facility manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations. (Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am

Register _____, _____ 2019 **PROFESSIONAL REGULATIONS**

12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am

____/____/____, Register _____)

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

DRAFT

Chapter 02. General Occupational Licensing Functions.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted.)

12 AAC 02.310 is amended to read:

12 AAC 02.310. Board of Pharmacy. (a) The following fees are established for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, wholesale drug distributors, and drug dispensaries:

- (1) **nonrefundable** application fee for initial license, **\$100** [\$60];
- (2) repealed 10/28/2000;
- (3) temporary pharmacist license fee, **\$50** [\$60];
- (4) emergency permit to practice pharmacy fee, **\$100** [\$110];
- (5) pharmacy intern license fee, \$30.

(b) The following license and registration fees for all or part of the initial biennial licensing or registration period and subsequent biennial license and registration renewal fees are established for pharmacists, pharmacy technicians, remote and other pharmacies, and wholesale drug distributors:

- (1) pharmacist, **\$200** [\$240];
- (2) wholesale drug distributor, \$500;
- (3) pharmacy, **\$200** [\$240];
- (4) drug room, **\$200** [\$240];
- (5) registered pharmacy located outside of the state, \$600;
- (6) pharmacy technician, **\$50** [\$60];
- (7) remote pharmacy, **\$200** [\$240];

(8) non-resident wholesale drug distributor, \$600;

(9) outsourcing facility, \$600;

(10) third-party logistics provider, \$600. (Eff. 11/20/86, Register 100; am 10/1/88, Register 107; am 5/28/93, Register 126; am 10/19/97, Register 144; am 10/28/2000, Register 156; am 6/13/2002, Register 162; am 6/23/2004, Register 170; am 2/15/2006, Register 177; am 5/18/2006, Register 178; am 6/11/2010, Register 194; am 5/18/2014, Register 210; am ____/____/_____, Register _____)

Authority: AS 08.01.065 **AS 08.80.159** AS 08.80.160

DRAFT

1 State of Alaska
2 Department of Commerce, Community and Economic Development
3 Division of Corporations, Business and Professional Licensing
4

5 Alaska Board of Pharmacy
6

7 DRAFT MINUTES OF THE MEETING
8

9 March 7, 2019 In-Person and Teleconference via OnBoard
10

11 By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62,
12 Article 6, a scheduled meeting of the Board of Pharmacy was held in-person at the
13 Robert Atwood Building, Conference Room ACC in Anchorage, Alaska and at the
14 State Office Building, 9th Floor, Commissioner's Conference Room in Juneau,
15 Alaska on March 7th and 8th, 2019.
16

17 These are draft minutes that have not yet been approved by the board.
18

19 Agenda Item 1 Call to Order/Roll Call Time: 9:05 a.m.
20

21 The March 7, 2019 meeting day was called to order by Chair, Rich Holt at 9:05 a.m.
22

23 Board members present, constituting a quorum:
24

25 Richard Holt, PharmD #PHAP2008, MBA – *Chair*
26 Leif Holm, PharmD #PHAP1606
27 Phil Sanders, RPh #PHAP776
28 James Henderson, RPh #PHAP1683 (Absent)
29 Lana Bell, RPh #PHAP893
30 Tammy Lindemuth, Public Member
31 Sharon Long, Public Member (Absent)
32

33 Division staff present:
34

35 Norman Thompson, Occupational Licensing Examiner
36 Allan Alcancia, Occupational Licensing Examiner
37 Laura Carrillo, Executive Administrator
38 Chelsea Childress, Records & Licensing Supervisor
39 Brian Howes, Investigator
40 Greg Francois, Chief Investigator
41 Melissa Dumas, Administrative Officer
42 Marylene Wales, Accountant

43 Members from the public present:

- 44
- 45 Catherine Kowalski, #PHAP926 (Petersburg Rexall Drug)
- 46 Mackenzie Peeler, #PHAC2981 (Petersburg Rexall Drug)
- 47 Dirk White, #PHAP811 (Harry Race Pharmacy)
- 48 Adele Davis, (Alaska Pharmacy Association, SEARHC)
- 49 Scott Watts, #PHAP899 (Ron’s Apothecary Shoppe)
- 50 Molly Gray, (Alaska Pharmacy Association)
- 51 Kane Olson, #PHAP1875 (via phone from Anchorage)
- 52 Daniel Nelson, #PHAP1413 (via phone from Fairbanks)
- 53 Karen Miller, #PHAP1109 (via phone from Fairbanks)
- 54 Andrew Jaconette, #MEDS5328 (via Anchorage)
- 55 Jordan Hussey, #123640 (via Anchorage)
- 56 Nancy Kavan, #PHAP1069
- 57 Joann Nelson (pharmacist)

58

59 Other members present:

- 60
- 61 Chris Kennedy, Administrative Law Judge
- 62 Kenneth Bressers, OMRO

63

64 **Agenda Item 2 Review/Approve Agenda**

Time: 9:09 a.m.

65

66 The board reviewed the agenda.

67

68 **On a motion duly made by Tammy Lindemuth, seconded by Lana Bell, and approved**

69 **unanimously, it was**

70

71 **RESOLVED to accept the March 7, 2019 agenda as written.**

	APPROVE	DENY	ABSTAIN	ABSENT
73				
74	Leif Holm	x		
75	Richard Holt	x		
76	Phil Sanders	x		
77	Lana Bell	x		
78	Tammy Lindemuth	x		
79	James Henderson			x
80	Sharon Long			x

81

82 The motion passed with no further discussion.

83

84

85 **Agenda Item 3** **Ethics** **Time: 9:09 a.m.**

86
87 The board then moved on to addressing ethics disclosures. In anticipation of discussing licensee’s
88 feedback on the Board of Pharmacy’s letter released on January 23, 2019 written by Chair Holt,
89 Mr. Holt clarified for the record that he will be addressing the matter as a board member. He
90 further clarified that when addressing the letter, it will have no bearing towards any particular
91 company or pharmacist, including any pharmacists whom he currently employs.
92

93 **Agenda Item 4** **Public Comment** **Time: 9:15 a.m.**

94
95 Federal Legislation and Employer Directives

96 Dirk White commented that as of January 1, 2020, there will be federal legislation requiring
97 pharmacists to review the Prescription Drug Monitoring Program (PDMP) prior to dispensing a
98 controlled substance. Through Chair Holt, Ms. Carrillo commented that each state has their own
99 registration, reviewing, and reporting requirements, and that licensees in Alaska are not required to
100 comply with this national directive. Chair Holt affirmed, stating pharmacists are not required to
101 review prior to dispensing under current state statute or regulation, and that he was not aware of
102 this requirement at this time, but was interested in researching this. Adele Davis commented that
103 corporations may be issuing mandates to its pharmacists requiring them to review before
104 dispensing.
105

106 **TASK 1**

107 Chair Holt and Laura Carrillo will look into the federal reviewing mandate that will go into effect
108 for pharmacists on January 1, 2020.
109 *(Completed on 03/11/19; Ms. Carrillo found an amendment to the Social Security Act/ Medicaid Partnership*
110 *Act from the 115 Congress [2017-2018 legislature] addressing an upcoming mandate. The mandate would require*
111 *states to notify the Centers for Medicaid and Medicare Services (CMS) by January 1, 2023 as to whether or not*
112 *they have state law requiring pharmacists to check the PDMP, not that reviewing by pharmacists will be required).*
113

114 Veterinary Patients and PDMP Patient Fields

115 Katherine Kowalski inquired about reviewing patient prescription history. Through Chair Holt,
116 Ms. Carrillo commented that both the Board of Veterinary Examiners and the Board of Pharmacy
117 sought legal advice on whether veterinarians can review the patient prescription history of the
118 animal’s owner, as the ability to do so was not clear in the veterinary statutes and regulations. Ms.
119 Carrillo informed the public that law ultimately opined that veterinarians can and should review
120 the animal owner’s patient prescription history since the potential to divert the controlled
121 substance lies with the human owner and not with the animal. Ms. Carrillo also stated that it was
122 up to the Board of Veterinary Examiners to come to establish standards for entering patient
123 information, i.e.: human owner’s date of birth rather than animal’s date of birth.
124
125
126
127

128 **TASK 2**

129 Laura Carrillo will follow-up with the veterinary board through its staff, Chelsea Childress and
130 Dawn Hannasch, on PDMP reviewing and reporting standards and patient identification criteria,
131 and the guidance the board has for its licensees, if any.
132 *(Completed on 03/11/19; Ms. Carrillo forwarded the legal opinion regarding this issue dated 09/12/2018 to the*
133 *Board of Veterinary Examiners staff and sent a template created on 08/02/2018 for the veterinary board to*
134 *facilitate the discussion on standards for entering information in patient fields).*

135
136 Transfer of unfilled controlled substances
137 Katherine Kowalski commented on transferring of unfilled controlled substances, stating that
138 there might be situations in which more than one controlled substance prescription is issued by
139 the same prescriber due to inability to transfer unfilled prescriptions, and inquired to the board
140 who would be responsible for the subsequent or duplicate prescription. Ms. Kowalski stated that,
141 for example, if a prescriber writes a prescription in Ketchikan, the patient travels to Petersburg
142 where the prescription can't be transferred to, so writes another prescription to be picked up at a
143 pharmacy location in Petersburg: who is responsible for the new prescription?

144
145 Informal Complaints
146 Dirk White informed the board that the nutritional bar, "Rx Bar" is being sold by an out-of-state
147 company in coffee shops and pharmacies throughout Alaska, and inquired whether it is a violation
148 of AS 08.80.430, which prohibits the use of pharmacy symbols unless a license is obtained under
149 AS 08.80. Mr. White also commented that there is a nutritional store in Sitka referring to itself as
150 an apothecary, citing AS 08.80.420 as a potential violation of certain advertisements prohibited.

151
152 PDMP Processing Delays
153 Adele Davis commented on the PDMP processing delays, noting that it is taking 10 -12 weeks for
154 access to be approved. Several members from the public reiterated this concern, including Dirk
155 White, Katherina Kowalski, and Scott Watts, who stated that pharmacists are not able to comply
156 with the mandate to review patient prescription history and inquired whether pharmacists will be
157 able to defend potential violations for non-compliance. Through Chair Holt, Ms. Carrillo again
158 clarified that pharmacists are not required to review patient prescription history, but that
159 timeliness of registration will depend on the date the individual is licensed to the date a complete
160 application to access the PDMP is submitted rather than administratively approved. Ms. Carrillo
161 acknowledge the delay in processing PDMP applications, which she stated is directly related to the
162 position being vacant for three months due to the continuation of the state hiring freeze. Ms.
163 Carrillo informed the public that in the two months preceding the vacancy, she was on maternity
164 leave, but that the board's investigator, Brian Howes, dedicated his free time to processing these
165 whenever possible. Ms. Carrillo further informed the public that she, Norman Thompson, and
166 Charles Ward, the division's marine pilot coordinator, are allocating time to processing these in the
167 order received, but that there is no fully-dedicated staff person to process the 2,600 registrations
168 manually. For reference, Ms. Carrillo stated most states have 4 – 9 full-time PDMP staff.

169

170 In the interim of hiring a dedicated PDMP staff member, Ms. Carrillo informed the public that
171 pharmacists could register as a delegate under AS 17.30.200(d)(4) as these accounts can be
172 approved relatively more expeditiously since they don't require validation documents.

173

174 **TASK 3**

175 Ms. Carrillo will review and approve “pharmacist delegate – licensed” accounts daily and will
176 update the pharmacist’s user role from the delegate role to the pharmacist role once the licensee’s
177 form and payment is processed. PDMP registration issue dates in the licensing database will reflect
178 the actual date approval was given.

179

180 January 23rd, 2018 Letter to Pharmacists

181 Daniel Nelson commented that he has been a pharmacist for almost 17 years and has always felt
182 personal pride in being a pharmacist, and that as a profession are respected members of the
183 community where people invest a lot of trust in them, but feels for the first time that the rust and
184 perception of the profession was severely undermined as a result of the letter. Mr. Nelson further
185 commented that the letter was patronizing and tone deaf to the opioid epidemic, adding that he
186 understands the intent of the letter was to address how to approach refusing a prescription, but
187 that the tone of the letter was overwhelmingly threatening and negative towards the pharmacists.
188 Mr. Nelson stated that the Board of Pharmacy has a responsibility to address and answer
189 questions about the letter, stating that the root of the issue came from a particular pharmacy that
190 was no longer able to purchase controlled substances from a wholesaler, which consequently left
191 hundreds of patients without a pharmacy almost overnight. Mr. Nelson inquired what the board’s
192 responsibility is when a wholesaler ceases to supply to a pharmacy, what recourse a pharmacy can
193 take when a wholesaler has terminated its contract, and whether there is due process in
194 investigating the quantity of controlled substances being purchased when it is perceived to be in
195 an egregious and alarming amount prior to that wholesaler being able to revoke a purchasing
196 contract. It was further stated that the medical board should be weighing in on this issue,
197 particularly when it comes to dangerous opioid and benzodiazepine combinations.

198

199 In response to Mr. Nelson, Chair Holt stated that there were multiple complaints raised to
200 different agencies within the state, and that the board was looped into the issue and asked to
201 provide a response. Chair Holt clarified that there were specific and actual scenarios that were
202 relayed to the board, and the letter was a multi-factorial approach to give a sweeping generalization
203 to remind pharmacists that they do have a right to refuse, but that the approach in which one does
204 so should be professional. Chair Holt expressed appreciate for the feedback on the tone of the
205 letter, but was hopeful that explaining the circumstances under which the letter was created will
206 help provide the public and licensees with a better understanding behind its intent.

207

208 In response to Mr. Nelson’s comment on due process prior to wholesalers revoking a purchasing
209 contract, Chair Holt stated the board does not regulate business contracts or are otherwise
210 involved in limitations in purchase agreements between wholesalers and pharmacies.

211

212 Jordan Hussey from Walgreens commented that pharmacists are experiencing backlash from
213 prescribers who just bring up the letter to try reinforcing that pharmacists cannot refuse to fill
214 prescriptions. Chair Holt responded that the letter does state that pharmacists have the right to
215 refuse, and offered the reminder that pharmacists must approach refusals with professionalism.
216 Chair Holt also commented that a follow-up FAQ document was done in collaboration with the
217 Board of Nursing and the Medical Board, and that they are continuing to try working
218 collaboratively with these boards to come out with a joint statement as there should be
219 professional dialogue between affected professions.

220
221 Karen Miller commented that she's been a retail pharmacist for 25 years and did see a recent shift
222 of prescribing in quantities that she had not seen before. Ms. Miller added that she did see what
223 she perceived to be egregious prescribing, but that prescribers would not pick up the phone or
224 make efforts to communicate with the pharmacy about the prescription. Ms. Miller also stated that
225 she and her colleagues do their best to scrutinize prescriptions to determine whether they are
226 legitimate, but may refuse simply because they don't have the supply as they see a high number of
227 palliative, hospice, and cancer treatment patients. With regards to the letter, Ms. Miller stated it
228 made her and her colleagues nervous about refusing.

229
230 Ms. Carrillo commented to the public that if a pharmacist has a concern about a prescriber or
231 another pharmacist licensee, that the division cannot look into a complaint unless it is done so
232 through the proper investigative process. Ms. Carrillo, through the Chair, encouraged the public to
233 file complaints when they believe there is an issue of safety at hand, which she explained could be
234 accomplished by submitting a Request for Contact Form to the Investigations Section. Ms.
235 Carrillo stated that there was information on this process included on the FAQ document, and
236 Molly Gray commented that the complaint process could be published through the AKPHA.

237
238 Dr. Andy Jaconette commented that he is a physician with a focus in interventional pain and
239 addiction medicine, and that he is very concerned about patients not being able to have their
240 prescriptions filled all of a sudden. Dr. Jaconette added that he has been prescribing the same
241 medications in the same quantity for the last 10 years, and that the sudden refusal to fills is
242 harmful to patients. Dr. Jaconette then inquired to the board whether they were aware of active
243 prosecutions against pharmacists dispensing in dangerous or unsafe quantities, to which Chair
244 Holt stated there are, but that he was not aware of any that are currently happening in Alaska. Dr.
245 Jaconette expressed frustration that pharmacists are encroaching on the practice of medicine by
246 attempting to provide a diagnosis and altering medications, adding that he is having to call
247 pharmacists because they are not calling his office. Chair Holt commented that the Board of
248 Pharmacy has been actively attempting to work with other prescribing boards to release a joint
249 statement since December, but that efforts have not been successful. To Dr. Jaconette's comment
250 on scope of practice, Chair Holt stated that pharmacists are obligated and have the authority to
251 evaluate prescriptions. Chair Holt also stated that SB 74 mandated that representatives from all
252 board were to convene as a subcommittee to establish prescribing limits, and that the committee
253 [CBPL's Joint Committee on Prescriptive Guidelines] was required to submit the recommendation
254 to the legislature; however, the legislature did not do anything with the recommendations. Chair

255 Holt added that the recommendations could have been a foundation on which to provide better
256 guidance to prescribers. Lana Bell thanked Dr. Jaconette for advocating for more support, and
257 added that when the board makes recommendations, it still has to go through the legislature,
258 which can be a time-consuming process.

259
260 Dr. Jaconette continued to express concern over the lack of communication between prescribers
261 and pharmacists, and the harm that is being done to patients as a result of refused dispensing.
262 Lana Bell expressed appreciation for Dr. Jaconette coming o defend his profession, his patients,
263 and his practice, but reiterated that all pharmacists are doing their best to address these efforts.
264 Ms. Bell added that pharmacists are highly trained in pharmacology and are here to be a good tool
265 for the prescriber, but that in her practice, she always defers to the physician in making the
266 ultimate decision. Ms. Carrillo stated that she would be holding a PDMP touch-base meeting on
267 March 11th and that she would be addressing the topic of improved collaboration amongst
268 affected boards.

269
270 **TASK 4**

271 Ms. Carrillo will follow-up with the board after the CBPL touch-base meeting on PDMP topics,
272 including the need for increased collaboration between boards and the need to release a joint
273 statement.

274
275 *Catherine Kowalski, Mackenzie Peeler, and Dirk White left the room at 10:04 a.m.*

276 *Allan Alcancia left the room at 10:14 a.m.*

277 *Scott Watts and Molly Gray left the room at 10:32 a.m.*

278 *Adele Davis left the room at 10:45 a.m.*

279
280 *Allan Alcancia entered the room at 10:18 a.m.*

281
282 **Agenda Item 5 PDMP Update**

Time: 10:26 a.m.

283
284 Letter from Board to director, Sara Chambers

285 Chair Holt presented a draft letter from the board to division director, Sara Chambers, requesting
286 additional resources to process PDMP registration applications more timely, noting a significant
287 delay with over 2,600 pending registration applications to be processed. The board reviewed the
288 letter.

289
290 **On a motion duly made by Tammy Lindemuth, Seconded by Lana Bell and with**
291 **unanimous approval to forward the letter requesting additional staff resources for the**
292 **PDMP to director Chambers, it was:**

293
294 **RESOLVED to send the letter dated March 7, 2019 to division director, Sara**
295 **Chambers, addressing the need for staff to process pending PDMP registrations.**

296
297

	APPROVE	DENY	ABSTAIN	ABSENT
298				
299	Leif Holm	x		
300	Richard Holt	x		
301	Phil Sanders	x		
302	Lana Bell	x		
303	Tammy Lindemuth	x		
304	James Henderson			x
305	Sharon Long			x

306

307 The motion passed with no further discussion.

308

309 **TASK 5**

310 Ms. Carrillo will forward the letter to director Chambers and will provide an update to the board
311 once complete.

312 *(Completed on 03/11/19; Ms. Carrillo also notified the board that director Chambers received approval to
313 continue with the PDMP program coordinator recruitment).*

314

315 PDMP Board Report: Pharmacy

316 Hearing nothing further on public comment, Laura Carrillo addressed the Board of Pharmacy
317 report for the PDMP update, which included information up to January 31, 2019. For the Board
318 of Pharmacy, there were 1972 currently registered pharmacists, with registration compliance at
319 94%; the highest compliance rate among all boards with PDMP requirements. Ms. Carrillo then
320 reviewed the breakdown of registered users by related user roles, including IHS, VA, military
321 dispensers, and pharmacist delegates. Ms. Carrillo noted to the board that despite being the only
322 profession not required to login or review patient prescription history pharmacists have the
323 highest login and review rates compared to those professions mandated to do so, which
324 demonstrates pharmacist’s efforts to maximize the PDMP. For threshold reporting, Ms. Carrillo
325 informed the board that 21 patients appeared to meet or exceed the established threshold of
326 receiving more than five prescriptions from more than five pharmacies over a three-month period
327 (5-5-3 threshold), and that notifications will be sent to respective boards. For the record, Ms.
328 Carrillo clarified that these unsolicited notifications that are sent to the boards do not disclose the
329 name of the licensee who contributed to a patient meeting or exceeding this threshold, but that
330 the notification is authorized in statute. In responding to DEA subpoenas, Ms. Carrillo responded
331 that the response rate is at 100%, with the majority of subpoenas received in 2018 was for
332 patients, followed by prescribers, and then dispensers.

333

334 Ms. Carrillo then informed the board that as of January 31, 2019, there were 181 delinquent
335 pharmacies, meaning that these pharmacies either failed to report at least one time within a week
336 up until June 30, 2018, or did not submit daily from July 1, 2018 to January 1, 2019. Due the
337 continued vacancy, letters have not been sent to these pharmacies notifying them of their
338 delinquent reporting status; however, Ms. Carrillo stated it is a priority to get notices sent once the
339 PDMP Program Coordinator position is filled.

340 **TASK 6**

341 Delinquent reporting notices will be sent to the 181 pharmacies by the PDMP Program
342 Coordinator.

343 *(In-progress).*

344

345 PDMP Report to the 31st Legislature

346 Ms. Carrillo presented the draft of the legislature to the board, which included updated data on
347 registration, reviewing, and reporting measures and various PDMP related activities. The board
348 reviewed the report.

349

350 **On a motion duly made by Lana Bell, Seconded by Phil Sanders and with unanimous**
351 **approval to submit the PDMP legislative report, it was:**

352

353 **RESOLVED to submit to the 31st Legislature the Prescription Drug Monitoring**
354 **Program report as written.**

355

	APPROVE	DENY	ABSTAIN	ABSENT
356 Leif Holm	x			
357 Richard Holt	x			
358 Phil Sanders	x			
359 Lana Bell	x			
360 Tammy Lindemuth	x			
361 James Henderson				x
362 Sharon Long				x

363

364 The motion passed with no further discussion.

365

366 **TASK 7**

367 Ms. Carrillo will submit the legislative report via director, Sara Chambers.
368 *(Completed on 03/11/2019; pending submittal to legislature via Senator Cathy Giessel).*

369

370 Enhanced Programmatic Desk Review (EPDR) by BJA

371 Ms. Carrillo informed the board that they had an EPDR scheduled with the Bureau of Justice
372 Assistance (BJA), in which a series of questions were asked regarding financial, administrative, and
373 programmatic matters related to the PDMP. Ms. Carrillo stated that Andy Jones, previously with
374 the Alaska Department of Health and Social Services' (DHSS) Office of Substance Misuse and
375 Addiction Prevention (OSMAP) was primarily responsible for providing responses to the
376 questions. Updates provided by Ms. Carrillo included ongoing activities, including enhancement
377 features to the AWARe platform and collaboration efforts with DHSS.

378

379

380

381

382 Letter of Support for CDC’s Overdose Data to Action Grant “OD2A”
 383 The board reviewed a draft letter prepared in support of the Opioid Data to Action (CDC-RFA-
 384 CD19-1904) grant to assist DHSS’s Injury Surveillance Program in applying for grant funds. The
 385 funds would be used to advance and evaluate state-level interventions for the PDMP, ultimately
 386 requiring the continuation of multi-state department collaborative efforts between DHSS and the
 387 PDMP. If funding is awarded, the PDMP would have two deliverables to comply with: 1.)
 388 improving database functionality and expanding the PDMP through improved intra- and inter-
 389 state interoperability. Ms. Carrillo informed the board that while there may be existing grant funds
 390 to cover enhancement features to comply with the database functionality aspect, additional funds
 391 would be particularly helpful with expanding sharing of data among in-state entities and out-of-
 392 state entities.

393
 394 **TASK 8**

395 Ms. Carrillo will request more information on solutions to comply with improving database
 396 functionality and improving intra- and inter-state functionality, and will continue to collaborate
 397 with Appriss Health and DHSS on these advancements
 398 *(Completed on 03/12/19; Ms. Carrillo submitted an internal request to submit a proposal for ASTHO/CDC*
 399 *to highlight PDMP successes; Ms. Carrillo also requested a cost estimation sheet from Appriss for*
 400 *enhancements/applications to assist in complying with the OD2A Grant, including: OpenBeds and ERvive).*

401
 402 **On a motion duly made by Tammy Lindemuth, Seconded by Rich Holt and with**
 403 **unanimous approval for the letter of support for the Overdose Data to Action grant, it was:**
 404

405 **RESOLVED to approve the letter of support for inclusion into the application for**
 406 **the Overdose Data to Action grant to be submitted by the Alaska Department of Health**
 407 **and Social Services.**

	APPROVE	DENY	ABSTAIN	ABSENT
410 Leif Holm	x			
411 Richard Holt	x			
412 Phil Sanders	x			
413 Lana Bell	x			
414 Tammy Lindemuth	x			
415 James Henderson				x
416 Sharon Long				x

417
 418 The motion passed with no further discussion.

419
 420 Military Health System PDMP (“MHS PMP”)

421 Ms. Carrillo informed the board that the military recently launched their own prescription drug
 422 monitoring program and presented a draft MOU she prepared for the military and the state
 423 PDMP to connect to each other. Ms. Carrillo stated that the interoperability specifications are still

424 in the development stages, but that she would follow-up once the Department of Defense returns
425 the MOU to the department.

426

427 **TASK 9**

428 Ms. Carrillo will follow-up with the board on the status of the MHS PMP. (*On-going*).

429

430 Delayed PDMP Registration Protocol

431 The board addressed the protocol for assessing delayed registrations. Ms. Carrillo included in the
432 board packet a letter template the Board of Nursing uses when notifying licensees that they may
433 have registered late with the PDMP. Rich Holt inquired how the board would assess late
434 registrations given the current 2,600 registration backlog. Ms. Carrillo stated that a delayed
435 registration wouldn't be determined based on the date the account is approved and access is given,
436 but rather the date from when the pharmacist is issued an Alaska license to the date they submit a
437 complete PDMP registration, including creation and submission of online credentials through
438 AWARe, as well as submission of the form and payment. Since the deadline to register for
439 existing licenses went into effect on July 17, 2017, the processing of late registrations would only
440 apply to newly licensed pharmacists. Chair Holt commented on the fact that not every pharmacist
441 is required to register, just those dispensing federally scheduled II – IV controlled substances in
442 Alaska. Ms. Carrillo inquired about when it is appropriate to gather the information on a
443 pharmacist's dispensing status. Investigator, Brian Howes, recommended that dispensing status
444 could be determined during the investigation of a complaint, at which time the discovery of non-
445 compliance with registration may be considered a secondary violation given there is a violation
446 found as a result of the initial complaint, and consequently a disciplinary action issued against the
447 pharmacist's license. Ms. Carrillo also suggested putting in an IT order for a dispensing
448 designation to be available for pharmacist license types.

449

450 The board also discussed delayed registrations, ultimately determining that they should be given 30
451 days to submit a complete PDMP registration application from the date they are issued an initial
452 pharmacist license. The courtesy letter will be modeled after the Board of Nursing letter and no
453 action will be taken since the letter will warn licensees that they must renew their PDMP
454 registration on time or may risk a disciplinary action against their license.

455

456 **On a motion duly made by Lana Bell, Seconded by Tammy Lindemuth and with**
457 **unanimous approval to set a grace period for registering with the PDMP, it was:**

458

459 **RESOLVED to set the registration window as 30-days of being issued an initial**
460 **pharmacist license to the date a complete PDMP application (including submission of**
461 **online credentials via alaska.pmpaware.net and the requisite form and payment, if**
462 **applicable) is submitted. A courtesy letter will be submitted to licensees reminding them**
463 **of their requirement to renew their registration timely.**

464

465

466

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			

467	Richard Holt	x	
468	Phil Sanders	x	
469	Lana Bell	x	
470	Tammy Lindemuth	x	
471	James Henderson		x
472	Sharon Long		x

473
474 The motion passed with no further discussion.

475
476 **TASK 10**

477 Ms. Carrillo will put in an IT work order to add the dispensation designation to the pharmacist
478 license category.
479 *(Completed 03/13/19; Ms. Carrillo put in the request via program coordinator, Colleen Kautz, who will request
480 this through IT).*

481
482 **TASK 11**

483 Chair Holt will draft a courtesy letter notifying newly licensed pharmacists that they have
484 potentially registered late based on the 30-day grace period.
485 *(Completed 03/10/19; Chair Holt drafted the letter and also suggested this be a good opportunity to assess
486 dispensation status; Ms. Carrillo drafted a form titled, ‘PDMP Exemption Statement for Non-Dispensing
487 pharmacists on 03/12/19 and submitted to publications specialist, Hannah Hamburg for finalizing).*

488
489 Chair Holt called for break at 11:23 a.m.
490 *Off record at 11:23 a.m.*
491 *On record at 11:29 a.m.*

492
493 **Agenda Item 6 Conference and Meeting Updates Time: 11:30 a.m.**

494
495 Controlled Substance Advisory Committee (CSAC)

496 Lana Bell addressed the CSAC, first reminding the board that legislation from FY18 resulted in
497 the shift of the CSAC chair position from the Department of Law to the Board of Pharmacy or
498 the Board of Pharmacy’s designee. Chair Holt designated this position to Lana Bell, who is the
499 current chair of the committee. Ms. Bell reiterated earlier concerns that due to the lack of clear
500 communication and direction into the continuation of administrative support to assist the new
501 chair in this capacity, it has been difficult to assert authority over the committee and schedule
502 subsequent meetings. Ms. Bell added that the committee is required to meet twice per year, but the
503 Department of Law has expressed that they would not be continuing to provide support, such as
504 publishing meeting dates, scheduling meetings, and writing meeting minutes. The authorizing
505 statute did not provide for the Board of Pharmacy staff to perform the necessary administrative
506 support to the CSAC, which makes being in the position of chair difficult to navigate. Ms. Bell
507 ultimately expressed she would like to consider that the chair appoint a new designee to this
508 position and further added the CSAC committee has great potential to mobilize resources to

509 address emerging issues requiring a multidisciplinary approach. Chair Holt agreed to entertain this
510 and recommended it be added to the March 8, 2019 agenda under Administrative Business,
511 Agenda Item #22.

512
513 Phil Sanders inquired as to whether the CSAC has accomplished any particular tasks, to which Ms.
514 Bell stated that they have; most recently, the CSAC addressed emergency scheduling with the
515 support and recommendation that unscheduled substance be scheduled on an emergency basis
516 when there is an immediate threat to public health and safety.

517
518 **Agenda Item 7 Investigative Report Time: 11:42 a.m.**

519
520 Investigator, Brian Howes was present in Anchorage to provide the board’s investigative report,
521 which included the opening of 22 matters and closing of 13. Mr. Howes also informed the board
522 that one was related to a licensing action and one that was related to PDMP registration, which he
523 recommended should be discussed under executive session.

524
525 **On a motion duly made by Rich Holt in accordance with AS 44.62.310(c)(2), the board**
526 **unanimously moved to enter executive session for the purpose of discussing subjects that**
527 **tend to prejudice the reputation and character of any person, provided the person may**
528 **request a public discussion.**

529
530 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

531
532 Staff members, Laura Carrillo, Norman Thompson, Allan Alcancia, and Brian Howes were
533 authorized to remain in the room.

534
535 *Off record for executive session at 11:45 a.m.*

536 *On record for public discussion at 12:08 p.m.*

537
538 Upon return from executive session, Chair Holt clarified for the record that no motions were
539 made under executive session.

540
541 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and with**
542 **unanimous approval to accept the voluntary surrender of Neil Holder, Alaska Pharmacist**
543 **License #PHAP1391, Case #2019-000186, it was:**

544
545 **RESOLVED to accept the voluntary license surrender of license # PHAP2124 by**
546 **Neil Holder. The voluntary surrender was based upon evidence of violations against AS**
547 **08.01.075, AS 08.80.261(a)(7), and AS 08.80.261(a)(8).**

548
549

	APPROVE	DENY	ABSTAIN	ABSENT
550 Leif Holm	x			
551 Richard Holt	x			

593 NABP to report to the NPDB, it would create a reciprocal relationship in which the board could
594 query the NPDB for applicants seeking initial licensure in Alaska.

595

596 **TASK 12**

597 Ms. Carrillo will follow-up with the NABP for more information on the pros of entering into this
598 agreement, including clarifying whether it would allow for the board to also query the NPDB for
599 applicants pursuing licensure in Alaska, and will also request which states have a current
600 agreement for adverse action reporting.

601 *(Initiated on 03/14/19; Ms. Carrillo sent an email to the NABP requesting additional information).*

602

603 Skilled Nursing Facilities

604 The board moved to discussion on skilled nursing facilities. Ms. Bell's impression was that the
605 questions being raised are most appropriate for medical directors of skilled nursing facilities, which
606 had to do with access to emergency medication kits and the use of automated drug cabinets. The
607 letter, initially sent by Matthew Keith, requested an opportunity to speak with the board directly
608 on this issue; however, Mr. Keith passed the baton to Piper Machamer, who was not present at
609 the meeting to address this with the board.

610

611 **TASK 13**

612 Ms. Carrillo will follow-up with Piper Machamer from Geneva Woods Pharmacy to request that
613 the questions related to emergency medication kits and automated drug cabinets be clarified.

614 *(Completed 03/18/19; Ms. Carrillo sent an email to Ms. Machamer requesting for specific questions on
615 03/14/19 and received a response on 03/18/19 indicating the interest/initiative is being withdrawn).*

616

617 Opioid Issue Feedback (Letter from Chair)

618 The board reviewed correspondence submitted by licensees expressing their opinions on the letter
619 released on January 23, 2019. Chair Holt reiterated that he supports pharmacists, their right to
620 refuse, their clinical judgment, and reminded the public that the intent of the letter was to address
621 the approach of refusing to fill a prescription. Tammy Lindemuth expressed how the letter was
622 received negatively by the pharmacy community and inquired whether there is any recourse the
623 board can take to remedy the relationship with its constituents. Lana Bell commented that the
624 board can continue to provide clarification as to the background and intent of the letter, but that
625 ultimately, it will require increased efforts between prescribing boards to provide better guidance.
626 Ms. Carrillo stated that she and Chair Holt created a draft joint statement that addressed the topic
627 of supporting prescribing and dispensing practices and the need to improve increased
628 communication and collaboration. Ms. Carrillo reminded the board that they would be holding a
629 meeting on March 11th with board staff, and Chair Holt recommended appointing delegates to
630 serve on a community for the purpose of giving input on this multidimensional issue.

631

632 **TASK 14**

633 Ms. Carrillo will follow-up with the board on the status of the PDMP touch-base meeting with
634 board staff affected by AS 17.30.200.

635 *(Initiated again on 03/14/19; Ms. Carrillo emailed Chair Holt with a status update on the meeting; the Medical*
 636 *Board EA indicated she would put the joint statement letter back on the board's radar, and Ms. Carrillo is active*
 637 *working with the Board of Dental Examiners appointed delegate, David Neilsen, to get his profession's perspective*
 638 *included in the letter).*

639
 640 IHS Pharmacist-in-Charge License Requirements

641 Norman Thompson included in the board packet correspondence from Robert Clark,
 642 President/CEO of Kakanak Hospital, which is a federal facility operating as Bristol Bay Area
 643 Health Corporation (BBAHC). BBAHC's pharmacy is currently licensed in Alaska but is a tribal
 644 health organization. Tribal organizations are exempt from state licensure requirements under the
 645 Indian Self-Determination and Education Assistance Act (ISDEAA) of 1975, however, the
 646 pharmacy pursued licensure in the state. Chair Holt commented to the board that BBAHC had
 647 inquired whether one of their pharmacists could serve as a pharmacist-in-charge without holding a
 648 pharmacist license in Alaska as the pharmacist holds an active license in another state. The initial
 649 interpretation was that because the pharmacy holds a license in Alaska, the pharmacy is ultimately
 650 subject to state law, including having a pharmacist-in-charge who holds a license under AS 08,
 651 which is a requirement under 12 AAC 52.200. This interpretation was relayed to BBAHC, to
 652 which Mr. Clark responded with reasoning justifying that the pharmacist-in-charge should not
 653 have to hold an Alaska pharmacist license due to the exemption under ISDEAA. The board
 654 ultimately decided that a legal opinion would need to be requested.

655
 656 **On a motion duly made by Lana bell, seconded by Phil Sanders, and approved**
 657 **unanimously, it was:**

658
 659 **RESOLVED to submit to the AAG a request to clarify whether Alaska-licensed**
 660 **pharmacies seeking exemptions to licensure requirements of its staff under ISDEAA can**
 661 **be granted for a pharmacist-in-charge.**

662

	APPROVE	DENY	ABSTAIN	ABSENT
663 Leif Holm	x			
664 Richard Holt	x			
665 Phil Sanders	x			
666 Lana Bell	x			
667 Tammy Lindemuth	x			
668 James Henderson				x
669 Sharon Long				x

670
 671 The motion passed with no further discussion.

672
 673 **TASK 15**

674 Ms. Carrillo will request a legal interpretation on whether a pharmacist for an Alaska-licensed IHS
 675 pharmacy can appoint a pharmacist-in-charge who does not hold a license under AS. Ms. Carrillo

719 **Agenda Item 8** **New Business**

Time: 1:02 p.m.

720
721 The board returned to discussion on correspondence items, beginning with regulations on partial
722 fills of schedule II medications.

723
724 Transfer of Unfilled Controlled Substances

725 Chair Holt commented that the NABP came out with a letter in 2017 regarding confusion over
726 federal regulations and transfers of prescriptions for schedule II controlled substances. The Drug
727 Enforcement Administration made an exception to title 21, code of federal regulations, Section
728 1306.25, such that a DEA-registered pharmacy that has filled an initial prescription could transfer
729 the original prescription to another DEA-registered pharmacy. This would allow the secondary
730 pharmacy to dispense any remaining refills permitted by the prescriber. Chair Holt commented
731 that the exception, however, did not outline guidance for verbal, faxed, or hardcopy orders, that
732 the only exception is for electronically prescribed controlled substance prescriptions. In addition,
733 Chair Holt added that the exception didn't provide guidance for the method in which to forward a
734 prescription, including documentation requirements. It is Chair Holt's understanding that at this
735 time, there is inconsistent practices over transferring of prescriptions because of the lack of clarity
736 in the guidance.

737
738 **Agenda Item 12** **Old Business**

Time: 2:00 p.m.

739
740 *Chris Kennedy, Administrative Law Judge, and Kenneth Bressers, representing OMRO pharmacy entered the*
741 *room at 2:00 p.m.*

742 *Chris Kennedy, Administrative Law Judge, and Kenneth Bressers, representing OMRO pharmacy left the room at*
743 *2:48 p.m.*

744
745 The board then addressed the OMRO case, which the board had denied registration to during
746 their May 10-11, 2018 meeting.

747
748 **On a motion duly made by Tammy Lindemuth in accordance with AS 44.62.310(c)(2), the**
749 **board unanimously moved to enter executive session for the purpose of discussing**
750 **subjects that tend to prejudice the reputation and character of any person, provided the**
751 **person may request a public discussion. It was:**

752
753 **RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).**

754
755 Staff members were not authorized to stay in the room.

756
757 *Off record for executive session at 2:02 a.m.*

758 *On record for public discussion at 2:48 p.m.*

759 Upon returning from executive session, Chair Holt commented that no motions were made under
760 executive session.

761

762 On a motion duly made by Tammy Lindemuth to adopt the ALJ's final decision to
 763 approve issuance of the out-of-state pharmacy registration, it was:

765 **RESOLVED** to accept the ALJ's final decision to issue the registration for OMRO
 766 Pharmacy.

	APPROVE	DENY	ABSTAIN	ABSENT
768 Leif Holm	x			
769 Richard Holt	x			
770 Phil Sanders	x			
771 Lana Bell	x			
772 Tammy Lindemuth	x			
773 James Henderson				x
774 Sharon Long				x

776
 777 The motion passed with no further discussion.

778
 779 **Agenda Item 8 New Business Time: 3:15 p.m.**

780
 781 The board returned to discussion on new business items, beginning with regulations on partial fills
 782 of schedule II medications.

783
 784 Transfer of Unfilled Controlled Substances

785 Chair Holt commented that the question boils down to whether a pharmacy can transfer a
 786 controlled substance prescription. Chair Holt prompted the board to determine whether the board
 787 should prepare a guidance statement. Ms. Lindemuth proposed drafting a position statement until
 788 further information could be obtained and Ms. Bell suggested the topic be tabled until the next
 789 meeting. The board discussed having the Department of Law review this issue, to which Mr.
 790 Sanders inquired what the specific ask would be. Ms. Bell stated that it would be to determine
 791 whether the board has the authority or if it is appropriate to weigh in on a federal rule.

792
 793 **On a motion duly made by Lana bell, seconded by Tammy Lindemuth, and approved**
 794 **unanimously, it was:**

795
 796 **RESOLVED** to submit to the AAG a request for input on whether the board can
 797 weigh in on a federal rule, particularly the issue concerning DEA guidance on transferring
 798 of controlled substance prescriptions.

	APPROVE	DENY	ABSTAIN	ABSENT
800 Leif Holm	x			
801 Richard Holt	x			

843 Ms. Carrillo will follow-up with Kevin Rew requesting a copy of California’s law on automated
844 dispensing and how the practice is being monitored. Ms. Carrillo will provide Mr. Rew’s responses
845 to the board for their next meeting.

846 *(Completed 03/14/19; Ms. Carrillo requested additional information from Mr. Rew; Mr. Rew provided requested*
847 *information to Ms. Carrillo on 03/15/19 for inclusion into the board’s next meeting packet).*

848
849 Unlicensed Practice

850 The board reviewed an article regarding an individual who posed as a pharmacist at a Walgreens in
851 California.

852
853 Prescription Adaptation

854 The board reviewed correspondence from Dennis McAllister from Express Scripts who inquired
855 whether the board would consider entertaining legislation enabling pharmacists to adapt
856 prescriptions as is done in Washington. Mr. Holm commented that it could improve relationships
857 with providers; however, Chair Holt commented dosage forms as written in Washington can’t be
858 changed in Alaska because it’s written in Alaska statutes. The board continued to discuss
859 prescription adaptation.

860
861 **TASK 19**

862 Phil Sanders will review existing statutes and regulations to propose the law based on Dennis
863 McAllister’s provided draft of Washington.

864
865 **TASK 20**

866 Ms. Carrillo will inform Dennis McAllister that the board will be looking into prescription
867 adaptation more closely and will address this again at their next meeting.
868 *(Completed 03/14/16; Ms. Carrillo informed Mr. McAllister of the status of the board’s attention to this*
869 *matter).*

870
871 **Agenda Item 12 Old Business Time: 3:42 p.m.**

872
873 The board returned to discussion of old business.

874
875 Continuing Education Audit

876 The board reviewed the outstanding continuing education audits for pharmacists for the renewal
877 period of July 1, 2016 to June 20, 2018. The hourly continuing education requirement for this
878 license type is 30 hours. Chair Holt inquired to Ms. Carrillo if the continuing education certificates
879 are screened in advance of board review, to which Ms. Carrillo affirmed.

880
881 **On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved**
882 **unanimously to accept the continuing education audits in compliance with 12 AAC 52.300-**
883 **350 for pharmacists: Christopher Sperry, Trevor Embry, Heidi Brainerd, Chad**
884 **Lamoureux, Jacob Mock, Dawn Erbeck, Dean Thorson, Dawn Hughes, Karen Nelson,**
885 **Robert Grogan, Mary Heaster, Beth Dobson, Mike Branson, William Altland, Lorraine**

886 Ball, Debra Spurlock, Marlene Perschbacker, Charlene Hampton, Preston Van Curen,
 887 Nichell Moore, Cynthia Lynn McCoy, Rodney Gordon, Adam Schwartz, Craig Eyer,
 888 Matthew Keith, Bridget Alem, Stephen Cole, Heidi Bernhoft, Rosalynda Uy, Sally
 889 Wilhelm, Mark De Zeeuw, Megan Wiegand, Sarah Schock, Justin Conrett, Joyce
 890 Durcanin-Robbins, Jessica Hinckley, Rachel Botson, James Bunch, Dharna Begich,
 891 Patrick Welch, Steven Miller, Dawn Shill, Rose Winkel, Janet Schwartz, Myra Flint-Smith,
 892 Leonard Bolog, John Evey, Donna Michaud, Richard Einhellig, Kristopher Swinney,
 893 Elizabeth Tressler, Renee Robinson, Young Oh, Theresa Castellanos, Katelyn Hilton,
 894 Benjamin Schultz, Erin Narus, Christine Latta, Cheri Cubbison, Medelina Richmond,
 895 Chelsea Dubbe, Michael Kristie, Shawna O'Shea, Grant Cleveland, Ericka Richards,
 896 Samantha Ervin, Stephanie Stolen, Enoch Ronduen, Dane Brubaker, Joel Phair, Angelina
 897 Lovell, Cory Collins, Peter Simonich, Amanda Hammila, Jeffery Moseley, Heidie Carlson,
 898 Richard Batson, Tina Horn, Johanna Ellerup Ann Stout, Ryan Trevithick, Douglas Chan,
 899 Warner Wolf, Laura Garza, Bryce Farrar, Brandon Boller, Cindy Tobias, Teresa Kriletich-
 900 Bruce, John McGilvray, Kendal Haihoi, John Bittner, Douglas Bartko, Molly Hull, Jerry
 901 Gottbe, and Kelly Smoot, it was:

902
 903 **RESOLVED** to accept the continuing education audits for the above mentioned
 904 pharmacists, who demonstrated compliance with the continuing education requirements
 905 under 12 AAC 52.300 – 12 AAC 52.350 for the 2016 – 2018 renewal period.
 906

	APPROVE	DENY	ABSTAIN	ABSENT
907 Leif Holm	x			
908 Richard Holt	x			
909 Phil Sanders	x			
910 Lana Bell	x			
911 Tammy Lindemuth	x			
912 James Henderson				x
913 Sharon Long				x

914
 915
 916 The motion passed with no further discussion.
 917

918 **TASK 21**

919 Ms. Carrillo and Mr. Thompson will send audit closed letters to the pharmacists whose continuing
 920 education audits were accepted. Audit flags will also be removed from these licensee's records and
 921 those who have not complied with the audit will be contacted by the paralegal.

922 *(Audit closed letters sent 03/19/19. Ms. Carrillo sent Marilyn Zimmerman an email regarding licensees who did*
 923 *not appear to comply with the continuing education requirement as of 03/14/19).*
 924

925 The board reviewed the outstanding continuing education audits for pharmacy technicians for the
 926 renewal period of July 1, 2016 to June 20, 2018. The hourly continuing education requirement for
 927 this license type is 10 hours.

928 On a motion duly made by Rich Holt, seconded by Tammy Lindemuth, and approved
 929 unanimously to accept the continuing education audits in compliance with 12 AAC 52.300-
 930 350 for pharmacy technicians: Katya Drobkov (Strul), Lorena Gebhardt, Kathryn Carleton,
 931 Susan Landreth, Ty Miller, Brittany Romans, Jaaliyah Alexander, Krista Yadao, Dorothy
 932 Luchansky, Yu Chung, Sherry Chambers, Linda Cossairt, Merry Gregg, Brenda Elmer,
 933 Alysia Johnson, Sherri Brown, Alysia Davis, Kathleen Karl, Gibran Sandine, Carolyn
 934 Tamanaha, Marylyn Peralta, James Lyle, Mailee Vue, Mackenzie Peeler, Mary Rardin,
 935 Lisa Severson, Shannon Riggs, Michelle Powell, Elba Escamilla, Kristi Sternitzke-Morton,
 936 Neil Kahl, Dana Cartwright, Albert Orenca, Nomi Smith, Racquel Green, Glaiza Kordus,
 937 Connie Coca, Christopher Harvey, Elisabeth Wood, Kiriakia Reutov, Sandra Taylor,
 938 Kristina Kolomeychuk, Lawrence Yuquimpo, Jennifer Vlasoff, Jessica Hulet, Maricel Tiu,
 939 Gaojer Yang, Virginia Ravina, James Driggers, Michelle Oakey, Amber Vanderlinden,
 940 Adam Maccabee, Ma Salao, Apolla Mojica, Constance Srebernak, Ashley Moitoso, Kelli
 941 Anderson, Bonny Holm, Agnes Velasco, it was:

942
 943 **RESOLVED** to accept the continuing education audits for the above mentioned
 944 pharmacy technicians, who demonstrated compliance with the continuing education
 945 requirements under 12 AAC 52.300 – 12 AAC 52.350 for the 2016 – 2018 renewal period.
 946

	APPROVE	DENY	ABSTAIN	ABSENT
947 Leif Holm	x			
948 Richard Holt	x			
949 Phil Sanders	x			
950 Lana Bell	x			
951 Tammy Lindemuth	x			
952 James Henderson				x
953 Sharon Long				x

954
 955
 956 The motion passed with no further discussion.
 957

958 **TASK 22**

959 Ms. Carrillo and Mr. Thompson will send audit closed letters to the pharmacists whose continuing
 960 education audits were accepted. Audit flags will also be removed from these licensee’s records and
 961 those who have not complied with the audit will be contacted by the paralegal.

962 *(In-process as of 03/14/19; Ms. Carrillo sent Marilyn Zimmerman an email regarding licensees who did not*
 963 *appear to comply with the continuing education requirement).*

964
 965 The board would be reviewing tabled applications on March 8th.
 966

967 Applications and Forms

968 Ms. Carrillo provided a spreadsheet on completed application updates and in-process updates for
 969 the board to review.

970 Annual Report

971 Chair Holt commented he would begin the initial draft of the annual report due June 1st.

972

973

974 **TASK 23**

975 Chair Holt will work on the annual report due June 1st.

976 *(In-progress).*

977

978 **Agenda Item 14 Review Lost/Stolen Rx**

Time: 3:56 p.m.

979

980 The board reviewed the DEA form for Safeway Pharmacy #1820 (license #120100). Chair Holt
981 noted this was the third report in the past 24 months. They also reviewed the initial notification
982 from Geneva Woods Mat-Su Pharmacy (PHAR414).

983

984 **TASK 24**

985 Ms. Carrillo will email Kristin Martin to inquire as to whether they submitted the DEA-106 report
986 to make sure they filed within the appropriate timeline according to federal regulation.

987 *(Completed 03/14/19; Ms. Carrillo sent a follow-up email to Kristin Martin).*

988

989 **Agenda Item 15 Adjourn**

Time: 4:04 p.m.

990

991 Tammy moved to adjourn the meeting at 4:04 p.m. and to recess until March 8th.

1 State of Alaska
2 DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
3 DIVISION OF CORPORATION, BUSINESS AND PROFESSIONAL LICENSING
4

5 Alaska Board of Pharmacy
6 Thursday, June 27, 2019
7 10:30 am
8

9 By the authority of AA 08.01.070(2) and AS 08.86.030, and in compliance with the provisions of AS
10 44.62, Article 6, a scheduled meeting of the Alaska Board of Pharmacy was held via
11 video/teleconference on Thursday, June 27th, 2019.
12

13 **These are DRAFT minutes prepared by the staff of the Division of Corporation, Business and**
14 **Professional Licensing. These minutes have not been reviewed or approved by the Board.**

15
16 **Written meeting minutes reflect a brief overview of the business conducted by the board during their**
17 **meeting. For a more detailed account, please request a copy of the meeting recording.**
18

19 **The Chair brought the meeting to order at 10:42 am**
20

21 **Agenda Item 1 - Roll Call**
22

23 **Board Members Present Constituting a Quorum:**

24 Dr. Richard Holt – Chair
25 Lana Bell
26 Phil Sanders
27 Sharon Long
28

29 **Board Members Absent:**

30 Dr. Leif Holm
31 James Henderson
32 Tammy Lindemuth
33

34 **Staff Members present:**

35 Dawn K Hannasch-Records and Licensing Supervisor
36

37 **Members of the Public Present:**

38 Jessica Adams
39 Dan Nielson
40 Jessica
41 Victor Kao
42 Adel Davis
43 Molly Gray
44 Justin Chung
45
46

47 **Agenda Item 2 - Review/Approve Agenda**

48

49 The Chair, Dr. Richard Holt brought the meeting to order and requested that each member review the
50 drafted agenda. Dr. Holt stated that there will not be a public comment period during this meeting
51 because the public comment period for this regulations project has closed.

52

53 **On a motion duly made by Lana Bell, seconded by Sharon Long, with unanimous consent it**
54 **was:**

55

56 **resolved to approve the agenda as drafted.**

57

58 **Agenda Item 3 – Ethics Disclosure**

59

60 Of the four board members present at the meeting, none had ethic concerns to disclose.

61

62 **Agenda Item 4 – Regulations**

63

64 Hearing nothing further, Dr. Holt brought the boards attention to their board packet, which contains all
65 the written public comments that were received regarding the current regulations project affecting 12
66 AAC 52.010 – 12 AAC 52.995. The public comment period closed on May 24, 2019. Dr. Holt read each
67 comment aloud for the benefit of the public.

68

69 One of the public comments offered a recommendation to the board for changes to 12 AAC 52.423(b).
70 Mr. Sanders stated that he would prefer to complete the current regulation project and then look at
71 other changes in the future. However, board members, Sharon Long and Lana Bell, would like to
72 proceed with the recommended changes now. Dr. Holt requested that staff add the subject to the next
73 meeting, and the board ultimately decided to table 12 AAC 52.470(d) for further review and discussion.

74

75 The board continued their review of each public comment.

76

77 **On a motion duly made by Lana Bell, seconded by Phil Sanders, with unanimous consent it**
78 **was:**

79

80 **resolved to approve the regulations as written and publicly noticed except for 12 AAC**
81 **52.470(d) relating to a 30-day supply.**

82

83 **Agenda Item 5 – Adjourn**

84

85 The board adjourned the meeting following discussion of regulations.

86

87

88 _____
89 Laura Carrillo for Dawn Hannasch Date

90

91

92 _____
Richard Holt, Chair Date

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

12 AAC 52.500(a) is amended to read:

(a) For the purpose of dispensing [A REFILL OF] a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(Eff. 1/16/98, Register 145; am 7/9/2017, Register 223; am ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030

The introductory language of 12 AAC 52.510(a) is amended to read:

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

...

12 AAC 52.510(a)(3) is repealed:

(3) **repealed** ____/____/____ [THE EQUIVALENT DRUG PRODUCT COSTS THE PATIENT LESS THAN THE PRESCRIBED DRUG PRODUCT]; and

...

12 AAC 52.510(b) is amended to read:

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the **terms** [TERM] "equivalent drug product" **or "interchangeable biological product" are** [IS] defined in AS 08.80.480. (Eff. 1/16/98, Register 145; am 10/9/2008, Register 188; am 6/29/2018, Register 226; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.530(a) is amended to read:

(a) **A** [EXCEPT AS PROVIDED IN (b) OF THIS SECTION, A] pharmacy or pharmacist may [NOT] accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed **if**

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or

(2) the medication was recalled by the manufacturer or FDA; and

(3) it is segregated from the normal pharmacy inventory and may not be dispensed.

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

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.610 is amended to read:

12 AAC 52.610. Wholesale drug distributor license. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary

qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The following checklist is established by the board for review of an application

[AN APPLICANT] for a wholesale drug distributor license. **A wholesale drug distributor license will be issued to an applicant who** [SHALL]

- (1) **submits a completed, notarized application** [APPLY] on **a** [THE] form provided by the department;
- (2) **pays** [PAY] the fees required in 12 AAC 02.310;
- (3) **provides** [PROVIDE] a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;
- (4) **provides** [PROVIDE] the name and the resume of the **facility manager** [PERSON] who will manage the wholesale distribution of drugs and the wholesale drug facility;
- (5) **submits** [SUBMIT]

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; **or** [AND]

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) **submits** [SUBMIT] completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; **and**

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located for non-resident wholesale drug

distributors.

(c) [(b)] An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

- (1) meet the requirements of **(b)** [(a)] of this section; and
- (2) be registered with the **DEA** [(DEA)].

(d) [(c)] Within 30 days of a change in **location, ownership, or** facility manager, the new facility manager must

- (1) submit the completed change of **facility** [PHARMACY] manager form provided by the department;
- (2) submit the applicable fees established in 12 AAC 02.105(3); and
- (3) meet the requirements of **(b)(4)** [(a)(4)] and (6) of this section.

(e) When a wholesale distributor ceases operations, the facility manager of the wholesale distributor shall notify the board on a form provided by the department the cessation of operations; the form must be submitted within 10 days after the cessation of operations. (Eff. 1/16/98, Register 145; am 8/21/2002, Register 163; am 1/17/2007, Register 181; am 6/29/2018, Register 226; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

12 AAC 52.620 is amended by adding a new subsection to read:

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid license under AS 08. (Eff. 1/16/98, Register 145; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480

AS 08.80.030 **AS 08.80.159**

12 AAC 52.625(b) is amended to read:

(b) The board will not approve an application for a wholesale drug distributor license unless the designated **facility** manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs. (Eff. 1/16/98,

Register 145; am ___/___/_____, Register _____)

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
 AS 08.80.030 **AS 08.80.159** AS 08.80.480

12 AAC 52.630(a) is amended to read:

(a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements [OR OFFICIAL UNITED STATES PHARMACOPOEIA (USP), 1995 REVISION, COMPENDIUM REQUIREMENTS,] to help ensure that the identity, strength, quality, and purity of the products are not affected. [IF A TEMPERATURE REQUIREMENT IS NOT LISTED FOR A DRUG, THE DRUG MAY BE STORED AT CONTROLLED ROOM TEMPERATURE AS DEFINED IN THE USP.]

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

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
 AS 08.80.030 **AS 08.80.159**

[**EDITOR'S NOTE:** A COPY OF THE UNITED STATES PHARMACOPOEIA MAY BE OBTAINED FROM THE UNITED STATES PHARMACOPOEIAL CONVENTION, INC., P.O. BOX 560, WILLISTON, VT 05495.]

The authority citation of 12 AAC 52.640 is changed to read:

12 AAC 52.640. Written policies and procedures.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.645 is changed to read:

12 AAC 52.645. Examination of drug shipments.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.650 is changed to read:

12 AAC 52.650. Records and inventories.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.660 is changed to read:

12 AAC 52.660. Returned, damaged, and outdated drugs.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.670 is changed to read:

12 AAC 52.670. Drug recalls.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.680 is changed to read:

12 AAC 52.680. Inspections.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.685 is changed to read:

12 AAC 52.685. Prohibition against direct distribution.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.690 is changed to read:

12 AAC 52.690. Salvage and reprocessing.

...

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 **AS 08.80.159**

The authority citation of 12 AAC 52.695 is changed to read:

12 AAC 52.695. Provisions not applicable.

• • •

Authority: AS 08.80.005 AS 08.80.157 **AS 08.80.159**
AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 6 to read:

12 AAC 52.696. Outsourcing facilities. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The following checklist is established by the board for review of an application for an outsourcing facility license; an outsourcing facility license will be issued to an applicant who

- (1) submits a complete, notarized application on a form provided by the department;
- (2) pays the fees required in 12 AAC 02.310;
- (3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;
- (4) provides the name and the resume of the designated facility manager;
- (5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the Food and Drug Administration (FDA).

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address shall apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager shall

(1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include

(A) the date the outsourcing facility ceased operations;

(B) arrange for the records of the outsourcing facility to be retained for two years.

(g) An outsourcing facility shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility shall be registered with the Food and Drug Administration as

a 503b outsourcing facility. (Eff. ____/____/____, Register _____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480

AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 6 to read:

12 AAC 52.697. Third-party logistics providers. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The following checklist is established by the board for review of an application for a third-party logistics provider license; a third-party logistics provider license will be issued to an applicant who

- (1) submits a complete, notarized application on a form provided by the department;
- (2) pays the fees required in 12 AAC 02.310;
- (3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;
- (4) provides the name and the resume of the designated facility manager;
- (5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and
- (6) submits completed fingerprint cards of the facility manager for evaluation and

investigation by the Department of Public Safety.

(c) Within 10 days of a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of a third-party logistics provider that has changed its name or physical address shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider shall apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager shall

- (1) submit to the board a written notice of the cessation of operations; the written notice must be submitted within 10 days after the cessation of operations and include
 - (A) the date the third-party logistics provider ceased operations;
 - (B) arrange for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures. (Eff. ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.920(a)(19) is amended to read:

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, **sexual orientation, gender identity**, or sex in the provision of a service that is part of the practice of pharmacy;

12 AAC 52.920 is amended by adding a new subsection to read:

(e) Failing to meet continuing education requirements will result in a \$100 civil fine per missing continuing education credit hour for pharmacists and a \$25 civil fine per missing continuing education credit hour for technicians. (Eff. 1/16/98, Register 145; am 6/7/2018, Register 226; am ___/___/_____, Register _____)

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

12 AAC 52 is amended by adding a new section to Article 10 to read:

12 AAC 52.925. Grounds for denial or discipline for criminal history. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant’s or licensee’s ability to practice competently and safely include

- (1) murder;
- (2) manslaughter;
- (3) criminally negligent homicide;
- (4) assault;
- (5) sexual assault;
- (6) sexual abuse of a minor;

(7) unlawful exploitation of a minor, including possession or distribution of child pornography;

(8) incest;

(9) indecent exposure;

(10) robbery;

(11) extortion;

(12) stalking;

(13) kidnapping;

(14) theft;

(15) burglary;

(16) forgery;

(17) endangering the welfare of a child;

(18) endangering the welfare of a vulnerable adult;

(19) unlawful distribution or possession for distribution of a controlled substance;

for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;

(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely. (Eff. ___/___/_____, Register _____)

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.985 Emergency Preparedness. (a) If, as a consequence of a natural disaster or terrorist attack, a state of emergency is declared by the governor 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.

(b) If, as a consequence of a natural disaster or terrorist attack, a state of 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, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) When a state of emergency has been declared, a pharmacist in the area of the declared emergency may dispense a one-time emergency refill prescription of up to a 30-day supply of a prescribed medication if

(1) in the pharmacist's professional opinion the medication is essential to the maintenance of life or to the continuation of therapy; and

(2) the pharmacist makes a good faith effort to reduce the patients prescription drug information to a written prescription marked "emergency prescription" and then files and maintains the prescription in accordance with 12 AAC 52.450.

(d) If a declared state of emergency continues for more than 21-days after a pharmacist dispenses an emergency prescription under (c) of this section, the pharmacist may dispense one additional emergency refill prescription of up to a 30-day supply of the prescribed medication.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110. (Eff. ___/___/____, Register _____)

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52 is amended by adding a new section to Article 11 to read:

12 AAC 52.993. Executive administrator. The executive administrator may

- (1) review and approve continuing education competency audits; audits that are not in compliance are to be reviewed by a board member;
- (2) attend state or national meetings or conferences on behalf of the board;
- (3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;
- (4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;
- (5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board. (Eff. ____/____/____, Register ____)

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

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

- (37) "moral turpitude" includes conduct that is considered contrary to community standards of justice, honesty, or good morals.

12 AAC 52.995 is amended by adding a new subsection to read:

- (e) In 12 AAC 52.610 – 12 AAC 52.697, "facility manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations. (Eff. 1/16/98, Register 145; am 5/5/2000, Register 154; am 11/10/2001, Register 160; am 8/21/2002, Register 163; am 2/15/2006, Register 177; am 8/12/2007, Register 183; am 9/11/2010, Register 195; am

Register _____, _____ 2019 **PROFESSIONAL REGULATIONS**

12/29/2011, Register 200; am 8/1/2014, Register 211; am 6/7/2018, Register 226; am

____/____/____, Register _____)

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

DRAFT

Chapter 02. General Occupational Licensing Functions.

(Words in **boldface and underlined** indicate language being added; words [CAPITALIZED AND BRACKETED] indicate language being deleted.)

12 AAC 02.310 is amended to read:

12 AAC 02.310. Board of Pharmacy. (a) The following fees are established for pharmacists, pharmacy interns, pharmacy technicians, pharmacies, wholesale drug distributors, and drug dispensaries:

- (1) **nonrefundable** application fee for initial license, **\$100** [\$60];
- (2) repealed 10/28/2000;
- (3) temporary pharmacist license fee, **\$50** [\$60];
- (4) emergency permit to practice pharmacy fee, **\$100** [\$110];
- (5) pharmacy intern license fee, \$30.

(b) The following license and registration fees for all or part of the initial biennial licensing or registration period and subsequent biennial license and registration renewal fees are established for pharmacists, pharmacy technicians, remote and other pharmacies, and wholesale drug distributors:

- (1) pharmacist, **\$200** [\$240];
- (2) wholesale drug distributor, \$500;
- (3) pharmacy, **\$200** [\$240];
- (4) drug room, **\$200** [\$240];
- (5) registered pharmacy located outside of the state, \$600;
- (6) pharmacy technician, **\$50** [\$60];
- (7) remote pharmacy, **\$200** [\$240];

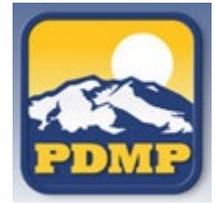
(8) non-resident wholesale drug distributor, \$600;

(9) outsourcing facility, \$600;

(10) third-party logistics provider, \$600. (Eff. 11/20/86, Register 100; am 10/1/88, Register 107; am 5/28/93, Register 126; am 10/19/97, Register 144; am 10/28/2000, Register 156; am 6/13/2002, Register 162; am 6/23/2004, Register 170; am 2/15/2006, Register 177; am 5/18/2006, Register 178; am 6/11/2010, Register 194; am 5/18/2014, Register 210; am ____/____/_____, Register _____)

Authority: AS 08.01.065 **AS 08.80.159** AS 08.80.160

DRAFT



Intent:

This report contains high-level information on the Prescription Drug Monitoring Program (PDMP) and is intended to provide a summary of registration and reporting data specific to your profession. Data in this report includes information through May 31, 2019.

Overview:

The PDMP began in 2008 and mandatory registration, reviewing, and reporting requirements went into effect in July 2017. All actively licensed practitioners with a valid DEA registration are required to register with the database; however, there are both practice-specific and supply-duration exemptions in AS 17.30.200(k) and (u) in which practitioners are not required to consult the PDMP. Generally, practitioners are required to review patient prescription history before prescribing, administering, and/or directly dispensing a federally scheduled II – IV controlled substance. If directly dispensing, practitioners must report this information to the PDMP. Indian Health Service, Veterans Administration, Military, and other federal practitioners and pharmacists are not required to register and are therefore not required to interact with the database.

Delegate access is allowed so long as the delegate holds an active license, certification, or registration under AS 08. Delegate access can help relieve time-constraints as reviewing and reporting tasks can be distributed to qualified staff.

Information, Updates, and Imminent changes:

1. PDMP fees for initial and continued access went into effect on April 22, 2018 by authority of AS 17.30.200, which was subsequently implemented under 12 AAC 02.107. This requires a \$25.00 fee to be submitted before access to the controlled substance prescription database is granted.
2. Beginning June 2018, the PDMP began separating federal practitioners and pharmacists from those *required* to register by updating user roles, e.g.: ‘Pharmacist’ to ‘IHS Dispenser’.
3. Beginning June 2018, all newly registered and renewed PDMP users are issued separate PDMP registration numbers, which are searchable by name under the program ‘Prescription Drug Monitoring Program’ at: <https://www.commerce.alaska.gov/cbp/main/Search/Professional>
4. Enhancement features of interest include Clinical Alerts, NarxCare, and the Compliance Module.
5. An enhancement feature that is currently in-progress is License Integration, for which the PDMP received grant funding from the Bureau of Justice Administration (BJA) to implement.
6. Beginning May 15, 2019, Board of Pharmacy Examiners’ staff assumed responsibility of processing initial and renewal registrations.
7. By summer 2019, NarxCare and the Compliance Module features will be in place, both of which are provided by our PDMP vendor, Appriss Health. NarxCare is a visual analytics feature based on patient risk-scores, and the Compliance Module will assist the PDMP manager and boards in monitoring mandatory use compliance.
8. An Awareness and Feedback Questionnaire for 2019, developed per the directive of the CDC, will be launched in September.

Data:

The Alaska State Board of Pharmacy regulates several license types, including pharmacists, pharmacy technicians, and pharmacy interns. All pharmacist licensees are required to register with the PDMP user role, 'Pharmacist', unless working for a federal employer (IHS, VA, military, etc.). Pharmacy technicians and interns may register as delegates for Pharmacist users.

As of May 31, 2019, there are a total of 7,332 registered users, 980 of which are registered using the 'Pharmacist' role and 45 are registered using the 'Pharmacist-in-Charge' role (Figure 1 A). Pharmacists are among the top 3 professions of registered users and the majority of active licensed pharmacists are registered; the proportion of total licensed pharmacists to other professions with the PDMP is 13%, where pharmacists have reached 95% registration compliance (Figure 2; excluding out-of-state pharmacists). Additional licensed pharmacists not represented under the 'Pharmacist' user role may be inclusive of other dispenser roles, including IHS Dispenser or VA Dispenser; the compliance rate may be higher than depicted in Figure 2 due to registration under other relevant user role categories.

Active PDMP Users

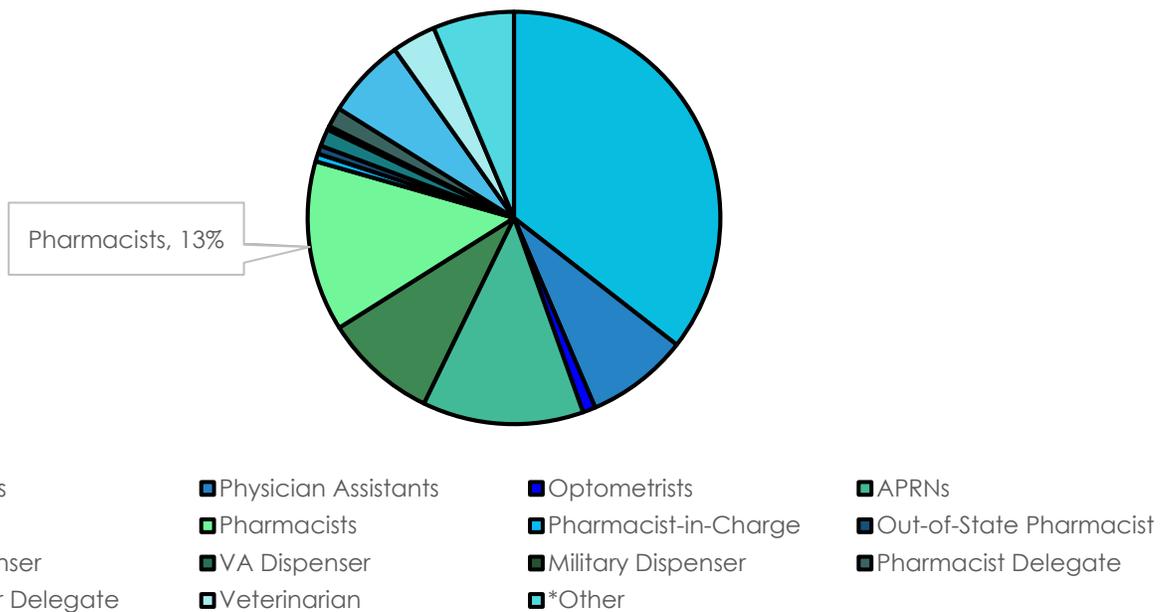


Figure 1 A. The Pharmacists user role category comprises 13% of actively registered users. A breakdown of additional pharmacy-related registrations are included in Figure 1 C. *Other includes admin and restricted admin; IHS, military, and VA prescribers; medical examiner/coroner; state Medicaid program; and medical examiner's delegate.

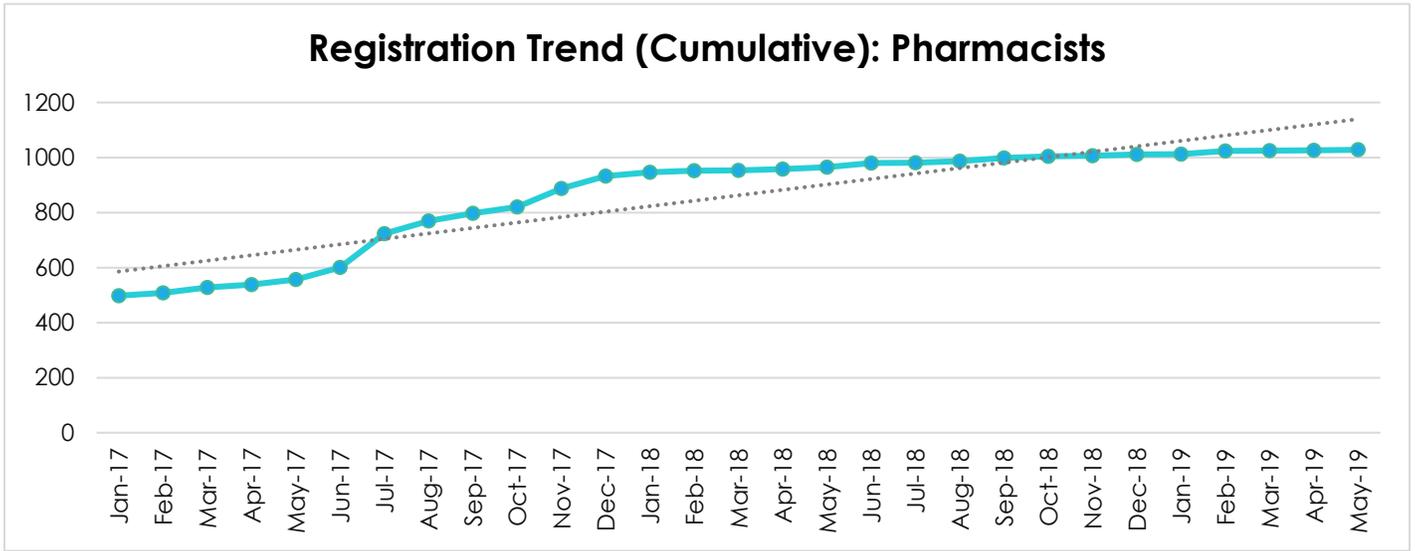


Figure 1 B. The PDMP registration trend for pharmacists from 2017 to 2018 reflects a steady increase over time. The trend from 2018 to 2019 reflects only a slight increase and appears to be leveling off. The base registration count at the end of 2016 was 493 pharmacists.

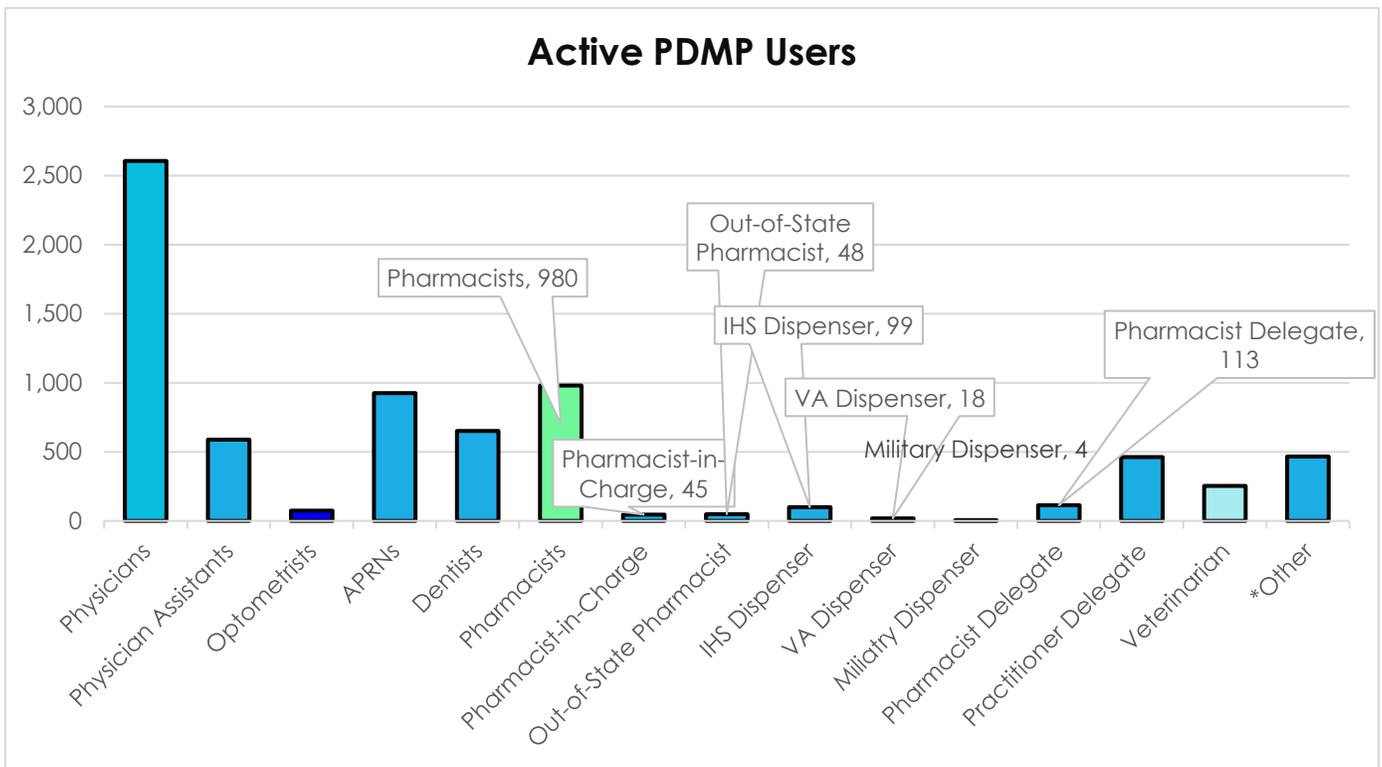


Figure 1 C. A breakdown of pharmacy-related user roles.

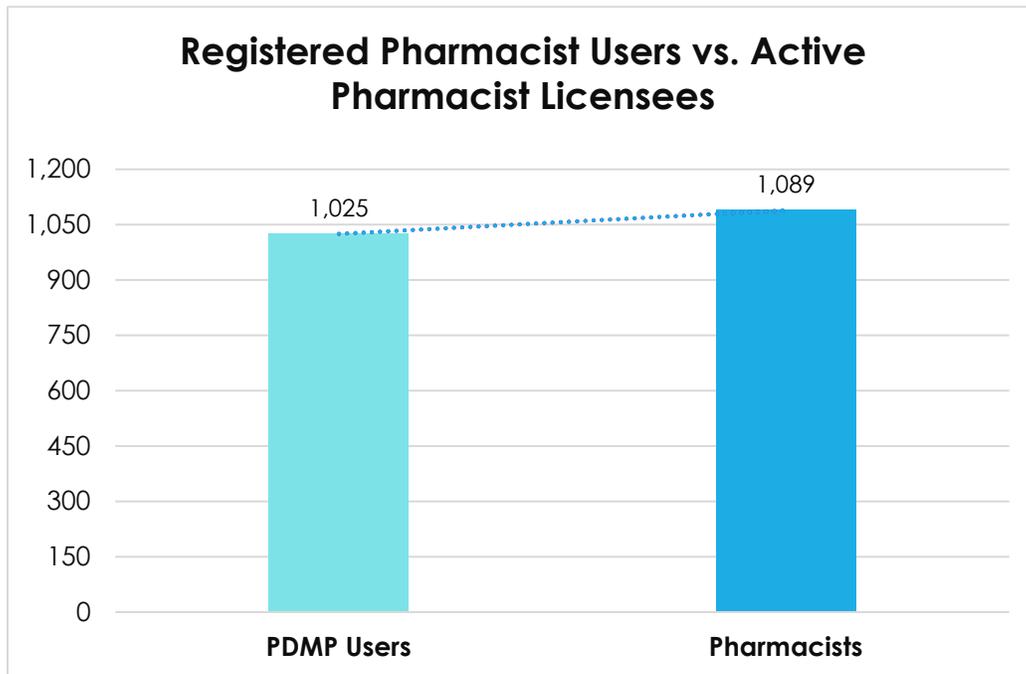


Figure 2. The proportion of licensed pharmacists to registered PDMP users (pharmacists and pharmacist-in-charge user roles; excludes out-of-state pharmacists). This represents a compliance rate of 94%, meaning only 6% of licensees potentially required to register are not yet registered or are registered under a federal user role category. When considering VA, IHS, and Military dispenser users (n=121), this compliance rate increases to 105% and may be inclusive of IHS, military, or VA pharmacists who also have an active Alaska pharmacist license.

The PDMP AWARe platform includes capabilities to run threshold reports when a patient has met or exceeded an established threshold. The Alaska Board of Pharmacy established a 5-5-3 threshold during their January 29 – 31, 2014 board meeting (Figure 3).

Threshold Period	Criteria	# of Patients
03-01-2018 to 06-01-2018	5 prescribers + 5 pharmacies over a three-month period	40
06-01-2018 to 09-01-2018	5 prescribers + 5 pharmacies over a three-month period	21
09-01-2018 to 12-01-2018	5 prescribers + 5 pharmacies over a three-month period	21
12-01-2018 to 03-01-2019	5 prescribers + 5 pharmacies over a three-month period	15

Figure 3. Threshold reports are generated every three months. The last report generated for 12-01-2018 to 03-01-2019 resulted in 15 instances in which a patient met or exceeded the threshold criteria. Boards are notified only when a licensee has contributed to a patient meeting or exceeding this threshold—licensee names are not disclosed.

The following figures (4 and 5) reflect pharmacist interactions with the PDMP AWARxE platform.

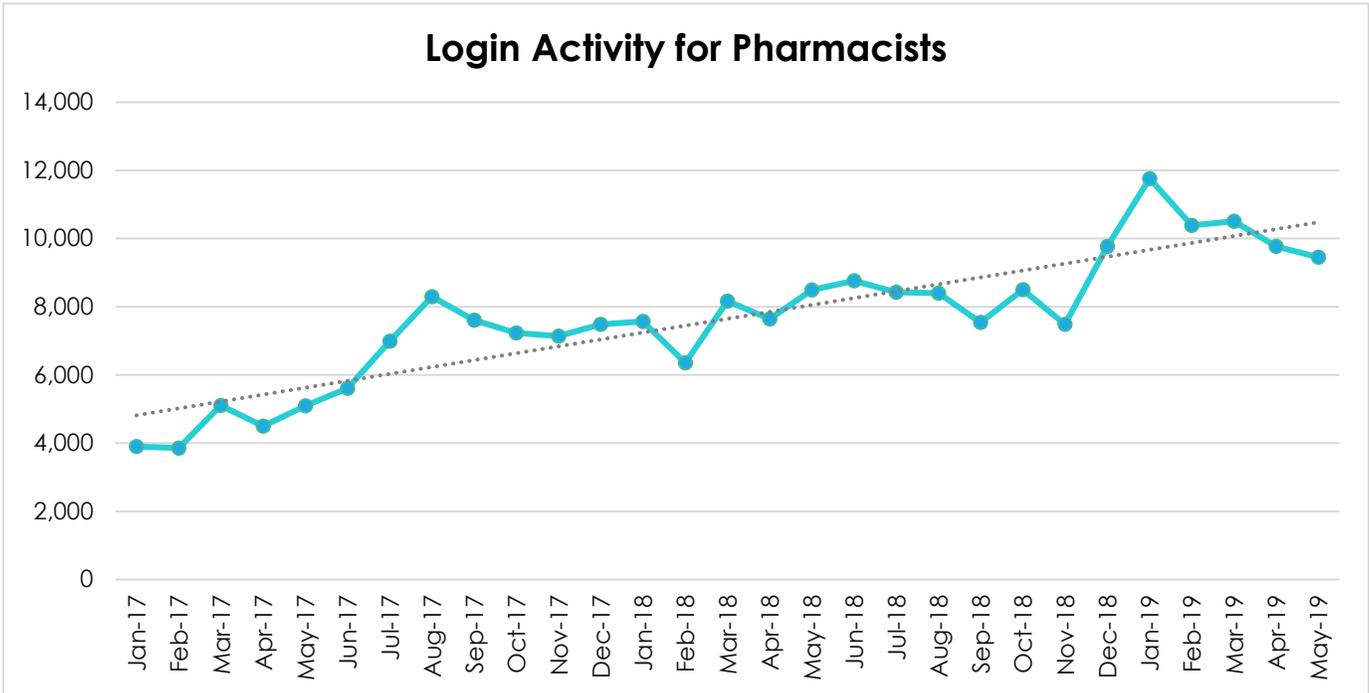


Figure 4. Pharmacists are not required to login to check patient prescription history, however, this graph shows that pharmacists are maximizing efforts to prevent doctor shopping of controlled substance prescriptions.

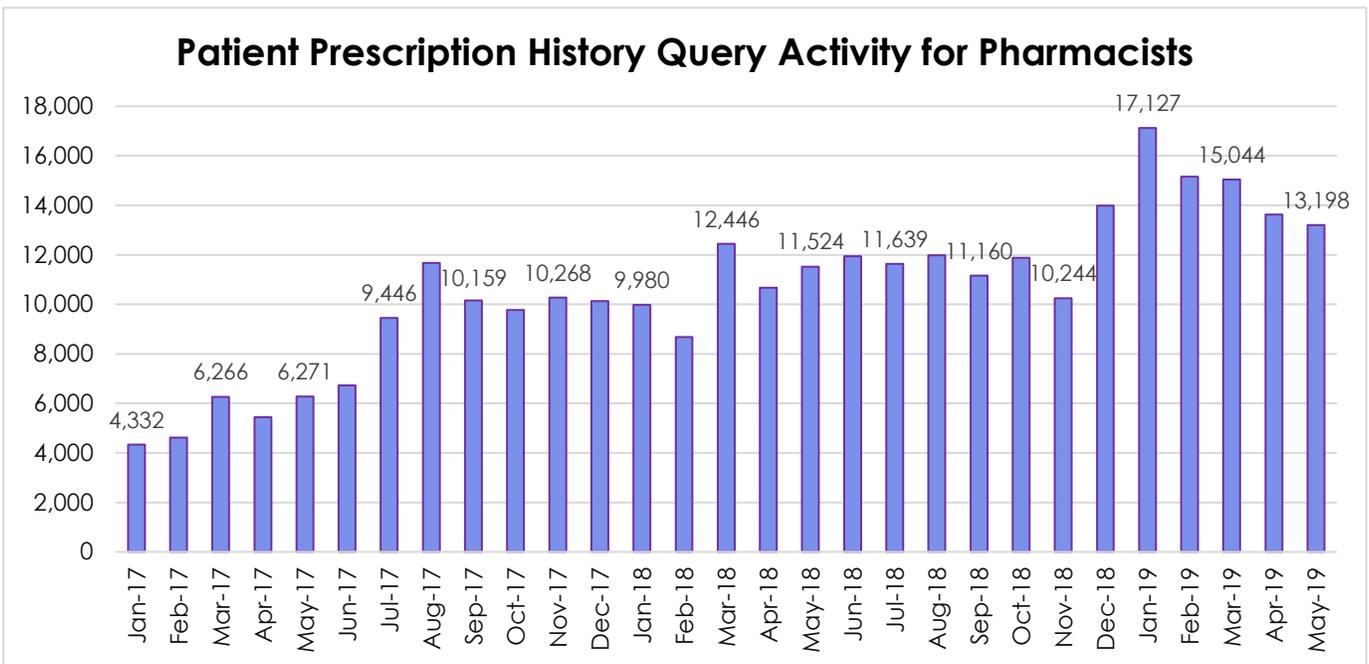


Figure 5. Pharmacists are not required to login to check patient prescription history, however, consistent with login activity trends, pharmacists are consulting the PDMP when dispensing medications.

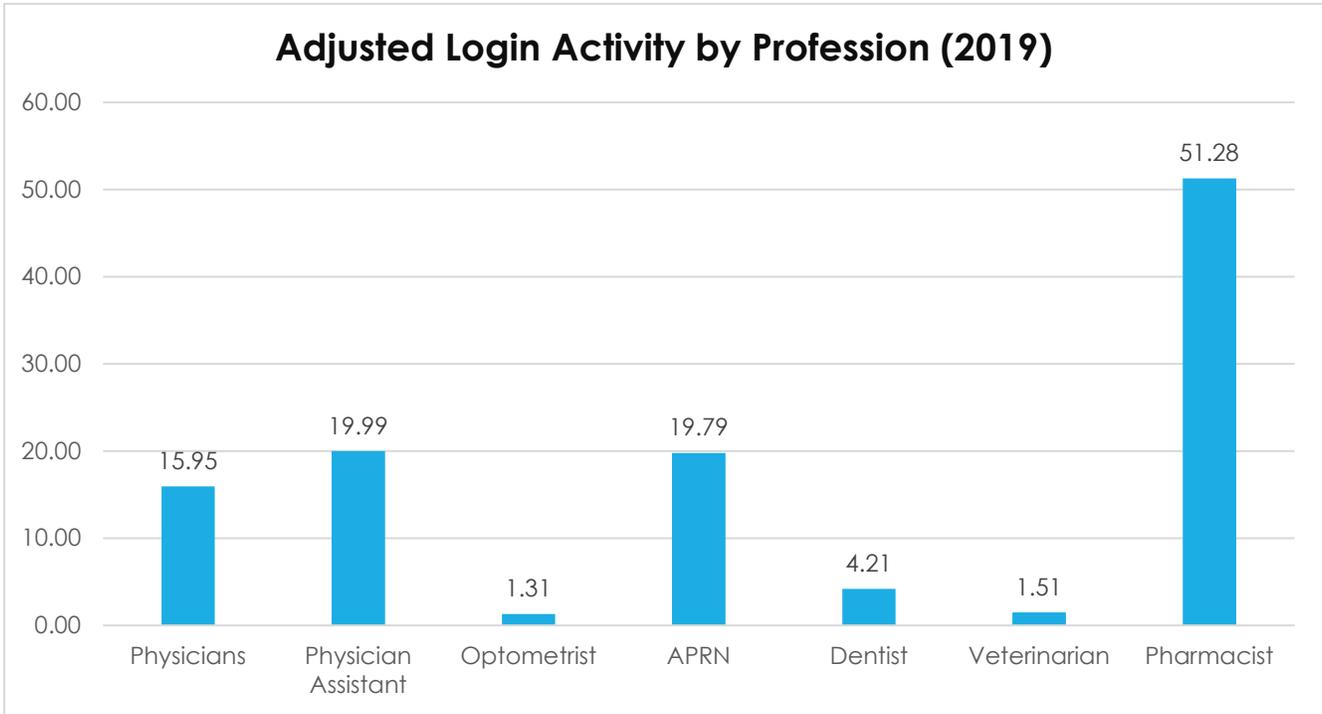


Figure 6. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest login rate adjusted by the number of registered users in their profession. The average login per pharmacist is 51 times in 2019. Optometrists have the lowest login rate per at 1 login per optometrist in 2019.

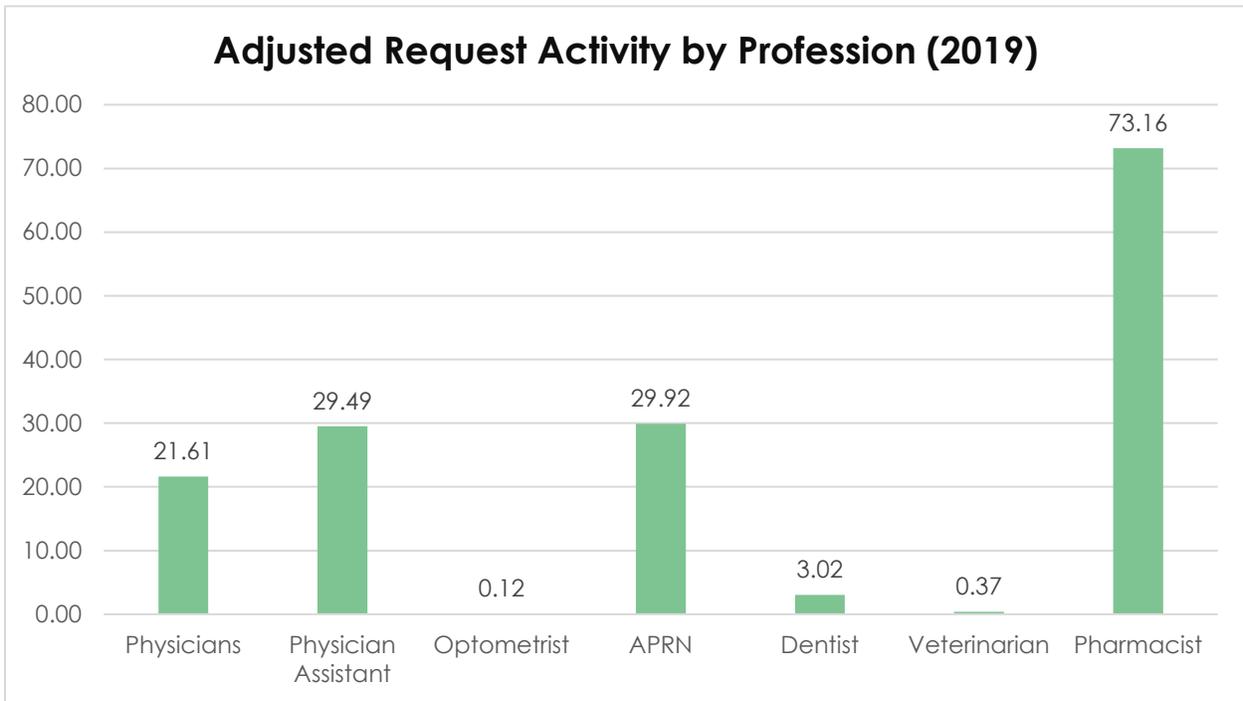


Figure 7. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest patient request activity adjusted by the number of registered users in their profession. The average login per pharmacist is 73 times in 2019. Optometrists have the lowest login rate per at less than one login per optometrist in 2019.

Contact: Elaine Brewer, PDMP Manager | 907-269-8404 | akpdmp@alaska.gov

Under AS 17.30.200(d)(1) and 12 AAC 52.860(b), local, state, and federal law enforcement officials may receive information contained within the PDMP upon a search warrant, subpoena, or order issued by an administrative law judge or court. The number of subpoenas issued by the Drug Enforcement Administration are included in figure 8, below.

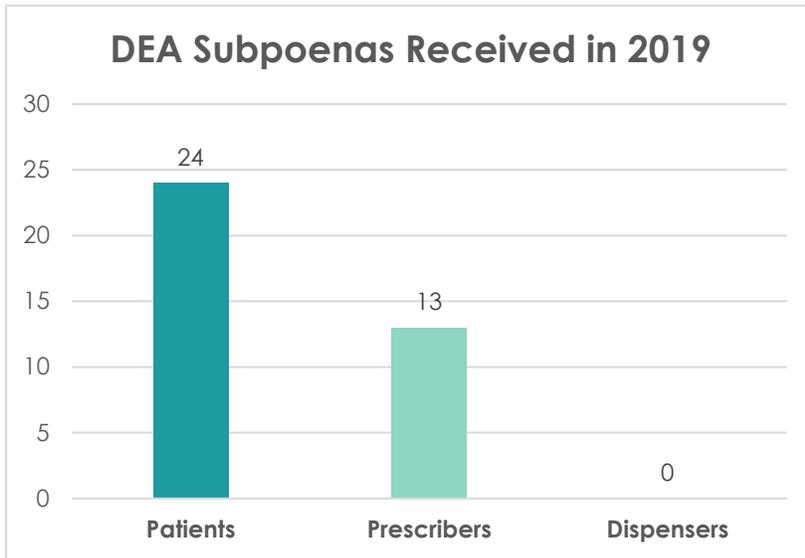


Figure 8. The PDMP manager responded to 100% of the DEA subpoenas received through April 2019. The PDMP manager has responded to 25 subpoenas and will respond to 12 pending subpoenas before the deadlines in June 2019.

Figure 9 captures the number of delinquent pharmacies through May 2019. Reporting is required daily per AS 17.30.200(b) and 12 AAC 52.865(b).

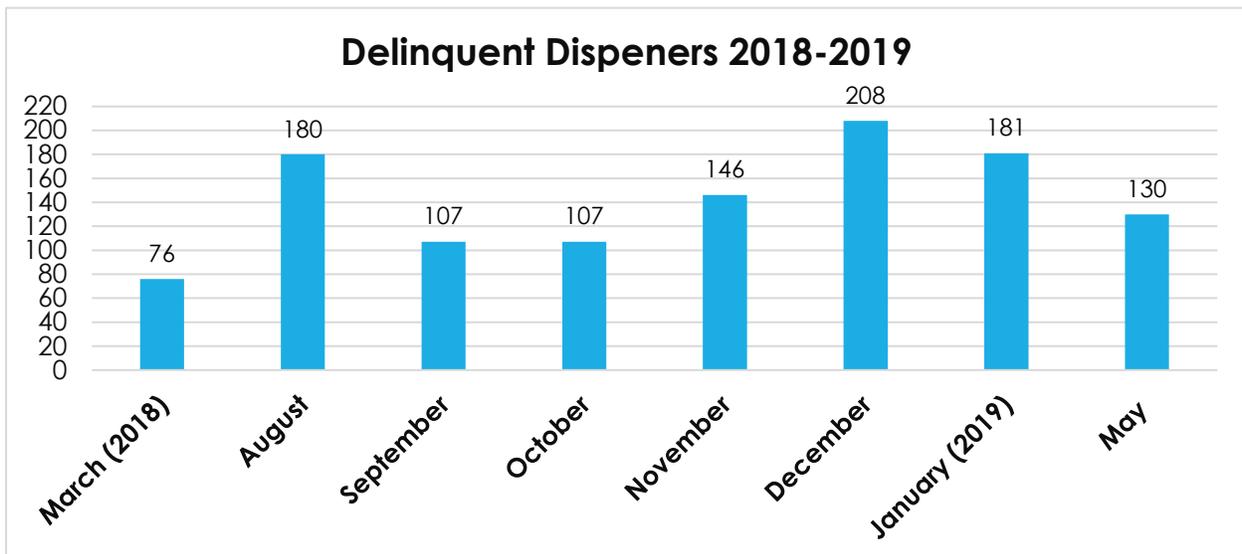


Figure 9. The number of delinquent dispensers has declined 28% since the last compliance report. Dispensers will continue to be contacted via mail to correct reporting gaps. This also includes delinquent prescribers required to report daily.

The following data (Figures 10 through 12) represents information not specific to any given profession and provides a general summary of PDMP trends as recorded in the controlled substance prescription database.

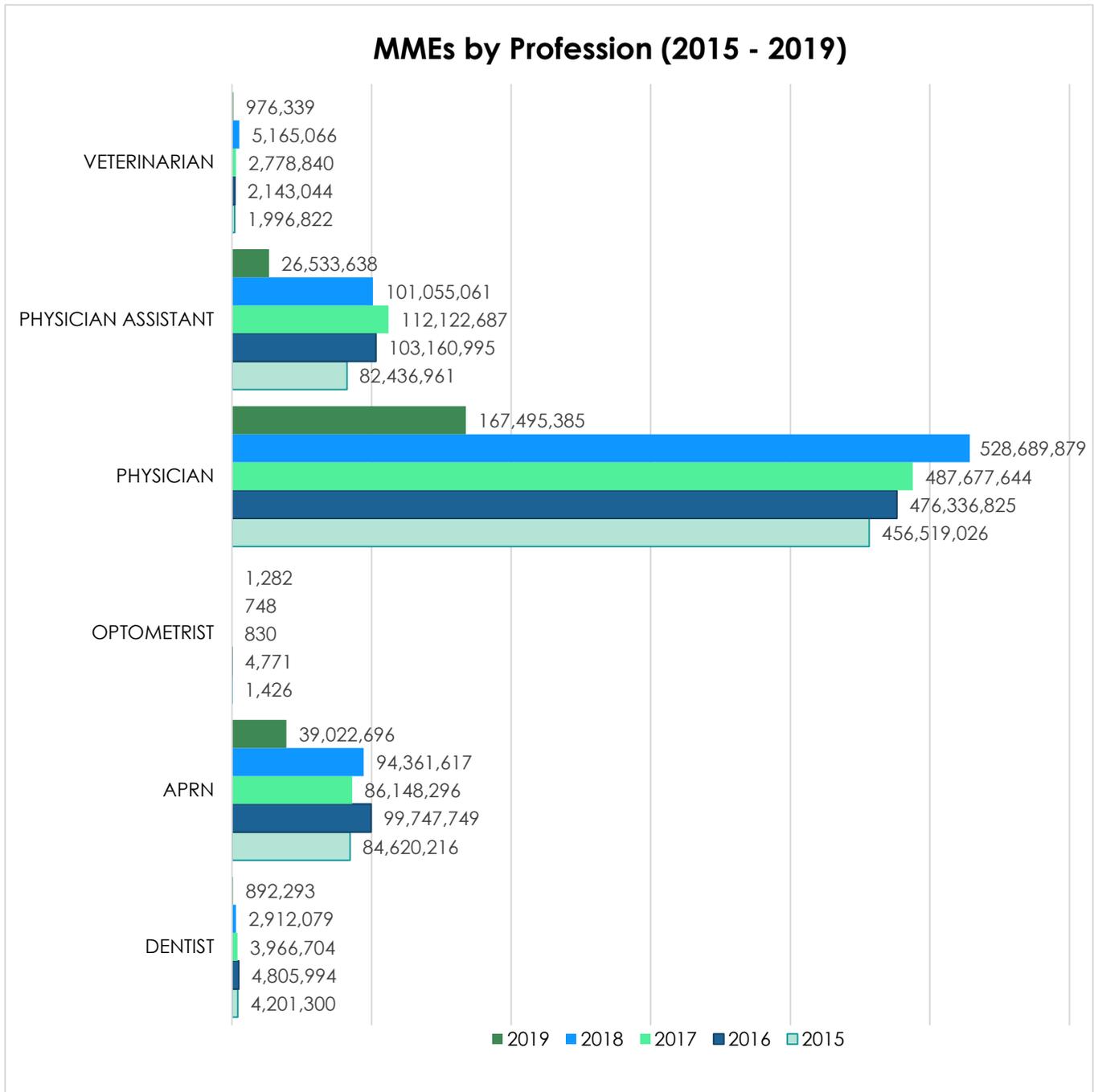


Figure 10. Total MMEs dispensed by profession from 2015 – 2019.

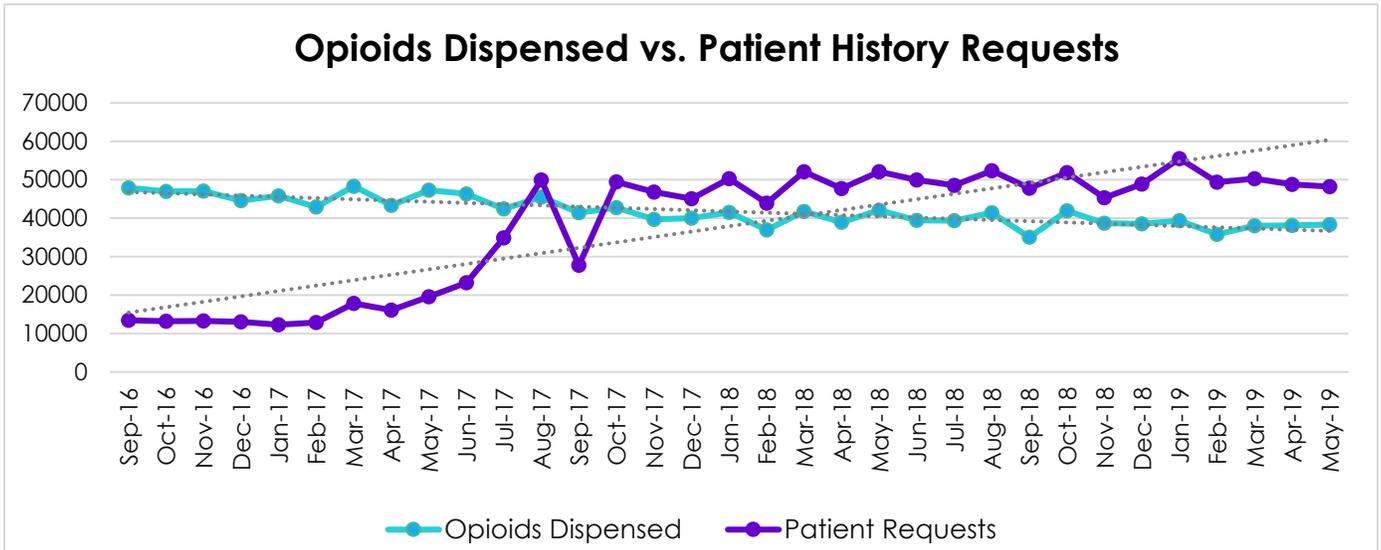


Figure 11. This graph shows the upward trend of patient prescription history requests in the PDMP, suggesting an inverse relationship between overall opioid dispensing in the state. The decrease in opioid dispensations may also be attributed to other factors, including prescriptive policies and salience of increased state-wide monitoring of prescribing practices as reflected in individual prescriber report cards.

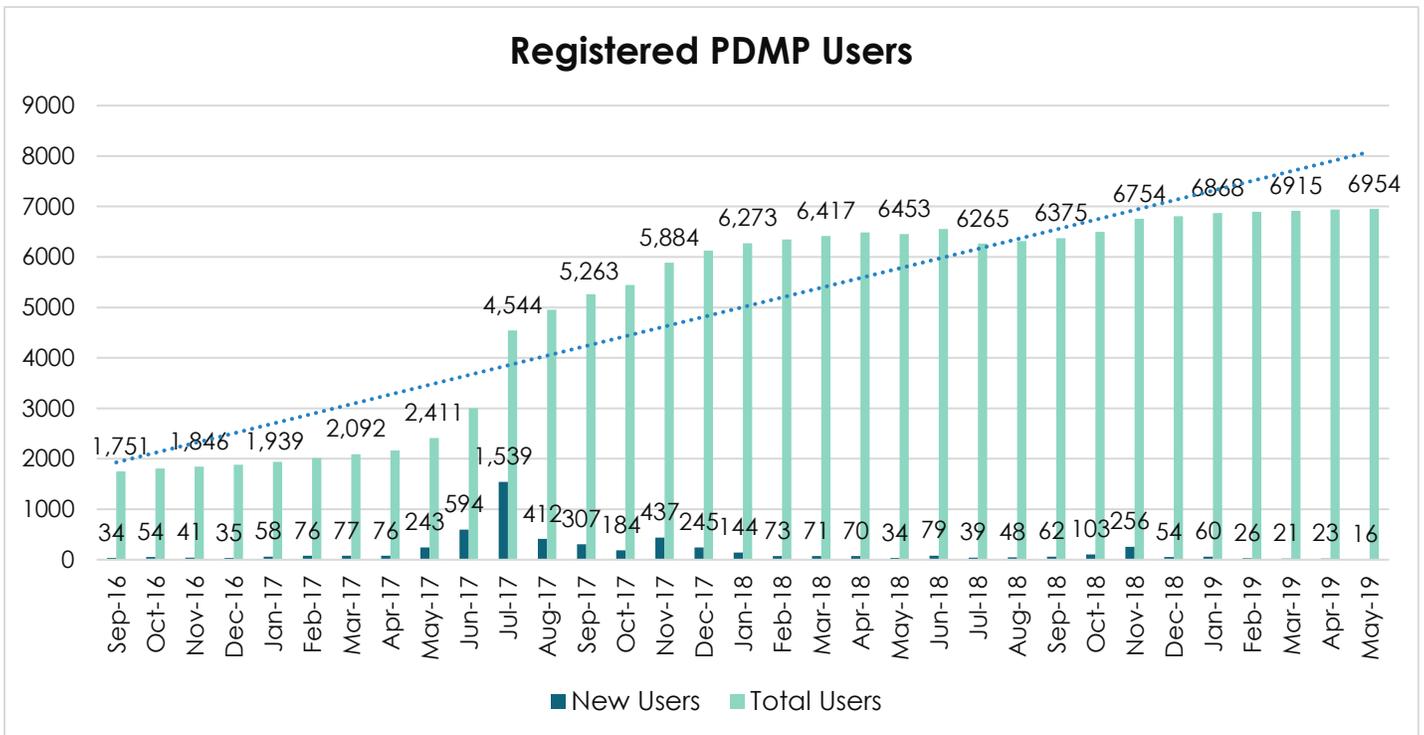


Figure 12. Registered users steadily increased following mandatory registration, but this appears to be leveling off in 2019.

PDMP REPORT FOR THE BOARD OF PHARMACY



November 12, 2019

Intent:

This report contains high-level information on the Prescription Drug Monitoring Program (PDMP) and is intended to provide a summary of registration and reporting data specific to your profession. This report includes data up to October 2019.

Overview:

The PDMP began in 2008 and is housed with the Board of Pharmacy under the Department of Commerce, Community, and Economic Development (DCCED) – Corporations, Business, and Professional Licensing (CBPL) section. Mandatory registration, reviewing, and reporting requirements went into effect in July 2017. All actively licensed practitioners with a valid DEA registration are required to register with the database; however, there are both practice-specific and supply-duration exemptions in AS 17.30.200(k) and (u) in which practitioners are not required to consult the PDMP. Generally, practitioners are required to review patient prescription history before prescribing, administering, and/or directly dispensing a federally scheduled II – IV controlled substance. If directly dispensing, practitioners must report this information to the PDMP on a daily basis. Information on exemptions can be found www.pdmp.alaska.gov under the Registration and Use Exemptions tab and includes information for federally-employed practitioners and pharmacists as well as information on situational exemptions to PDMP use. If mandatory registration and use exemptions do not apply and a licensee fails to register with the PDMP, disciplinary action may be taken by the State Medical Board.

Delegate access is allowed so long as the delegate holds an active license, certification, or registration under AS 08. Delegate access can help relieve time-constraints as reviewing and reporting tasks can be distributed to qualified staff.

General Information and Updates:

- PDMP fees for initial and continued access went into effect on April 22, 2018 by authority of AS 17.30.200, which was subsequently implemented under 12 AAC 02.107. This requires a \$25.00 fee to be submitted before access to the controlled substance prescription database is granted.
- Beginning June 2018, the PDMP began separating federal practitioners and pharmacists from those required to register by updating user roles, e.g.: 'Pharmacist' to 'IHS Dispenser'.
- Beginning June 2018, all newly registered and renewed PDMP users are issued separate PDMP registration numbers, which are searchable by name under the program 'Prescription Drug Monitoring Program' at: <https://www.commerce.alaska.gov/cbp/main/Search/Professional>
- An Awareness and Feedback Questionnaire, developed per the directive of the CDC, was made available from May 2018 to June 2018. Out of 402 total respondents, 79 (19.70%) pharmacists participated. An analysis of the results by NPC Research was provided in September 2019 and can be found at:
<https://www.commerce.alaska.gov/web/cbpl/ProfessionalLicensing/PrescriptionDrugMonitoringProgram/PDMPSurveyResults.aspx>

PDMP REPORT FOR THE BOARD OF PHARMACY



- There are currently 20 pending accounts in AWARe, one for a military dispenser, and one for an out-of-state pharmacist. Authority to provide access to military prescribers and dispensers is given by AS 17.30.200(f) and authority to provide access to out-of-state providers is given by AS 17.30.200(d)(4).

Enhancements:

- On September 9th, 2019, **NarxCare** was integrated into the existing AWARe platform. NarxCare provides visual analytics snapshots upon a patient query so providers can make more informed clinical decisions based on a patient's overdose risk score (ORS), which is a value between 0 and 900 and provides an odds ratio for unintentional death.
- An **Awareness and Feedback Questionnaire** for 2019 will be launched either before the new year or shortly after the new year.
- The **Compliance Module feature** went live on August 21st and now allows providers to view their own compliance with the patient prescription reviewing mandate.
- A **License Integration** enhancement project is imminent and will provide automatic verification of licensure status, e.g.: active or inactive between CBPL's licensing database, Portal, and the AWARe platform. For existing users, this means providers who do not renew their professional license will be automatically deactivated in the PDMP.
- **Clinical Alerts** will go live in the coming months, which will give real-time alerts to providers when a patient has met or exceeded a prescription threshold threshold.
- The PDMP will be required to engage in interstate datasharing through **RxCheck**, which was developed by the Bureau of Justice Assistance (BJA). The Integrated Justice Information Systems Institute (IJIS) assists the BJA and states in facilitating interstate connections.

Datasharing:

- Idaho
- Louisiana
- Massachusetts
- Military PDMP (pending)
- Minnesota
- Montana
- North Dakota
- Oregon (pending)
- Puerto Rico (pending)
- Rhode Island
- South Carolina
- Texas (pending)
- Washington
- Wyoming (pending)

PDMP REPORT FOR THE BOARD OF PHARMACY



Data:

The Alaska State Board of Pharmacy regulates several license types, including pharmacists, pharmacy technicians, and pharmacy interns. All pharmacist licensees are required to register with the PDMP user role, 'Pharmacist', unless working for a federal employer (IHS, VA, military, etc.). Pharmacy technicians and interns may register as delegates for Pharmacist users.

As of October 31, 2019, there are a total of 7,871 registered users, 1,255 of which are registered using the 'Pharmacist' role and 30 are registered using the 'Pharmacist-in-Charge' role (Figure 1A). A breakdown of registered users by all professions is shown in Figure 1B. Note that the registration trend by year graph is no longer provided because Appriss Tableau includes pharmacist delegates, IHS dispensers, VA dispensers, and out-of-state pharmacists in the registration by month ad hoc report, which cannot be filtered out.

Pharmacists' registration compliance has reached over 100%, which may be due to some accounts still in active status although their professional pharmacist license has lapsed or expired. The registration compliance (Figure 2; excluding out-of-state pharmacists). Additional licensed pharmacists not represented under the 'Pharmacist' user role may be inclusive of other dispenser roles, including IHS Dispenser or VA Dispenser; the compliance rate may be higher than depicted in Figure 2 due to registration under other relevant user role categories.

Active PDMP Users

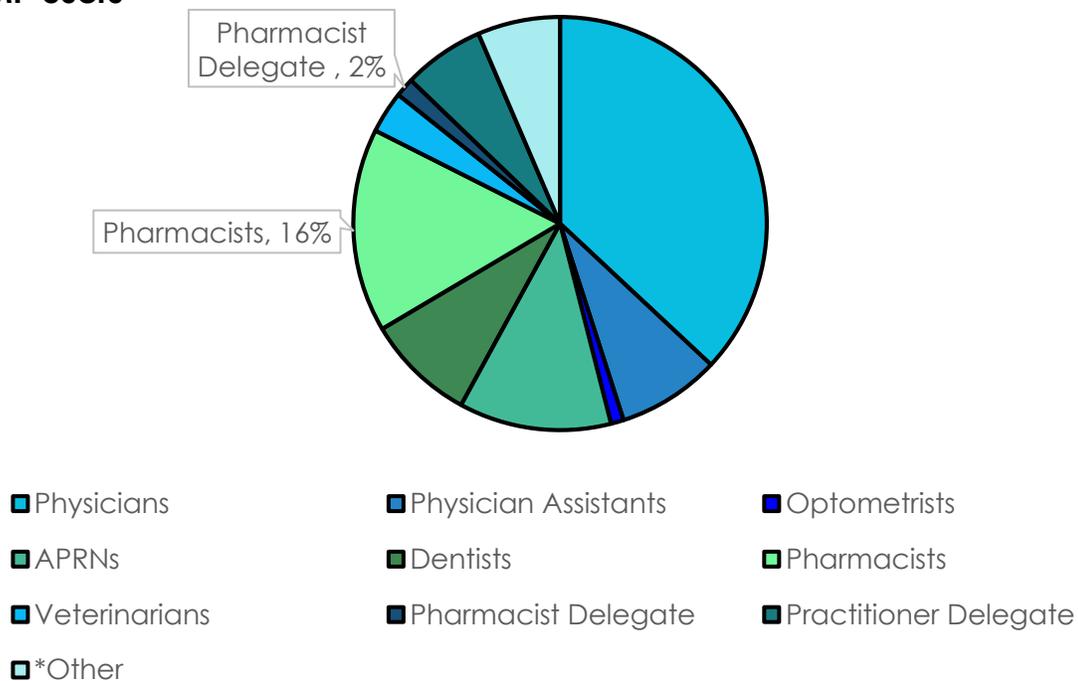


Figure 1A. The Pharmacists user role category comprises 13% of actively registered users. A breakdown of additional pharmacy-related registrations are included in Figure 1B. *Other includes admin and restricted admin; IHS, military, and VA prescribers; medical examiner/coroner; state Medicaid program; and medical examiner's delegate.

PDMP REPORT FOR THE BOARD OF PHARMACY

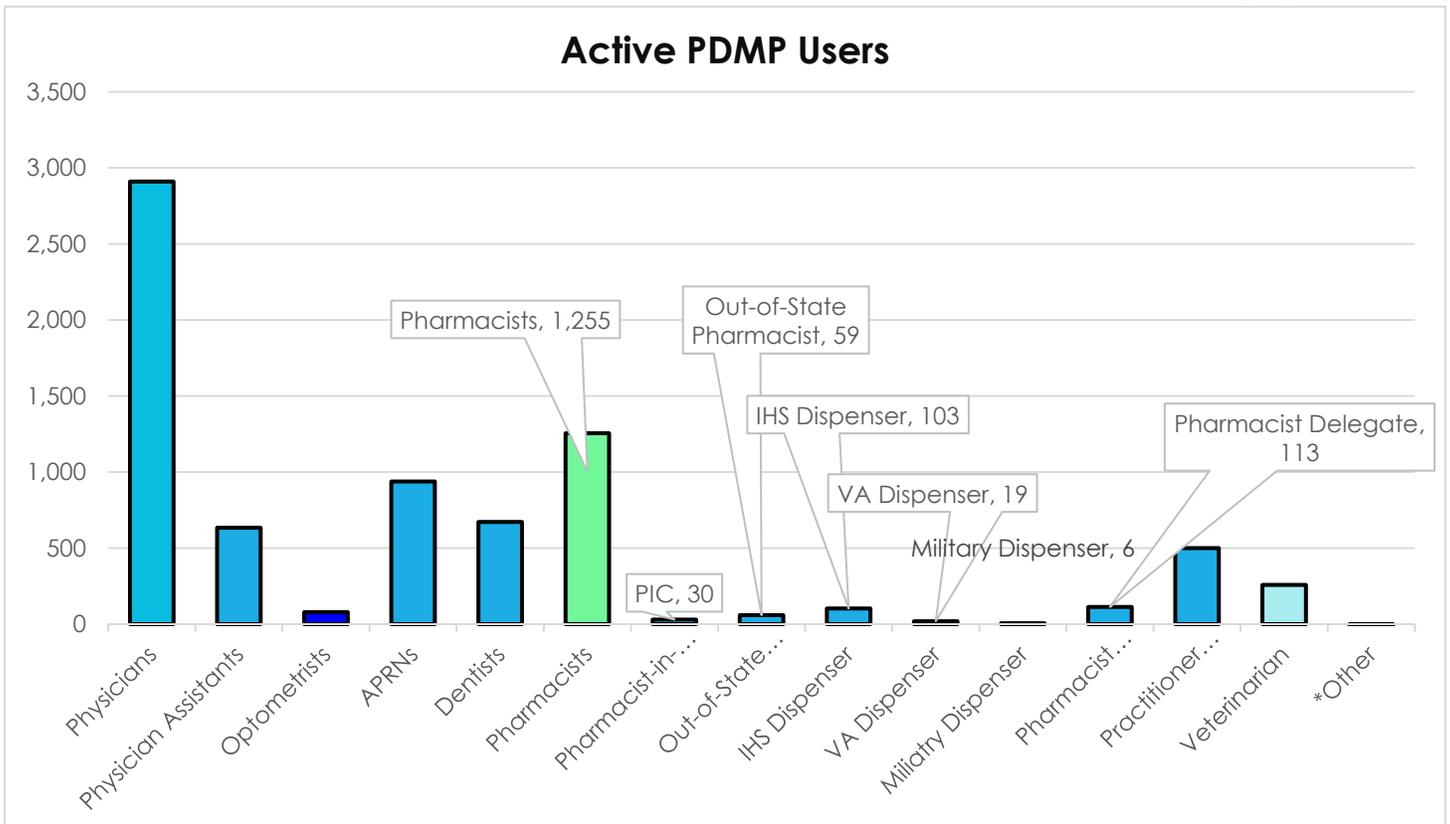


Figure 1B. A breakdown of pharmacy-related user roles.

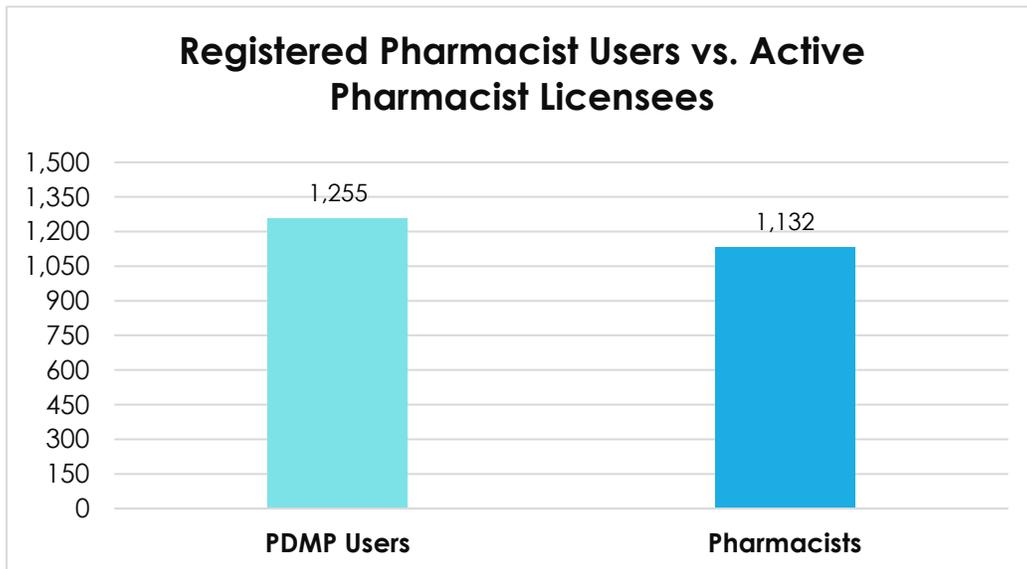


Figure 21. The compliance rate is over 100%; the discrepancy in total registered pharmacists versus the number of pharmacist licensees may be explained by users who selected the 'Pharmacist' or 'Pharmacist-in-Charge' user role but are actually IHS, military, or VA dispensers, or by registered users who have not submitted the account deactivation form but have a lapsed or expired professional pharmacist license under AS 08. Once license integration is live, accounts held by lapsed or expired pharmacists will automatically be deactivated.

PDMP REPORT FOR THE BOARD OF PHARMACY



The following figures (3 and 4) reflect pharmacist interactions with the PDMP. Figure 5 shows the overlap of logins versus patient queries while figure 6 shows the proportion of pharmacy license types performing patient queries. Figures 7 and 8 show adjusted logins by profession.

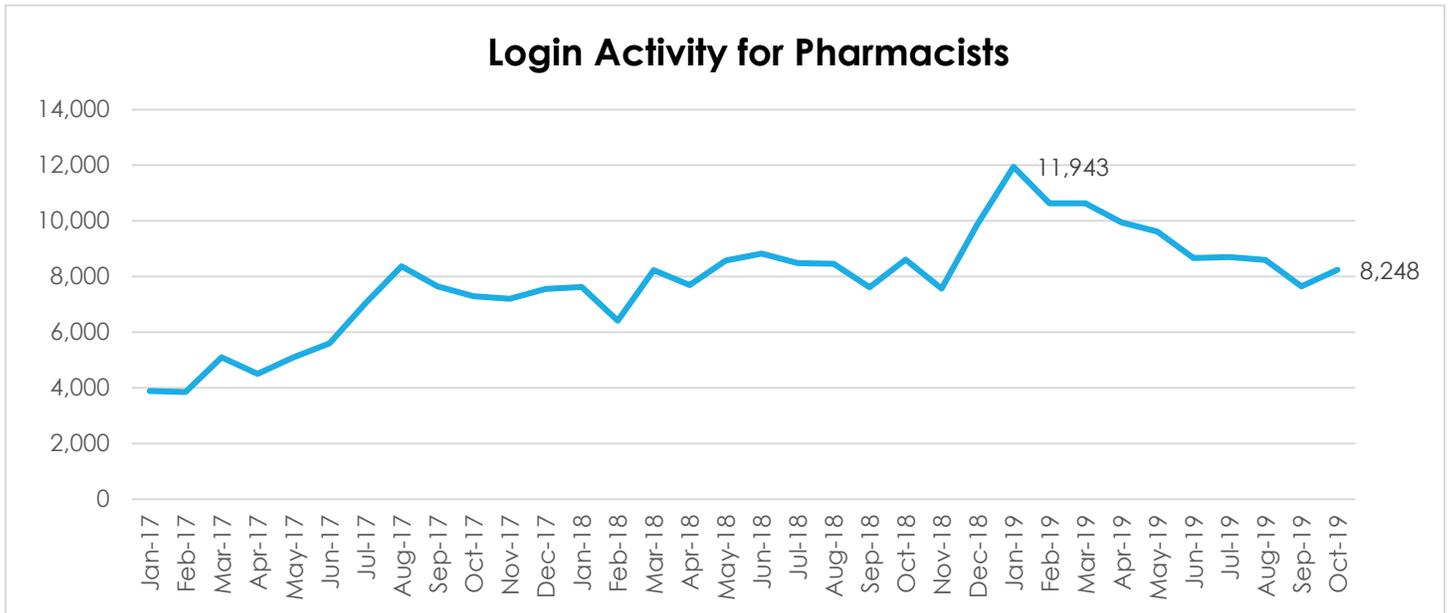


Figure 3. The login activity for pharmacists (user role = 'Pharmacist' and 'Pharmacist in Charge') shows an upward trend. Logins peaked in January 2019 with 11,713 logins.

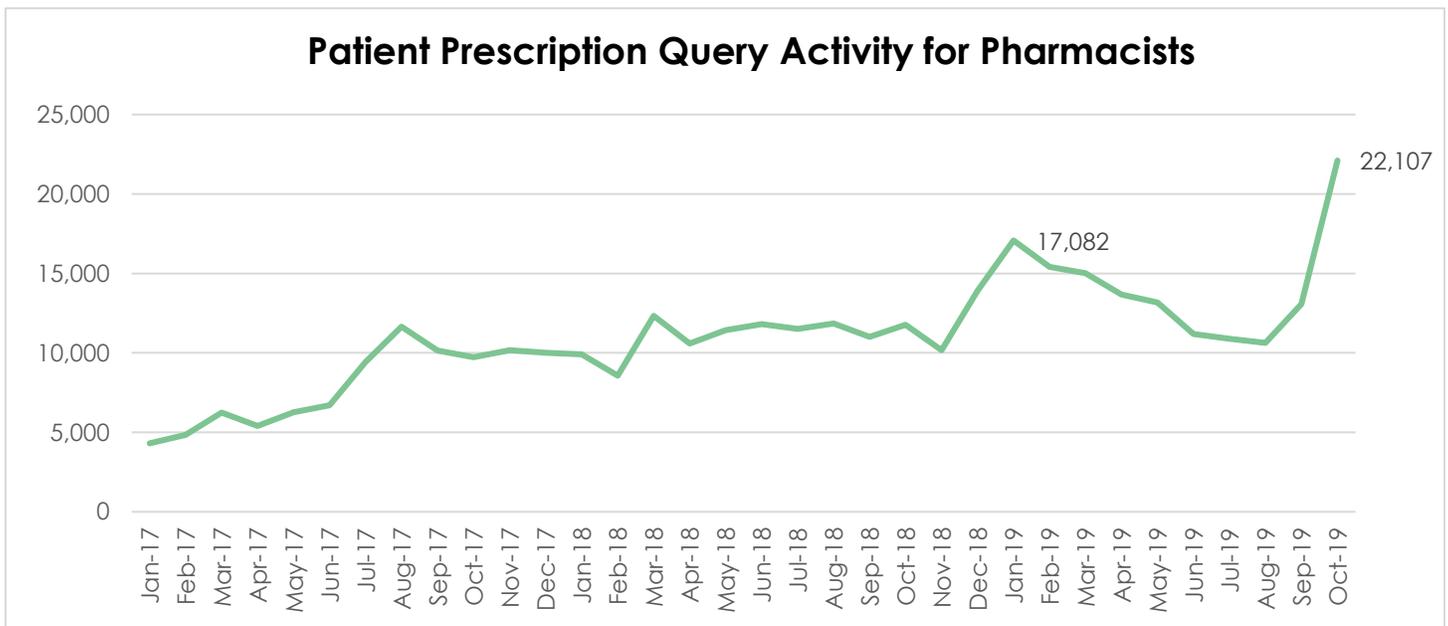


Figure 4. Pharmacists are not required to login to check patient prescription history, however, consistent with login activity trends, pharmacists are consulting the PDMP when dispensing medications.

PDMP REPORT FOR THE BOARD OF PHARMACY

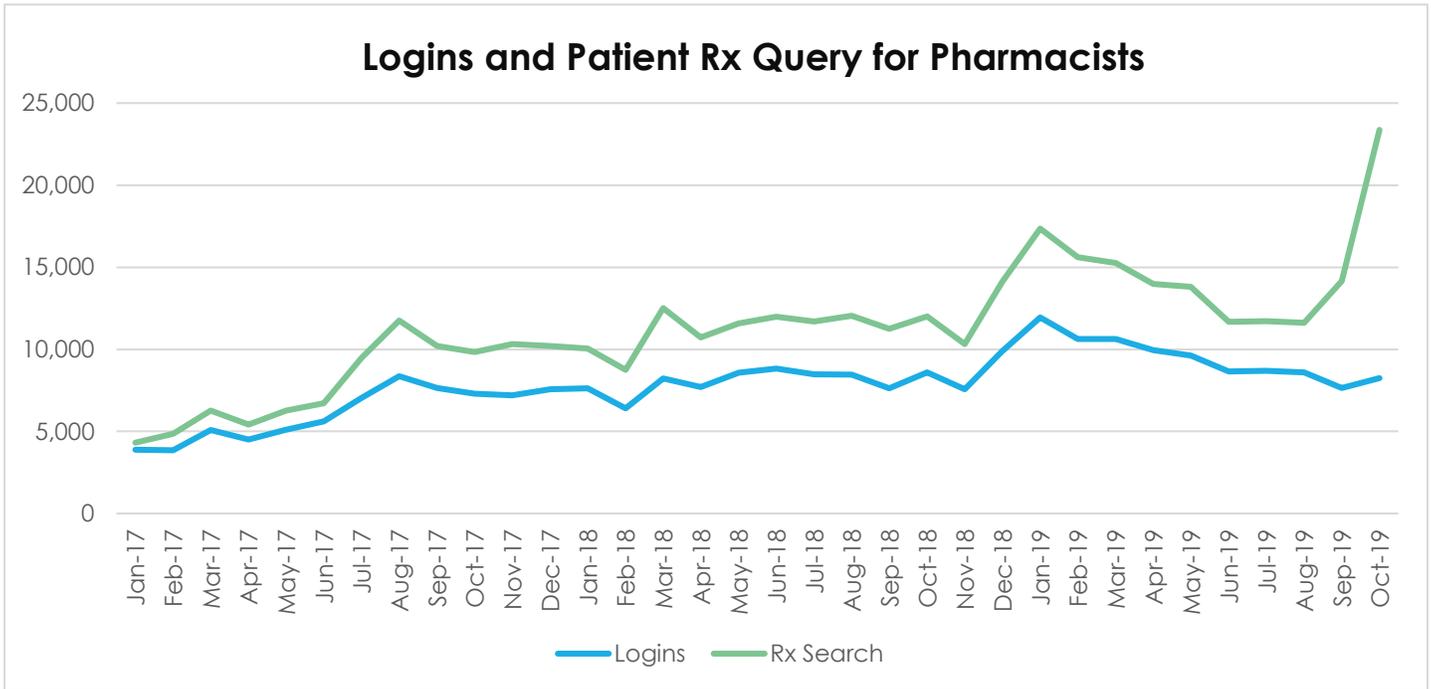


Figure 5. Logins vs. patient prescription history searches shows a synchronous trend.

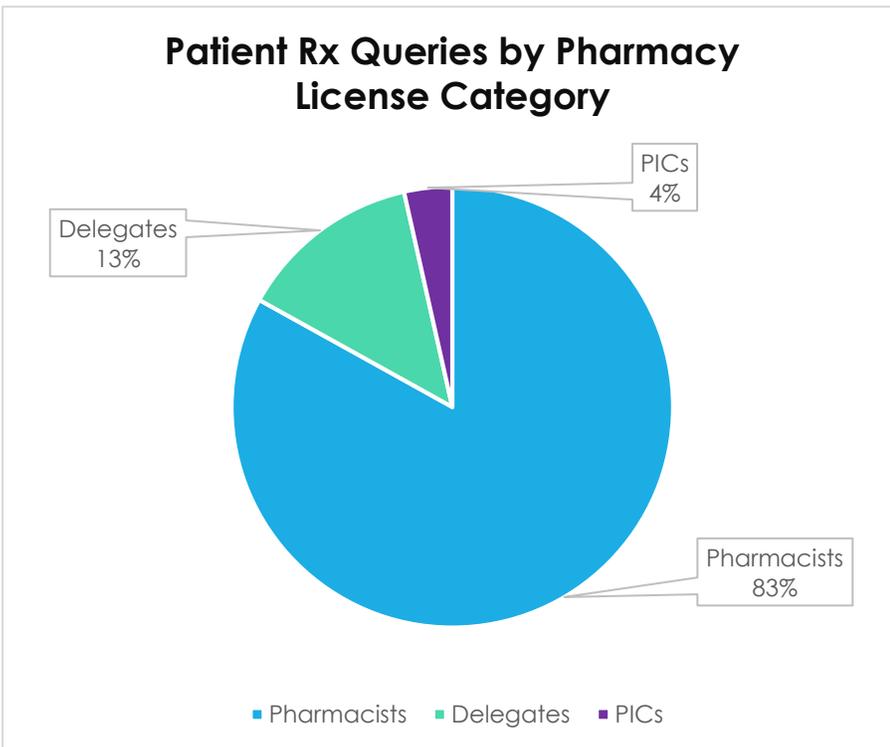


Figure 6. 13% of pharmacist delegates (technicians or interns) are querying patients' prescription history on behalf of pharmacists.

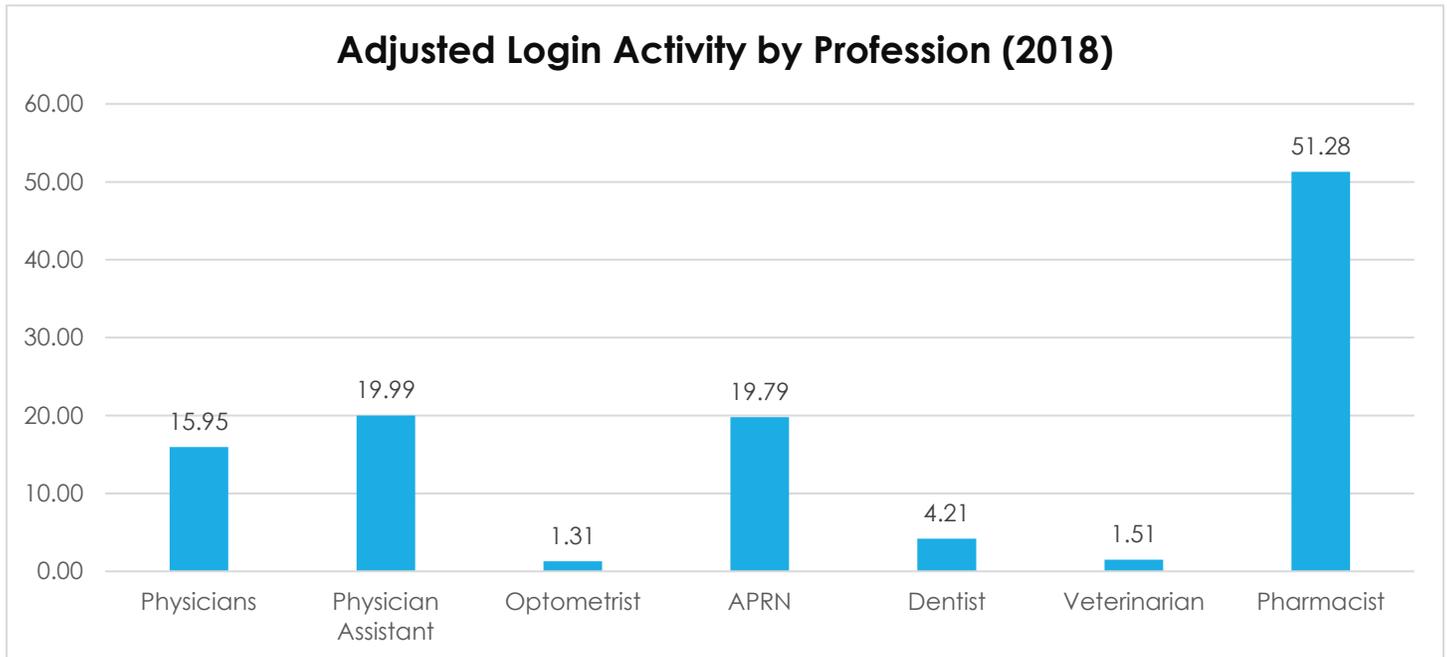


Figure 7. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest login rate adjusted by the number of registered users in their profession. The average login per pharmacist is 51 times in 2019. Optometrists have the lowest login rate per at 1 login per optometrist in 2018. *This data has not been updated since June 2019.

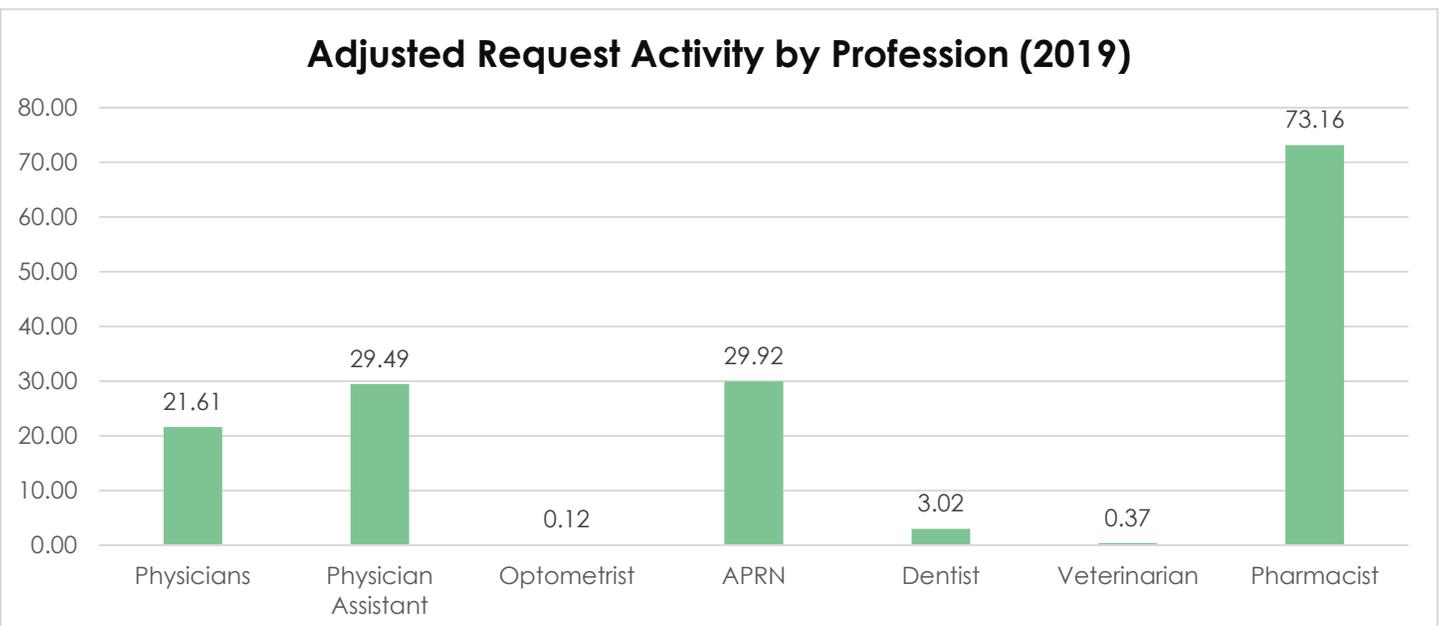


Figure 8. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest patient request activity adjusted by the number of registered users in their profession. The average login per pharmacist is 73 times in 2019. Optometrists have the lowest login rate per at less than one login per optometrist in 2019. *This data has not been updated since June 2019.

PDMP REPORT FOR THE BOARD OF PHARMACY



The PDMP AWARe platform includes capabilities to run threshold reports when a patient has met or exceeded an established threshold. The Alaska Board of Pharmacy established a 5-5-3 threshold during their January 29 – 31, 2014 board meeting (Figure 9).

Threshold Period	Criteria	# of Patients
03-01-2018 to 06-01-2018	5 prescribers + 5 pharmacies over a three-month period	40
06-01-2018 to 09-01-2018	5 prescribers + 5 pharmacies over a three-month period	21
09-01-2018 to 12-01-2018	5 prescribers + 5 pharmacies over a three-month period	21
12-01-2018 to 03-01-2019	5 prescribers + 5 pharmacies over a three-month period	15

Figure 9. Threshold reports are generated every three months. The last report generated for 12-01-2018 to 03-01-2019 resulted in 15 instances in which a patient met or exceeded the threshold criteria. Boards are notified only when a licensee has contributed to a patient meeting or exceeding this threshold—licensee names are not disclosed.

Under AS 17.30.200(d)(1) and 12 AAC 52.860(b), local, state, and federal law enforcement officials may receive information contained within the PDMP upon a search warrant, subpoena, or order issued by an administrative law judge or court. The number of subpoenas issued by the Drug Enforcement Administration are included in figure 8, below.

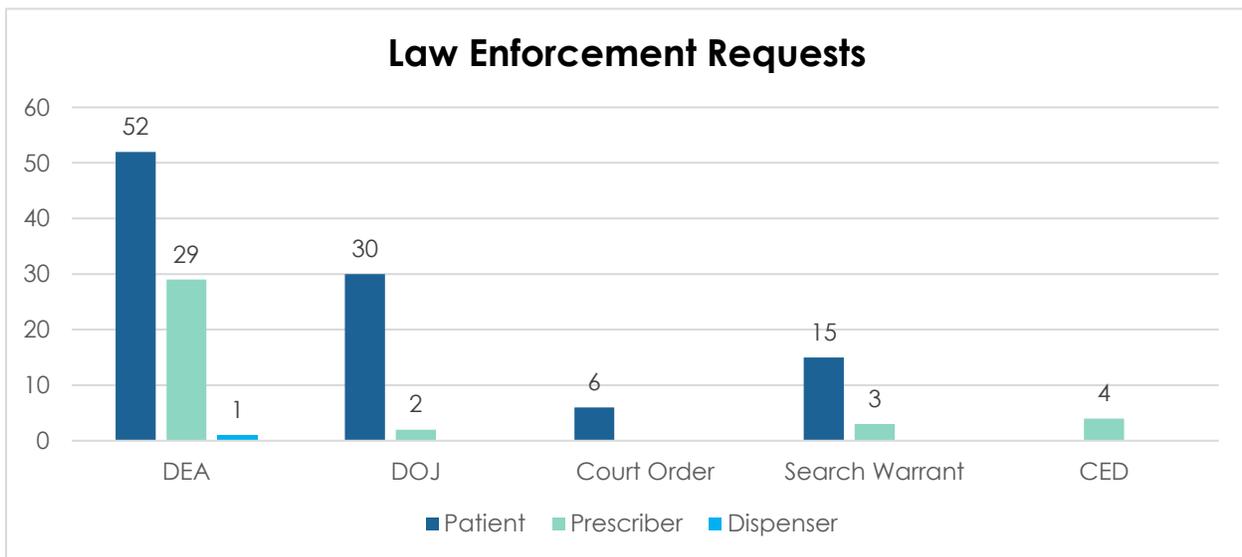


Figure 10. The PDMP manager responded to 100% of the subpoenas (n = 138) received by law enforcement agencies in 2019.

PDMP REPORT FOR THE BOARD OF PHARMACY



Figure 11 captures the number of delinquent pharmacies through May 2019. Reporting is required daily per AS 17.30.200(b) and 12 AAC 52.865(b).

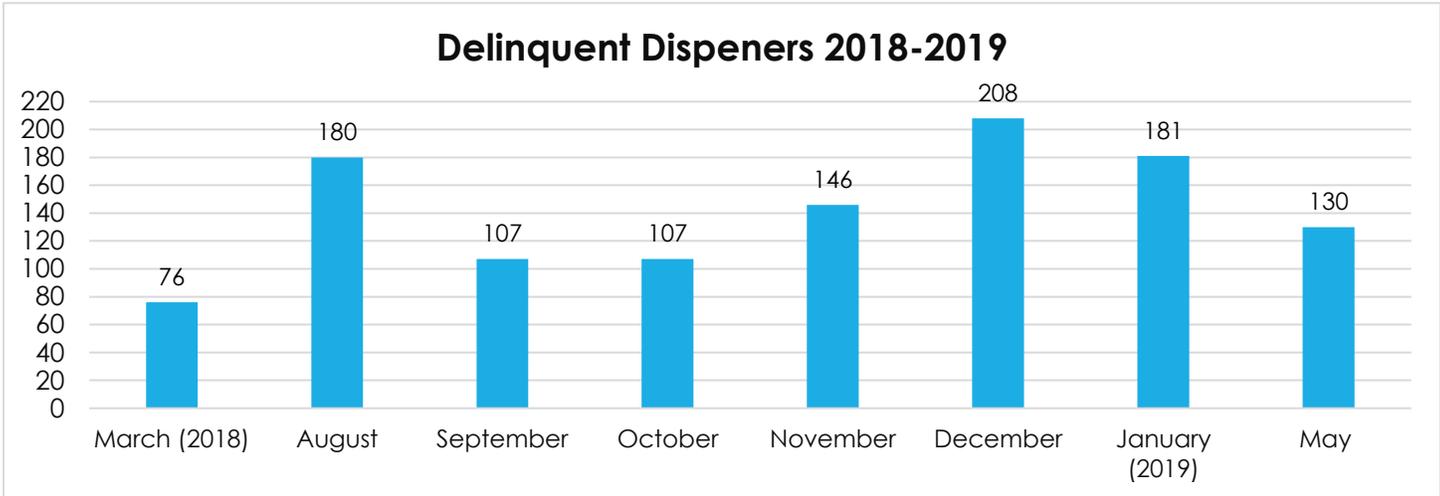


Figure 11. The number of delinquent dispensers has declined 28% since the last compliance report. Dispensers will continue to be contacted via mail to correct reporting gaps. This also includes delinquent prescribers required to report daily.

The following data (Figures 10 through 11) represents information not specific to any given profession and provides a general summary of PDMP trends.

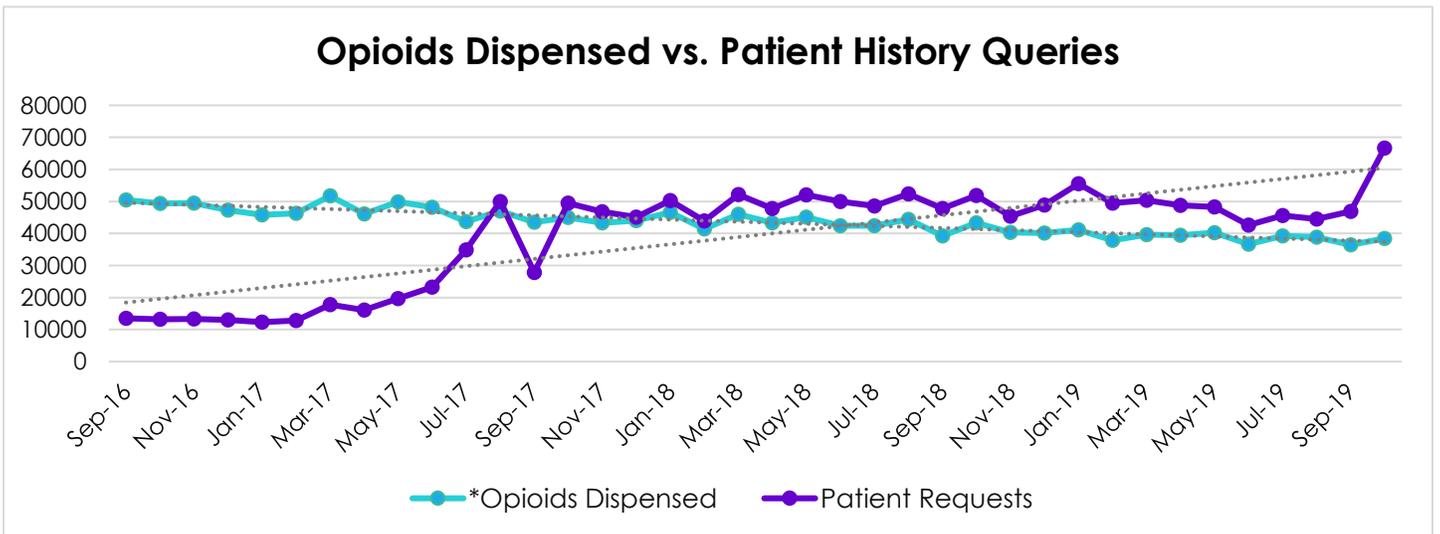


Figure 12. This graph shows the upward trend of patient prescription history requests in the PDMP, suggesting an inverse relationship between overall opioid prescribing and dispensing in the state. The decrease in opioid dispensations may also be attributed to other factors, including prescriptive policies, opioid continuing education, and salience of increased state-wide monitoring of prescribing practices as reflected in individual prescriber report cards. *Due to the number of delinquent pharmacies who are in non-compliance with the daily reporting requirement, the number of opioids dispensed may be under represented.

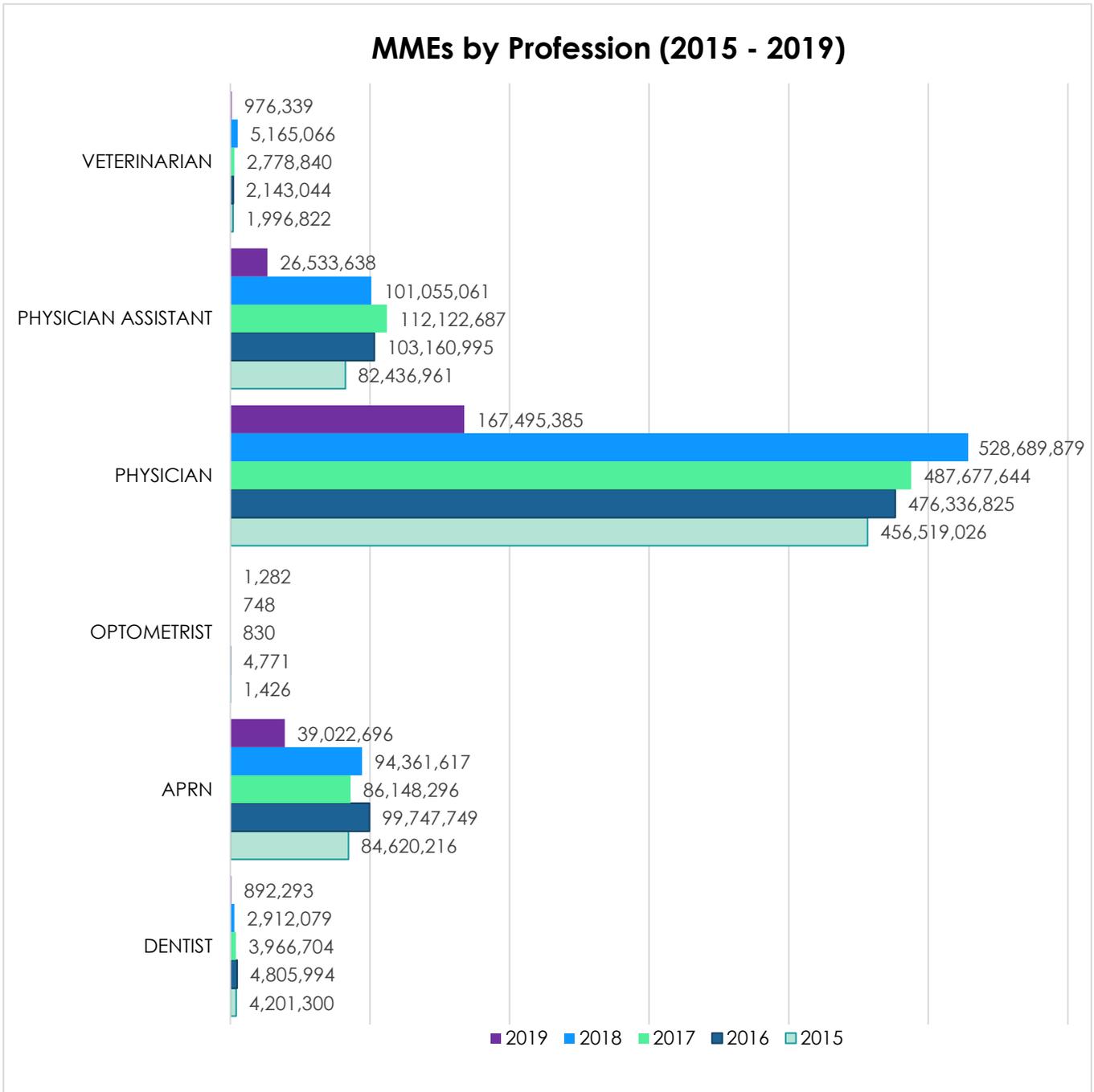


Figure 13. Though opioid prescriptions decreased from 2017 to 2018, total MMEs increased, suggesting prescriptions issued in longer days' supply.

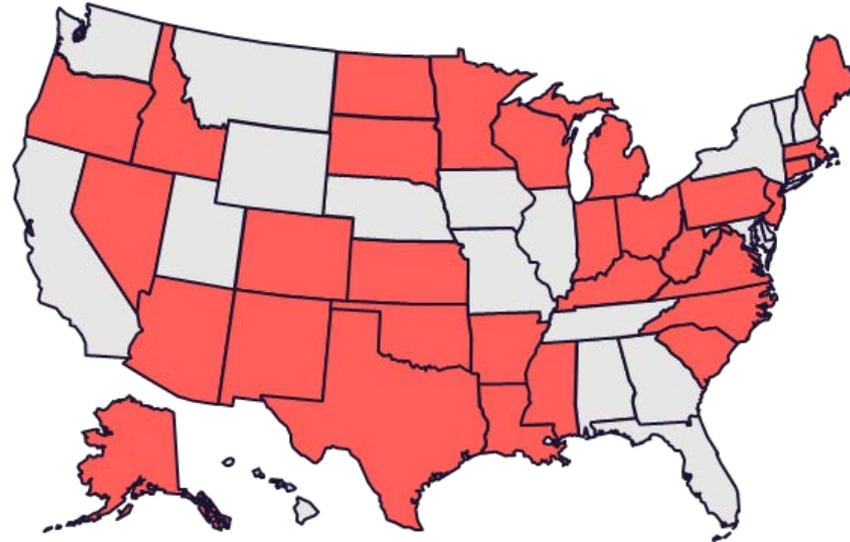
Bureau of Justice Assistance

Award Title: State of Alaska PDMP Implementation and Enhancement Project	
Award Description:	
<p>The Harold Rogers Prescription Drug Monitoring Program (PDMP) is being incorporated into the FY 2017 Comprehensive Opioid Abuse Site-based Program. The purpose of this program is to improve collaboration and strategic decision-making of regulatory and law enforcement agencies and public health officials to address prescription drug and opioid misuse, save lives, and reduce crime. This is made possible through the collection and analysis of controlled substance prescription data and other scheduled chemical products through a centralized database administered by an authorized state agency. The Comprehensive Opioid Abuse Site-based program was developed as part of the CARA legislation signed into law on July 22, 2016. In FY 2017, the Implementation and Enhancement Projects category of funding available through the PDMP grant program will provide funding and technical assistance to state governments that have a pending or enacted enabling statute or regulation requiring the submission of controlled substance prescription data to an authorized state agency. Funding must be used for mandatory national meetings in Washington, D.C.; work closely with BJAs designated training and technical assistance (TTA) provider(s); any applicant that requests funds to implement information sharing with other state PDMPs must use technical solutions that are compliant with the National PMIX Architecture. In addition, grant funds may also be used to support a combination of the allowable use categories to establish or enhance a PDMP system; facilitate the exchange of information and collected prescription data and other scheduled chemical products among states; develop a training program for system users; produce and disseminate educational materials; support collaborations with law enforcement, prosecutors, public health officials, treatment providers, and/or drug courts; facilitate electronic information sharing among states in compliance with the National PMIX Architecture; expand monitoring to Schedules II, III, IV, and V; improve the quality and accuracy of PDMP data; develop or enhance the capacity to provide unsolicited reports of controlled substance prescribing to authorized individuals or entities and assess the efficiency and effectiveness of the PDMP program or specific PDMP initiatives.</p> <p>Alaskas PDMP is underutilized only 22% of potential prescribers are registered. Grant funds will assist Alaska in assessing levels of awareness of the PDMP among health care practitioners; identifying statewide trends in controlled substance prescribing; increasing provider self-awareness of prescribing habits; expanding the data collected by increasing usage of the PDMP, and recommending policy changes to prevent opioid overuse, misuse, abuse, and overdose. The current PDMP program will be enhanced by adding a Prescriber Report Card function to track prescribing habits.</p> <p>CA/NCF</p>	
Awardee Name: State of Alaska, Department of Health and Social Services	Award Number: 2017-PM-BX-0006
Solicitation Title: BJA FY 17 Comprehensive Opioid Abuse Site-based Program: Harold Rogers Prescription Drug Monitoring Program (PDMP) Implementation and Enhancement Projects	Fiscal Year: 2017
Supplement Number: 00	Amount: \$255,462.00
Earmark: No	Recovery Act: No
State/Territory: AK	County: Anchorage
Congressional District: 00	Award Status: Open

Prescription Drug Monitoring Programs and Appriss Health

April 11, 2018

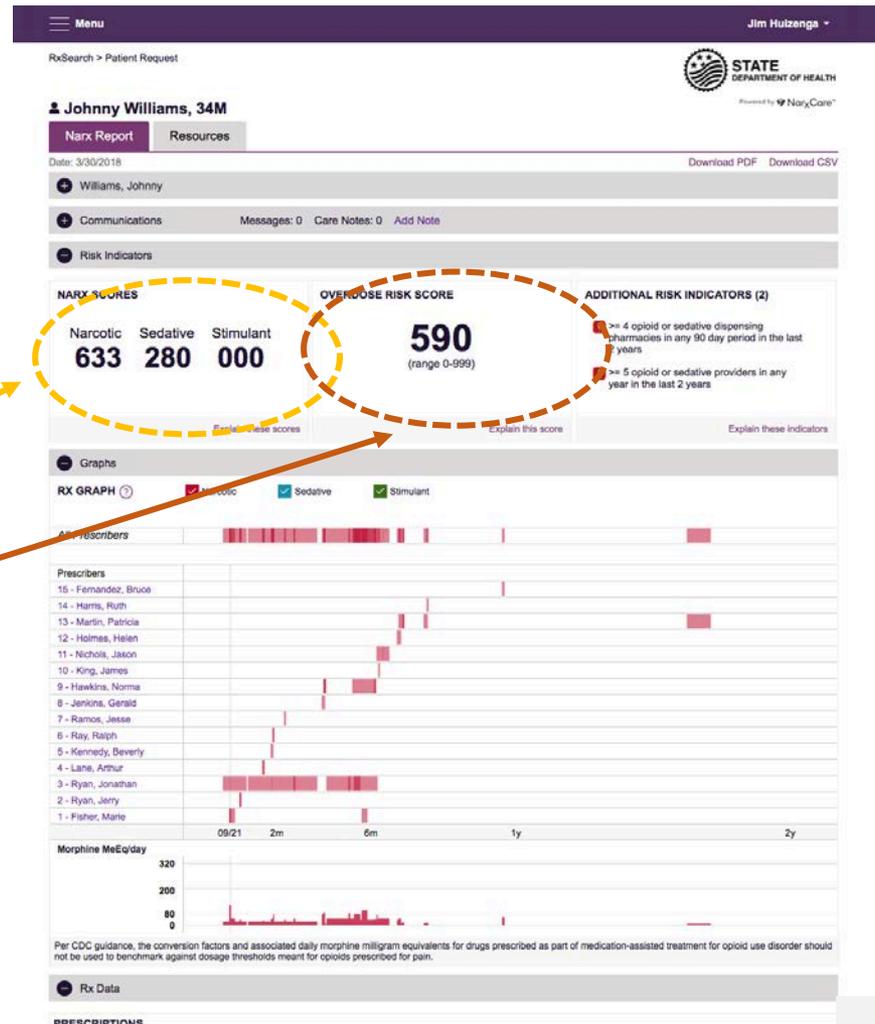
- Appriss Health Review
- NarxCare Overview
- Data Science and the PDMP
 - Narx Scores
 - Overdose Risk Score
 - How are doctors using the scores
- New tools to manage the opioid epidemic
 - Messages and Care Notes
 - Criminal justice records (social determinant of risk)
 - Provider Risk Scores
- Discussion



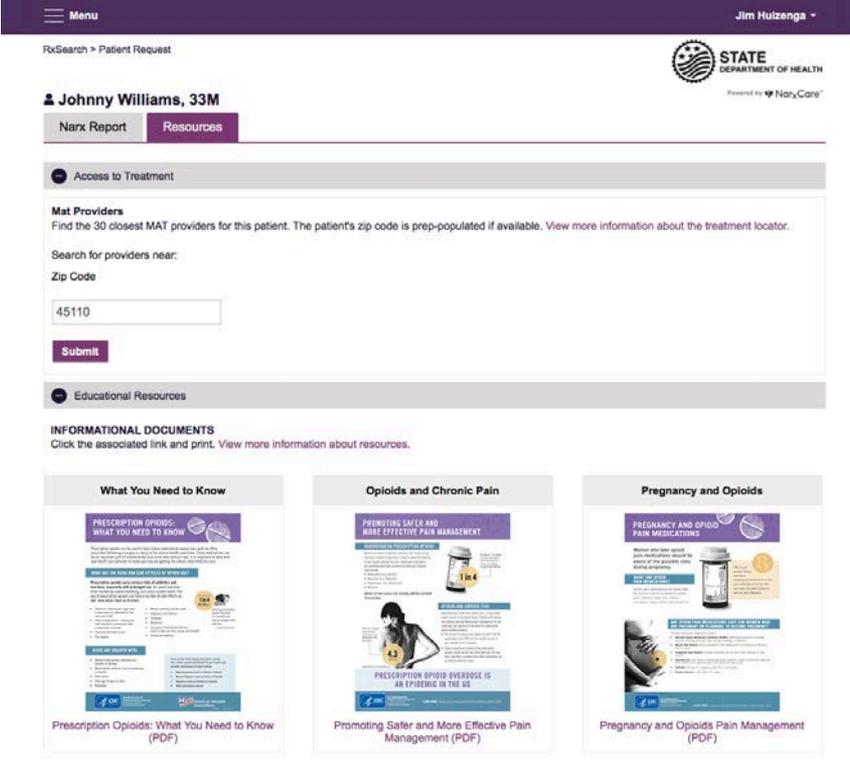
NarxCare

- More than 2,400 facilities have been integrated throughout 33 states
- Approximately 65% of Gateway integrations include NarxCare
- 25 million PMP reports are integrated within workflow every month
- OH, PA, AZ, KS, IN and MA have funded PMP Gateway integrations for all PMP users in the state
- MI and VA have funded NarxCare integrations for all PMP users in the state
- 3 additional states are in the contracting phase to fund statewide integrations

- NarxCare is a substance use disorder prevention and management platform
- Use scores and alerts to distill PMDP data into more easily assessed format
 - Similar concept other patient scores (e.g., cardiovascular risk scores)
- Two type of scores:
 1. **Narx Scores:** Percentile-based scores indicating utilization of the PMDP for three different types of controlled substances
 2. **Overdose Risk Score:** Score based on a predictive model of overdose death, creating using machine learning techniques
- Provides a care coordination platform that allows for peer to peer messaging, care notes, referrals – supporting the care of our highest at risk individuals



- Resources tab used to introduce “What now”? Functionality such as MAT locator and CDC resources.
 - More advanced technology for obtaining referrals and appointments are in development.
- We believe there are valuable 3rd party resources that could be integrated, and we are in exploratory discussions with several companies.
 - Video DOT
 - Level of care assessments
 - Patient facing applications



Menu Jim Huizenga

RxSearch > Patient Request

STATE DEPARTMENT OF HEALTH
Powered by NarxCare

Johnny Williams, 33M

Narx Report Resources

Access to Treatment

Mat Providers
Find the 30 closest MAT providers for this patient. The patient's zip code is prep-populated if available. View more information about the treatment locator.

Search for providers near:
Zip Code
45110
Submit

Educational Resources

INFORMATIONAL DOCUMENTS
Click the associated link and print. View more information about resources.

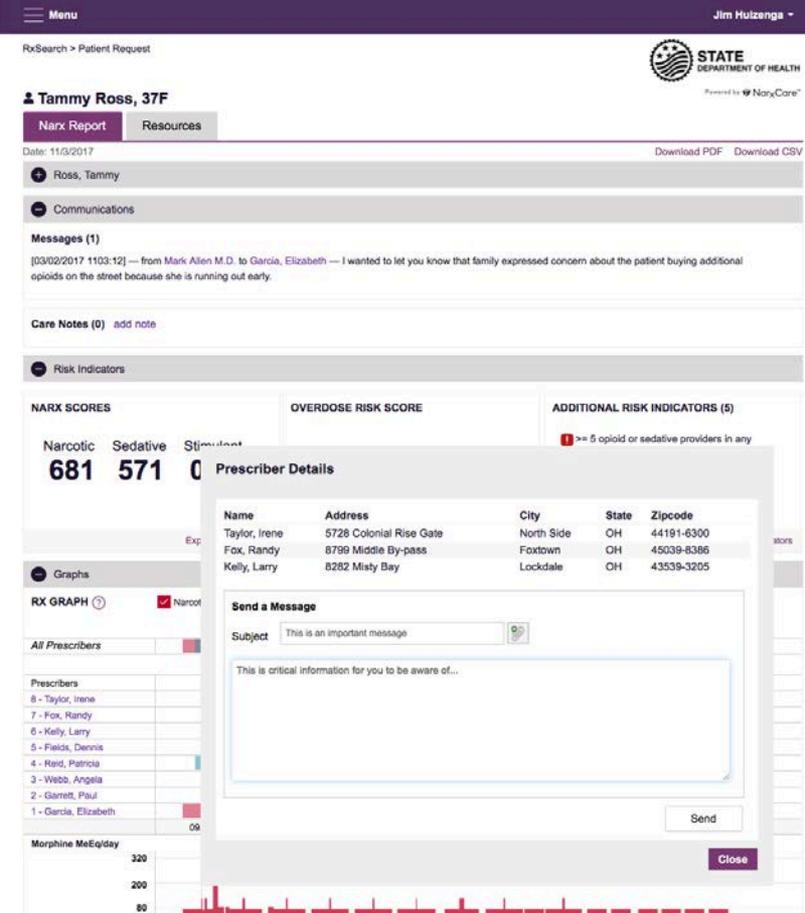
What You Need to Know
PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW
Prescription opioids are powerful pain relievers that can help you manage your pain. However, they can also be addictive and can lead to overdose and death. It's important to use them safely and responsibly. This document provides information on how to use prescription opioids safely and responsibly.

Opioids and Chronic Pain
PROMOTING SAFER AND MORE EFFECTIVE PAIN MANAGEMENT
Chronic pain is a common condition that affects millions of people. Opioids are often prescribed to manage chronic pain, but they can be addictive and can lead to overdose and death. This document provides information on how to manage chronic pain safely and effectively.

Pregnancy and Opioids
PREGNANCY AND OPIOID PAIN MANAGEMENT
Pain management during pregnancy is a complex issue. Opioids are often prescribed to manage pain during pregnancy, but they can be addictive and can lead to overdose and death. This document provides information on how to manage pain during pregnancy safely and effectively.

Prescription Opioids: What You Need to Know (PDF)
Promoting Safer and More Effective Pain Management (PDF)
Pregnancy and Opioids Pain Management (PDF)

- Messages and Care Notes being launched in approving states in 2018
- One Click access to an email style interface to allow for provider to provider (pharmacist to provider) messaging.
- Care Notes can be uploaded and contain important information relevant for any treating provider or pharmacist.
 - Supports document upload and display such as care plans, treatment agreements, etc.



Menu Jim Hulzenga

RxSearch > Patient Request

STATE DEPARTMENT OF HEALTH
Powered by NarxCare

Tammy Ross, 37F

Narx Report Resources

Date: 11/6/2017 Download PDF Download CSV

Ross, Tammy

Communications

Messages (1)

[03/02/2017 1103:12] — from Mark Allen M.D. to Garcia, Elizabeth — I wanted to let you know that family expressed concern about the patient buying additional opioids on the street because she is running out early.

Care Notes (0) add note

Risk Indicators

NARX SCORES OVERDOSE RISK SCORE ADDITIONAL RISK INDICATORS (5)

Narcotic Sedative Stimulant

681 571 0

Prescriber Details

Name	Address	City	State	Zipcode
Taylor, Irene	5728 Colonial Rise Gate	North Side	OH	44191-6300
Fox, Randy	8799 Middle By-pass	Foxtown	OH	45039-8386
Kelly, Larry	8282 Misty Bay	Lockdale	OH	43538-3205

Send a Message

Subject This is an important message

This is critical information for you to be aware of...

Send Close

Graphs

RX GRAPH Narx

All Prescribers

Prescribers

8 - Taylor, Irene

7 - Fox, Randy

6 - Kelly, Larry

5 - Fields, Dennis

4 - Reid, Patricia

3 - Webb, Angela

2 - Garnett, Paul

1 - Garcia, Elizabeth

Morphine Meq/day

320

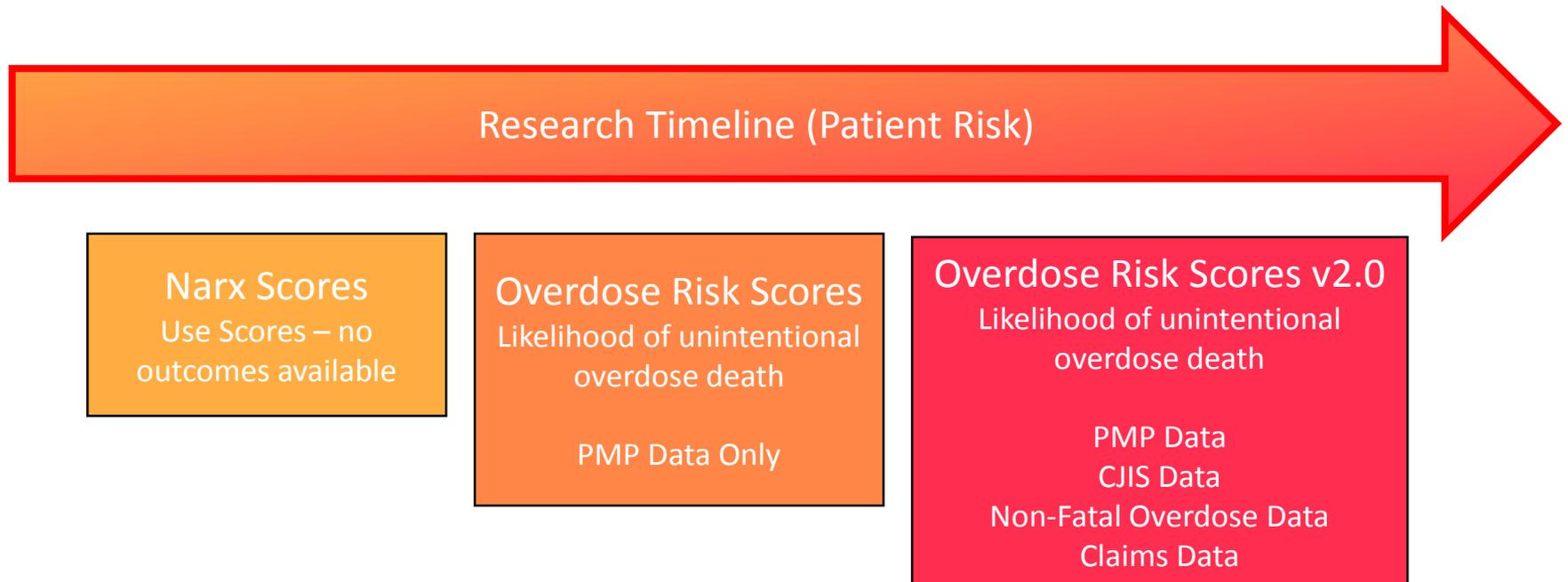
200

80

0

- NarxCare includes state of the art tools and additional access to our Data Science Team
- Team Makeup
 - 25 staff on team
 - 9 PhD, 10 MS
- Disciplines
 - Epidemiology, Biostatistics, Applied Math, Applied Statistics, Computer Science, Criminology, Business, Information Systems, Political Psychology, Economics, Computer Information Systems, Mechanical Engineering
- Universities
 - Princeton, Emory, UCLA, UC Berkeley, UCI, Pepperdine, University of Illinois, Cal Poly, No. AZ Univ., James Madison, Univ. of Iowa, USC, Cal Poly, University of Bristol, Union University, Utica

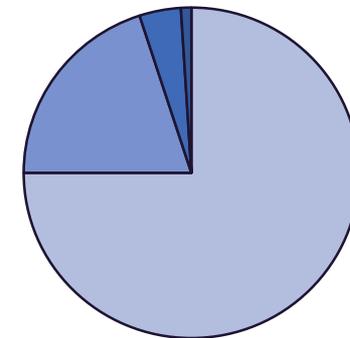
Data Science Applied to Patient Risk Evaluation



- Developing increasingly accurate risk scores as more data becomes available

- Calculated for narcotics, sedatives, and stimulants separately
- Percentile ranking of several frequency of use metrics for a single patient compared to the larger PDMP population, combined to give an even distribution of scores
- Ranges from 000-999
- As the scores increase, so does the presence of:
 - Multiple providers
 - Multiple pharmacies
 - Higher MME
 - Overlaps

Distribution of Narx Scores



■ < 200 ■ 200-499 ■ 500-650 ■ >650

Lois White		List	Recent	Search
Acct Number: 1836593821	DOB: 2/16/1959	Immunizations: None	Narx: Nar 661, Sed 632, Stim 000	
MRN: #324561	Gender: M	Allergies: aspirin, latex, peanuts	Fall Risk Score: 6	
Bed: 10	Code: Full Code	Adv Directive: Yes	Attending: Dr. Goodall	

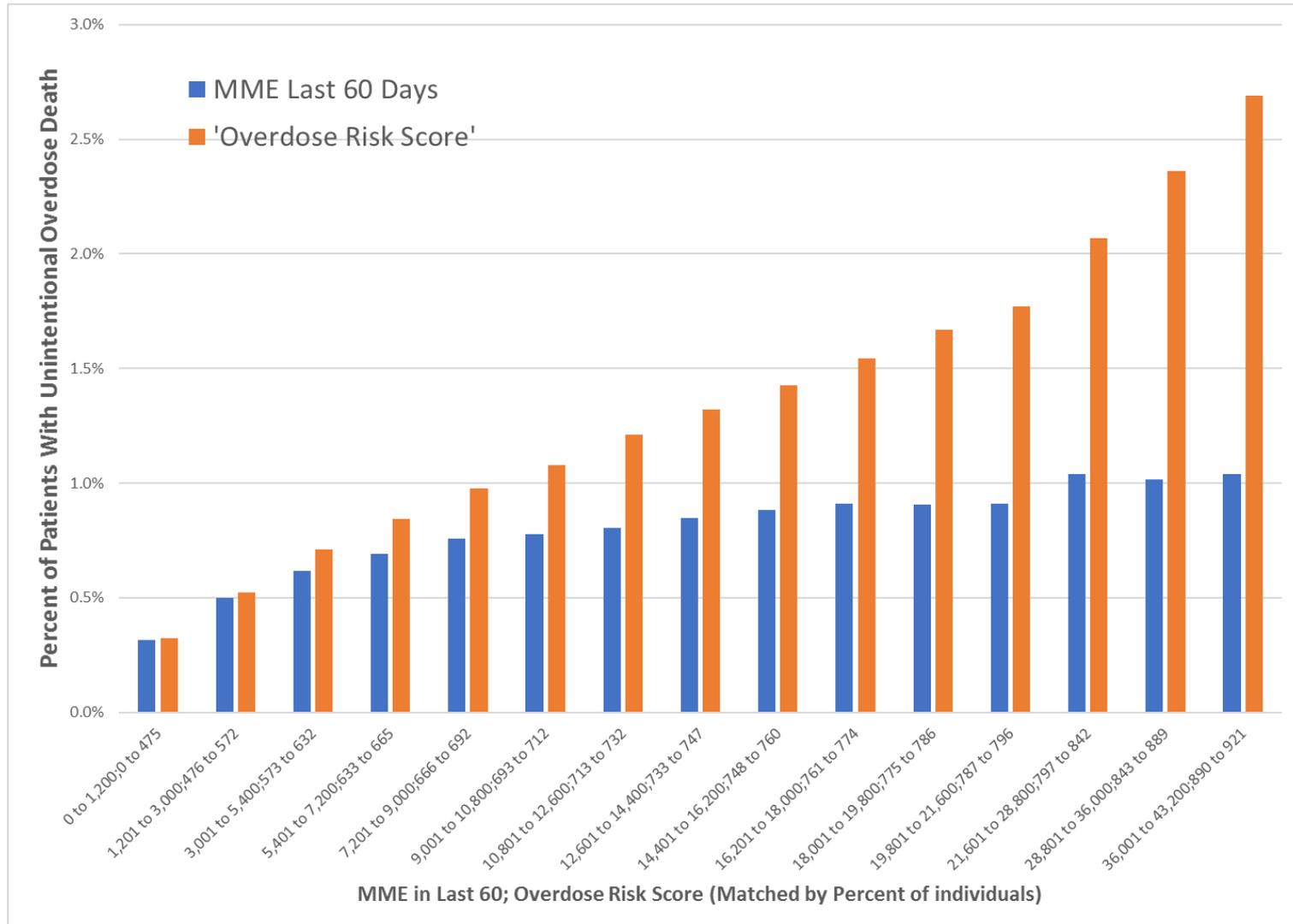
Narx Scores In Workflow

- Validated Narx Scores on a 1:100 case control sample in Ohio.
- Each unintentional overdose death case was matched to 100 non-deaths at date of death
- Highest Narx Score was computed in the 1-year prior to death date (or sample date for the controls)
- Clear monotonic association seen between higher Narx Score and odds of death
- $P < 0.0001$ compared to baseline group (Narx Score < 100)

Narcotic Score	Living	Deceased	OR	95% Lower CI	95% Upper CI	P-Value
000 - 099	71,701	80	1.0			
100 - 199	27,153	238	7.9	6.1	10.1	$P < 0.0001$
200 - 299	19,546	220	10.1	7.8	13.0	$P < 0.0001$
300 - 399	21,002	234	10.0	7.7	12.9	$P < 0.0001$
400 - 499	16,303	297	16.3	12.7	20.9	$P < 0.0001$
500 - 599	8,629	305	31.7	24.7	40.6	$P < 0.0001$
600 - 699	3,005	188	56.1	43.1	73.0	$P < 0.0001$
700 - 799	1,062	90	76.0	55.9	103.3	$P < 0.0001$
800 - 899	283	32	101.3	66.2	155.2	$P < 0.0001$
900 - 999	16	3	168.1	48.0	588.0	$P < 0.0001$
Total	168,700	1,687				

- Predicts a patient's risk of opioid-related overdose death on a 0 to 999 scale
- 10 variables were selected for the final model that capture aspects of:
 - High MME
 - Rate of narcotic use over time
 - Rate of sedative use over time
 - Number of pharmacies visited
 - Number of providers visited
 - Rate of unique providers visited over time

Appriss Health's Overdose Risk Score: Predictive Power Compared to MME in the Past 60 Days



- Validated in 3 states (OH, AZ, MI) with approximately 20,000 cases of unintentional overdose death

OD Risk	Original Validation Odds Ratio OARRS
0-199	Ref.
200-299	10
300-399	12
400-499	25
500-599	44
600-699	85
700-799	141
800-999	194
900-999	329

OD Risk	Odds Ratio Arizona PDMP 2011-2016 Decedents
0-199	Ref.
200-299	2
300-399	4
400-499	5
500-599	10
600-699	19
700-799	46
800-999	94
900-999	155

OD Risk	Odds Ratio Michigan PDMP 2013-2015 Decedents
0-199	Ref.
200-299	2
300-399	3
400-499	5
500-599	11
600-699	30
700-799	64
800-999	56
900-999	351

How Doctors Are Using the Scores

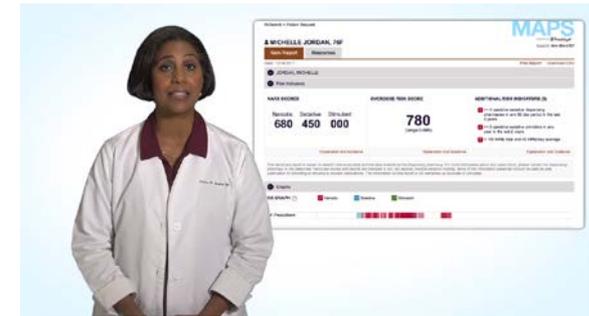
Instructions on How Prescribers Should Use the Scores



Type-Specific Use Scores

Prescribers
Morphine Milligram Equivalency
Pharmacies
Overlapping Prescriptions

NarxCare MAPS



Narx Score

75% score less than 200
5% score more than 500
1% score more than 650

NarxCare MAPS

	60 days	6 mos	1 year	2 years	Avg	Wt		
Prescribers	85	76	84	64	77	1	77	
Pharmacies	78	56	62	49	61	1	61	
Morphine milligram eq	74	87	88	87	84	3	252	
Lorazepam milligram eq	0	0	0	0	0	1	0	
Overlaps	41	70	64	52	57	2	114	
Weighted Average (sum/8)								63
Number of Active Narcotic Prescriptions								2
Narcotic Score								632

NarxCare MAPS

Score/Range 010 - 200

Notes Approximately 75% of scores fall in this range. Occasionally, patients in this score range have a remote history of high usage (> 1 year ago).

Recommendations Review use patterns for unsafe conditions. Discuss any concerns with patient. If previously high usage exists with recent abstinence consider risk/benefits of new prescription.

NarxCare MAPS



17-year-old Male
Basketball Player
Severe ankle sprain

NarxCare MAPS

Score/Range > 650

Notes Approximately 1% of scores fall in this range. Some patients records may still be within prescriber expectations, with some level of multiple provider episodes, overlapping prescriptions, or elevated milligram equivalency.

Recommendations Review use patterns for unsafe conditions. Discuss any concerns with patient. Consider contacting other providers directly, pharmacy lock-in program, taper and/or discontinuation of medication, or inpatient admit or outpatient evaluation and treatment.

NarxCare MAPS



81-year-old Female
Decreased level of consciousness
Closed head injury

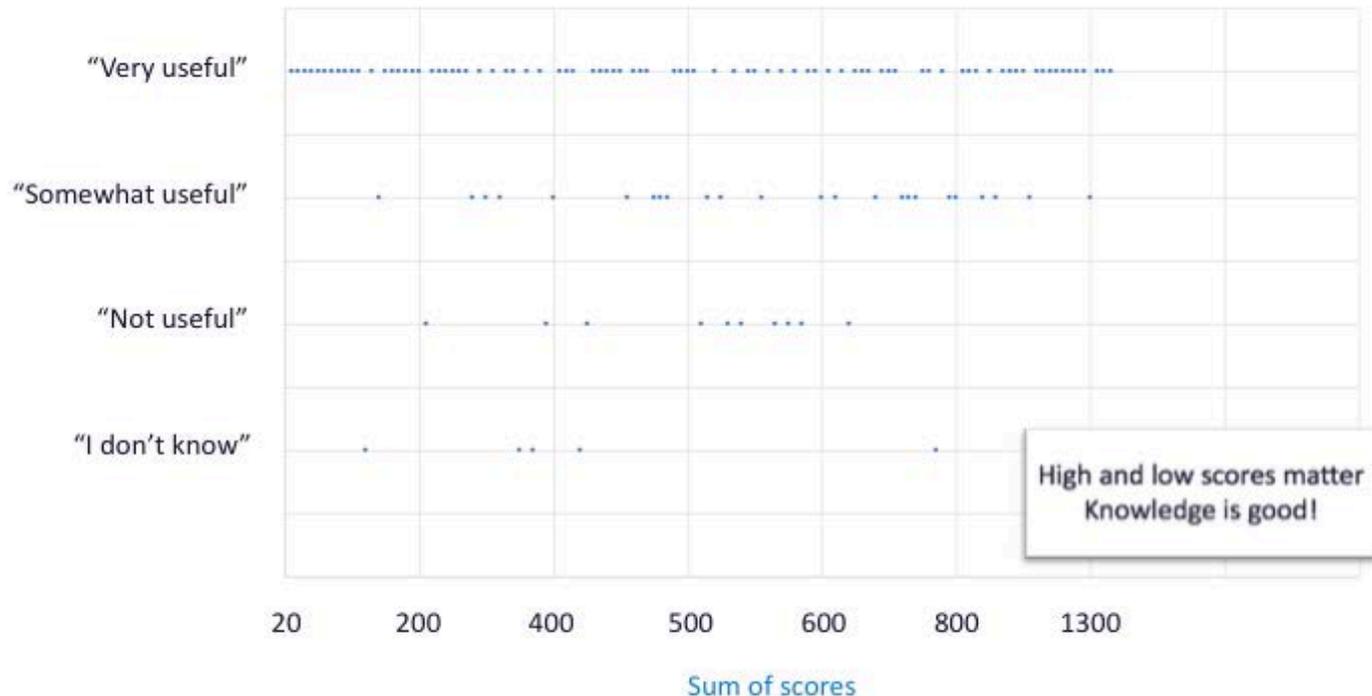
NarxCare MAPS

Provider Survey 1:

- *In line survey during actual patient encounter*
 - *16,030 questions asked, 2197 responses (13.7%)*
 - *Single question per report*

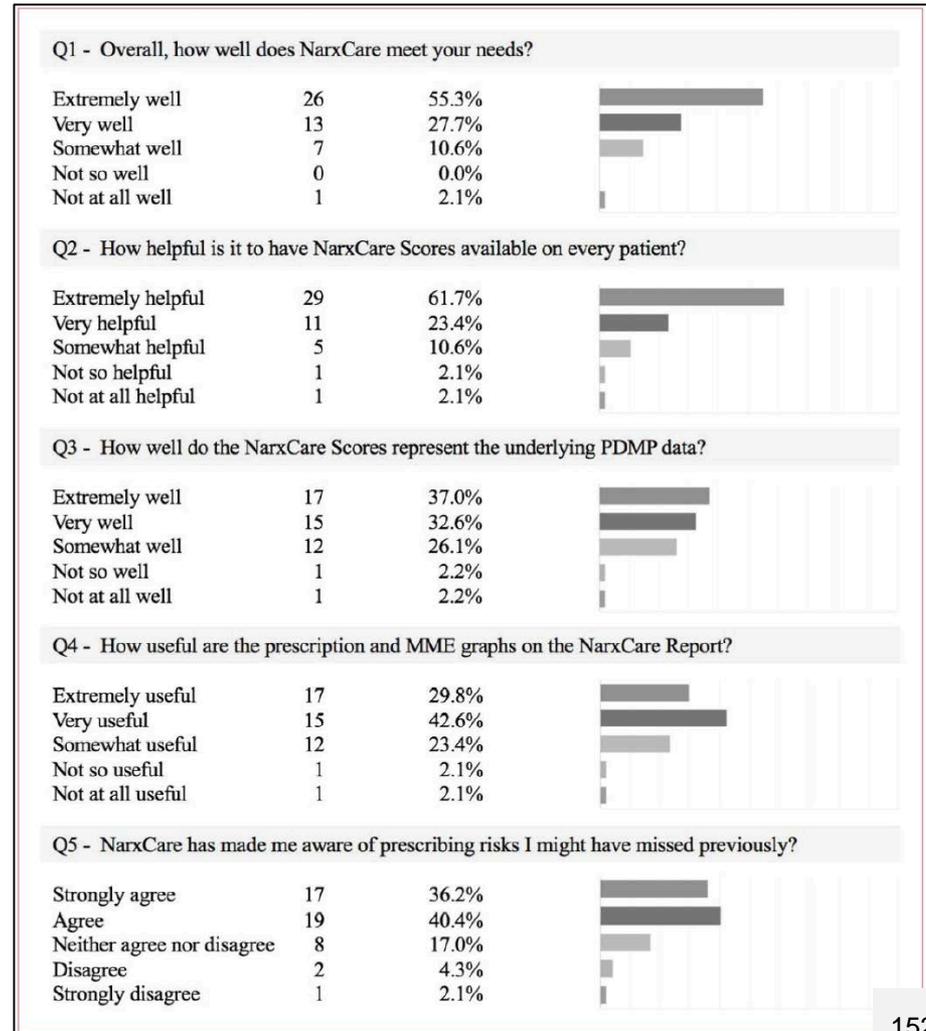
Results:

- *Time savings associated with scores and graphs approximately 60 seconds per report*
- *Usefulness and appropriateness of scores rated highly*



Provider Survey 2:

- *Off line survey with 10 questions*
 - *Response rate 21% (47/223)*
- *Net promotor score 50*
- *Time savings assessment 75 seconds*
- *Satisfaction received high marks (>90% in all categories)*



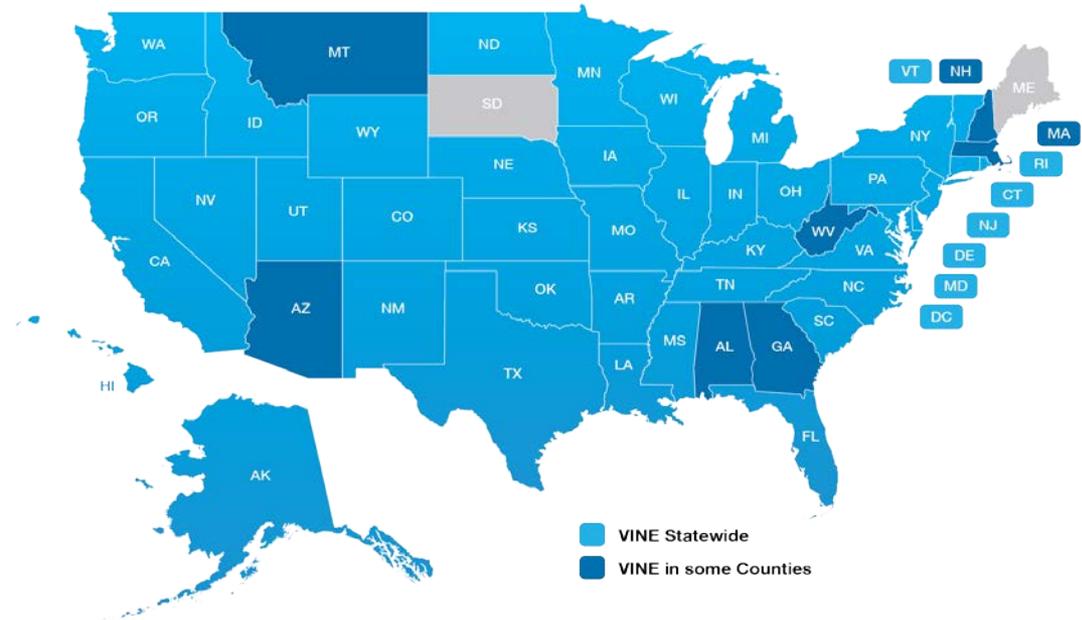
New Tools Being Incorporated

- **Unified Patient Identification**
 - Appriss ID—Appriss proprietary identity system
- **Expansion of the Overdose Risk Score**
 - Boosting analysis by incorporating criminal justice data
 - Claims data
- **New Scores**
 - Misuse
 - Substance Use Disorder
- **State Administrator Support**
 - Identification of high risk prescribers (Prescriber Risk Score)
 - Statewide Opioid Assessments
- **Pharmacy Monitoring Platform**
 - Appriss monitors pharmacy inventory and provides an analytics platform for retailers such as Walmart to identify fraudulent events which involve personnel in the supply and distribution chain
- **Retail Fraud**
 - Approached one retailer to examine association of non-receipted returns with opioid use
- **Publications**

Appriss collects more than 9 million incarceration records annually from over 2,300 facilities

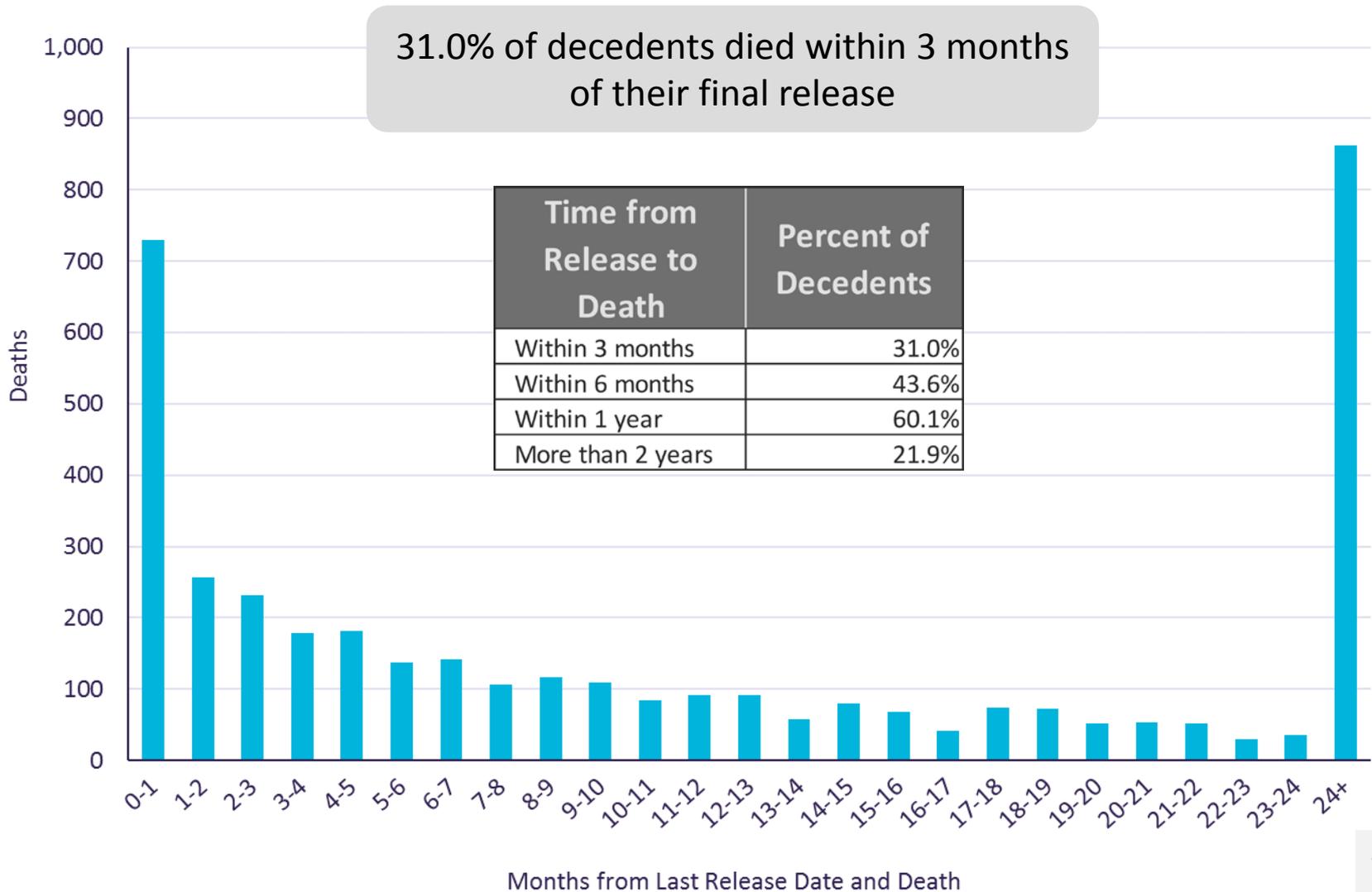
- Partnership with Ohio to assess the added value of criminal justice data being incorporated into the overdose risk score
- **56%** of patients who died of a drug-related overdose were ever incarcerated at an Ohio jail
- **7.5 times higher** death rate among patients with bookings, compared to the death rate among all patients
- Death rate is **14.5 times higher** among patients charged with a drug-related offense than among all patients

- Appriss is in the process of rolling out AL
- Appriss is in discussions with AZ, GA, MA, ME and MT for statewide VINE



	Non-Decedents	Decedents	Total	Death Rate per 100
<i>All Ohio PDMP Patients</i>	7,990,898	6,716	7,997,614	0.08
All Patients Ever Incarcerated	622,019	3,780	625,799	0.60
Patients with a Drug-Related Charge	74,080	869	74,949	1.16
-With a Schedule I-V Drug-Related Charge	6,347	55	6,402	0.86
-With a Heroin-Related Charge	5,479	81	5,560	155

Time from Release to Death (n=3,933)



Boost in Predictive Power from Combining Criminal Justice and PDMP Data

- With minimal additional criminal justice data, the overdose risk score correctly identifies more decedents than it can using only PDMP history
- KS score improved by 34%
- 28.8% more decedents were identified by the top 10% of scores

Top 10th Percentile of Score	Number of Decedents	Number of Patients	Death Rate per 1,000
Original Overdose Risk Score	709	33,546	21
Including Criminal Justice Data	913	33,546	27
Improvement	+28.8%		+6

What does the model predict?

60 Day Death Rate for the Prescriber's Patients =

$$\frac{\textit{Number of patients who die within 60 days of a prescription}}{\textit{Total number of patients for the prescriber}}$$

What information does Appriss Health use to predict risk?

50+ variables are created which characterize the prescriber (example categories below):

- Prescriber characteristics (e.g. specialty)
- Prescribing behavior (e.g. average MME/LME)
- Prescriber's patient characteristics (e.g. average age)
- Prescriber's patient behavior (e.g. proportion of patients seeing 2+ prescribers)

What technology/methods does Appriss Health use?

Machine learning models combine information to predict death rates

Findings to date:

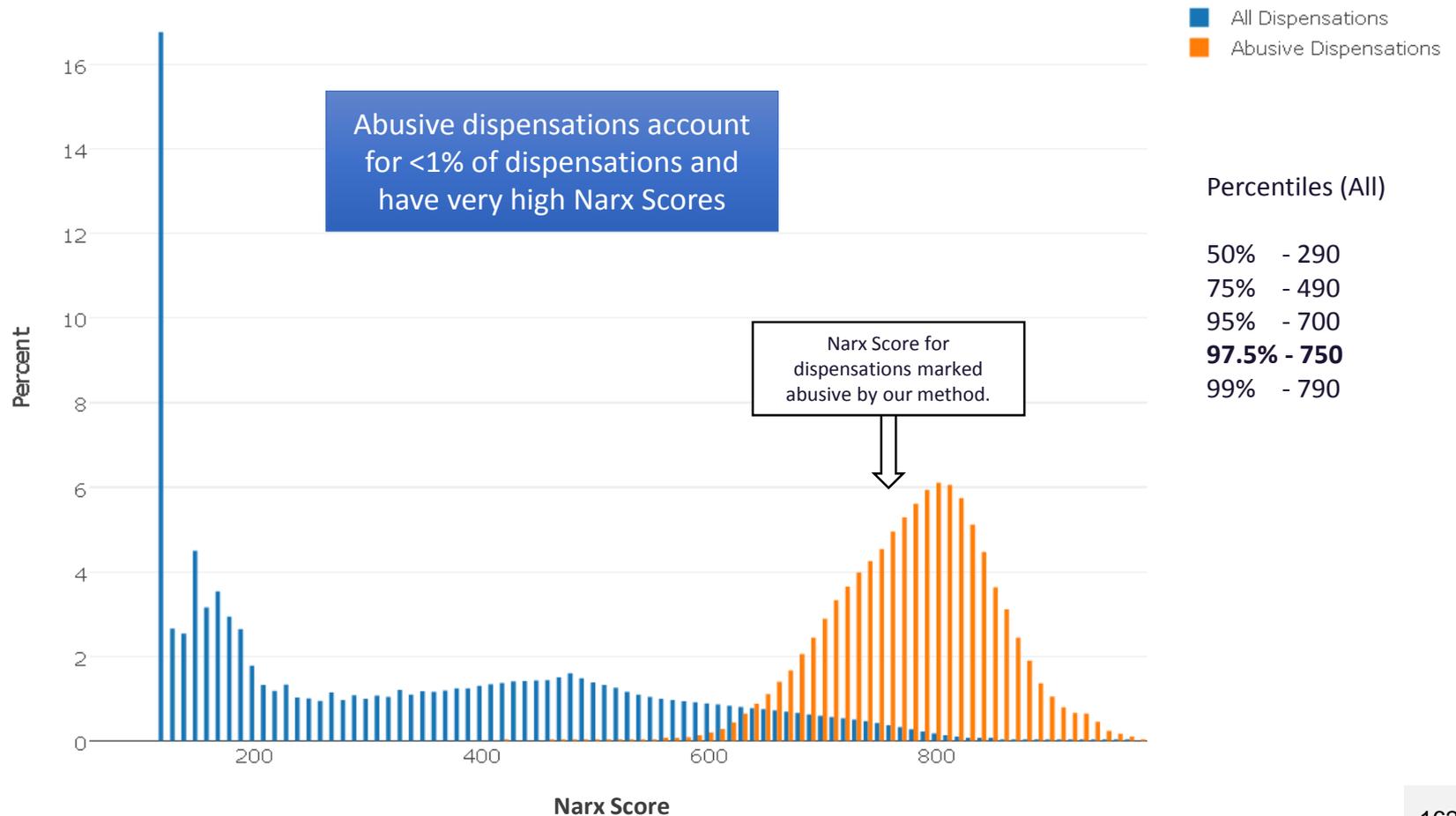
Top 10% of scoring providers associated with almost half of all deaths in a state.

- NarxCare is a substance use disorder platform with built in risk scores, integrated care coordination, and patient management functionality
- NarxCare tools have been built with a world class Data Science Team (DST)
- Providers greatly approve of our scores, visualization, and tools.
- We are constantly innovating with new scores, new data usage, and improved functionality

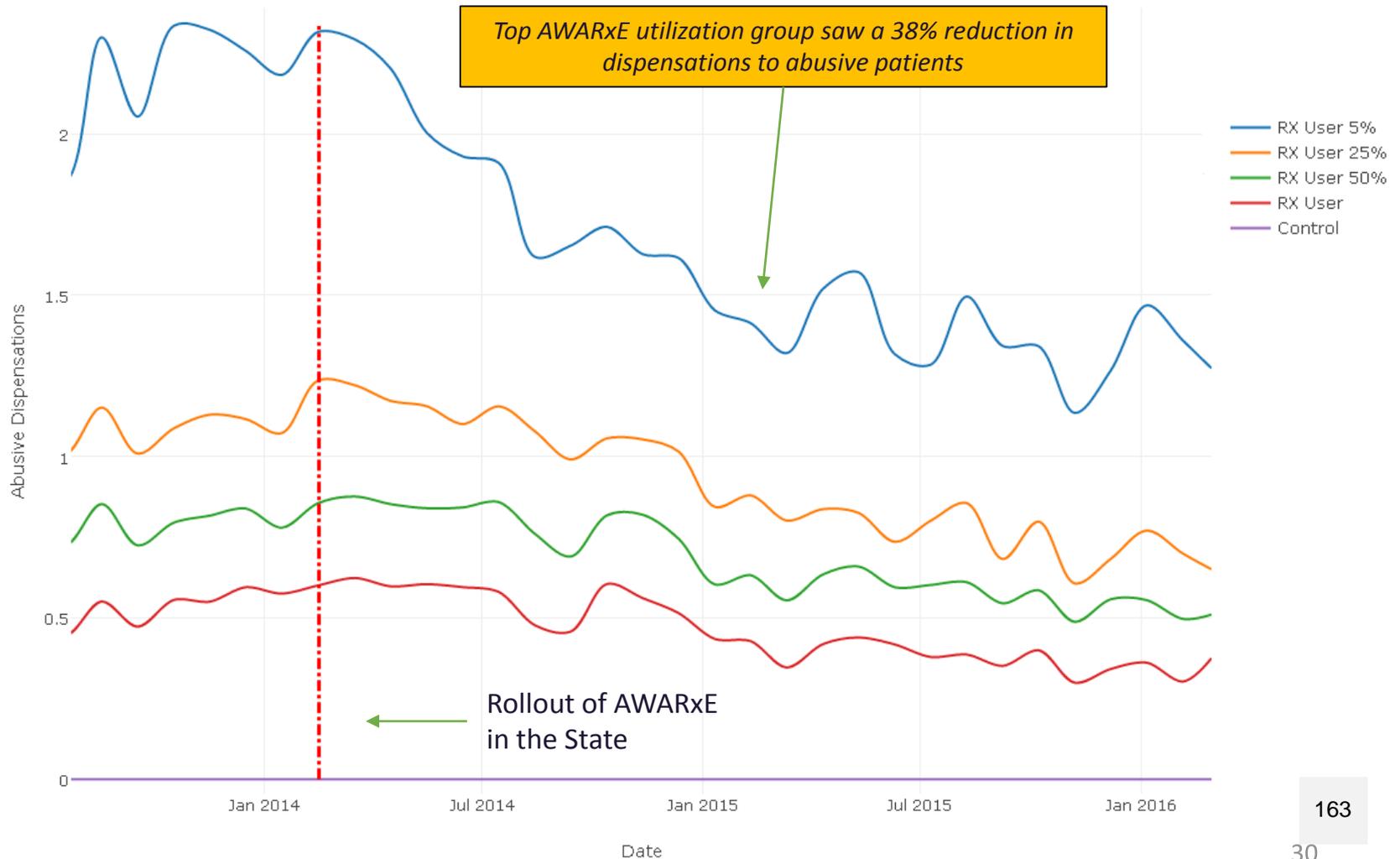
Appendix

- **Defining a Dispensation to an Abusive Patient**
 - Marked abusive if all key variables are in the top 10 percentile for a patient
 - Number of narcotic prescriptions in the last 365 days
 - Number of narcotic prescribers in the last 365 days
 - Number of narcotic pharmacies in the last 365 days
 - Total narcotic supply in days in the last 365 days
 - Total Morphine-Milligram-Equivalent in the last 365 days
 - In each state, using this method on average ~1% of narcotic dispensations were identified as to abusive patients. This equates to ~0.15% to 0.3% of patients.
- **How Well Does a Prescriber Use the Aware PMP Program**
 - To measure the impact of PMP the enrolled doctors were divided into 4 categories ranking from the highest to the lowest usage of the PMP,
 - RX User 5%: Top 5 percentile by RX search request count (best users of PMP)
 - RX User 25%: Top 25 percentile by RX search request count.
 - RX User 50%: Top 50 percentile by RX search request count.
 - RX User: All doctors enrolled in the PMP with at least one request.
 - Control Group: Doctors that have never made a request using the state's PMP.

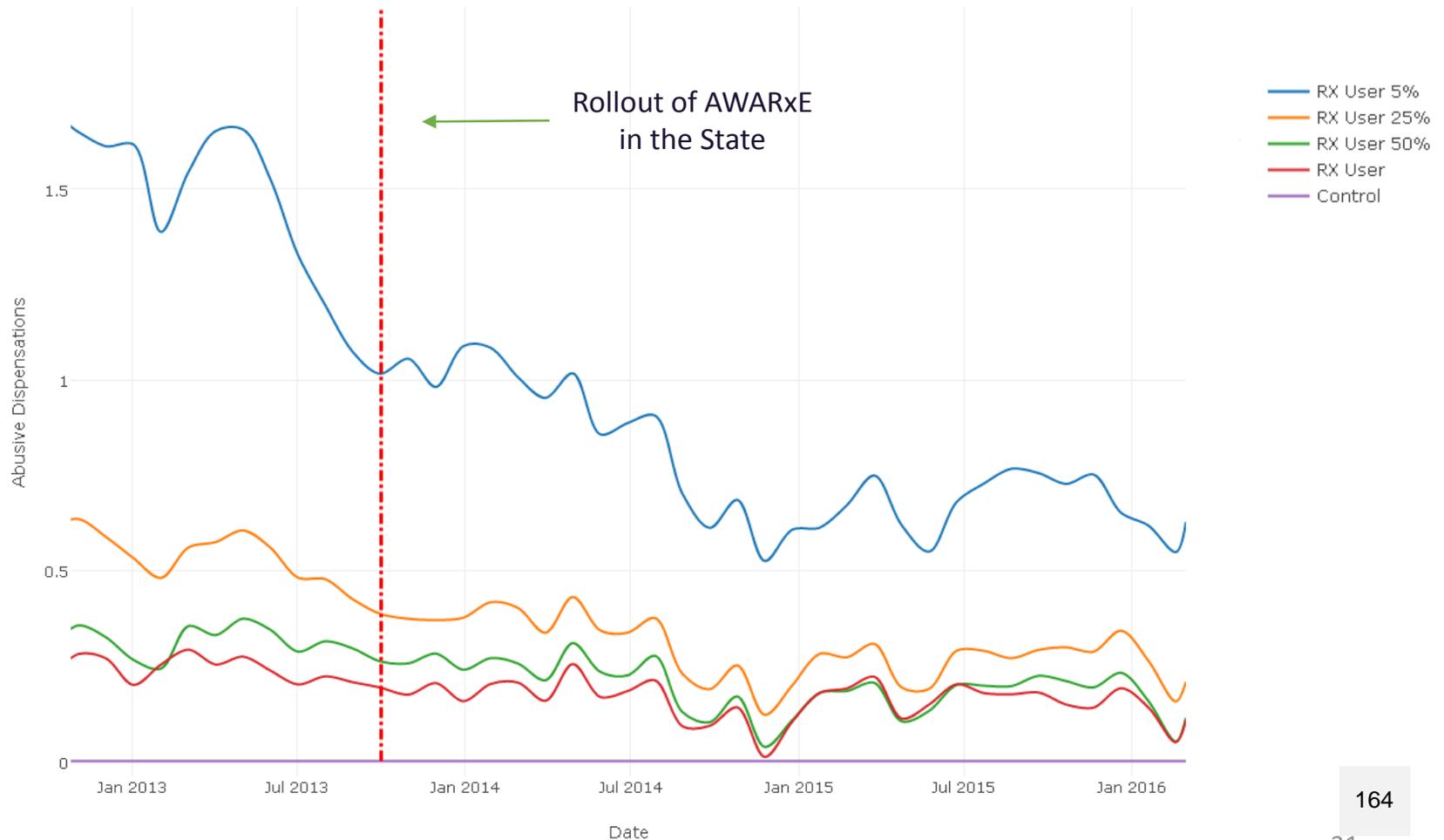
Narx Scores vs. Abusive Definition



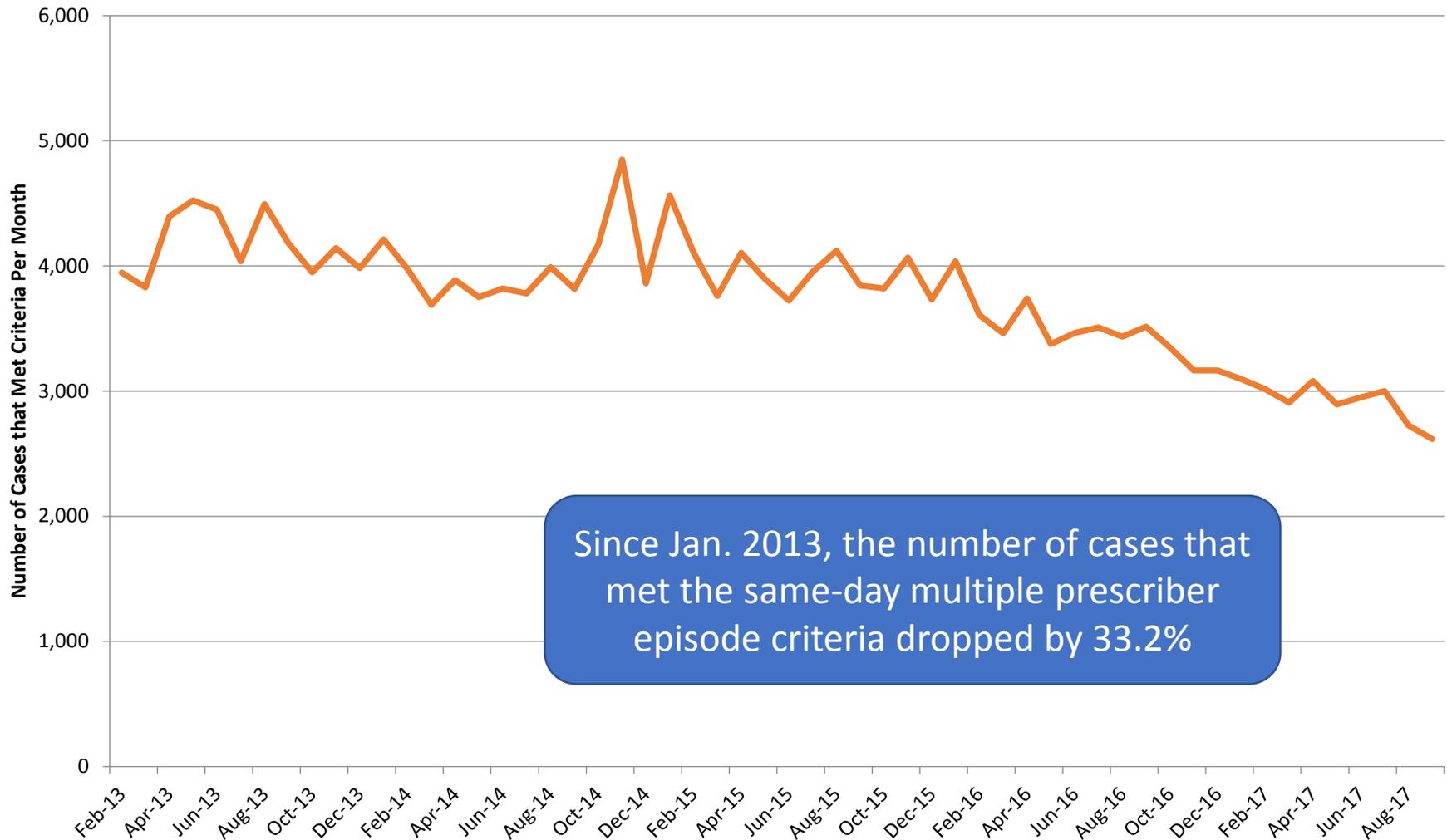
Percentage of Narcotic Dispensations to Abusive Patients by PMP Aware Usage Category (Idaho)



Percentage of Narcotic Dispensations to Abusive Patients by PMP Aware Usage Category (Mississippi)



Number of PDMP Patients Meeting Same-Day Multiple Prescriber Episode Criteria



State: Michigan PDMP Oct. 2012-Oct. 2017, All PDMP Prescriptions
Criteria: Same person, at least two prescriptions from two different provider DEA numbers filled on same day, AND at least two different pharmacies visited on same day

Analytics, tools and technology to help care teams address substance use disorder and improve patient outcomes

Appriss Health developed the NarxCare platform to provide a more comprehensive approach to addressing substance use disorder. NarxCare aids care teams in clinical decision-making, provides support to help prevent or manage substance use disorder, and empowers states with the comprehensive platform they need to take the next step in the battle against prescription drug addiction.

WWW.APPRISHEALTH.COM/NARXCARE

NarxCare is a comprehensive platform to identify, prevent and manage substance use disorder (SUD). It empowers prescribers and dispensers to identify patients that may be at risk for prescription drug addiction, overdose and death, and equips clinicians and care teams with the tools and technology they need to help those patients. Now, with NarxCare, clinical decisions can be supported with objective insights into potential drug misuse or abuse, and patients can be provided with the care they need.

NarxCare aggregates and analyzes prescription information from providers and pharmacies and presents interactive, visual representations of that information, as well as advanced analytic insights, complex risk scores and more to help physicians, pharmacists and care teams to provide better patient safety and better patient outcomes. The platform can also accommodate additional information sources to create more holistic risk models, assessments and alerts.

The identification of patients at risk is only the beginning of a comprehensive platform needed to impact the increasing prevalence of substance use disorder. NarxCare extends beyond information and insights to provide tools and resources to enable care teams to support patient needs. Increasing access to treatment through medication-assisted treatment (MAT) locators, improving patient education and engagement through CDC information sheets and mobile apps¹, and enabling the coordination of care across the continuum through powerful care team communications¹ are key NarxCare features that are widely recognized as critical to success. These resources can be used to help patients in need, at the right time, in a meaningful way, quickly and easily, at the point of care.

This information, insight and functionality is all accessed through existing electronic health records (EHR) or pharmacy management systems, so there is no logging in or out of secondary websites or trying to manage user names or passwords. NarxCare is also available right in the PDMP where enabled by the state. The platform is presented in three main modules: The Narx Report, Resources and Care Team Communications.

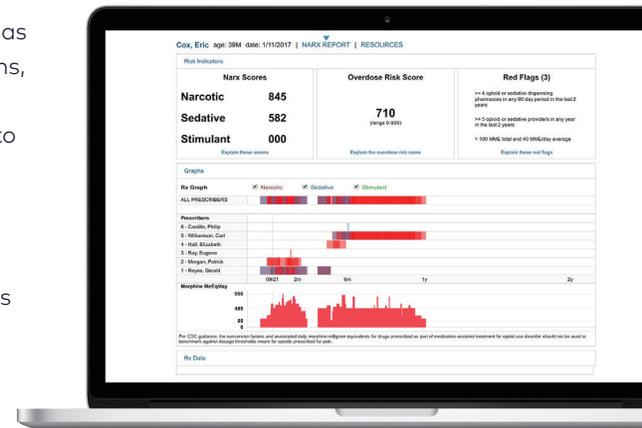
The Narx Report

The Narx Report includes a patient's NarxScores, Predictive Risk Scores, Red Flags, Rx Graph and PDMP Data, as well as access to Resources and Care Team Communications all in a single, easy-to-use interface. See Image 1.0.

¹ Currently in development.

The Benefit

Care teams make informed decisions quickly and confidently to help patients.



* Image 1.0: The Narx Report

The NarxScores

Every Narx Report includes type-specific use scores for narcotics, sedatives, and stimulants. These scores are based on a complex algorithm factoring in numbers of prescribers, morphine milligram equivalents (MME), pharmacies, and overlapping prescriptions. Scores are quantified representations of the data in the PDMP and range from 000-999 with higher scores equating to higher risk and misuse, and the last digit always represents the number of active prescriptions.

The Predictive Risk Scores

These composite risk scores incorporate relevant data (PDMP and non-PDMP) into advanced and

customized predictive models to calculate a patient's risk of a host of outcomes, including overdose and addiction. Non-PDMP data sets may include medical claims data, electronic health records, EMS data and criminal justice data. The Overdose Risk Score is featured in Image 1.0.

The Red Flags

There are multiple, fully configurable and customizable PDMP- and non-PDMP-based red flags. When present, a red flag, or a combination of red flags, may contribute to the risk of unintentional overdose or other adverse events.

The Rx Graph

The Rx Graph is simple, clear, and comparative. The interactive display

allows you to view all the information you need, analyze data, and click into specific data points to see more detail. You can easily visualize and understand patterns in prescribing and usage behaviors, as well as identify overlapping prescriptions.

The PDMP Data

The PDMP Report is the definitive source for controlled substance data, a critical component to any SUD strategy, through its access to multi-state PDMP data. The PDMP Report aggregates two years of historical prescription data from providers and pharmacies, including quantities and active prescriptions.

The Resources

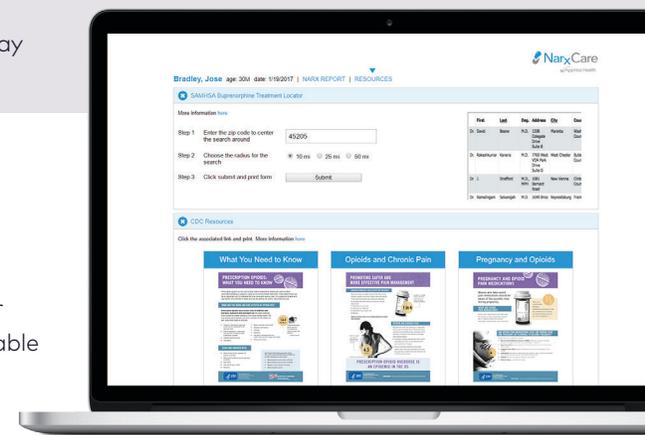
The NarxCare Resources module equips clinicians and care teams with the tools needed to increase access to treatment and improve patient education and engagement. The MAT locator automatically finds convenient locations for treatment and enables clinicians to help patients in need. The CDC Resources enable clinicians to educate and engage patients by providing context-sensitive information when patients need it most. And all content is fully configurable, enabling states, health systems and pharmacies to include custom treatment options or information sources. All features are accessible with a single click and automatically contextualized to an individual patient's demographics. See Image 2.0.

The Care Team Communications

Perhaps the most powerful tool in the prevention and treatment of substance use disorder is collaboration and coordination of care. NarxCare takes advantage of the pervasiveness of the PDMP and its prominent role in controlled substance use to enable messaging, including the transmission of documents, among clinicians and care team members across the continuum of care.

Messaging enables coordination of care among physicians, pharmacists, care managers, behavioral health providers and other professionals caring for patients. These professionals can share care plans and pain contracts, highlight gaps in care, refer patients for support or treatment and improve integration of behavioral health and primary care.

Additionally, NarxCare enables care notes and clinical alerts, allowing providers or the PDMP to add critical patient information to the platform such as history of overdose, specific medication restrictions, caregiver support or other relevant clinical or social information. The platform can also display automatically-generated clinical alerts triggered by customizable algorithms based on PDMP and non-PDMP data. Once added, this information can be viewed by treating providers, pharmacists and care teams in line with the PDMP data to enable the best possible care.



* Image 2.0: Resources

The Value

Appriss Health knows that the delivery of NarxCare, a comprehensive substance use disorder platform, is the best way to ensure that prescribers, dispensers, and states support the health of their patient populations.

Change Order	
Description:	AK Licensing Reverification
Appriss Service (the "Service"):	PMP AWARe: The Service shall be considered completed upon delivery in production
Date Created:	8/5/19
Billing Agent:	Alaska Department of Commerce, Community, and Economic Development – Board of Pharmacy
Billing Address:	PO Box 110806 Juneau, AK 99811
Billing Contact:	Laura Carrillo laura.carrillo@alaska.gov 907-465-1073
Customer Relationship Manager:	Nicole Dubree ndubree@apprisshealth.com

High Level Description of Project
Automatic license reverification to provide automatic reverification to the Alaska PDMP.
Background/Business Justification
Alaska Board of Pharmacy would like the ability to auto-verify existing AK PDMP users via automatic license verification.

In Scope
Alaska will have the ability to send user account registration data via sFTP for the purpose of verifying a user account record in PMP AWARe. The expectation is that the State will upload a license file to the sFTP daily; an automatic nightly process will validate each user.
The account update service shall apply to the following roles: <ul style="list-style-type: none"> • Dentist • Nurse Practitioners/Clinical Nurse Specialist • Pharmacist • Pharmacist in Charge • Physician Assistant • Physician (MD, DO)

- Podiatrist (DPM)
- Medical Resident with Prescriptive Authority
- Veterinarian
- Optometrist
- Pharmacist's Delegate – Licensed
- Prescriber Delegate – Licensed

For the above roles, the following fields must be required for auto-verification:

1. **Professional License Number** (may require light data cleaning in order to remove errant spacing, punctuation, and case)
2. **Date of Birth**
3. **Last Name**

If an existing user account meets the required field-level validations for their role, their account shall remain in approved status. Any user that is invalid according to the rules defined above will be deactivated.

Deactivated users will receive the following email:

To: UserEmail@host.com
From: no-reply@PMPAWARE.net
Subject: Your Alaska PDMP Account Has Been Deactivated

Your Alaska PDMP account has been deactivated due to the status of your professional license not being active, or because there is a discrepancy with the name, date of birth, or license number identifier(s) in the personal information details of your Alaska PDMP account. To correct your personal information details, please contact the appropriate licensing board by referencing the contact information below.

- **Dental**

Phone: (907) 465-2542

E-mail: boardofdentalexaminers@alaska.gov

- **Medical, Including Physician Assistants**

Phone: (907) 269-8163

E-mail: medicalboard@alaska.gov

- **Nursing**

Phone: (907) 269-8161

E-mail: boardofnursing@alaska.gov

- **Optometry**

Phone: (907) 465-2541

E-mail: boardofoptometry@alaska.gov

- **Pharmacy**

Phone: (907) 465-1039

E-mail: akpdmp@alaska.gov

- **Veterinary**

Phone: (907) 465-1037

E-mail: boardofveterinaryexaminers@alaska.gov

If your PDMP account has been correctly deactivated due to the status of your license, please disregard this notice. In the event you renew your professional license, please submit the form titled, "PDMP Account Status Change Form", found at pdmp.alaska.gov, along with the \$25.00 payment, if applicable, so that your PDMP account can be manually activated.

Thank You,
Alaska Prescription Monitoring Program

Out of Scope

- Addition of eligible reverification user roles outside of those listed in change order.
- Addition of required fields for reverification outside of Professional License Number, Date of Birth, and Last Name.
- Changes to account deactivation email following change order signoff.

Assumptions

Scope of services does not include auto-account creation.

Fees and Conditions	
<p>This Change Order form must be signed, and returned by the expiration date to move forward with this request. Once a signed Change Order is received, the task will be planned for estimated completion month listed below. All Fees are payable to Appriss Inc. as set forth in the Agreement without set-off, deduction, or other withholding. The fees are non-cancelable and non-refundable. Unless otherwise modified herein, the terms of the Agreement remain in place and unmodified.</p>	
Estimated Completion Month	
Fee(s)	\$30,000
Form Expiration Date	9/30/19

Appriss Inc.

**Alaska Department of Commerce, Community,
and Economic Development – Board of
Pharmacy**

 Robert Cohen, President Appriss Health

 Authorized Signatory

MANDATORY USE COMPLIANCE MODULE

The Mandatory Use Compliance Module within the PDMP system is designed to help PDMP users better understand and manage the opioid crisis through a scalable configuration tool by tracking a provider's interaction with and access of the PDMP. This tool is provided within the PDMP application which allows for a continuous workflow.

The outcomes available within the tool include but may not be limited to:

- Reports for the State PDMP Administrators of the providers' review history
- Reports for Licensing Boards (or other roles as defined by the State) of their Licensees' (and/or managed users/roles) review history
- Reports for providers of their missed reviews

REPORT LOGIC

Mandatory Use Patient Request Match to Prescriber History –

The system will query for each prescriber, determine which patients were prescribed the selected drug(s) for the configurable duration and/or supply and were not queried in the PMP (or through PMP Gateway) by the prescriber or the prescriber's delegate within the time period configured.

Mandatory Use Patient Request Match to Pharmacist History –

The system will query for each pharmacist, determine which patients were dispensed the selected drug(s) for the configurable duration and/or supply and were not queried in the PMP (or through PMP Gateway) by the pharmacist or the pharmacist's delegate within the time period configured.

REPORT DETAIL

Mandatory Use Report – A role(s) can be configured to request a report on which patients were not requested in the PMP (or PMP Gateway) where a prescription was written by a specific prescriber or filled by a specific pharmacist by Provider DEA Number or other unique identifier (possibly NPI or License Number) and Fill Date range or Written Date range.

Mandatory Use Summary Report – A role or user can be configured to receive via email or SFTP an automated report which reports all healthcare providers or a configured subset of healthcare providers by role and their count of missed patients on a monthly basis.

MyRx Mandatory Use Report - A healthcare role(s) can be configured to request a report showing which patients the provider missed.

National Center for Injury Prevention and Control Data Driven Prevention Initiative

Overview

Awardees Name: Alaska Department of Health and Social Services

Grantee #: 5 U17 CE924872-02

Budget Year: 2018

FOA #: CE16-1606

Title: Data Driven Prevention Initiative (DDPI)

Approved Amount: \$1,350,000.00

Reviewed by: Yessenia Ibarra, Minda Reed, Amber Robinson

Base or Enhanced: ENHANCED

Strategy: Prevention in Action

Major Activity: Make PDMPs easier to use and access

Major Activity Summary: The PDMP state website located at www.pdmp.alaska.gov was assessed for its available resources and quality of instructions in November 2017. The PDMP Manager identified four options for making the PDMP platform easier to use and access:

- 1.) Update registration instructions for primary users and delegates - Instructions were revised and posted to the website on 11/14/2017 to include the step-by-step process of successfully registering with visual cues.
- 2.) Improve formatting of website for better readability - The layout of resources on the PDMP were rearranged and reconfigured to make instructions and pertinent resources easy to identify. Improvements included adding icons for PDFs and webpages and listing resources in a conceptual rather than fragmented order.
- 3.) Provide conspicuous contact information for PDMP assistance - The PDMP Manager and AWARxE support contact numbers are redundantly displayed to make contact information easily accessible when questions arise pertaining to PDMP use and access.
- 4.) The PDMP manager has been conducting outreach activities since January 2018. A survey was developed on 03/27/18 to gauge specific topics practitioners look to that will improve the ease of PDMP use and access.

Major Activity Challenges: Changes to the PDMP state website cannot be done directly; for website maintenance and additions, the PDMP manager must submit change requests to the publications specialist. This can cause changes to be delayed.

Comments

- **Major Strengths:**
 - Use of survey to inform “ease of use and access” work is a data-driven approach to this activity.
 - Face-to-face meetings are an important tool for generating buy-in and it is good to see them used to gather strategic planning input.

- **Major Weaknesses:**

Year 3 work plans were not included for:

 - Move toward universal PDMP registration and use
 - Contact non-enrolled prescribers
 - DHSS access to AKPDMP datasets
 - Enhance communication between programs and partners

- **Recommendations:**
 - Has the team considered unscheduled visits (e.g. academic detailing model) to conduct PDMP outreach?
 - AK DHSS should work closely with CDC evaluation officer to ensure continued alignment between the evaluation plan, work plan and logic model.

-

- **Other Relevant Comments:**
 - What is the current percent of user registration in the state of Alaska (in 2016 it was 23%)?
 - Currently, what is the main pain condition that opioids are being prescribed for (i.e., low back pain, post-surgical pain, acute pain, etc.)?
 - In the state of Alaska, is over-prescribing by clinicians more of an issue than opioid misuse/abuse by patients?
 - Will the licensing board be involved in recommending participation in PDMP registration and training?
 - What is the status on the surveys that were mailed to licensed practitioners in Juneau?
 - Is this mailed survey different than the online questionnaire?
 - Is the year 3 questionnaire (March 2019) different than year 2 questionnaire (March 2018) and “consumer satisfaction” survey?
 - Have you explored what it would take to create or purchase a “license integration” feature for the PDMP?
 - What kinds of alerts does the new alert module contain?
 - Who are the stakeholders who have been engaged in the development of the statewide strategic PDOP plan?

Sub-Activity: Enhancing PDMP Use for Clinical Decision-making

Sub-Activity Year 1 Progress: Two websites are under development: 1. Opioids.alaska.gov will consolidate information and assist users to navigate internet-based resource; and 2. Alaska Center for Health Data and Statistics hosting surveillance reports, queryable data sets, and geospatial analysis maps. The website managers solicit input from the AKPDOP advisory group on scope, depth, and usefulness of developed materials; and assures the website URL address is added to other associated State of Alaska websites.

Until a qualified candidate is hired, DHSS is assisting DCCED to develop materials for hosting on both the DHSS and DCCED websites. The PDMP Manager and Division Operations Manager participate as members of the AKPDOP Advisory group and are primary PDMP liaisons to the Board of Pharmacy.

Sub-Activity Year 2 Progress: The PDMP Manager made phone calls to clinics located in the Juneau area to gauge interest in scheduling shadowing visits for the purpose of improving practitioners' understanding of PDMP mandated use. On 01/22/2018, a visit to a clinic was conducted, where the PDMP manager was able to discuss topics relating to mandatory reviewing requirements, data reporting, and delegate access. While the visit was successful (14% success rate; 1 of 7 agreed to visit), this method of scheduling on-site outreach activities was ineffective as there has been a low response rate to participate. On March 15, the PDMP manager drafted a survey as another approach to gauging whether practitioners would be willing to participate. The PDMP manager's supervisor reviewed the draft on 03/23/18, and the survey was finalized on 03/27/18. The PDMP manager plans to mail the survey out to 188 actively licensed practitioners in Juneau by 03/27/18.

Sub-Activity Year 3 Work Plan: By September 2018 (Year-2), the PDMP Manager will increase outreach and education activities by 30%.

The PDMP Manager in collaboration with the AKPDOP advisory group will: 1. continue to assist with the development of content for a consolidated website that provides links to information and resources. Information will include regularly distributed state and national surveillance metrics and reports and educational resources such as clinical practice guidelines for prescribing opioids for chronic pain, and use of PDMP to improve patient safety and protect patients.

The PDMP Manager will continue to assist with the development and improvements to opioid websites that consolidates information and links to other websites to ease navigation of internet and other electronic information including, but not limited to, regularly released reports on surveillance metrics—Essential resources for healthcare providers may cover a broad range of topics, including educating the public on the consequences of misusing drugs, safe storage and disposal of medication, working with older adults with poor medication compliance or instruction retention, patients needing chronic pain management, and working with individuals that have a substance abuse disorder.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding also partially supports personnel costs for a full-time PDMP manager and travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Sub-Activity: Identify AKPDMP Barriers and Limitations

Sub-Activity Description: By March 2018, the PDMP manager, with the assistance of the DDPI Education Coordinator and DDPI advisory group will review a “consumer satisfaction” survey to solicit input from enrolled and non-enrolled prescribers and dispensers and determine awareness statutes, regulations, and policies pertaining to the AKPDMP; and to identify system limitations, barriers, and other improvement needs (e.g., training).

Sub-Activity Year 1 Progress: The part-time (0.5 FTE) PDMP manager continues to support the PDMP along with support from the AKPDMP database contractor. A new position description for a full-time (1.0 FTE) PDMP coordinator has been approved by Alaska Department of Human Resource and the position posted in-state and nationally. A qualified candidate has not yet been hired for the Juneau-based position and has been re-posted for hire. The QPM and Education Specialist have engaged the current PDMP manager to develop training materials and to coordinate key informant interviews to be completed by July 31, 2017.

Sub-Activity Year 2 Progress: The PDMP state website located at www.pdmp.alaska.gov was assessed for its available resources and quality of instructions in November 2017. The PDMP Manager identified four options for making the PDMP platform easier to use and access: 1.) Update registration instructions for primary users and delegates - Instructions were revised and posted to the website on 11/14/2017 to include the step-by-step process of successfully registering with visual cues. 2.) Improve formatting of website for better readability - The layout of resources on the PDMP were rearranged and reconfigured to make instructions and pertinent resources easy to identify. Improvements included adding icons for PDFs and webpages and listing resources in a conceptual rather than fragmented order. 3.) Provide conspicuous contact information for PDMP assistance - The PDMP Manager and AWA RxE support contact numbers are redundantly displayed to make contact information easily accessible when questions arise pertaining to PDMP use and access. 4.) The PDMP manager has been conducting outreach activities since January 2018. A survey was developed on 03/27/18 to gauge specific topics practitioners look to that will improve the ease of PDMP use and access.

Sub-Activity Year 3 Work Plan: By October 2018, the PDMP manager, with the assistance of the DDPI Education Coordinator and DDPI advisory group will review a “consumer satisfaction” survey to solicit input from enrolled and non-enrolled prescribers and dispensers and determine awareness statutes, regulations, and policies pertaining to the AKPDMP; and to identify system limitations, barriers, and other improvement needs (e.g., training). The survey will be re-deployed to collect input for further improvements to training and identify new and continuing limitations, barriers and other needed improvements to maximize the use of the AKPDMP.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding also partially supports personnel costs for a full-time PDMP manager and travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Sub-Activity: Assess professional awareness levels and use

Sub-Activity Year 1 Progress: The PDMP manager was hired in September 2017.

Sub-Activity Year 2 Progress: The Awareness and Feedback Questionnaire team developed an implementation plan, including a logic model and timeline in February, 2018. Questions were developed between February - March and are currently being fine-tuned.

Sub-Activity Year 3 Work Plan: By March 2019, the PDMP manager will deploy the online awareness and feedback questionnaire for distribution to 100% of registered users. Survey response will be used to improve PDMP use by healthcare providers to help improve informed treatment decisions for the most appropriate medical care for their patients; assess their understanding of current and pending regulations and providing avenues to comment.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding also partially supports personnel costs for a full-time PDMP manager and travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Major Activity: Move toward universal PDMP registration and use

Major Activity Summary: Increase Enrollment of Dispensers and Prescribers—In 2016, registered Alaska Prescription Drug Monitoring Program (AKPDMP) users represent only 23% of the total potential participants. This low rate of participation suggests the need for increased outreach to prescribers to improve their understanding of addiction and overdose in Alaska and heightened awareness to better identify patients who may have or are developing dependencies. The findings also suggest that dispensers are relying on prescribers to adequately monitor patients' prescription history and ability to manage pain, indicating another area for outreach.

Major Activity Challenges: The challenges were identifying and narrowing down specific individuals to include in distinct partnerships. The PDMP Manager wasn't hired until September, 2017, so becoming familiar with the program itself carried an inherent learning curve that affected the understanding of specific stakeholder roles needed for the program activities.

Sub-Activity Description: By July 1, 2017, the PDMP will identify and contact non-enrolled dispensers and prescribers that must enroll by the July 17th, 2017 deadline.

Sub-Activity Start Date: May 2017

Sub-Activity End Date: December 2017

Sub-Activity Status: Completed

Sub-Activity Year 1 Progress: Three mass mail outs regarding mandatory PDMP registration were sent out in the summer of 2017 between May and August. Following the mandatory registration effective date, the PDMP manager sent out a letter to non-registered users reminding them of this requirement on November 6, 2017. The letter was sent out to over 2,000 licensees who were potentially required to register; the PDMP does not have a license integration feature to readily identify all licensees who are required to register, so the roster of licensees were based on the list of current registered users and the division's internal list of actively licensed professionals housed in its licensing database. Due to the absence of a license integration feature, some practitioners who were in fact registered appeared on the roster of individuals who were not registered; this was caused by discrepancies in names entered in the professional licensing database versus how they were entered in the PDMP. In addition, the division does not track DEA registration status, so some practitioners who did not hold a DEA registration also received the notice. The PDMP manager continues to make salient the registration requirement by posting notices to the PDMP state website.

Sub-Activity: Contact Non-enrolled Prescribers

Sub-Activity Description: By July 1, 2017, the PDMP will identify and contact non-enrolled dispensers and prescribers that must enroll by the July 17th, 2017 deadline. The PDMP manager will develop a list of all licensed dispensers and DEA licensed prescribers and a list of DEA licensed prescribers not yet enrolled in AKPDMP; identify areas of heavy prescribing using AKPDMP data; and develop a plan to increase targeted outreach to healthcare professional by 30% annually.

Sub-Activity Start Date: May 2017

Sub-Activity End Date: December 2017

Sub-Activity Status: Completed

Sub-Activity Year 1 Progress: Three mass mail outs regarding mandatory PDMP registration were sent out in the summer of 2017 between May and August.

Sub-Activity Year 2 Progress: Following the mandatory registration effective date, the PDMP manager sent out a letter to non-registered users reminding them of this requirement on November 6, 2017. The letter was sent out to over 2,000 licensees who were potentially required to register; the PDMP does not have a license integration feature to readily identify all licensees who are required to register, so the roster of licensees were based on the list of current registered users and the division's internal list of actively licensed professionals housed in its licensing database. Due to the absence of a license integration feature, some practitioners who were in fact registered appeared on the roster of individuals who were not registered; this was caused by discrepancies in names entered in the professional licensing database versus how they were entered in the PDMP. In addition, the division does not track DEA registration status, so some practitioners who did not hold a DEA registration also received the notice. The

PDMP manager continues to make salient the registration requirement by posting notices to the PDMP state website.

Sub-Activity Funding Type: Base funds

Major Activity: Conduct public health surveillance with PDMP data and publicly disseminate reports and quarterly or semi-annually on CDC-directed metrics

Major Activity Summary: Develop quarterly and annual data reporting criteria—The PDMP Manager, in collaboration with and assistance from the AKDPOP Epidemiologist and the AKPDMP advisory group, will develop quarterly reporting criteria to supplement annual reports (as required under Alaska statute and regulation) to the Board of Pharmacy and the Alaska Control Substance Advisory Committee.

Major Activity Challenges: Currently the AKPDMP Manager provides AKPDMP reports that can only be generated with the PDMP software package. Additional in-depth analysis and identification of “hot spots” cannot be performed until the amended Alaska Administration Code (regulation) governing access to the AKPDMP data is approved by the Dept. of Law and a policy for administering a data sharing agreement is implemented. It is anticipated that the review by the Dept. of Law will not be completed until May or June of 2018.

Sub-Activity: DHSS Access to AKPDMP datasets

Sub-Activity Description: Within 60 days of the effective date detailed in amended Alaska Administrative Code(s) that regulate access to AKPDMP data, the Dept. of Community Commerce and Economic Development (DCCED) Operations Director and the AKPDMP Manager will develop policy for providing a data to DHSS.

Sub-Activity Start Date: September 2016

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Amended regulations that will provide access to PDMP data is under review by the Alaska Board of Pharmacy. Once completed, the DCCED (where the PDMP is located) will provide a data agreement to DHSS or will solicit an MOA between DCCED and DHSS. The agreement will allow individuals that are approved by the DHSS Commissioner to have access to the AKPDMP data.

Sub-Activity Year 2 Progress: Amended regulations that will provide access to PDMP data are currently under review by the Alaska Dept. of Law. Once completed, the DCCED will provide either a data agreement to DHSS to allow access to PDMP data to individuals authorized DHSS Commissioner.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Until access is authorized, funding was provided to the AKPDMP to procure an alert module to provide information to prescribers. The APhRIS module allows the PDMP manager/coordinator to set the array and threshold of alerts.

Strategy: Planning

Major Activity: Develop prescription drug and heroin abuse prevention plan

Major Activity Summary: Alaska Prescription Drug Overdose Prevention (PDOP) project will maintain key leadership for an advisory group and statewide strategic plan development workgroup to finalize and implement Alaska's Statewide Strategic AKDPOP Plan. Leadership and workgroup members (along with additional members from the multi-agency Incident Command Structure (ICS) that was established with the Declaration of Health Emergency) will serve as coordinators for Alaska's statewide strategic PDOP planning activities. Subject matter representatives will work with the Strategic Plan Project Leader, in collaboration with other advisory groups, during regularly scheduled meetings to finalize a Statewide Strategic AKPDOP Plan for presentation to stakeholders. This approach will be highly effective and collaborative and aims to prevent redundancy.

Major Activity Challenges: Due to the addition of town hall meetings, the original timeline was pushed back by 6 months. In addition, personnel changes limited capacity to meet the original timeline for completion of the community outreach sessions that were scheduled throughout the state. However, the Strategic Plan Project group worked collaboratively to complete the schedule. As a result of the community outreach, unintended benefits occurred, such as community collaborations and people accessing treatment.

Sub-Activity: Development of Statewide Strategic PDOP Plan

Sub-Activity Description: By September 2018, the Quality Performance Manager (QPM) will review the 2017-18 schedule and coordinate meetings with internal and external entities to finalize and implement a Statewide Strategic PDOP Plan.

The QPM will work with internal and external entities on a variety of topic areas to review strategic input documents, identify objectives, initiatives, measures, and resources to drive the overall statewide plan. Strategic input documents are informed by community outreach feedback, Opioid Policy Task Force recommendations, policies, data, laws and regulations, national recommendations and current funding sources for targeted and broad implementation. In addition to this external input, they will also include internal input.

Sub-Activity Start Date: September 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: The AKPDOP Advisory Committee was established and began to: 1) engage partners across disciplines, sectors, and institutions to promote well-being and positive behaviors, as well as acknowledging cultural diversity to assure affirmative outcomes; and 2) facilitate collaboration among Alaska’s diverse professional sectors to recruit expertise in planning activities, identify priority actions, and reduce redundancy of efforts. An annotated outline of a statewide plan based on the Report and Recommendations from the Alaska Opioid Prevention Task Force was used as the foundation for the statewide strategic PDOP plan that incorporated sub-workgroups to draft strategic plan sections for presentation during the Year-1 stakeholder’s sessions.

Sub-Activity Year 2 Progress: The QPM and the newly established Office of Substance Misuse and Addiction Prevention staff have partnered with state agencies and community action groups to complete 9 interactive community events and held “meet and greet” meetings in 11 communities with a variety of stakeholders to gather input on the overall statewide strategic plan. The Strategic Planning Project staff continue to engage partners across disciplines, sectors, and institutions to continuously gather input. The community outreach process has facilitated collaboration across different organizations and people where silos previously existed, recruited expertise in planning activities from among Alaska’s diverse professionals needed to reduce opioid use and misuse, identify both state- and community-level priority actions, and to continue to identify gaps and redundancy of efforts.

Sub-Activity Year 3 Work Plan: By September 2019, the Quality Performance Manager (QPM) will review the 2018-19 schedule and coordinate meetings to implement and improve a Statewide Strategic AKDPOP Plan. An annual schedule of activities will be developed to gather and incorporate comments from stakeholders including, but not limited to, assessment of emerging issues and identification of new priority actions.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Current funding supports personnel, travel, and other expenses needed to complete work on the statewide plan including transcription costs, web development, telephone conferencing fees, and evaluation processes. Funding also supports travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Sub-Activity: Review of Legislative Actions

Sub-Activity Description: By September 2018, Policy Project Leader will be review and update the PDOP - Alaska Statute, Regulation, and Policy index, as needed, to assure accurate documentation of legislative actions. The updated copy (with documented revision date footnoted) will be posted to the DHSS Opioid Workgroup SharePoint site.

The purpose of this review is to facilitate strategic planning at the state- and community-levels.

This activity was initiated under the Policy Evaluation Strategy and was moved to support the Strategic Plan Strategy.

Sub-Activity Start Date: January 2017

Sub-Activity End Date: August 2019

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: This activity was initiated under the Policy Evaluation Strategy and was moved to support the Strategic Plan Strategy.

Major Activity: Develop Partnerships

Major Activity Summary: For broad implementation of Alaska’s statewide strategic PDOP plan necessitates coordinated efforts to attain maximum outcomes of prevention strategies. In addition, partner collaboration is needed to assess community needs, develop new interventions identified in the plan, initiate processes to fill data and knowledge gaps, improve dissemination of surveillance metrics and summary reports, and assess findings from a forthcoming policy analysis, and provide additional recommendations.

DHSS Opioid Workgroup is composed of DHSS program staff that utilize information provided by the ICS and may be participating in the ICS. The combination of these two work groups assist with identifying and developing new partnerships, maintaining the extensive partner working groups effectiveness, and incorporating community input to the strategic planning process.

Sub-Activity: Annual PDOP Project Leaders and Activities

Sub-Activity Year 1 Progress: All permanent and temporary staff were in-place to fill roles as detailed in the Yr-1 work plan. Since several key staff were located with DHSS but outside of the Section of Epidemiology, reimbursable service agreements were developed and approved to provide funding for their work contribution. Due to personnel changes and re-organization, the Informatics position was eliminated and funding of the Quality Performance Manager was expanded from 0.2 to 0.5 FTE.

Sub-Activity Year 2 Progress: Internal DHSS key staff located outside of the Section of Epidemiology continue to participate via reimbursable service agreements to provide funding for their work contribution. External to DHSS, the project has partnered with 9 community-based organizations including: Alaska Native Tribal Health Consortium Substance Abuse Prevention Initiative; Ketchikan Wellness Coalition-Drug-free Communities; North Slope Borough; Bristol Bay Opioid Task Force; Mat-Su Health Foundation, Mat-Su Opioid Task Force, and United Way of Mat-Su Thrive Fairbanks Opioid Working Group and Fairbanks Wellness Coalition; Homer Opioid Task Force; Mobilizing for Action thru Planning and Partnerships (MAPP); Change for Kenai; and Juneau Alliance for Mental Health.

Expanded departmental partners include Department of Public Safety, Alaska Guard, DHSS- Divisions of Behavioral Health, Public Health (including Public Health Nursing, Health Analytics and Vital Records),

Sub-Activity Year 3 Work Plan: By August 2019, the QPM will expand coordination and enhancement of relationships among the following: 1) intra-departmental relationships; 2)

community relationships; 3) inter-departmental relationships; 4) tribal systems relationships; 5) military/VA relationships.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding was used to support work done by DHSS staff including reimbursable service agreements of external SOE key staff and project leaders to provide oversight and coordination of strategic planning, complete assigned strategy activities, and improve and expand key partnerships statewide..

Sub-Activity: Enhance Communication between Programs & Partners

Sub-Activity Description: By September 2018, the Project Director will assure that the ICS leadership provides situation reports that will be posted to a SharePoint file. SharePoint access will be provided to the Opioid Workgroup (PDOP Advisory) to assist with the development of new professional and community partnerships to facilitate activities designed to reduce the impact of licit and illicit opioid and other illicit drug misuse.

Sub-Activity Year 1 Progress: The Opioid Workgroup was adopted as the AKPDOP Advisory that began to: •Engage partners across disciplines, sectors, and institutions to promote well-being and positive behaviors, as well as acknowledging cultural diversity to assure affirmative outcomes; and •Facilitate collaboration among Alaska’s diverse professional sectors to recruit expertise in planning activities, identify priority actions, and reduce redundancy of efforts. On February 16, 2017, Gov. Walker signed Administrative Order 283, implementing a multi-agency Incident Command System (ICS) led by the Department of Health and Social Services (DHSS). These actions follow the Governor’s Feb. 14, 2017 disaster declaration that establishes a statewide Overdose Response Program under Alaska’s Chief Medical Officer and enables wide distribution of naloxone. In response, DHSS has activated the ICS to manage this event. Using the ICS in conjunction with the AKPDOP Advisory Committee incorporates representation from other professional sectors to quickly initiate statewide activities and facilitate real-time strategic prevention planning.

Sub-Activity Year 2 Progress: The Opioid Workgroup and the ICS workgroup are a partnership that is comprised of multi-state agency members. Personnel from the Alaska PDMP, law enforcement, criminal justice, school-based prevention & education, and provider and public information agencies also contribute resources. On a bi-weekly basis, ICS team meets to discuss various updates with the ultimate goal of improving health outcomes in our state. Targeted objectives include efforts to: reduce and control access to opioids; reduce risk of opioid misuse, abuse, and dependence; increase screening, referral, and treatment options; strengthen harm reduction efforts, including overdose prevention and syringe exchange programs; support recovery through reimbursement and support of peer support services and partnerships to support second chance employers hiring people in recovery; enhance collaboration to address barriers to coordinated care, strengthen partnerships with public safety and community coalitions for community prevention, and to mitigate the collateral consequences of incarceration for drug-related offences. The Opioid Workgroup meets monthly to review DHSS activities and provide reports to assure communication across all sectors.

Comments

- Major Strengths:
 - The ADPDOP has facilitated robust multi-agency partnerships to advance Alaska’s PDO prevention efforts, including identification of priority areas at the state and county levels and fostering collaborations to reduce redundancy.
- Major Weaknesses:
- Recommendations:
- Other Relevant Comments:
 - Consider highlighting success stories of outcomes due to partnership development and expansion.

Major Activity: DATA

Enhance surveillance of prescription drug and heroin abuse and overdose

Major Activity Summary: Maintaining and improving routine data collection and analysis of fatal and non-fatal drug overdoses is a fundamental objective of the PDOP. Key data needed to understand and fully assess opioid use, misuse, dependency, and overdose includes, but is not limited to, vital records, hospital inpatient discharge /ED visit data, EMS run data, behavioral risk surveys/PRAMS/CUBS data, treatment services data, Medicaid use and Medicaid Part D data, crime reporting statistics, and PDMP data.

Major Activity Challenges: Data managers have different timelines for collection and scheduled release. This is compounded by a decentralized process to access data. While the work of the Substance Abuse Epidemiology Workgroup has made strides to centralize data in one website and compile database information into a “data directory”, there is still a multitude of dataset that still need to be incorporated, or if present, enhanced to provide the maximum access to recent and archived datasets.

Comments

- Major Strengths:
- Major Weaknesses:
 - ESOOS and its funded NVDRS and morbidity work is not part of DDPI funding and should be removed from DDPI-related reporting. ESOOS is separately funded from DPPI.
- Recommendations:

- Emphasize progress on major activities highlighted in the DDPI evaluation and work plans, e.g. identification of hotspots and improvements in data quality, reporting, utility, etc.
- Other Relevant Comments:
 - Ensure that major activities reported in progress updates have corresponding evaluation activities.

Sub-Activities

Sub-Activity: Coordination of Opioid Surveillance & Reporting

Sub-Activity Description: By September 1, 2017, the Alaska Substance Abuse Epidemiology Workgroup (SEW) chairperson and the PDOP Epidemiologist will continue to maintain and incorporate key data providers into the workgroup, meet monthly to assess and revise an annual schedule of data release timelines, routine reports, and other deliverables.

The SEW functions as the key data provider workgroup whose participants include, but are not limited to, data system and surveillance managers, research and program analysts, and epidemiologists representing surveillance systems collecting vital records/health statistics, hospital discharge systems/ED, EMS, behavioral risk surveys, PRAMS/CUBS, treatment services, Medicaid, crime reporting, and PDMP. As the PD works concurrently as the Lead Epidemiologist for the SEW, the PD will lead surveillance activities to update information in the Alaska Epidemiology Profile on Substance Use. This partnership is essential to timely data collection and dissemination as well as eliminating duplication of efforts.

This activity is on-going throughout the entire 3-year project period.

Sub-Activity Start Date: September 2016

Sub-Activity End Date: August 2019

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Data collection and analysis is an on-going activity since the release of data varies from department to department and program to program. The SEW continues to meet quarterly to work on updating and revising the Alaska Substance Abuse Epidemiology Profile. The work on the revised updated report is on-going and will be generated using data entered into the Alaska Indicator-Based Information System (AK-IBIS) as well as incorporating summary reports from data providers that are not yet participating to enter data in AK-IBIS.

In addition, the PD and SEW has reviewed the datasets currently available within the AK-IBIS and additional datasets from providers for inclusion in the system generated report. At this time, all indicators have been developed and submitted for approval to be hosted on AK-IBIS.

Data to fill data gaps are being sought for evaluation and future inclusion in AK-IBIS and the Substance Abuse Epidemiology Profile.

Sub-Activity Year 2 Progress: Data collection and analysis is an on-going activity since the release of data varies from department to department and program to program. The SEW continues to meet at least quarterly to work on updating and revising the Alaska Substance Abuse Epidemiology Profile. The work on the revised updated report is on-going and will be generated using data entered into the Alaska Indicator-Based Information System (AK-IBIS) as well as incorporating summary reports from data providers that are not yet participating to enter data in AK-IBIS. A file of updated tables and charts will be posted to the Section of Epidemiology website as work progresses to finalize the report in AK-IBIS.

The PD and SEW continued to review datasets currently available within the AK-IBIS and solicited additional datasets from providers for inclusion in the system generated report. At this time, all additional indicators have been developed and submitted for approval to be hosted on AK-IBIS. Data to fill data gaps are being sought for evaluation and future inclusion in AK-IBIS and the Substance Abuse Epidemiology Profile.

Deliverables in Year-2 include a new opioid data dashboard that can be accessed at: <http://dhss.alaska.gov/dph/Director/Pages/heroin-opioids/data.aspx>; and a new Section of Epidemiology report entitled, “Health Impacts of Opioid Use in Alaska” that is under review and scheduled for release in mid-May 2018.

Sub-Activity Year 3 Work Plan: By September 1, 2018, the Alaska Substance Abuse Epidemiology Workgroup (SEW) chairperson and the PDOP Epidemiologist will continue to maintain and incorporate key data providers into the workgroup, meet monthly to assess and revise an annual schedule of data release timelines, routine reports, and other deliverables.

The SEW functions as the key data provider workgroup whose participants include, but are not limited to, data system and surveillance managers, research and program analysts, and epidemiologists representing surveillance systems collecting vital records/health statistics, hospital discharge systems/ED, EMS, behavioral risk surveys, PRAMS/CUBS, treatment services, Medicaid, crime reporting, and PDMP. As the PD works concurrently as the Lead Epidemiologist for the SEW, the PD will lead surveillance activities to update information in the Alaska Epidemiology Profile on Substance Use. This partnership is essential to timely data collection and dissemination as well as eliminating duplication of efforts.

This activity is on-going throughout the entire 3-year project period.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports personnel assigned to collect, code, and enter opioid use and overdose data into the NVDRS; and supports personnel costs, supplies, software, and other ITS expenses for data cleaning, analysis, and reporting. Funding also supports travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Sub-Activity: Enhanced Opioid Overdose Death Surveillance

Sub-Activity Year 1 Progress: The Section of Epidemiology (SOE) provided personnel services to maintain key surveillance agreements. The Section's injury epidemiologist is the Project Director and the Principal Investigator for the Alaska Violent Death Report System (AKVDRS) and has established processes for data importation from the Division's Section of Health Analytics and Vital Records (HAVRS) for all manners of death exclude natural deaths, which are then reviewed and coded for opioid drug overdoses prior to entry into the AKVDRS. Currently, mortality data is provide on a monthly schedule to the Section of Epidemiology.

The Alaska NVDRS program expanded its contract's agreement to assist with opioid overdose case abstraction. The contractor is trained in the CDC NVDRS methodology for abstraction and has several years of experience. The contractor is also an instructor for the university's School of Nursing, and is able to provide additional consultative services on various drugs that may be in combination with opioid(s) used.

In addition, the SOE maintains agreements with the State Medical Examiner Office for autopsy and toxicology results along with law enforcement and military investigation reports.

Sub-Activity Year 2 Progress: Currently, mortality data is provide on a monthly schedule to the Section of Epidemiology. The Alaska NVDRS program employed a new contractor to assist with data abstraction and data entry into the NVDRS. The contractor was trained in the CDC NVDRS methodology for abstraction and has several years of experience. The contractor is also an nurse and is able to provide additional consultative services on various drugs that may be in combination with opioid(s) used.

AKVDRS abstractors are able to request key surveillance documents for drug overdose cases including investigation reports from state medical examiners and law enforcement agencies as well as military investigations. The NVDRS captures demographic, circumstance(s), and environment factors, investigation reports and state specific variables also capture information associated with acute drug poisoning pre- and post-event, including route of exposure, history and indications of substance abuse, drug(s) used, medical treatment/therapy, trauma care and survival time that may provide insight on emerging trends and patterns.

Sub-Activity Year 3 Work Plan: By September 1, 2019 (Year-3), the AKVDRS Principal Investigator will approve continuation of data on all drug overdose deaths occurring in Alaska. The abstracted information pertaining to unintentional opioid overdose deaths will be entered into the National Violent Death Reporting System (NVDRS) , coded as "Unintentional opioid drug poisonings" to differentiate the opioid cases from other drug poisonings.

Data entered into the NVDRS will expanded our understanding of circumstances associated with opioid and other drug overdose incidents as well as criminal activities that may be associated with these incidents. Effective January 1, 2018, as part of the CDC's Enhanced State Opioid Overdose Surveillance grant, all decedent suspected of drug use are tested for prescription and illicit opioid drugs to determine drug use as contributory cause of death.

This activity spans across the entire 3-year project period.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports personnel assigned to collect, code, and enter opioid overdose mortality data into the NVDRS; and supports personnel costs, supplies, software, and other ITS expenses for data cleaning, analysis, and reporting. Funding also supports travel expenses associated with mandatory (required per the grant agreement) to attend a once annual CDC sponsored meeting in Atlanta, GA.

Sub-Activity: Enhanced Opioid Morbidity Surveillance

Sub-Activity Year 1 Progress: All MOUs/MOAs have been reviewed and confirmed to assure access to overdose data. The Section of Health Analytics and Vital Records (HAVRS) collects data from all health facilities across Alaska. Facilities are now required to change reporting processes to use the new Health Facility Data Reporting System (HFDRS). Data sets for 2015 (the first data set available using the HFDRS) is available but will need to be revised as facility work to upload data into the new system. Hospital discharge and ED data is provided on an annual basis until all health facilities are capable of submitting data on a quarter schedule. It is anticipated that HFDRS data will become available on a quarterly basis in late 2017. As data release schedules become more stable, an annual schedule will be generated and posted online.

Training has been provided to program and database managers create data indicators in the Alaska Indicator-Based Information System (AK-IBIS) who have begun to upload datasets. AK-IBIS structure is flexible and provides both queryable datasets and visual graphics to aid community planners and program managers to improve and evaluate infrastructure and services. In addition, AK-IBIS allows database managers to retain control of limiting analyses essential to maintaining confidentiality and security. Reporting formats include Borough/Census Areas, economic, behavioral health to assess health outcomes. Applications for tribal health regions are being developed.

Sub-Activity Year 2 Progress: All MOUs/MOAs have been reviewed and confirmed to assure access to overdose data. The HAVRS collects data from all health facilities across Alaska. Facilities are now reporting into the new Health Facility Data Reporting System (HFDRS) with the exception of one health facility. Data sets for 2016 (the second annual data set was available using the HFDRS) is available but needed to be revised as facility work to upload revised and late submission data into the new system. The first three quarters of the 2017 data set was made available and we are currently awaiting the 4th quarter transmission.

Sub-Activity Year 3 Work Plan: By January 1, 2019, the PDOP Epidemiologist will receive quarterly inpatient, outpatient, and emergency department datasets from the Alaska Section of Health Statistics and Vital Records for analysis and an annual summary report for short-, intermediate, and long-term measures for the Data Strategy.

The Alaska Section of Health Statistics and Vital Records (HAVR) is responsible for health facility data collection and reporting from all health facilities in Alaska. The section provides quarterly data set that are available 3-months after the close of the preceding quarter. The section

reports morbidity data uses ICD-10-CM coding (effective in October 2016). Completion of opioid overdose morbidity data indicators will be completed annually.

This activity spans across the entire 3-year project period.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports the activities of the Epidemiologist to analyze and report findings from the analysis.

Major Activity: Enhance public health access and application of data from [multiple] sources

Major Activity Summary: Routine reporting will improve strategic planning and intervention development at the national, state, and local levels. Data dissemination will: 1) improve tracking of project level success; 2) increase access to timely data for project evaluation and modifications to intervention processes and practices; and 3) enhance public and professional access to data for public health application. The Division of Public Health will present regional frequency and rates using public health regions. Whenever possible, data will be presented by behavioral health and tribal health regions to maximize use by PDOP strategic partners.

Major Activity Challenges: None at this time.

Sub-Activities

Major Activity: Identify and provide technical assistance to high-burden communities and counties, especially efforts to address problematic prescribing

Major Activity Summary: The goal of this of this multi-year intervention is to assess and improve public awareness of high-risk behaviors associated with abuse prescription drugs and its consequences. A series of focus groups will be conducted to ascertain level and diversity of awareness within Alaska using selected high-risk communities (both urban and rural) in order to develop communications to improve public knowledge about opioid drug misuse, overuse, and abuse. The first focus groups will aim to improve understanding of community knowledge, attitudes, beliefs and behaviors related to preventing abuse and overdose of prescription drugs and safe storage and disposal. The second focus groups will use that information to create messages that motivate positive behavior changes among the target audience. Prior to creating the public education campaign, the program will conduct a baseline statewide telephone survey of the public to measure knowledge, attitudes, beliefs, intentions, and behaviors that can be monitored for change following the campaign. The AKPDOP Committee will review messages and materials to provide additional feedback on the media and social marketing campaign to include advice and suggestions to improve content and message delivery. Telephone surveys and key informant interviews will be used as performance measures in Year-2 and Year-3 as detailed in our evaluation plan including statewide telephone survey and key

informant interviews. Both will measure effectiveness of program planning and change of knowledge, attitudes, beliefs, intentions and behaviors following implementation of the social marketing/media campaign. In Year-2 and Year-3, a series of community outreach meetings will be scheduled to gather additional input on community-level action plans and community needs. This will then feedback into develop of new education materials, expanded broadcasting, and modification of messages designed to enhance awareness and improve knowledge, well-being and safety of Alaska residents.

Major Activity Challenges: A deeper analysis of key informant interview responses was needed following the initial summary report provide by the contractor. The reason for the deeper analysis was the need more granular information that could distributed to programs and project leaders. These could then be defined into action items inclusively for strategic planning. Carryover funds from Year-1 supported analysis to be conducted and reported by UAA-ISER. The information was also incorporated into their overall evaluation of Year-1 and Year-2 implementation processes associated with these activities.

In addition, the reorganization of personnel and the establishment of the Office of Substance Misuse and Addiction Prevention necessitated the negotiation and establishment of new contractual agreements for media development and placement in Year-2.

Comments

- Major Strengths:
- Major Weaknesses:
- Recommendations:
 - Qualitative analyses is a key technique to understanding a public health outcome and tailor interventions. Consider building internal capacity.
- Other Relevant Comments:
 - How were high-burden communities selected for key informant interviews and focus groups

Sub-Activity: Improving Community Awareness Levels

Sub-Activity Year 2 Progress: The Education Coordinator provided oversight of a contract to conduct the second round of telephone surveys and key informants interviews in urban and rural communities. Telephone surveys for Year-2 were completed in January 2018. Key informant interviews are scheduled for July 2018. The detailed analysis of Year-1 key informant interviews is completed. Year-1 and Year-2 telephone surveys are currently being coded and analyzed by UAA-ISER. Findings will be used to support this activity as well as activities being conducted by the Policy Evaluation, PDMP, RRP-Prescriber Education, and the DDPI Evaluation groups.

Sub-Activity Year 3 Work Plan: By September 1, 2018, the Education Coordinator will review all contract agreements and specifications to conduct needed telephone surveys and key

informant interviews in urban and rural communities and continued development of social media and marketing materials.

Year-3 focuses on the production and placement of social marketing/media in Alaska's urban and rural communities. Alaska communities are diverse and some communities are geographically isolated. Consultation with CDC Education Specialists will help assure uniform messages and facilitate discussions with other rural states.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Base funding supported personnel costs and contracts designated for fulfilling education activities. In addition, supplemental funds were used to expand media reach and frequency especially in rural areas of Alaska..

Sub-Activity: Enhancing Community Action

Sub-Activity Description:

To address the rising incidence of heroin and opioid abuse in Alaska, the Advisory Board on Alcoholism and Drug Abuse, Division of Public Health, and the Alaska Mental Health Trust Authority co-facilitate an Alaska Opioid Policy Task Force (AOPTF). The goal of the AOPTF is to provide recommendations to the Governor and Legislature. The task force consisted of members representing the public systems significantly affected by issues related to opioid abuse while representing the diversity of Alaska's communities. The community outreach process conducted by the Office of Substance Misuse and Addiction Prevention identified 13 communities that were identified as having a higher risk for opioid misuse and overdose and/or having an establish community opioid action plan in-place as the statewide opioid prevention strategic plan was being developed.

Sub-Activity Start Date: January 2018

Sub-Activity End Date: April 2018

Sub-Activity Status: Completed

Sub-Activity Year 1 Progress: This Sub-Activity was not conducted in Year-1.

Sub-Activity Year 2 Progress: Community involvement is vital to curbing substance abuse and establishing a viable statewide strategic plan. The goal of this of this multi-year intervention is to improve public awareness of high-risk behaviors associated with abuse prescription drugs and its consequences as well as capture information on community needs and activities currently in-place or pending funding. This activity is an extension of our Year-1 Rapid Response Project to enhance community awareness and knowledge. The activity is now incorporated into Strategy 2: Community Outreach.

Community hubs included in this year's outreach included Anchorage, Mat-Su (Wasilla), Kenai Peninsula (Homer, Kenai, Soldotna), Lake and Peninsula (Dillingham), Interior (Fairbanks), Northern (Nome, Barrow), Southeast (Juneau, Sitka) Community meetings were facilitated by

the QPM and facilitation notes were transcribed for coding and analysis. The findings will be provided back to the communities and will be used to support strategic plan development activities.

Sub-Activity Year 3 Work Plan: By April 2019, the QPM and representatives from the Office of Substance Misuse and Addiction Prevention will conduct a series of town hall meetings, community cafes, and “meet & greet” sessions to facilitate implementation of the first statewide opioid strategic plan and to gather information as part of a needs assessment/implementation improvement plan and to solicit participation in future prevention activities under development. Key representation from these communities will also participate in stakeholder meetings.

Sub-Activity Funding Type: Supplemental funds

Sub-Activity Funding Description: Funding supported travel to community “hubs”. Alaska encompasses 1,391 communities that are spread over a 656,425 square mile area for its source documents. The majority of the source agencies are typically situated in “hub” communities that are not accessible by a road system and only by aircraft. Travel in Alaska does incur transportation costs that other states do not have including the necessity to use air travel to/from population community hubs (e.g., Juneau, Sitka, Bethel, Kotzebue, Barrow).

Sub-Activity: Analysis of Survey and Interview Responses

Sub-Activity Year 2 Progress: Due to the lack of technically proficient personnel in DHSS to complete this form of analysis, UAA-ISER was contracted to perform coding of responses and conducted in-depth analyses of literal text using ATLAS software. Findings will be provided in written reports to the PD, Education Coordinator, and QPM for education development and strategic planning purposes. Information will be posted to the Opioid Work Group SharePoint site for general usability by all team members.

Sub-Activity Year 3 Work Plan: By July 1, 2019, the PD, Ed Coordinator, and QPM will establish a contractual agreement with UAA-ISER to code and in-depth analyzes of literal text collected from Year-3 Community Outreach activities including 1) town hall meetings, community cafes, and “meet & greet” sessions and 2) scheduled telephone surveys and key informant interview response, culminating in written reports of these analysis findings.

Note: Funding will be incorporated in the Year-3 Supplemental budget narrative.

Sub-Activity Funding Type: Carryover funds

Sub-Activity Funding Description: Year-2 utilized carryover funds. Due to the lack of technically proficient personnel, UAA-ISER was contracted to perform coding of responses and conducted literal text analysis using ATLAS software. Findings will be provided in a written report to the Education Coordinator. Information will be posted to the Opioid Work Group SharePoint site for general usability by all team members. Year-3 analyses of survey and interview responses will be supported by Year-3 Supplemental funds, if provided.

Major Activity: Conduct a rigorous evaluation on a law, policy, or regulation designed to prevent opioid overuse, misuse, abuse, and overdose

Major Activity Summary: The University of Alaska Anchorage (UAA) - Institute for Social and Economic Research (formerly part of the UAA - Justice Center) will lead the effort to conduct a rigorous evaluation of laws, policies, and regulations designed to prevent heroin and opioid overuse, misuse, abuse, and overdose. Of particular interest are public health surveillance statutes within and outside of Alaska and the power to use prescription drug monitoring program data to conduct epidemiological investigations involving heroin and prescription opioids. Other areas of interest may include proposed legislation pertaining to naloxone access, pain clinic laws, and recent marijuana use.

Year-1 will focus on an intensive review and compilation of Alaska laws in effect, proposed for scheduling, recently passed and proposed, and repealed and initiate a gap analysis designed to prevent heroin and opioid overuse, misuse, abuse, and overdose. . Of particular interest are public health surveillance statutes within and outside of Alaska and the power to use prescription drug monitoring program data to conduct epidemiological investigations involving heroin and prescription opioids.

Year-2 will focus on reporting of findings to Strategic Planning committees and legislative actions pertaining to scheduling of controlled substances and the Good Samaritan law as it relates to drug overdose events.

Year-3 will focus on Alaska case law on the aforementioned topics as directed by the AKPDOP Advisory, ICS work group, and other partners.

Major Activity Challenges:

Comments

- Major Strengths:
- Major Weaknesses:
- Recommendations:
 - Please share the policy review report when it is complete. Also, if DDPI funds were used to create a report, please reference the DDPI funding number in the acknowledgements.
- Other Relevant Comments:

Sub-Activity: Statute, Regulation, and Policy Review

Sub-Activity Description: By January 2017, the UAA - ISER will initiate a policy and regulation review project. The policy and regulation review will include: • a thorough literature review of

existing publications and reports; • an analysis of statutory and regulatory language as well the impact of legislation with the goal of identifying promising legislative and regulatory practices for consideration; • an assessment of the AKPDMP processes in regard to universal use requirements, real-time reporting, and proactive use in Alaska relative to other states; and • an outline the history of related legislation in Alaska and review best practices regarding laws, policies, and regulations implemented outside of Alaska that are designed to prevent overuse, misuse, abuse, and overdose of heroin and prescription drugs.

By March 2018, a gap analysis will be completed and a draft report will be provided to the PD. A final copy of the gap analysis and index of Alaska Laws will be provided to the Strategic Planning work groups and the Project Leaders.

Sub-Activity Start Date: September 2016

Sub-Activity End Date: June 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Due to significant delays in approval of a reimbursable service agreement with the University of Alaska Anchorage-Justice Center and discussions with the CDC Evaluation Program Officer, the Policy Review project timeline was pushed back 6 months. In addition, following the Governor’s Declaration of Health Emergency, several laws were introduced and/or passed. The information will be included as an appendix to the written gap analysis report.

The project staff initiated – • a literature review of existing publications and reports; • an analysis of statutory and regulatory language as well the impact of legislation with the goal of identifying promising legislative and regulatory practices for consideration; • an assessment of the AKPDMP processes in regard to universal use requirements, real-time reporting, and proactive use in Alaska relative to other states; and • an outline the history of related legislation in Alaska and review best practices regarding laws, policies, and regulations implemented outside of Alaska that are designed to prevent overuse, misuse, abuse, and overdose of heroin and prescription drugs.

Sub-Activity Year 2 Progress:

As part of statewide strategic prevention plan, existing agency rules, policies, and regulations need to be evaluated to assure authority and direction are provided to agencies assigned administrative roles and that emerging issues and challenges can be met. With input from and direction provide by the AKPDOP advisory group, UAA-ISER will continue in-depth review of select policies as part of Alaska’s strategic planning initiative. UAA-ISER will complete its written annual report.

A draft of the Policy Review Gap Analysis report was completed and is waiting for comment from the Div. of Public Health (DPH) Director and Office of Substance Misuse and Addiction Prevention (OSMAP). The final report will be presented to the ICS team and AKPDOP (Opioid Workgroup).

Sub-Activity Year 3 Work Plan: By January 2019, the UAA - ISER will update the legislative index of statutes, regulations and policy and update the information for posting to the Opioid Work Group SharePoint site and other DHSS websites.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports a reimbursable service agreement to conduct the aforementioned activities.

Sub-Activity: PDMP Policy Assessments

Sub-Activity Description: By June 2018, UAA-ISER will complete its initial assessment of Alaska laws, policies, and regulations designed to prevent heroin and opioid overuse, misuse, abuse, and overdose and provide a presentation; evaluate level of knowledge and understanding of PDMP users and Board of Pharmacy Board members pertaining to the need for education and training initiatives such as academic detailing; and access to PDMP data by external agency; and written report on its finding to the AKDPOP advisory group and stakeholders, as well as to the boards and advisory councils identified in the assessment.

This activity spans across Year-1 and Year-2 of the activity.

Sub-Activity Start Date: September 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Following UAA-ISER completion an initial assessment of Alaska laws, policies, and regulations of PDMP laws and policies, a process evaluation of the PDMP will be conducted with the goals of supporting and enhancing PDMP use generally and ensuring PDMP data will be available and used for surveillance purposes and to inform responses to the prescription drug problem. UAA-ISER completed a series of key informant interviews. Questions included– 1. What are the facilitators and barriers to prescribers and their delegates using the PDMP? a. To what extent do prescribers consistently review patient prescription reports and upload prescription data in a timely manner? b. What changes would improve the PDMP? c. What challenges prevent regular use of the PDMP? 2. To what extent do PDMP users perceive that Alaska’s current PDMP legislation will reduce misuse, diversion and overdose? 3. What are the barriers and facilitators to using PDMP data for to inform surveillance and responses to the opioid problem?

Information collected is being analyzed and a final report will be provided to the AKPDOP (Opioid Workgroup) as well as the Div. of Public Health (DPH) Director and Office of Substance Misuse and Addiction Prevention (OSMAP).

Sub-Activity Year 2 Progress: To evaluate level of knowledge and understanding of PDMP users and the need for education and training initiatives such as academic detailing (Academic detailing as “university or non-commercial-based educational outreach,” UAA-ISER completed a series of key informant interviews. Questions included– 1. To what extent do PDMP users

(and/or other stakeholders) perceive that Alaska PDMP incorporates evidence-based practice and provides educational initiatives that support and promote PDMP use? 2. What are PDMP user's attitudes and beliefs regarding the use of PDMP data for active surveillance to support effective public health prevention and reduce prescription drug overdose? 3. To what extent do user of the PDMP have adequate training in opioid prescribing, pain management, screening for substance abuse, proper storage and disposal of prescription opioids? 4. What changes in knowledge, skills, and attitudes have occurred among PDMP users have resulted from education and training?

Information collected is being analyzed and a final report will be provided to the AKPDOP (Opioid Workgroup) as well as the Div. of Public Health (DPH) Director and Office of Substance Misuse and Addiction Prevention (OSMAP).

Sub-Activity Year 3 Work Plan: Activity is completed.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports a reimbursable service agreement to conduct the aforementioned activities.

Sub-Activity: CSA Policy Assessment

Sub-Activity Description: By August 2018, UAA-ISER will complete an evaluation of the Controlled Substances Act scheduling authority and process is proposed in order to determine whether the content of legislation and manner in which it has been implemented effectively protects Alaskans from novel psychoactive substances and analogues deemed to be dangerous; and provide a written report of its findings.

Sub-Activity Start Date: June 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Following UAA-ISER completion an initial assessment of Alaska laws, policies, and regulations of – CSA: Alaska statute § 11.71.100 establishes a Controlled Substances Advisory Committee in the Department of Law. The committee, according to § 11.71.110 shall (1) advise the governor of the need to add, delete, or reschedule substances in the schedules in AS 11.71.140 - 11.71.190 which cover scheduled drugs levels as outline in Federal law. The scheduling authority is outlined in § 11.71.120. AS § 11.71.120 indicates that the governor shall introduce legislation for scheduling substances in accordance with the recommendation of the committee to add, delete, or reschedule a substance. Additional authority to address Illicit Synthetic Drugs is addressed in § 17.21.010-§ 17.21.090; –an evaluation of the Controlled Substances Act scheduling authority and process was proposed in order to determine whether the content of legislation and manner in which it has been implemented effectively protects Alaskans from novel psychoactive substances and analogues deemed to be dangerous. Due to significant delays in approval of a reimbursable service

agreement with the University of Alaska Anchorage-Justice Center and discussions with the CDC Evaluation Program Officer, the Policy Review project timeline was pushed back 6 months.

Sub-Activity Year 2 Progress: To evaluate the Controlled Substances Act scheduling authority and process, UAA-ISER completed a series of key informant interviews. Questions included– 1. Does Alaska’s Controlled Substances Act provide an efficient and effective process for scheduling novel psychoactive substances and analogues? 2. What are the intended and unintended consequences of the current emergency scheduling process for novel psychoactive substance and/ analogues in Alaska?

Information collected is being analyzed and a final report will be provided to the AKPDOP (Opioid Workgroup) as well as the Div. of Public Health (DPH) Director and Office of Substance Misuse and Addiction Prevention (OSMAP).

Sub-Activity Year 3 Work Plan: By August 2019, UAA-ISER will complete and written report on– Liability waiver - Conduct a feasibility analysis of expanding liability waiver protection (AKA Good Samaritan statute) to include syringe and needle service or exchange programs. Evaluate policies designed to expand protection afforded through liability waivers that protect Good Samaritans not only from prosecution but also from arrest, violations of probation or parole, and violations of domestic violence protection orders; and Emergency scheduling - Evaluation of current policy and policy enhancements that provide for emergency scheduling of novel psychoactive substances (including synthetics, analogues, and designer drugs) through regulation or other more efficient means than statutory change in Alaska.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports a reimbursable service agreement to conduct the aforementioned activities.

Major Activity: Conduct a rigorous evaluation on a law, policy, or regulation designed to prevent opioid overuse, misuse, abuse, and overdose

Major Activity Summary: The purpose of the prescription drug monitoring (PDMP) database is to house data regarding every prescription for a federally scheduled substance (II, III, or IV) dispensed in the state to a person other than those administered to a patient at a health care facility. AS § 17.30.200 (d) 10 authorizes that the Pharmacy Board may allow Department of Health and Social Services (DHSS) access to de-identified PDMP data for the purpose of identifying and monitoring public health issues in the state. No MOU is currently in place to guarantee that PDMP data will be shared with DHSS or to specify a timeline and process for how the data may be shared.

AS § 17.30.200 (d) 11 k notes that pharmacy board regulations must ensure that PDMP data be purged from the PDMP database after two years from the date on which individual prescriptions are dispensed. Legislation does not specify whether any data provided to DHSS must also be periodically purged. Therefore, a process evaluation of the PDMP will be

conducted with the goals of supporting and enhancing PDMP use generally and ensuring PDMP data will be available and used for surveillance purposes and to inform responses to the prescription drug problem.

Major Activity Challenges: We also experienced a challenge to our plan to evaluate changes in knowledge and skill of PDMP users as a result of education and training efforts. Our evaluation plan involved conducting pre-tests of knowledge before education/training events and measuring change with post-tests following education/training events. The challenge we faced stems from the fact that Alaska's current efforts to educate and train PDMP users rely on conveying information via the website and by mailing information to licensees. An opportunity to measure change with pre and post tests may be available when a web-based continuing education course is launched. However, the launch is scheduled to take place in the fall of 2018 precluding our ability to collect and report on data in the second year of the grant as planned.

We experienced a challenge when attempting to evaluate the impact of the Good Samaritan statute objectively. Our evaluation strategy was to measure the extent to which Good Samaritans who call for help on behalf of someone who is overdosing are or are not prosecuted for drug crimes. The Anchorage Fire Department and the Anchorage Police Department, the two largest first responders in Alaska, do not keep records of the names of Good Samaritans. Without a list of Good Samaritans, it is impossible to pull Department of Law data documenting the existence or lack of prosecution for drug crimes. The absence of data on Good Samaritans was supported by a finding from our gap analysis that Alaska does not have a statute requiring the reporting of non-fatal opioid overdoses to the PDMP, state or local health department.

Comments

- Major Strengths:

- Major Weaknesses:

- Recommendations:
 - Consider evaluating knowledge of Good Samaritan laws, rather than the lack of prosecution of those who avail themselves of the laws.
 - Consider diversifying your sample of key informants based on the questions you have selected for them. Are BoP members the best to answer why PDMP use is not more widespread?

- Other Relevant Comments:
 - The PDMP training sub-activity seems better suited to another strategy, rather than the Policy Evaluation strategy.
 - Consider exploring unintended consequences of the regulation to purge PDMP data within 2 years of dispense date.
 - Are you still planning to explore law enforcement attitudes surrounding Good Samaritan laws, per the evaluation plan?

- Evaluation plan does not reflect all of the key policy evaluation questions listed here. Ensure that the evaluation plan is updated to align with work plan and progress reporting.

Sub-Activity: Process Evaluation of the AKPDMP

Sub-Activity Description: By June 2018, the Policy Project Lead will conduct an evaluation of the AKPDMP and provide a report of its findings to the PD, the Opioid Work Group and DHSS Medical Officer. Key interviews will be conducted among Board of Pharmacy members and other select persons. Questions to be posed are–

1. What are the facilitators and barriers to prescribers and their delegates using the PDMP?
 - a. To what extent do prescribers consistently review patient prescription reports and upload prescription data in a timely manner?
 - b. What changes would improve the PDMP?
 - c. What challenges prevent regular use of the PDMP?
2. To what extent do PDMP users perceive that Alaska’s current PDMP legislation will reduce misuse, diversion and overdose?
3. What are the barriers and facilitators to using PDMP data for to inform surveillance and responses to the opioid problem?

Sub-Activity Start Date: January 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity: Process Evaluation of Alaska CSA

Sub-Activity Description: By June 2018, the Policy Project Lead will conduct an evaluation of processes associated with the Alaska Controlled Substance Act (CSA) and provide a report of its findings to the PD, the Opioid Work Group and DHSS Medical Officer. Key interviews will be conducted among Alaska Controlled Substance Advisory Council members and other select persons. Questions to be posed are– 1. Does Alaska’s Controlled Substances Act provide an efficient and effective process for scheduling novel psychoactive substances and analogues? 2. What are the intended and unintended consequences of the current emergency scheduling process for novel psychoactive substance and/ analogues in Alaska?

Sub-Activity Start Date: January 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity: PDMP Training & Initiative Needs

Sub-Activity Description: By June 2018, the Policy Project Lead will conduct key informants interviews to evaluate the level of knowledge and understanding among PDMP users and their needs for education and training. A report of its findings will be provided to the PD, the Opioid Work Group and DHSS Medical Officer. Key interviews will be conducted among Board of Pharmacy members and other select persons. Questions to be posed are–

1. To what extent do PDMP users (and/or other stakeholders) perceive that Alaska PDMP incorporates evidence-based practice and provides educational initiatives that support and promote PDMP use?
2. What are PDMP user’s attitudes and beliefs regarding the use of PDMP data for active surveillance to support effective public health prevention and reduce prescription drug overdose?
3. To what extent do user of the PDMP have adequate training in opioid prescribing, pain management, screening for substance abuse, proper storage and disposal of prescription opioids?
4. What changes in knowledge, skills, and attitudes have occurred among PDMP users have resulted from education and training?

Sub-Activity Start Date: January 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity: Policy Evaluation of the Good Samaritan Act

Sub-Activity Description: By August 2018, the Policy Project Lead will initiate key informants interviews to evaluate the level of knowledge and understanding among PDMP users and their needs for education and training. A report of its findings will be provided to the PD, the Opioid Work Group and DHSS Medical Officer. Key interviews will be conducted among Board of Pharmacy members and other select persons. Questions proposed are–

1. To what extent are PDMP users, other stakeholders, and the public aware of the Alaska Good Samaritan statute?
2. To what extent do other laws impact law enforcement in compliance with the Good Samaritan statute?
3. Are there training needs or training improvement that could benefit law enforcement surrounding the Good Samaritan Statute?

Sub-Activity Start Date: June 2018

Sub-Activity End Date: August 2019

Sub-Activity Status: Planned

Sub-Activity Year 1 Progress: Not initiated in Year-1.

Sub-Activity Year 2 Progress: Not yet approved for initiation in Year-2.

Sub-Activity Year 3 Work Plan: By August 2018, the Policy Project Lead will initiate key informants interviews to evaluate the level of knowledge and understanding among PDMP users and their needs for education and training. A report of its findings will be provided to the PD, the Opioid Work Group and DHSS Medical Officer. Key interviews will be conducted among Board of Pharmacy members and other select persons. Questions proposed are–

1. To what extent are PDMP users, other stakeholders, and the public aware of the Alaska Good Samaritan statute?
2. To what extent do other laws impact law enforcement in compliance with the Good Samaritan statute?
3. Are there training needs or training improvement that could benefit law enforcement surrounding the Good Samaritan Statute?

Sub-Activity Funding Type: Base funds

Major Activity: Implement an RRP to advance an innovative prevention approach

Major Activity Summary: By September 31, 2018, the Education Coordinator will initiate the development of a Provider Education Campaign.

In conjunction with Year-1 key informant interview analysis findings concerning training and education needs and the completion of a separate AKPDMP prescriber survey on barriers and limitations to PDMP use, priority areas of improvement will be identified. The information will then be used to increase provider knowledge of pain management and alternative techniques that may be employed by current pain reliever prescribers and future clinicians. Information from this two-pronged approach in assessing needs, limitations, and barriers will assist the State with designing and implementing future improvements and improving the longevity and utility of the PDMP in Alaska to reduce behaviors associated with prescription drug overuse and abuse.

Major Activity Challenges: Challenges include recent legislative requirements for prescribers of controlled substances (i.e., 2-hour continuing education in opioids, pain management and addiction mandated at the time of license renewal). Licensing boards are currently (until July) developing regulation for the mandate. The regulation is scheduled to become effective in July 2018. Providers will need to respond to this mandate at the time of renewal and many licensees will be renewing between the months of September and December. This leaves limited time for the Education Coordinator to consider regulations while developing materials.

Comments

- Major Strengths:
- Major Weaknesses:

- Recommendations:
- Other Relevant Comments:
 - The description of this activity sounds similar to the PDMP training sub-activity above. Are they the same? If not, how are they different?

Sub-Activities

Sub-Activity: Development of Prescriber Education Materials/Media

Sub-Activity Description: By September 2017, the Education Coordinator will initiate exploration of CDC prescriber education materials, best practices by other states, and develop a potential program design for implementation in Year-3.

This activity includes, but not limited to, identifying training modules used by other states and nationally. Developing, implementing, and analyzing results from Survey Monkey queries to collect input from physicians, physician assistants, and nurse practitioners licensed in Alaska.

Sub-Activity Start Date: September 2017

Sub-Activity End Date: August 2018

Sub-Activity Status: In Progress

Sub-Activity Year 1 Progress: Data collection only. This Sub-Activity was consolidated with the PDMP Key Informant Interviews conducted at the end of Year-1 and again in Year-2.

Sub-Activity Year 2 Progress: Due to the lack of support to analyze the responses, a contractual agreement was established with UAA-ISER to complete the coding and analysis of the key informant interviews and provide a written report to the PD, the Strategic Plan Project Leader, Education Coordinator, the PDMP manager, and the Opioid Work Group. A preliminary report will be provided to the Education Coordinator and the newly hired Nurse Consultant who is tasked with development of a prescriber education campaign.

Sub-Activity Year 3 Work Plan: By September 2018, the Education Coordinator and Nurse Consultant/Subject Matter Expert will initiate implementation of CDC and state prescriber education materials, and further develop aspects of the provider education program potentially including elements of academic detailing and “hub and spoke” models for clinician-based prescriber education.

Sub-Activity Funding Type: Base funds

Sub-Activity Funding Description: Funding supports personnel assigned to develop this activity. In addition, supplemental funds, if approved, will be used to further develop materials not otherwise supported.

Planning Indicators

- **Other Relevant Comments:**

PfS Indicators

- Non-categorical PDMP indicators for 2017 are not completed. Please provide information justifying this.
- Indicator 23, 25, 26, and 27 are not completed and the notes fields do not contain an explanation. Please provide information justifying these blanks.
- The rate of MPE doubled in 2016 compared to 2014. Are there hypotheses about this trend?
- Encouraged indicators were not completed. Please provide information justifying this. The encouraged indicators are recommended for exploration and future reporting:
 - #1 “High-burden areas have been identified (yes or no)”
 - #5 “Number of academic detailing sessions” if considering this activity for PDMP outreach
 - Policy Evaluation: #21 “Increase in the number/percent of stakeholders aware of policy/law,” #24 “Description of policy’s implementation status,” #25 & 26, “Description of policy’s facilitators/barriers”
 - All indicators for the Rapid Response Project-#27-33 to describe the barriers, facilitators, unintended consequences and implementation of the proposed project.

Budget

Comments: The budget included the three separate components for Planning and Data, Prevention in Action and Supplemental activities. Total amount requested is \$1,350,000. However, in Grant Solutions, the total amount requested was only \$750,000. We will be recommending that the full amount be awarded (\$1,350,000).

All contractual elements are included and are in line with the requirements of the funding announcement.

X 

Yessenia Ibarra

May 23, 2018

From: [Hull-Jilly, Deborah C \(HSS\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: Strategy #4 for new OD2A grant
Date: Monday, February 25, 2019 4:38:11 PM
Attachments: [image001.png](#)
[image002.png](#)
Importance: High

Here is Strategy #4 is for the PDMP for the new grant application—

STRATEGY 4: Prescription Drug Monitoring Programs (Required)

Overview: PDMPs are databases that collect patient-specific prescription information at the point of dispensing. PDMPs continue to be validated as an effective strategy affecting prescribing behavior and improving opioid-related outcomes. PDMPs can inform clinical practice and protect patients at heightened risk of opioid misuse, abuse, and overdose. Robust PDMP implementation is associated with decreased opioid-related overdose deaths. In addition, PDMPs can be utilized as a public health surveillance tool and provide public health authorities with timely information that rapidly identifies “hot spots” or geographic areas with disproportionately higher rates of opioid prescribing and allow for targeted interventions such as academic detailing, or clinical training and outreach.

A primary purpose of this funding is to support recipients as they implement strategies to advance the development and expansion of existing PDMPs and increase their utilization as a public health surveillance tool and clinical decision-making tool. This funding seeks to leverage Federal funding to ensure that recipients scale up the use of PDMP data through interoperability. This funding also aims to incentivize and improve nationwide overdose tracking systems that will help resources to be rapidly deployed to hard-hit areas.

CDC recognizes that PDMPs operate differently from state to state, as each is operated under different purview and management. **Applicants who can demonstrate the ability to improve PDMP functionality as outlined below AND attain intra- and interstate interoperability will receive an additional \$215,000 per year in funding.**

TABLE 4.1: Prescription Drug Monitoring Programs funding activities (BASE)

Activities: applicants must select activities that demonstrate improved PDMP functionality to receive base funding.	Recommended Sub-activities: below CDC has listed some recommended sub-activities applicants can select to meet the PDMP functionality requirement. These sub-activities are not required; applicants can choose from the recommended activities or applicants can propose sub-activities that are not listed below if they improve PDMP functionality – please
	provide detail on how these actions support the strategy.
Universal use among providers within a state	Universal PDMP registration and use that includes a streamlined and simplified PDMP registration process. Other sub-activities as needed to advance universal use among providers.
Inclusion of more timely or real-time data contained within a PDMP	Improving PDMP infrastructure or information systems to support reduced data collection intervals. Developing and disseminating information or guidance to aid in reducing the PDMP data collection interval.

	Other sub-activities as needed to increase timely or real-time data.
Actively managing the PDMP in part by sending proactive (or unsolicited) reports to providers to inform prescribing	Designing, validating, or refining algorithms for identifying high-risk prescribing activity to use as a trigger for proactive reports.
	Improving PDMP infrastructure or information systems to support proactive reporting and data analysis, including enhancing reporting system to increase frequency and quality of reporting.
	Developing and disseminating information or guidance to aid in proactive reporting. (example guidance for opioid naïve patients, patients with overlapping opioids and benzodiazepines).
	Integrating CDC or state guideline-concordant tools such as cumulative morphine milligram equivalent (MME) calculations into patient PDMP reports.
	Incorporating prescriber notification of patient overdose deaths
	Other sub-activities as needed to reduce PDMP data collection interval.
Ensuring that PDMPs are easy to use and access by providers	Facilitate improved delegate access and training.
	Expand access to PDMPs via a health information exchange.
	Support PDMP training efforts in high-burden regions.
	Other actions as needed to make PDMPs easier to use and access.

In addition to the activities required in the base option, applicants may seek additional funds to make PDMP data more actionable both within and across states borders, **applicants should propose strategies that improve both intrastate interoperability and interstate interoperability.** Applicants are required to propose activities that:

- Integrate the PDMP with other health systems data
- Integrate across state lines/interstate interoperability

TABLE 4.2: Prescription Drug Monitoring Programs funding activities (ENHANCED)

Activities: applicants must select activities that demonstrate improved both intra- and interstate interoperability. Applicants must select at least 1 activity within each grouping in order to qualify for additional funding.	Recommended Sub-activities: below CDC has listed some recommended sub-activities applicants can select to meet the expanded funding requirements. These sub-activities are not required; applicants can choose from the recommended activities or applicants can propose sub-activities that are not listed below if they improve intra- and interstate interoperability – please provide detail on how these actions support the strategy.
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Integrate the PDMP with other health systems data	Integrate PDMP data with electronic health records (EHRs).
	Health Information Technology infrastructure data integration/Health Information Exchange (HIEs) integration.
	Other actions as needed to integrate PDMPs with other health systems data within the state.
Integrate across state lines/interstate interoperability	Facilitate electronic information sharing among states in compliance with the National Prescription Monitoring Information Exchange (PMIX) Architecture.
	Other actions as needed to integrate PDMPs across state lines/interstate interoperability.

Deborah

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The Only Federally Designated, Non-Proprietary, No-Cost Solution for Sharing PDMP Data Across State Lines and Integrating with Electronic Health Records, Pharmacy Management Systems, and Health Information Exchanges.

Improving Access to PDMP Data Nationwide

Access to comprehensive prescription drug information is an important part of combatting the national opioid epidemic. It is critically important that state Prescription Drug Monitoring Programs (PDMPs) are able to maintain ownership of their PDMP data and control over access to their PDMP data. As a non-proprietary, state-governed solution, RxCheck removes excessive financial and technological barriers to sharing interstate PDMP data with electronic health record systems, pharmacy management systems, and health information exchanges. The goal of RxCheck is to ensure that all healthcare providers and pharmacists can have streamlined access within their existing workflows to comprehensive prescription data from any state PDMP.

Proven Success

RxCheck is a proven and reliable solution for interstate data sharing and integration. Several states are actively sharing data using RxCheck, and in 2018, Kentucky used RxCheck to integrate with Owensboro Health, which is averaging 55,000 queries per month with an average RxCheck response time of one second.

“Our decision to go with RxCheck was simple,” explained Dr. David Danhauer, System Vice President and Chief Medical Information Officer at Owensboro Health. “Minimal costs! Our true value is the seamless integration and immediate access to critical PDMP data at the point of care.”

How Does RxCheck Compare?

	RxCheck	PMP InterConnect & PMP Gateway
Cost	<p>RxCheck imposes no fees for interstate sharing and the ability to integrate PDMP data with EHRs, pharmacy management systems, and HIEs. No strings attached. No fees for states or their users.</p> <p>PDMP data is not treated as a commodity. Each state maintains ownership and complete control over access to their PDMP data.</p>	<p>Interstate sharing is offered at no cost, with the caveat that any integration utilizing PMP InterConnect must use a costly proprietary solution.</p> <p>Granting EHRs access to PDMP data comes with subscription fees that cost some states millions of dollars per year.</p>
Control	<p>RxCheck is governed by participating states. Accordingly, it is specifically designed and continually updated to meet the states needs to ensure the best and most effective routes for PDMP data delivery.</p>	<p>The National Association of Boards of Pharmacy (NABP) controls the PMP InterConnect hub and a for-profit company controls the integration product.</p>
Integration of data	<p>RxCheck offers true and seamless integration of PDMP data into patients’ medical records. Where allowable under state law the data can be retained by healthcare organizations to review and conduct quality improvement processes to ensure prescribing best practices are being implemented and adopted in their facilities. No additional vendor cost.</p>	<p>Does not integrate PDMP data with patients’ medical records. Instead, data is presented using HTML, often in a pop-up window.</p>

	RxCheck	PMP InterConnect & PMP Gateway
Security	RxCheck offers end-to-end security of protected health information (PHI) and personally identifiable information (PII).	The integration product unencrypts and translates the data, meaning there is no end-to-end security of sensitive PDMP data.
Audit Trail	RxCheck provides a comprehensive audit trail, including requestor identification and organization information.	PMP InterConnect does not collect or provide an audit trail with requestor identification or organization information.

State Participation

As of March 2019, 4 states are connected, and 22 states are in the process of connecting to RxCheck. A map of the RxCheck member states and their connection status can be found at www.rx-check.org.

Certain grants from the Bureau of Justice Assistance (BJA) and the Centers for Disease Control (CDC) require state PDMPs to connect to the RxCheck hub. The RxCheck connection supports other state partners who choose to share data via RxCheck, however each state maintains full control on how they choose to request interstate data sharing, who they share with, and how they integrate with electronic health record systems, pharmacy management systems and health information exchanges.

States have installed and configured a connection to
RxCheck in as quickly as one day.

Connecting to the RxCheck hub is straightforward process with no fees for connection and use. Grant funding is available to cover fees that may be imposed by a PDMP system vendor.

Protection from Information Blocking

RxCheck protects states from existing or potential PDMP information blocking by bypassing unreasonable financial and technological barriers that slow down the progress of integrating interstate PDMP data with electronic health record systems, pharmacy management systems, and health information exchanges.

According to the Office of the National Coordinator for Health Information Technology (ONC), information blocking occurs when a person or entity, such as an IT vendor, knowingly and unreasonably interferes with the exchange and use of electronic health information, which is a right protected by the Health Insurance Portability and Accountability Act (HIPAA) of 1996.

Examples of information blocking:

- Fees that make data exchange cost prohibitive.
- Organizational policies or contract terms that prevent sharing information with patients or health care providers.
- Technology designed or implemented in non-standard ways that inhibit the exchange of information.
- Patients or health care providers becoming “locked in” to a specific technology or health care network because data is not portable.

More information about information blocking can be found at www.healthit.gov/topic/information-blocking.

More Information

For additional information on the RxCheck Governance Board, please visit www.rx-check.org. For detailed information on connecting to RxCheck, including frequently asked questions, technical specifications, and screenshots of the RxCheck console, please visit <https://coapresources.org/pdmp/RxCheck>.



MEMORANDUM

DATE: May 21, 2019
TO: Alaska Board of Pharmacy
THROUGH: Sonia Lipker, Senior Investigator
FROM: Brian Howes, Investigator
RE: Investigative Report for the Board of Pharmacy / June 6-7, 2019 Meeting

The following information was compiled as an investigative report to the Board of Pharmacy for the period of March 5 – May 21, 2019. This report includes all investigations, complaints, and intake matters handled since the last report. The Division opened nine (9) matters and closed twenty-nine (29) matters. Eleven (11) matters remains on going and/or under active investigation.

Matters opened by the Paralegal in Juneau, regarding continuing education audits and license action resulting from those matters are not covered in this report.

OPEN – 10

<u>Case #</u>	<u>Case Status</u>	<u>Profession</u>	<u>Violation</u>	<u>Date</u>
2017-000945	Complaint	OUT OF STATE PHARMACY	Fraud or misrepresentation	09/06/17
2018-001285	Complaint	PHARMACY	Negligence	10/31/18
2019-000048	Complaint	OUT OF STATE PHARMACY	Violation of licensing regulation	01/14/19
2019-000126	Complaint	PHARMACIST	Unprofessional conduct	03/18/19
2019-000253	Complaint	OUT OF STATE PHARMACY	Violation of licensing regulation	04/23/19
2018-000795	Investigation	OUT OF STATE PHARMACY	Unlicensed practice or activity	12/27/18
2018-001258	Investigation	PHARMACIST	Drug diversion	12/27/18
2018-001271	Investigation	OUT OF STATE PHARMACY	Falsified application	04/11/19
2019-000001	Investigation	OUT OF STATE PHARMACY	Falsified application	02/28/19
2019-000214	Investigation	OUT OF STATE PHARMACY	Violation of licensing regulation	04/22/19

Probation – 1

2017-000167	Jamie Wakefield Pharmacy Technician	Out of Compliance	(06/13/2017)
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Closed - 29

<u>Case #</u>	<u>Case Status</u>	<u>Profession</u>	<u>Violation Type</u>	<u>Date</u>	<u>Closure</u>
2018-000623	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense

<u>Case #</u>	<u>Case Status</u>	<u>Profession</u>	<u>Violation Type</u>	<u>Date</u>	<u>Closure</u>
2018-000624	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000625	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000627	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000633	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000839	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000840	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000841	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000846	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000850	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-000993	Closed-Intake	PHARMACY TECHNICIAN	License application problem	03/14/19	Review Complete
2018-001016	Closed-Intake	PHARMACIST	Violation of licensing regulation	03/12/19	No Action - Minor Offense
2018-001316	Closed-Intake	PHARMACIST	Unprofessional conduct	04/17/19	Incomplete Complaint
2019-000099	Closed-Intake	PHARMACY	Standard of care	03/29/19	Incomplete Complaint
2019-000100	Closed-Intake	PHARMACY	Standard of care	03/12/19	Incomplete Complaint
2019-000149	Closed-Intake	RETAIL PHARMACY	Unprofessional conduct	03/12/19	Incomplete Complaint
2019-000157	Closed-Intake	PHARMACIST	Unprofessional conduct	03/14/19	Incomplete Complaint
2019-000164	Closed-Intake	PHARMACY	Unprofessional conduct	03/14/19	Incomplete Complaint
2019-000213	Closed-Intake	PHARMACIST	Unprofessional conduct	03/29/19	Incomplete Complaint
2019-000301	Closed-Intake	PHARMACY	Violation of licensing regulation	04/24/19	Incomplete Complaint
2019-000333	Closed-Intake	PHARMACY	Unprofessional conduct	05/08/19	Incomplete Complaint
2019-000340	Closed-Intake	PHARMACIST	Unprofessional conduct	05/08/19	Incomplete Complaint
2019-000367	Closed-Intake	PHARMACY	Unprofessional conduct	05/15/19	Incomplete Complaint
2019-000385	Closed-Intake	PHARMACY	Unprofessional conduct	05/15/19	Incomplete Complaint
2019-000386	Closed-Intake	PHARMACIST	Standard of care	05/15/19	Incomplete Complaint
2018-000213	Closed-Complaint	PHARMACIST	Unprofessional conduct	03/13/19	License Lapsed - Flagged Do Not Renew
2019-000062	Closed-Complaint	PHARMACIST	Unprofessional conduct	04/05/19	No Action - No Violation

<u>Case #</u>	<u>Case Status</u>	<u>Profession</u>	<u>Violation Type</u>	<u>Date</u>	<u>Closure</u>
2018-000963	Closed- Investigation	PHARMACY	Contested license denial	04/23/19	Other (See Abstract)
2019-000186	Closed- Investigation	PHARMACIST	Criminal action - conviction	03/14/19	License Action

-End of Report-



MEMORANDUM

DATE: October 31, 2019
 TO: Board of Pharmacy
 THRU: Greg Francois, Chief Investigator
 FROM: Carl Jacobs, Investigator *CJ*
 RE: Investigative Report for the November 14, 2019 Meeting

The following information was compiled as an investigative report to the Board for the period of May 22, 2019 thru October 30, 2019; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegal in Juneau, regarding continuing education audits and license action resulting from those matters are not covered in this report.

OPEN - 15

<u>Case Number</u>	<u>Violation Type</u>	<u>Case Status</u>	<u>Status Date</u>
OUT OF STATE PHARMACY			
2017-000945	Fraud or misrepresentation	Complaint	09/06/17
2019-000048	Violation of licensing regulation	Complaint	01/14/19
2019-000253	Violation of licensing regulation	Complaint	04/23/19
2018-000795	Unlicensed practice or activity	Investigation	12/27/18
2018-001271	Falsified application	Investigation	04/11/19
PHARMACIST			
2019-001186	Unprofessional conduct	Intake	10/11/19
PHARMACY			
2019-001148	Incompetence	Intake	10/08/19

2018-001285	Negligence	Complaint	10/31/18
2019-000535	Violation of licensing regulation	Complaint	06/11/19
2019-000721	Violation of licensing regulation	Complaint	07/23/19
2019-000988	Negligence	Complaint	09/18/19

PHARMACY TECHNICIAN

2019-000739	Unethical conduct	Intake	07/26/19
2019-000771	Violation of board order	Intake	08/07/19
2019-000936	License application problem	Intake	08/30/19
2019-000720	Negligence	Complaint	08/22/19

Closed - 9

<u>Case #</u>	<u>Violation Type</u>	<u>Case Status</u>	<u>Closed</u>	<u>Closure</u>
OUT OF STATE PHARMACY				
2019-000001	Falsified application	Closed-Investigation	08/27/19	Application Withdrawn
2019-000214	Violation of licensing regulation	Closed-Investigation	09/27/19	Advisement Letter
PHARMACIST				
2019-000680	Standard of care	Closed-Intake	09/11/19	Incomplete Complaint
2019-000899	License application problem	Closed-Intake	10/04/19	Review Complete
2019-001178	Action in another state	Closed-Intake	10/15/19	Review Complete
2019-000126	Unprofessional conduct	Closed-Complaint	09/23/19	No Action - No Violation
2018-001258	Drug diversion	Closed-Investigation	07/26/19	License Action
PHARMACY				
2019-000719	Unprofessional conduct	Closed-Intake	09/11/19	Incomplete Complaint
2019-000728	Incompetence	Closed-Intake	09/11/19	Incomplete Complaint

END OF REPORT



NABP

National Association of
Boards of Pharmacy

NABP – Programs and Services Review

Alaska Board of Pharmacy

November 14, 2019

Bill Cover, RPh

Member Relations and Government Affairs Director



NABP

National Association of
Boards of Pharmacy

NABP Clearinghouse

- National database of educational, licensure, and disciplinary information on pharmacists practicing in member states
- In addition, Houses information reported by boards on actions against:
 - Wholesale distributors
 - Pharmacies
 - Pharmacy Owners
 - Technicians
 - Interns
 - Manufacturers
 - Controlled Substance Licenses
- Mandated by NABP Constitution and Bylaws
 - Utilize to process requests for license transfer
 - Submit licensure and disciplinary information





NABP

National Association of
Boards of Pharmacy

NABP Clearinghouse, Continued

- Vital component of the pharmacist licensure transfer process or the NABP e-LTP®
- Accessible to board staff via NABP e-Profile Connect portal
- Licenses in multiple states
 - Each board where the individual or facility is licensed will receive information via the e-Profile Alerts section of the Clearinghouse about actions taken by any of the other boards
- Reporting is efficient using the e-Profile Connect portal
- NABP can act as agent in reporting discipline to NPDB
 - NPDB reporting is required under federal law
 - One step reporting on eProfile Connect portal to NABP and NPDB
 - 33 states have NABP designated as their reporting agent

How to Authorize NABP as the Reporting Agent

- Complete the NABP Letter of Agreement and return it to NABP.
- Go to the NPDB website and [register your organization](#), if it is not already registered.
- Visit the [How to Designate an Authorized Agent](#) page on the NPDB for instructions on how to make NABP your reporting agent. When filling out the form, you will need the following information for NABP.
 - Data Bank Identification Number: 1955
 - Agent Organization Name: National Association of Boards of Pharmacy
 - City: Mount Prospect
 - State: Illinois
 - ZIP Code: 60056
- After NABP receives your signed Letter of Agreement and accepts the NPDB agent registration form, the Association can begin submitting information to NPDB on your board's behalf.



DMEPOS

Durable Medical Equipment, Prosthetics, Orthotics and Supplies Accreditation Program

- Program approved by CMS and Launched in 2006
- Ensures Medicare beneficiaries receive the appropriate products, services and patient care related to DMPOS products
- Cost effective program

DMEPOS Standards

- Focused on ensuring Medicare patients are receiving the appropriate products, services and patient care

DMEPOS Accreditation Standards:

- Facility and key personnel licensure
- Organizational and administrative structure
- Fiscal and human resources management
- Product safety, vendor and product authentication
- Procurement and inventory
- Information management
- Compliance and performance management
- Intake and assessment/delivery and set-up
- Beneficiary and/or caregiver services and follow-up

DMEPOS Products Approved for Accreditation by NABP

- Blood Glucose Monitors and Supplies
- Breast Prostheses and Accessories
- Canes and Crutches
- Commodes/Urinals/Bedpans
- Continuous Positive Airway Pressure (CPAP) Devices and/or Supplies
- Diabetic Shoes/Inserts
- Enteral Nutrients, equipment and supplies
- External Infusion Pumps
- Heat & Cold Applications
- Insulin Infusion Pumps and Supplies
- Nebulizer Equipment and Supplies
- Orthotics
- Ostomy Supplies
- Parenteral Nutrients, Equipment and Supplies
- Respiratory Assist Devices
- Seat Lift Mechanisms
- Surgical Dressings
- Urological Supplies
- Walkers



DMEPOS- Process

- **Policy and Procedures Review:**
 - NABP will send a Policy & Procedure Assessment to help you prepare and organize the required documentation.
 - NABP will review the materials to confirm compliance with both the NABP program standards and the CMS Quality Standards.
- **Licensure Verification:**
 - NABP will review and verify that relevant licenses held by the pharmacy and pharmacist-in-charge are current and active.
- **Unannounced On-Site Survey:**
 - An NABP surveyor will conduct an unannounced inspection to confirm the submitted policies and procedures are in place and evident in the day-to-day operation of the pharmacy.
 - CMS requires that surveys are unannounced.

DMEPOS Single Pharmacy Accreditation Fees

Application Fee: \$1,250
NABP Survey Fee: \$1,500
NABP Survey Travel Fee: \$500
Participation Fee (Year 1): \$125
Year 1 Subtotal: \$3,375
Annual Participation Fee Year 2: \$125
Annual Participation Fee Year 3: \$125

**Estimated Total for three-year
accreditation*: \$3,625**

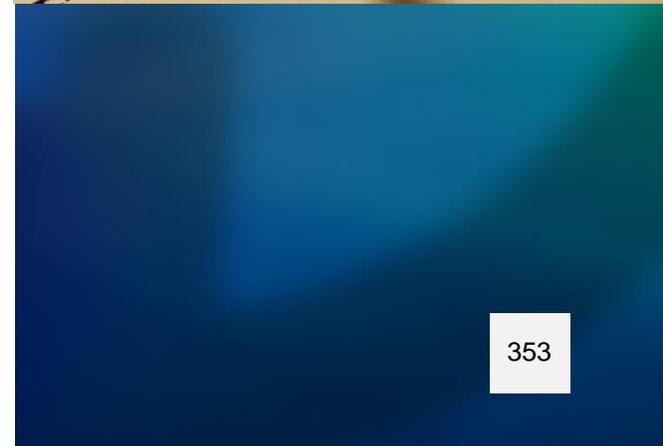


NABP

National Association of
Boards of Pharmacy

Pre-NAPLEX

- Prepares the applicant for the NAPLEX test experience
 - Content corresponds to the NAPLEX Competency Statements
- Available for on-line internet completion
- 100 questions in 140 minute session
- Can take the exam twice only
- Register for exam by logging into NABP eProfile account
- Seven days to take exam after registration
- \$65 fee per testing session





NABP

National Association of
Boards of Pharmacy

VIPPS

- Verified Internet Pharmacy Practice Sites Accreditation
- Launched in 1999 to provide patients with a resource for safe online pharmacy sites
- 95% of pharmacy websites are out of compliance with US laws
- Requires website verification via the NABP .pharmacy program
- Must demonstrate compliance with resident and nonresident state laws for states to which it dispenses prescription drugs
- Applicant must also demonstrate compliance related to:
 - Patient privacy
 - Security of prescription orders
 - Quality assurance policies
 - Consultation between pharmacists and patients
- Requires an on-site inspection



VIPPS

- **Independent Community-Based Pharmacy**

- A pharmacy with three or fewer stores, only licensed and doing business in its home state, receiving or facilitating orders to purchase prescription drugs over the internet from patients located in the home state
- Total Application Fee = \$6,000
 - ✓ \$3,000 application fee
 - ✓ \$3,000 survey fee

- **Chain Drugstore, Mass Retailer, HMO Pharmacy, PBM Pharmacy**

- A pharmacy licensed in more than three states, receiving or facilitating orders to purchase prescription drugs over the internet from patients in only those states in which the pharmacy is licensed
- Total Application Fee = \$8,000
 - ✓ \$5,000 application fee
 - ✓ \$3,000 survey fee

- **Independent Pharmacy**

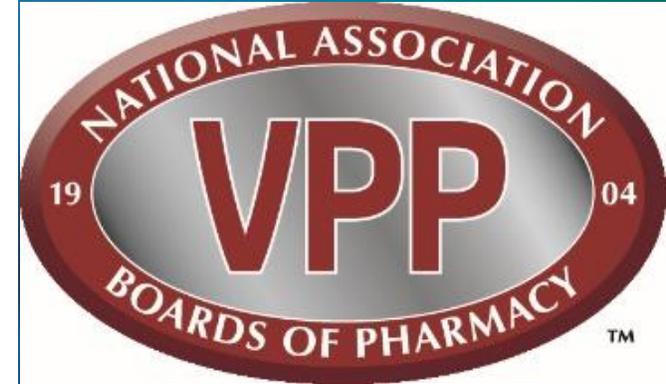
- A pharmacy with an internet practice that is limited to one to three states (states doing business in/shipping into one to three pharmacy licenses), receiving or facilitating orders to purchase prescription drugs over the internet from patients located in only the three licensed states.
- Total Application Fee = \$5,000
 - ✓ \$2,000 application fee
 - ✓ \$3,000 survey fee





Verified Pharmacy Program

- Developed to fill the gaps in the nonresident pharmacy system and provide states complete information needed to make licensing decisions
- Extrapolate the successes of the Electronic Licensure Transfer Program[®] for pharmacists and apply it to facilities that want to operate in multiple states
- Create an NABP e-Profile for each pharmacy and link to e-Profiles for key pharmacy personnel
- Create an inspection clearinghouse to facilitate the sharing of inspection reports/results



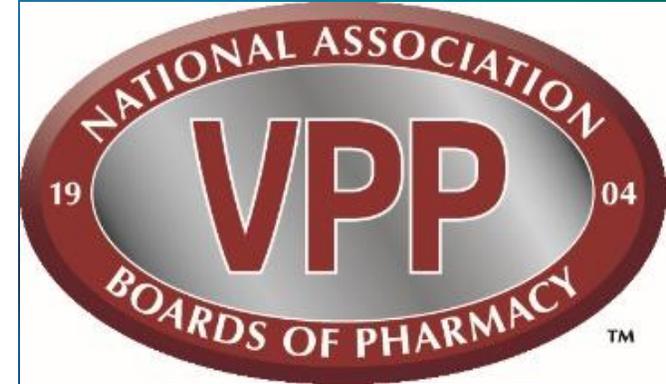


NABP

National Association of
Boards of Pharmacy

Verified Pharmacy Program

- Verify pharmacy licenses (resident/non-resident)
- Verify pharmacist-in-charge (PIC) licenses
- Verify that a qualified inspection has occurred, either by the resident state in accordance with the established uniform standards, or by NABP
- Report any disciplinary action by another state
- Perform on-site inspection, if required
- All information will be packaged through VPP
 - accessible on Board e-Profile Connect interface



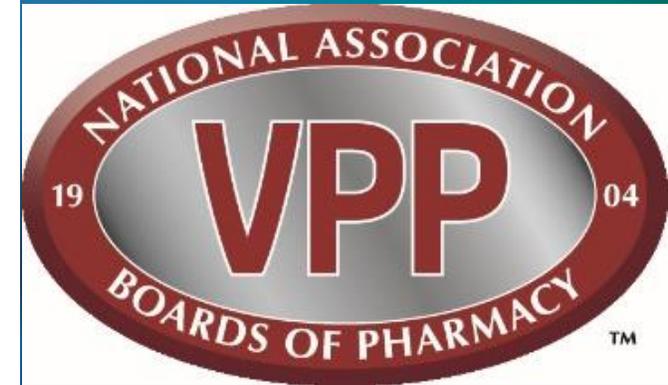


NABP

National Association of
Boards of Pharmacy

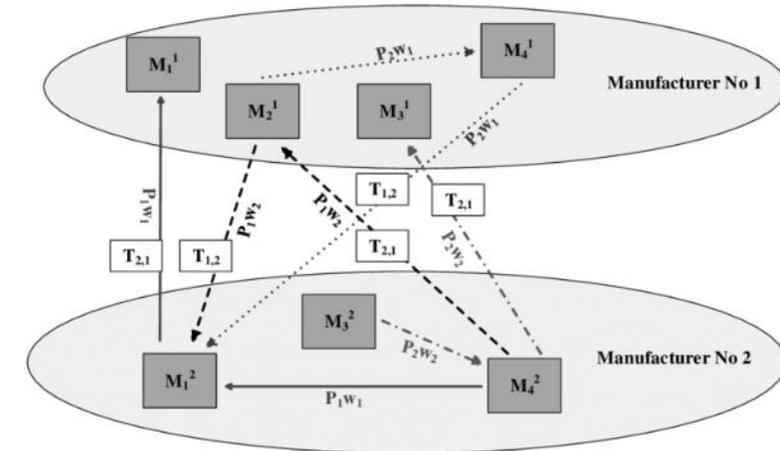
VPP Utilization by States

- 48 states utilize VPP in some manner
- Required by Michigan for all non-resident sterile compounding pharmacies. NABP is an approved inspection entity for all in-state MI sterile compounding pharmacies
- Required by Virginia for non-resident sterile compounding pharmacies, if resident state inspection can not show compliance with USP Chapter 797
- Utah requires a VPP inspection or resident board inspection to blueprint standards for all non-resident compounding pharmacies within 2 years of application.
- NABP is an approved inspection entity by regulation or policy in CO, IA, FL, KS, LA, NC, ND, OH, PA, TX, and WA



“Virtuals”

- Definitions:
 - **Virtual Wholesaler**- means a person who facilitates or brokers the transfer of drugs, devices or cosmetics without taking physical possession of the drugs, devices or cosmetics.
 - **Virtual Manufacturer**- means a person that owns the new drug application or abbreviated new drug application for a drug or device and which contracts with others for the actual manufacturing of the drug or device.
- Pro’s:
 - High utilization of third party logistics providers which creates the efficient movement of prescription drugs across the drug supply chain
- Con’s:
 - Numerous examples of “virtuals” that operate in a residence. This causes issue with compliance and record keeping inspections
 - Complicated business models that provide large separation between title holder and entity that either distributes or manufactures the drug can open up opportunities for counterfeit product to be introduced into the drug supply chain



NABP Services for Distributors

- Accreditation
 - Verified Accredited Wholesale Distributor (VAWD)
 - Criteria is Compliant with Federal Law (DSCSA) after updates in 2014
- Wholesale Distributor Inspection (WDI) Program:
 - Uniform DSCSA compliance assessment of wholesale distributors
 - Protection of citizens against the ongoing threats to our nation's drug supply



NABP Services for Distributors

- Accreditations and Inspections available for States and Facilities:
 - Wholesale Distributors (including Virtual)
 - Reverse Distributors
 - Third Party Logistics Providers (3PLs)
 - Manufacturers
 - Repackagers
 - 503B (Outsourcer Facilities)



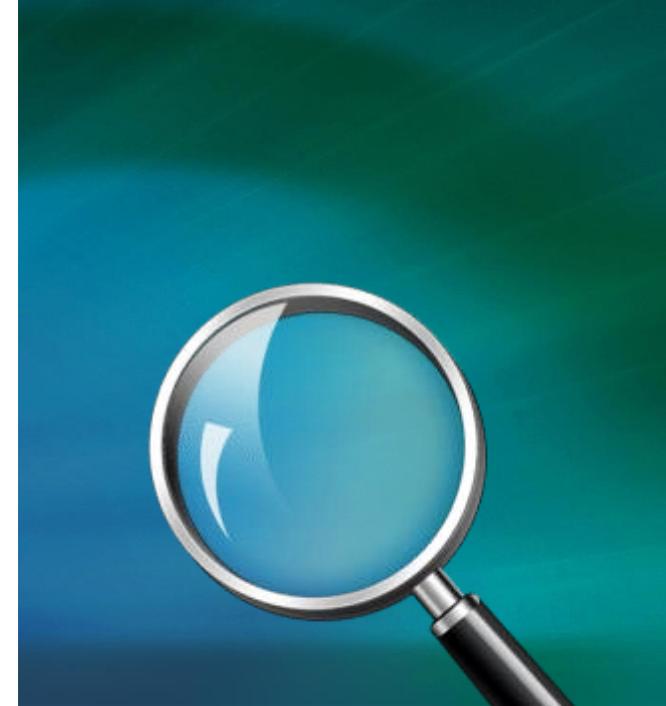
Accreditation – VAWD®

- Launched 2005, almost 15 years ago, to assist States with combating proliferation of counterfeit drugs
- Covers prescription drugs and devices
- 640+ Accredited Facilities
- Located in 46 States and 1 Territory
- 24 States recognize VAWD
- Time to Accreditation based on preparedness of applicant and willingness to comply with law and criteria.
 - In general 6 – 9 months but as little as 2 – 3 when prepared



Wholesale Distributor Inspection (WDI) Program

- Launched Fall 2019
- Based on NABP's long established expertise and experience in protecting the nation's drug supply through its Accreditation of Wholesale Distributors
- Inspection Focus adopted from VAWD (see comparison)
- Snapshot of Wholesaler's operation at a point in time



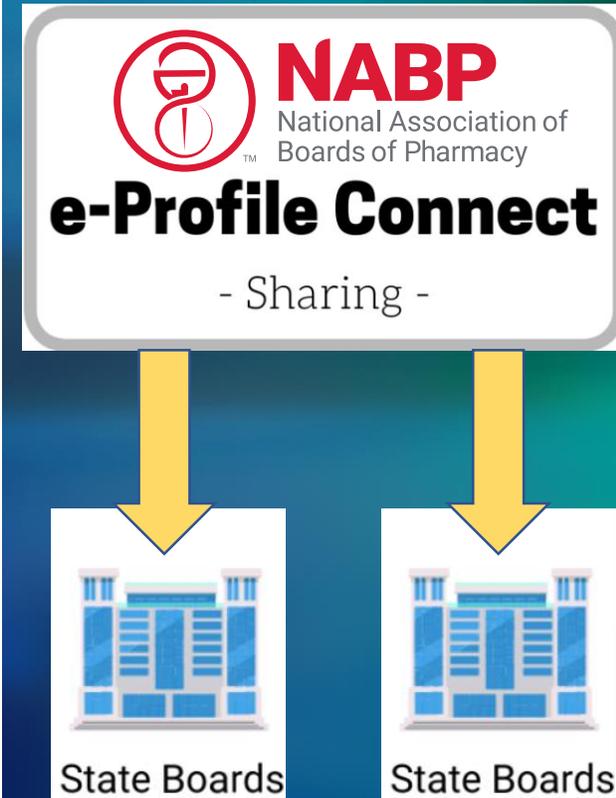
Wholesale Distributor Inspection (WDI) Program

- Similar to VPP
- WD applies for an inspection
 - Pays fee;
 - Completes application;
 - Submits required documents
 - Agrees to Terms and Conditions:
 - Including that results will be shared with state boards of pharmacy and federal regulators
- Once the application is complete, NABP conducts an unannounced inspection within 8 weeks



Benefits of Inspection Program

- **e-Profile Access**
 - Inspection sharing across states
 - Aids boards of pharmacy in making informed licensure decisions
- **Inspection Services**
 - Uniform inspection program – Distributors
 - Determine compliance with DSCSA, State licensing requirements
 - Personalized state inspection projects





NABP

National Association of
Boards of Pharmacy

Facility e-Profile: License Dashboard

Facility e-Profile: Overview

NABP

Applications Facility License Review

DOM SMOKE TEST FACILITY LBN | e-Profile ID: 1374775 [Click Here to Change Facility](#)

- ✓ Facility Info
- ✓ Contacts
- ✓ Ownership
- ✓ Facility Licenses
- ✓ Staff Licenses
- ✓ Disciplinary Questions
- ✓ Application Questions
- ✓ Choose Programs
- ✓ Program Questions
- ✓ Review

Add Facility License Edit

Please include all applicable licenses/permits/registrations associated with your facility, including, but not limited to, any pending, closed, inactive, and active licenses held by the business entity; any licenses issued to any other entity located at the same address; all nonresident licenses, state controlled substance licenses, DEA registration, sterile compounding licenses, outsourcing licenses, nuclear/radiopharmaceutical licenses, wholesale distribution, etc.

To upload multiple licenses at once, download the [Template.csv](#) file and fill it according to the instructions provided in [Instructions.pdf](#). Click on [Import CSV](#) to select the file, then click on [Verify & Submit](#)

[Template.csv](#)
[Instructions.pdf](#)
[Import CSV](#)
[Verify & Submit](#)

[Export to CSV](#)

Sel...	State/Ag...	License Type	License Number	Expiration Date	PIC e-Profile ID	PIC Hour...	Status
<input type="checkbox"/>	IL	Pharmacy			No PIC Associated		Not Licensed
<input type="checkbox"/>	AL	Pharmacy	114444	12/31/2040	No PIC Associated		Active/Good Stan...
<input type="checkbox"/>	NV	Pharmacy	PH03142	10/31/2020	No PIC Associated		Active/Good Stan...
<input type="checkbox"/>	NJ	Non-Resident Pharmacy	28RO00090200	06/30/2019	No PIC Associated		Active/Good Stan...
<input type="checkbox"/>	NM	Non-Resident Pharmacy	PH00004236	12/31/2019	No PIC Associated		Active/Good Stan...
<input type="checkbox"/>	NY	Non-Resident Pharmacy	32425	10/31/2019	No PIC Associated		Active/Good Stan...
<input type="checkbox"/>	ND	Non-Resident Pharmacy	Phar1342	06/30/2019	No PIC Associated		Active/Good Stan...



NABP

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Boards of Pharmacy

Facility e-Profile: License Dashboard

Facility
e-Profile:
Overview

Facility Information Review

e-Profile ID: 1374775

[Click Here to Change Facility](#)

Details **Business Information** Business Questions Activities Inspection History Accreditation History Disciplinary Action

Business Hours (required)*

[Edit](#)

Day	Timings
Sunday	Open 24 Hours
Monday	Open 24 Hours
Tuesday	Open 24 Hours
Wednesday	Open 24 Hours
Thursday	Open 24 Hours
Friday	Open 24 Hours
Saturday	Open 24 Hours

Schematic Diagram (required)*

Select document and click the upload arrow

[Add File\(s\)](#)



Store Front (required)*

Select document and click the upload arrow

[Add File\(s\)](#)



Blackout Dates

Count: 0 | Max: 20

[Add](#)

Please select the dates which your facility is unavailable for inspection for any reason

NABP Surveyors

- There are currently 50+ surveyors located in 24 states
- Our staff and surveyor and document reviewers' backgrounds include:
 - Distribution Managers for Major Manufacturers and Wholesale Distributors
 - Wholesale drug distribution and supply chain integrity experts
 - Boards of pharmacy and Distributor Regulation Officials - executive officers, board members, compliance officers, and inspectors (current / retired)
 - Community pharmacy, hospital pharmacy, sterile compounding, nuclear pharmacy, home infusion
 - Law enforcement, regulatory compliance, Federal Bureau of Investigations, Drug Enforcement Administration, FDA-OCI, Secret Service, and Internal Revenue Service, including undercover work and criminal investigations for these agencies
 - Military, Department of Health and Human Services, Medicare fraud, and prescription monitoring programming





VAWD Accreditation vs. Wholesale Distributor Inspection Comparison

Focus Item	VAWD Accreditation	Distributor Inspection
Application submitted to NABP with fee	YES	YES
Supplemental documents submitted to NABP	YES	YES
• Policy and Procedures Submitted	YES	NO
• Policy and Procedures Reviewed and Remediated	YES	N/A
• Drug Source list submitted and examined closely	YES	YES
• Records may be requested from Drug Source list	YES	Reviewed onsite
• License/Registrations verified	YES	YES
• Attestation of Compliance with VAWD Criteria	YES	NO



VAWD Accreditation vs. Wholesale Distributor Inspection Comparison

Focus Item	VAWD Accreditation	Distributor Inspection
Time from Application to survey/inspection	Varies / 4-5 m	< 90 days
Onsite Survey / Inspection	YES	YES
Survey/Inspection scheduled	YES	NO
Post-Survey / Inspection Remediation	YES	NO
Yearly information update and document submission	YES	NO
Survey/inspection documents available to State	NO	YES

Questions?

Disciplinary Clearinghouse and NPDB Reporting

Instituted more than 50 years ago, and computerized in 1984, the NABP Disciplinary Clearinghouse database was created to assist the boards of pharmacy in making informed licensure-transfer decisions.

- The Clearinghouse:
 - is a national database of educational, competence, licensure, and disciplinary information on pharmacists practicing in NABP's member states and jurisdictions;
 - also houses information reported by the member boards of pharmacy on actions taken against wholesale distributors, pharmacies, pharmacy owners, pharmacy technicians, interns, and those holding controlled substance licenses; and
 - assists the state boards in assessing the acceptability and qualifications of candidates requesting the transfer of pharmacist licenses into their jurisdiction.
- Accurate and timely reporting to the NABP Clearinghouse by the state boards:
 - is essential to maintaining the integrity of the licensure transfer process among the states;
 - is required by the NABP Constitution and Bylaws; and
 - allows the boards to maintain the integrity of patient safety as a whole.
- Timely reporting to the NABP Clearinghouse allows the state boards to meet their National Practitioner Data Bank (NPDB) reporting obligations:
 - NPDB is an alert or flagging system intended to facilitate a comprehensive review of the pharmacist's professional credentials.
 - 33 state boards designate NABP as their reporting agent for purposes of reporting final adverse actions on pharmacists to NPDB.
- For state boards that have designated NABP as their reporting agent for NPDB:
 - The board reports disciplinary actions to NABP electronically
 - NABP transmits all records to NPDB for the board and provides regular feedback
 - NABP completes all audit requests initiated by NPDB
 - One-spot processing for the boards as they do not have to report separately to NPDB and NABP
- For the purposes of maintaining the Clearinghouse, state boards that have not designated NABP as their reporting agent for NPDB must still report disciplinary actions to NABP, and are responsible for reporting to NPDB on their own.
- Reporting initial disciplinary actions and follow-up actions is pivotal to maintaining accurate information about the current status of the subjects it describes.
- All boards whose licensees have been disciplined will receive a real-time alert via the NABP e-Profile alerts. Reports include:
 - State of discipline
 - Pharmacist demographics
 - The disciplinary action
 - Basis for the discipline
 - Duration of the action

DMEPOS Accreditation Program

Launched in 2006, the NABP durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program, approved by the Centers for Medicare and Medicaid Services (CMS), is the cost-effective and reliable choice for pharmacies seeking DMEPOS accreditation. In an effort to further its mission to protect the public health, NABP sought and was approved by CMS to accredit licensed pharmacies supplying DMEPOS products.



During the DMEPOS accreditation process, NABP will:

- verify pharmacy licensure;
- screen the NABP Disciplinary Clearinghouse;
- review supplemental documents and policies and procedures; and
- perform unannounced on-site surveys.

Pharmacies accredited through the NABP DMEPOS program:

- help to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS products; and
- position themselves to be able to participate in the CMS competitive bidding process.

Products for Approval

NABP is approved to accredit suppliers of the following DMEPOS products:

- Diabetic equipment and supplies
- Enteral and parenteral nutrients, equipment, and supplies
- Off-the-shelf, non-custom products and supplies
 - Orthotics
 - Mobility aids
 - Wound care supplies
 - Urological aids
 - Medical supplies
 - Respiratory aids

DMEPOS Accreditation Program Fees

Single Pharmacy Accreditation Fees

Application Fee	\$1,250
NABP Survey Fee	\$1,500
NABP Survey Travel Fee	\$500
Participation Fee (Year 1)	\$125

Year 1 Subtotal	\$3,375
Year 2 Annual Participation Fee	\$125
Year 3 Annual Participation Fee	\$125
Estimated Total for Three-Year Accreditation*	\$3,625

**Accreditation fees are subject to change.*

Credit card payment is required for Year 1 when the application is submitted. If a pharmacy does not have a successful survey, an additional survey and fees will be required to continue on the accreditation process.

A separate fee structure applies to suppliers with more than one facility. For information on fees for two or more facilities that have common ownership and follow the same policies and procedures, please contact DMEPOS staff at dmeapos@nabp.pharmacy.

Once awarded, DMEPOS accreditation is issued for a three-year term. NABP requires an annual compliance review and program participation fees in Years 2 and 3. Reaccreditation prior to the expiration date of the current accreditation is necessary to maintain continuous accreditation.

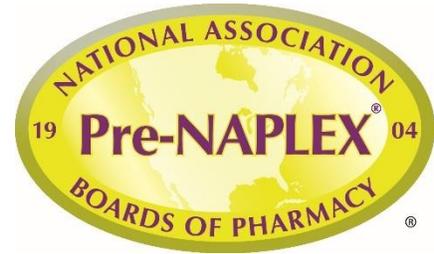
Contact DMEPOS staff at dmeapos@nabp.pharmacy for information on the costs and requirements for accreditation of multiple pharmacy locations.

DMEPOS-Accredited Pharmacies

For the most up-to-date list of DMEPOS pharmacies, visit the Programs section under DMEPOS on the NABP website at www.nabp.pharmacy.

Pre-NAPLEX

Launched in 2003, the Pre-NAPLEX® is the only North American Pharmacist Licensure Examination® (NAPLEX®) practice examination written and developed by NABP. The Pre-NAPLEX is intended to benefit pharmacy students who are preparing for the NAPLEX. However, anyone who is interested may register and take the Pre-NAPLEX; there are no eligibility requirements to take the Pre-NAPLEX. The questions on the Pre-NAPLEX are actual questions that have previously appeared on the NAPLEX. The form contains questions based on the same blueprint used for the NAPLEX.



- The Pre-NAPLEX is similar to the actual NAPLEX in many ways. Candidates who take the Pre-NAPLEX will have a chance to “preview” the NAPLEX experience before examination day.
- The questions on the Pre-NAPLEX are actual questions that have previously appeared on the NAPLEX.
- The Pre-NAPLEX is a 140-minute, internet-based examination that consists of 100 items.
- The current fee for the Pre-NAPLEX is \$65.
- The Pre-NAPLEX offers two forms and can be taken up to two times, at any time on any day.
- In preparation for the Pre-NAPLEX, students are encouraged to review the NAPLEX competency statements and the associated skills and knowledge of an entry-level pharmacist.
- The Pre-NAPLEX score is intended to provide the candidate with information on performance when answering a subset of test questions under pre-testing conditions. NABP does not claim a strong performance on the Pre-NAPLEX predicts passing the NAPLEX.
- To take the Pre-NAPLEX, a computer running either Microsoft Windows or Mac OS operating system software is required.
- To register for the Pre-NAPLEX, candidates go to their e-Profile and click on Exam Services.

.Pharmacy Verified Websites Program

On June 19, 2014, NABP executed a Registry Agreement with the Internet Corporation for Assigned Names and Numbers to be the registry operator for the new .pharmacy Top-Level Domain (TLD). The .pharmacy TLD launched in fall 2014 and provides consumers around the world a means for identifying safe online pharmacies and resources.



Internet Fuels Global Public Health Threat

- Illegal prescription drug sales and counterfeit medicines threaten patient safety worldwide:
 - Diseases needlessly left untreated
 - Illness and death due to toxic substances
 - Prescription drug abuse on the rise
- Of nearly 11,500 internet sites reviewed, NABP found that 96% appear to be operating in conflict with pharmacy laws and practice standards.

.Pharmacy TLD Promotes Patient Safety

Because the means to easily recognize safe online pharmacies is important for consumers worldwide, NABP is making the new domain available to legitimate online pharmacies and related entities that are located in the United States as well as in other countries.

- Patient safety is the central goal of the .pharmacy initiative.
- Consumers worldwide can be sure the medications they buy online are authentic and safe.
- NABP will ensure that only legitimate website operators that adhere to pharmacy laws in the jurisdictions in which they are based and to which they sell medicine will be able to register .pharmacy domain names. For example, a pharmacy that is licensed in another country and is selling prescription drugs to patients in the US would not be eligible for .pharmacy because it is violating US federal law that prohibits importation.

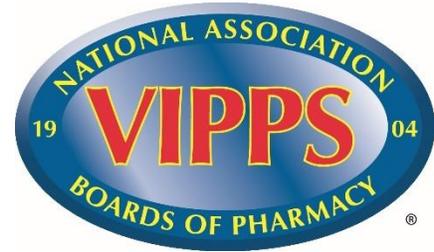
Global Community Supports Initiative

In developing the .Pharmacy Verified Websites Program, NABP partnered with international regulators, pharmacy organizations, and law enforcement agencies that share the Association's concern about illegal online drug sellers distributing products that endanger patient health. NABP continues to work cooperatively with regulators and stakeholders worldwide to maintain universal internet pharmacy standards.

Stakeholders that have supported NABP's .pharmacy initiative include many groups in the global pharmacy community including the Alliance for Safe Online Pharmacies, Eli Lilly and Company, European Alliance for Access to Safe Medicines, FDA, Gilead Sciences, Inc, International Pharmaceutical Federation, Janssen Pharmaceuticals, Inc, LegitScript, Merck/MSD, National Association of Pharmacy Regulatory Authorities, Pfizer, and the state boards of pharmacy.

VIPPS Accreditation Program

Launched in 1999, the Verified Internet Pharmacy Practice Sites® (VIPPS®) program was established in response to public and regulatory agency concerns regarding safety of internet pharmacy practices, to provide a means for the public to distinguish between legitimate and illegitimate pharmacy websites.



NABP announced in April 2018 that all prospective VIPPS applicants must obtain and maintain .pharmacy verification *prior* to applying for VIPPS accreditation. At the time of application, the .pharmacy domain must be active (used as either the primary domain or redirecting to the verified website) and maintained throughout the VIPPS application process and for as long as the pharmacy is VIPPS-accredited. If multiple websites are to be included in the accreditation, each site must have its own .pharmacy domain prior to applying through VIPPS.

The VIPPS program and its accompanying VIPPS seal of approval identifies to the public those pharmacy websites which:

- are appropriately licensed in each state they ship pharmaceuticals;
- are legitimately operating via the internet; and
- have successfully completed a 20-point criteria review and on-site survey.

Among other areas, the VIPPS Criteria examine:

- license compliance;
- how the patient's or caregiver's identity is verified;
- patient medication consultation;
- steps taken to ensure the confidentiality of patient medical records; and
- how medications are dispensed.

VIPPS Facts

- A full listing of VIPPS-accredited pharmacies is available in the Programs section under VIPPS on the NABP website, www.nabp.pharmacy.
- The VIPPS accreditation program is voluntary.
- The VIPPS program is supported by Food and Drug Administration and Drug Enforcement Administration.

Steps to VIPPS Accreditation

- Apply for and obtain .pharmacy verification.
- Submit a VIPPS application, required documents, and specified fees to NABP.
- Review policies and procedures to ensure adherence to the program's criteria.
- Verify license status with member state boards.
- Perform an on-site survey.

After Achieving Accreditation:

- Once accredited, an annual review and reaccreditation are performed.

- To ensure continued compliance, all VIPPS-accredited sites are resurveyed once every three years.

VIPPS Program Fees

Fee Schedule

- Schedule A - Independent Community-based Pharmacy (three or fewer stores)
- Schedule B - Internet Pharmacy, Health Maintenance Organization, Pharmacy Benefit Manager, Chain Drugstore, Mass Retailer
- Schedule C - Independent Pharmacy, one pharmacy with an internet practice that is limited to one to three states (pharmacy only possesses one to three pharmacy licenses)

Application Fee

- Schedule A
 - \$3,000 application fee (includes the first year's annual participation fee)
 - \$3,000 survey fee
 - **\$6,000 total fees**
- Schedule B
 - \$5,000 application fee (includes the first year's annual participation fee)
 - \$3,000 survey fee
 - **\$8,000 total fees**
- Schedule C
 - \$2,000 application fee (includes the first year's annual participation fee)
 - \$3,000 survey fee
 - **\$5,000 total fees**

Annual Participation Fee

- Schedule A
 - \$2,000 if a non-resurvey year
 - \$5,000 if a survey year (\$2,000 annual participation fee + \$3,000 re-survey fees)
- Schedule B
 - \$4,000 if a non-survey year
 - \$7,000 if a survey year (\$4,000 annual participation fee + \$3,000 re-survey fees)
- Schedule C
 - \$1,000 if a non-survey year
 - \$4,000 if a survey year (\$1,000 annual participation fee + \$3,000 re-survey fees)

Additional Fees

Administrative fees may be assessed for the following occurrences:

- Time extension requests
- Protracted policy and procedure (P&P) reviews
- Delays related to survey scheduling
- Protracted survey remediation
- Ownership change processing

This list is not all-inclusive.

An applicant for VIPPS accreditation or a VIPPS-accredited entity that has more than five dispensing facilities shall submit an additional fee of \$600 with the application and the annual participation fee.

An applicant for VIPPS accreditation or a VIPPS-accredited entity that has more than one dispensing facility may require additional surveys to confirm program compliance. In that case, the applicant would be subject to additional survey fees.

A portion of the VIPPS application fees cover a complete review of one set of P&Ps. If an applicant has more than one set of P&Ps that need to be reviewed (such as those that are site-specific), additional administrative fees of up to \$1,000 per set will be assessed; fees are determined by the number of documents that need to be reviewed. If, at any point during the application or post-accreditation process, the scope of the pharmacy changes (ie, ownership, location, types of products offered) or the P&Ps undergo revisions, these documents may need to be resubmitted and reviewed at cost.

We reserve the right to levy administrative fees for extraordinary processing related to an application.

When Fees Are Due

Application fee, plus any applicable additional facilities fees and survey fees, is due with the application submission. Any additional reviews required during or after the accreditation will only be conducted after payment is received by NABP.

Annual participation fee, plus any applicable additional facilities fee, is due prior to renewal of accreditation.

Acquiring or Opening Facilities

NABP must be notified when an applicant or accredited organization opens a new pharmacy facility. A \$400 processing fee must be submitted for each new or added facility. VIPPS staff should be contacted for fee information related to newly acquired pharmacy facilities.

From: vpp@nabp.pharmacy
Cc: [NABP Executive Office](#)
Subject: Verified Pharmacy Program Update - Availability of VPP Inspection Reports
Date: Tuesday, October 15, 2019 7:51:24 AM
Attachments: [VPP Inspection Reports in ISN_10-15-2019.xlsx](#)



847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS AND DESIGNATED STAFF – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: October 15, 2019
RE: Verified Pharmacy Program Update – Availability of VPP Inspection Reports

The National Association of Boards of Pharmacy® (NABP®) would like to notify you of the additional Verified Pharmacy Program® (VPP®) inspection reports now available in the [Board e-Profile Connect](#). Please see the attachment for a list of pharmacies that have a VPP inspection report available in the system. **The pharmacies with the most recently added reports are highlighted at the top of the list.** For your convenience, we have included the names of the pharmacies, basic demographic information, and the facility e-Profile IDs, all of which will assist you in searching for a specific facility e-Profile within the Board e-Profile Connect and view the documents under the VPP Inspection Sharing Network (ISN). Additionally, this document is in an Excel format to allow for sorting and filtering. Please note the attached list is for exclusive use by NABP and the boards of pharmacy. Distribution to or use by a third party is prohibited without NABP's prior written authorization.

As a reminder, you will notice varying names of the files available in VPP system including "Application," "VPP Inspection Report," "VPP Highlight of Findings" and "Inspection Response." Additionally, each document will be clearly labeled as provided by the Applicant or NABP to create a clearer distinction between pharmacy-provided data and NABP-verified data. Explanation for each type of file is below:

- **Application** = This file contains the pharmacy's VPP application and all supplemental data provided by the pharmacy.
- **VPP Inspection Report** = This file contains the completed VPP inspection report for the pharmacy.
- **VPP Highlight of Findings** = This file contains a brief highlight of any findings from the VPP Inspection.
- **VPP Inspection Bundle** = This file contains the full VPP information for the pharmacy, including the application, VPP inspection report, listing of the license verification, and board orders (if applicable).
- **Inspection Response** = This file contains follow-up information provided directly by the pharmacy and may include narrative responding to the VPP inspection findings, clarifications and documentation to serve as a supplement to their inspection report, and/or corrective actions in place. As a note, each facility may provide responses to NABP's findings in the report, which may include steps taken to correct any noncompliant items, within 30 calendar days of receiving their inspection report. Responses provided after 30 calendar days will not be uploaded to the e-Profile.

If you have any questions, please contact VPP staff via e-mail at vpp@nabp.pharmacy or via phone at 847/391-4400.

Access to the Board e-Profile Connect must be pre-approved and requested directly by the board of pharmacy executive officer. If an individual requires access to VPP for the purpose of performing inspection services for the board of pharmacy and does not already have access, NABP requests that the executive officer send an e-mail to eProfileAccess@nabp.pharmacy with the individual's name, position with the board of pharmacy, and e-mail address.

2017 Resources and Responsibilities Survey

Wholesale Distributors - Investigate	34	81%
Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming		
Wholesale Distributors – Inspect	32	76%
Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Virginia, Washington, West Virginia, Wyoming		
Nonresident Wholesale Distributors – Investigate	27	64%
Arizona, Arkansas, California, Colorado, Idaho, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming		
Nonresident Wholesale Distributors – Inspect	18	43%
Arizona, Arkansas, California, Idaho, Iowa, Kansas, Kentucky, Michigan, Minnesota, Mississippi, Nevada, North Dakota, Ohio, Oregon, South Dakota, Virginia, Washington, West Virginia		
Virtual Wholesalers – Investigate	17	40%
Arizona, Arkansas, California, Indiana, Iowa, Michigan, Minnesota, Mississippi, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, South Dakota, Tennessee, Virginia, West Virginia		
Virtual Wholesalers – Inspect	13	31%
Arizona, Arkansas, California, Indiana, Michigan, Minnesota, Nevada, New Mexico, North Dakota, Ohio, South Dakota, Virginia, West Virginia		
Brokers – Investigate	14	33%
Arkansas, California, Indiana, Iowa, Michigan, Minnesota, Mississippi, Nevada, New Mexico, Ohio, Oregon, South Dakota, Virginia, Wyoming		
Brokers – Inspect	11	26%
Arkansas, California, Indiana, Michigan, Minnesota, Nevada, New Mexico, Ohio, Oregon, South Dakota, Virginia		
Third-Party Logistics Providers (3PLs) – Investigate	19	45%
Arkansas, California, Indiana, Michigan, Minnesota, Mississippi, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Utah, Virginia, West Virginia, Wyoming		
Third-Party Logistics Providers (3PLs) – Inspect	16	38%
Arkansas, California, Indiana, Michigan, Minnesota, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Virginia, West Virginia		
Nonresident 3PLs – Investigate	15	36%
Arkansas, California, Indiana, Michigan, Mississippi, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Pennsylvania, South Dakota, Utah, West Virginia, Wyoming		
Nonresident 3PLs – Inspect	8	19%
Arkansas, California, Michigan, Nevada, North Dakota, Ohio, South Dakota, West Virginia		
Community Pharmacies – Investigate	38	90%
Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wyoming		
Community Pharmacies – Inspect	36	86%
Arizona, Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, West Virginia, Wyoming		

MANUFACTURERS AND VIRTUAL MANUFACTURERS DISTRIBUTING ONLY THEIR OWN PRESCRIPTION DRUGS AND DEVICES APPLICATION INSTRUCTIONS

(See Md. Code Ann., Health Occ. § 12-6C-03(b)(2) for complete requirements)

- Complete the attached Maryland Board of Pharmacy's **Application for Manufacturers and Virtual Manufacturers Distributing Their Own Prescription Drugs and Devices**. Be sure to check the box for the relevant application type (New, Renewal, Ownership Change, Relocation, or Reinstatement).

NOTE: Pursuant to Md. Code Ann., Health Occ. § 12-6C-03(b)(2), manufacturers and virtual manufacturers distributing only their own prescription drugs and/or devices approved by the U.S. Food and Drug Administration into or within Maryland are not required to comply with requirements under the Wholesale Distribution Permitting and Prescription Drug Integrity Act beyond those required by federal law. An abbreviated wholesale distributor application and attachments must be completed by these entities in order to be considered for a Maryland wholesale distributor permit.

- Submit the completed application with all attachments and a check made payable to the Maryland Board of Pharmacy in the appropriate amount to:

Maryland Board of Pharmacy, PO BOX 2024, Baltimore, MD 21203-2024.

- Applications sent overnight or through priority mail must be addressed to the appropriate lockbox and sent to:

**First Data /Remitco, Attn: Maryland Board of Pharmacy / LOCKBOX #7693,
400 White Clay Center Drive, Newark, DE 19711**

- The application process must be completed within one year from submission of the initial application. Applicants failing to complete the process within one year will be required to submit a new application.
- Manufacturers completing this form must satisfy the definition of “manufacturer” as provided in 21 C.F.R. 205.3(d): *Manufacturer means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.*
- Manufacturers distributing their own prescription drugs approved by the U.S. Food and Drug Administration must provide the following items with their application:
 - A copy of the facility's most recent FDA inspection;
 - Documentation of FDA registration as an establishment approved to distribute prescription drugs; and
 - The appropriate application fee (\$1,750 for New, Renewal, Ownership Change, or Relocation applications; \$3,250 for Reinstatement applications).
- Virtual manufacturers completing this form must satisfy the definition of “virtual manufacturer” as defined in COMAR 10.34.22.02(new): *Virtual Manufacturer [means] an entity that engages in the manufacture of drug or device products for which it:(i) Owns the NDA or ANDA number, if a prescription drug;(ii) Owns the UDI number, as available, for a prescription device;(iii) Contracts with a contract manufacturing organization for the physical manufacture of the drug or device product; (iv) Is not involved in the physical manufacture of the drug or device product; and (v) At no time takes physical possession of, or stores, the drug or device product.* A “Virtual Manufacturer” may include entities that are identified as a broker, own-label distributor, sponsor manufacturer, private-label manufacturer, or contract manufacturer.

- The information and qualifications required for Virtual Manufacturers to obtain a permit, beyond that required by federal law, do not apply to a virtual manufacturer that provides the following information to the Board:
 - A list of drug or device products it distributes;
 - A list of the NDA or ANDA numbers associated with each drug it distributes;
 - A list of the UDI numbers, as available, associated with each device it distributes;
 - The name and facility address of the contract manufacturer for each drug or device product it distributes;
 - Verification of current FDA registration for each contract manufacturing facility listed;
 - If the contract manufacturer distributes into this State, the wholesale distributor permit number for the contract manufacturer;
 - If the contract manufacturer does not distribute into this State, the name and Maryland's wholesale distributor permit number for the entity that physically distributes the product into this State;
 - A statement affirming that the virtual manufacturer does not contract the manufacture or distribution for drugs or devices other than those for which it owns the NDA, ANDA, or UDI numbers;
 - An attestation by the owner of the virtual manufacturer that it does not hold product;
 - A copy of existing licensure from the state in which it is located, if applicable;
 - A valid federal licensure or registration, as verified by the Board; and
 - The appropriate application fee (\$1,750 for New, Renewal, Ownership Change, or Relocation applications; \$3,250 for Reinstatement applications).

NOTE: Please allow four to six weeks for the Board to process your completed application.

NOTE: The application fee is a non-refundable, administrative fee.

Maryland Board of Pharmacy

4201 Patterson Avenue
 Baltimore MD 21215-2299
 Phone: 410-764-4759
 Fax: 410-358-6207

www.dhmh.maryland.gov/pharmacy



**APPLICATION FOR MANUFACTURERS AND VIRTUAL
 MANUFACTURERS DISTRIBUTING THEIR OWN
 PRESCRIPTION DRUGS OR DEVICES**

BOARD USE ONLY	
Permit Number:	
Approval Date:	
Approval By:	

Please print clearly in ink or type in upper case letters only.

Complete all application sections and sign. **Incomplete forms will delay the issuance of your permit.**

APPLICATION TYPE				
○ New Application Fee: \$1,750.00	○ New Ownership Fee: \$1,750.00	○ Renewal Fee: \$1,750.00	○ Relocation Fee: \$1,750.00	○ Reinstatement Fee: \$3,250.00

1. APPLICANT INFORMATION	
A. Name of Manufacturer: <i>(name in which firm is doing business)</i>	
Maryland Permit Number:	

B. Facility Address <i>(physical location of establishment which should be reflected on all sales invoices and shipping documents):</i>			
Street Address:		Suite #:	
City:		State:	Zip Code:
Telephone #:		Fax #:	
Web Site Address:		Email Address:	
Federal Tax ID #:			

C. Type of Business (check all that apply):		
<input type="checkbox"/> Sole Proprietorship	<input type="checkbox"/> Partnership	<input type="checkbox"/> C Corporation
<input type="checkbox"/> S Corporation	<input type="checkbox"/> LLC	<input type="checkbox"/> Other (please explain):

D. Legal Name (if different from Manufacturer Name):	
State of Incorporation:	
Date of Incorporation:	

E. Parent Company Name (to include any and all parent companies that have direct or indirect control over the applicant)	
--	--

F. State and Federal permit/license/registration numbers <i>(attach additional pages if necessary):</i>	
LICENSING BODY	PERMIT / LICENSE / REGISTRATION NUMBER

G. Name of Applicant			
Name:		Title:	
Phone #:		Email Address:	

2. SIGNATURE OF AUTHORIZING OFFICIAL

By signing this application, I solemnly affirm under the penalties of perjury that the company manufactures and distributes (or virtually manufactures and distributes) its own products only. I further certify that the contents of this application are true to the best of my knowledge, information, and belief and that I am aware of and will meet the requirements of the Maryland Pharmacy Act and Maryland Board of Pharmacy regulations pertaining to Wholesale Distribution Permitting. I understand that in a Maryland wholesale distributor permit may be revoked if any assertion made in this application is found to be false.

Signature of Authorizing Official:	_____
Name and Title:	
Date:	

4. LIST OF DESIGNEE

If applicable, list the names of person and/or entity that you authorize the Board to release information about your application:

Name of Organization	Name of Person	Title

5. ATTESTATION FOR VIRTUAL MANUFACTURERS

By signing this attestation, I hereby affirm that the company does not contract the manufacture or distribution of drugs or devices other than those for which it owns the NDA, ANDA, or UDI numbers. I further certify that the company does not hold product.

Signature of Authorizing Official:	_____
Name and Title:	
Date:	

6. APPLICATION CHECKLIST		
Application Fee (\$1,750 or \$3,250)	<input type="radio"/> YES	<input type="radio"/> NO
Proof of FDA Registration	<input type="radio"/> YES	<input type="radio"/> NO
Most Recent FDA Inspection Report (if applicable)	<input type="radio"/> YES	<input type="radio"/> NO
Ownership Information (if applicable) (name(s) title(s) and position(s) all of owners, partners and officers)	<input type="radio"/> YES	<input type="radio"/> NO

For Virtual Manufacturers:		
List of NDA, ANDA, and/or UDI Numbers	<input type="radio"/> YES	<input type="radio"/> NO
List of Drugs and/or Devices	<input type="radio"/> YES	<input type="radio"/> NO
List of Contract Manufacturers	<input type="radio"/> YES	<input type="radio"/> NO
List of Contract Distributors (if applicable)	<input type="radio"/> YES	<input type="radio"/> NO



**VIRTUAL WHOLESALE DISTRIBUTOR
WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS**

CAREFULLY READ ALL INSTRUCTIONS. Failure to complete all fields, provide necessary supplemental documentation and correct fee will delay the application process. If a question is not applicable, answer as N/A.

"Virtual Wholesale Distributor " means any person engaged in wholesale distribution of dangerous drugs in or into Ohio which:

- (1) Has title but does not take physical possession of dangerous drugs;
- (2) Is licensed by the state board of pharmacy as a wholesale distributor pursuant to section [4729.52](#) of the Revised Code with a virtual wholesale distributor classification; and
- (3) Shall be registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

Applicable for the following:	
<ul style="list-style-type: none"> ▪ Virtual Wholesale Distributors (OAC 4729-9-28) - Please refer to the rule OAC 4729-9-28 of the Ohio Administrative Code for additional the requirements to be licensed as a virtual wholesale distributor. 	
<input type="checkbox"/>	Completed Application with original (wet ink) signatures – no copies
<input type="checkbox"/>	Correct Fee (Check made payable to: Treasurer, State of Ohio): <ul style="list-style-type: none"> • \$950.00 to distribute non-controlled substances ONLY. • \$1,000.00 to distribute non-controlled and controlled substances.
<input type="checkbox"/>	Corporation papers and/or articles of incorporation or Limited Liability (LLC) papers for the pharmacy must be attached (See 4b on Application).
<input type="checkbox"/>	Responsible Person and all owners/officers must submit to a criminal records check (See Question 15).
<input type="checkbox"/>	Legal and Disciplinary Questions (See 16 & 17 on Application) If the answer to any of the legal or disciplinary questions is yes, include the person’s title, duties, and responsibilities, a detailed account (including date, place, circumstances, and disposition of the matter), and copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions) with this application.
<input type="checkbox"/>	Responsible Person (RP) must meet the requirements stated in the rule 4729-5-11 of the Ohio Administrative Code (See 19 on Application). If the responsible person on the application has any of the disciplinary actions or criminal convictions listed in rule 4729-5-11 of the Ohio Administrative Code and is seeking approval from the Board, provide a request by the responsible person that includes a detailed account (including date, place, circumstances, and disposition of the matter) and copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions) with this application.
<input type="checkbox"/>	Non-Resident licensure inquiry affidavit (non-Ohio applicants only). Form must be provided to the Board by the applicant’s home state licensing authority (see page 14 of the application).



VAWD Accreditation (non-Ohio applicants, if applicable) – Rule 4729-9-28 of the Ohio Administrative Code requires an out-of-state entity to maintain verified-accredited wholesale distributors (VAWD) accreditation from the National Association of Boards of Pharmacy ***if*** they are not licensed in the entity's home state.

**Mail completed application along with any attachments and fee to:
State of Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus OH 43215**



**VIRTUAL WHOLESALE DISTRIBUTOR
WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS**

CAREFULLY READ ALL INSTRUCTIONS. Failure to complete all fields, provide necessary supplemental documentation and correct fee will delay the application process. If a question is not applicable, answer as N/A.

Application fee is \$950.00 for the distribution of non-controlled substances; \$1,000.00 to distribute non-controlled and controlled substances.

Please make check payable to "Treasurer, State of Ohio"

APPLICATION AND PAYMENT SHOULD BE MAILED TO: 77 SOUTH HIGH STREET, 17TH FLOOR, COLUMBUS, OH 43215

PLEASE TYPE OR PRINT LEGIBLY

1. LICENSE REQUEST

<input type="checkbox"/> Change <input type="checkbox"/> New	Proposed opening date or date of change (or indicate facility is currently open)	If change, give current WDDD License Number
If change, select ALL that apply: <input type="checkbox"/> Name <input type="checkbox"/> Ownership <input type="checkbox"/> Business Type (if currently licensed as a wholesale distributor of dangerous drugs.)		

2. NAME, ADDRESS AND PHONE NUMBER OF BUSINESS BEING LICENSED

Business Name (i.e. reflected by signage/ letterhead /how you will answer phone)			County
Street Address (No P.O. Box)	City, State	Zip Code	Phone (include area code)
Mailing Address, City, State, Zip Code (if different from above)			Fax (include area code)

3. INDIVIDUAL TO CONTACT REGARDING ABOVE LOCATION, BETWEEN 8 AM AND 5 PM WEEKDAYS - Individual to contact if there are questions regarding the application (must be the Responsible Person or designee).

Name	Title
E-mail	Phone (include area code)

For State of Ohio Board of Pharmacy Use Only								
Control #	Amt Received	Office/Field	Class	BT	Drug Category	License	New #	Same #
					II III			

77 South High Street, 17th Floor, Columbus, Ohio 43215



4. APPLICANT INTENDS DOING BUSINESS AS (Select One) - Indicate the applicant's type of business organization

<input type="checkbox"/> Government	<input type="checkbox"/> Corporation	<input type="checkbox"/> Partnership	<input type="checkbox"/> Limited Liability Company
<input type="checkbox"/> Sole Proprietorship			

4a. NAME OF GOVERNMENT AGENCY (if applicable)

Name

4b. OWNERSHIP INFORMATION – Corporations must attach a copy of articles of incorporation; limited liability companies must attach a copy of articles of organization or certificate of formation. These documents may be contained in the business files usually maintained by the applicant's business office.

Leave blank if Government Agency

Entity/Charter number	Federal Tax ID or EIN Number	State where incorporated
-----------------------	------------------------------	--------------------------

4c. LIST ANY OTHER NAMES THE ENTITY WILL BE CONDUCTING BUSINESS UNDER (Attach separate sheet if necessary)

--

5. LIST OTHER TERMINAL DISTRIBUTOR OR WHOLESALER DISTRIBUTOR OF DANGEROUS DRUG LICENSES ISSUED BY THE STATE OF OHIO BOARD OF PHARMACY POSSESSED BY THE APPLICANT

License Numbers Only

6. LIST WHOLESALER DISTRIBUTOR LICENSES ISSUED BY OTHER STATES POSSESSED BY THE APPLICANT (include license number and state)

--

7. HAS THE ENTITY EVER BEEN DENIED A LICENSE OR REQUESTED TO WITHDRAW OR HAS IT WITHDRAWN AN APPLICATION FOR LICENSURE IN THIS OR ANY OTHER STATE?

<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, please provide the name of the licensing agency and approximate date of application and the reason why:
--	---

8. TRADE, CORPORATE, OR PARTNERSHIP NAME AND ADDRESS - Owner of the location to be licensed.

Name	Title
Mailing Address, City, State, Zip Code	
Previous Trade, Corporate, Or Partnership Name(s) & Address(es)	Phone (including area code)
<i>If many, check box and attach separate sheet to this application</i> <input type="checkbox"/>	

9. TYPE OF DRUGS -Check the type(s) of dangerous drugs you distribute, direct to distribute, or intend to distribute, at wholesale.

Application is hereby made for a certificate as a Wholesale Distributor of Dangerous Drugs, as provided in sections 4729.52 & 4729.53 of the Ohio Revised Code, as follows:	
<input type="checkbox"/> Category II (Non-controlled drugs only) (\$950.00)	<input type="checkbox"/> Category III (Controlled/Non-controlled drugs) (\$1,000.00) <i>(if checked, must complete questions 10-11)</i>

10. DRUG SCHEDULES DISTRIBUTED (Check all that apply)

Enclose a copy of the DEA registration.

Schedule I <input type="checkbox"/>	Schedule II <input type="checkbox"/>	Schedule III <input type="checkbox"/>	Schedule IV <input type="checkbox"/>	Schedule V <input type="checkbox"/>
DEA Number			Expiration Date	

11. QUALIFICATIONS FOR LICENSURE

Applicant hereby certifies and agrees to provide, upon request, proof satisfactory to the State of Ohio Board of Pharmacy that:

- (1) The applicant is of good moral character or, if the applicant is an association or corporation, that the managing officers are of good moral character;
- (2) The applicant is equipped as to land, buildings, and paraphernalia to properly carry on the business for which this license is requested;
- (3) The applicant's trade connections are such that there is a reasonable probability that the applicant will apply all controlled substances possessed by him/her to sale at wholesale for: (check all that apply)

Scientific Purposes
 Experimental Purposes
 Medicinal Purposes
 Instructive Purposes
 Return Service Only

- (4) The applicant is in sufficiently good financial condition to carry out his/her obligation;
- (5) The granting of this license is in the public interest.

12. OTHER THAN THE NAME AND ADDRESS BEING REGISTERED- List the names and addresses of the site(s). If the sites are licensed in Ohio, provide the wholesale distributor number.

A. Are the records of sales kept at any other location? No Yes

If yes, provide the name and address of the location:

B. Are drugs shipped from any other location? No Yes

If yes, provide the name and address of the location:

C. Can the purchaser order drugs from any other address? No Yes

If yes, provide the name and address of the location:

D. Are drugs transferred to any other location for the purposes of storage or research? No Yes

If yes, provide the name and address of the location:

13. E-MAIL ADDRESS TO RECEIVE YOUR OHIO LICENSE(S). **MUST BE THE RESPONSIBLE PERSON OR DESIGNEE.** (State of Board of Pharmacy no longer mails licenses via postal mail).

Name of the individual that will print the license	
E-mail of the individual that will print the license	Phone (including area code)

14. PROVIDE A NARRATIVE DESCRIPTION OF THE TYPE OF BUSINESS ACTIVITIES (PLEASE BE SPECIFIC) THAT WILL BE CONDUCTED AT THIS LOCATION THAT REQUIRES THE APPLICANT TO BE ISSUED A WDDD LICENSE -
Provide on a separate sheet if necessary.

**Indicate your web site address (if applicable), and type of business being conducting in Ohio.
A narrative must be provided or the application is considered incomplete.**

Note: Please include a list of 3PL's that you are contracted with and the type of dangerous that you will be wholesaling.

16. APPLICANT LEGAL AND DISCIPLINARY QUESTIONS – Failure to answer the following questions makes your application incomplete, delaying the licensing process. Answering incorrectly could be a violation of Ohio law, see ORC 4729.56 and 2921.13.

Please note that **Applicant** includes all the following (when applicable):

- The business entity
- Owner
- Operator
- Corporate officers, including: president, vice president, secretary, treasurer, CEO, CFO, or any equivalent position
- Partner(s)
- Sole proprietor
- Any other person, including employees, with access to drug stock*

*Access to drug stock includes not only physical access, but also any influence over the handling of prescription drugs (i.e. dangerous drugs) such as purchases, inventories, issuance of medical orders, etc. It does not include employees/contractors such as maintenance, janitorial, IT or other staff that may need limited supervised access to areas where prescription drugs or D.E.A. controlled substance order forms are kept.

For more information on answering the legal/disciplinary questions, visit: www.pharmacy.ohio.gov/legalquestions.

****If the answer to any of the following questions is yes, include the person’s title, duties, and responsibilities, a detailed account (including date, place, circumstances, and disposition of the matter), and copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions)****

<p>16a. Has the applicant ever been convicted of, or are there charges pending for, a felony or misdemeanor drug offense under state or federal law?</p> <ul style="list-style-type: none">▪ This includes a court granting intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC or TLC), or other diversion programs.▪ Felony or misdemeanor drug offenses must be included regardless of whether the case has been expunged or sealed or the equivalent thereof. <i>This applies to question 16a only.</i>▪ Note: Minor misdemeanor drug convictions <u>are not</u> required to be reported. ORC 2925.11(D). <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>16b. Has the applicant ever been convicted of, or are there charges pending for, any other felony under state or federal law?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>16c. Within the past 10 years, has the applicant ever been convicted of, or are there charges pending for, a misdemeanor theft offense as described in division (K)(3) of section 2913.01 of the Ohio Revised Code.</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>
<p>16d. Has the applicant ever been excluded or directed to be excluded from participation in a Medicare or state health care program, or is any such action pending?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>

16e. Has the applicant ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is any such action pending?

Yes No

16f. Has the applicant ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the applicant's license or registration?

Yes No

16g. Has the applicant ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that was based in whole or in part, on the applicant's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

Yes No

17. RESPONSIBLE PERSON LEGAL AND DISCIPLINARY QUESTIONS - Failure to answer the following questions makes your application incomplete, delaying the licensing process. Answering incorrectly could be a violation of Ohio law, see ORC 4729.56 and 2921.13.

In accordance with [rule 4729-5-11 of the Administrative Code](#), the responsible person is responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of a facility with a wholesale distributor of dangerous drugs license.

For more information on answering the legal/disciplinary questions, visit: www.pharmacy.ohio.gov/legalquestions.

****If the answer to any of the following questions is yes, include the person's title, duties, and responsibilities, a detailed account (including date, place, circumstances, and disposition of the matter), and copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions)****

17a. Has the responsible person ever been convicted of, or are there charges pending for, a felony or misdemeanor drug offense under state or federal law?

- This includes a court granting intervention in lieu of treatment (also known as treatment in lieu of conviction, ILC or TLC), or other diversion programs.
- Felony or misdemeanor drug offenses must be included regardless of whether the case has been expunged or sealed or the equivalent thereof.
- Note: Minor misdemeanor drug convictions are not required to be reported. ORC 2925.11(D).

Yes No

17b. Has the responsible person ever been convicted of, or are there charges pending for, any other felony under state or federal law?

Yes No

17c. Within the past 10 years, has the responsible person ever been convicted of, or are there charges pending for, a misdemeanor theft offense as described in division (K)(3) of section 2913.01 of the Ohio Revised Code.

Yes No

17d. Has the responsible person ever been convicted of, or are there charges pending for, a crime of moral turpitude as defined in section [4776.10](#) of the Ohio Revised Code?

Yes No

17e. Has the responsible person ever been convicted of, or are there charges pending for, a crime (felony or misdemeanor) involving an act of moral turpitude?

Yes No

17f. Has the responsible person ever been excluded or directed to be excluded from participation in a Medicare or state health care program, or is any such action pending?

Yes No

17g. Has the responsible person ever been denied a license by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction, or is any such action pending?

Yes No

17h. Has the responsible person ever been the subject of an investigation or disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that resulted in the surrender, suspension, revocation, or probation of the responsible person's license or registration?

Yes No

17i. Has the responsible person ever been the subject of a disciplinary action by the Drug Enforcement Administration or appropriate issuing body of any state or jurisdiction that was based in whole or in part, on the responsible person's prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug (i.e. prescription drug), or is any such action pending?

Yes No

17j. Has the responsible person ever been convicted of, or are there charges pending for, a misdemeanor related to, or committed in, the person's professional practice (i.e. medical, dental, nursing, pharmacy, etc.)?

Yes No

17k. Has the responsible person ever been convicted of a traffic offense involving alcohol, regardless of whether the original charge – such as Driving Under the Influence (DUI), Driving While Intoxicated (DWI), Operating a Vehicle while Impaired (OVI), Operating a Motor Vehicle while under the Influence (OMVI) or the equivalent in another jurisdiction – was ultimately reduced or plead to a different offense other than the original charge?

Yes No

18. STATEMENT OF APPLICANT (Person who may legally sign for the business)

Statement must be manually signed (**wet ink – NO COPIES**) and completed by the individual who may legally sign for the business and can verify the information provided in this application is true, correct, and complete. Failure to do so makes your application incomplete, delaying the licensing process.

NAME	TITLE	
PHONE (INCLUDING AREA CODE)	E-MAIL	
<p>I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE THAT I AM AUTHORIZED TO PURSUE THIS APPLICATION ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS APPLICATION IS TRUE, CORRECT, AND COMPLETE. I HEREBY ACKNOWLEDGE THAT IF THE LICENSE APPLIED FOR IS GRANTED, THE LICENSE-HOLDER SHALL SUBMIT TO THE JURISDICTION OF THE STATE OF OHIO BOARD OF PHARMACY AND TO THE LAWS OF THIS STATE FOR THE PURPOSE OF ENFORCEMENT OF CHAPTERS 2925., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE AND ALL RELATED LAWS AND RULES.</p> <p>I FULLY UNDERSTAND THAT SUBMISSION OF THIS APPLICATION WITH THE STATE BOARD OF PHARMACY CONSTITUTES PERMISSION FOR ENTRY AND ON-SITE INSPECTION BY AN AUTHORIZED BOARD AGENT IN ACCORDANCE WITH RULE 4729-9-09 OF THE OHIO ADMINISTRATIVE CODE.</p>		
SIGNATURE OF APPLICANT	DATE	DATE OF BIRTH OR SOCIAL SECURITY NUMBER

19. STATEMENT OF PERSON RESPONSIBLE FOR COMPLIANCE WITH OHIO LAW AND RULES (RESPONSIBLE PERSON)

Pursuant to [rule 4729-5-11 of the Ohio Administrative Code](#), the responsible person on a wholesale distributor of dangerous drugs license is responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of dangerous drugs.

UNLESS OTHERWISE APPROVED BY THE BOARD, NO RESPONSIBLE PERSON FOR A LOCATION LICENSED AS A WHOLESALE DISTRIBUTOR OF DANGEROUS DRUGS SHALL:

- (a) Have ever been denied a license by the drug enforcement administration or appropriate issuing body of any state or jurisdiction.
- (b) Have been the subject of any of the following by the drug enforcement administration or licensing agency of any state or jurisdiction:
 - (i) A disciplinary action that resulted in the suspension or revocation of the person's license or registration; or
 - (ii) A disciplinary action that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, storing, personally furnishing, compounding, supplying or selling a controlled substance or other dangerous drug.
- (c) Have been convicted of any of the following:
 - (i) A felony;
 - (ii) A misdemeanor related to, or committed in, the distribution of dangerous drugs;
 - (iii) An act of moral turpitude; or
 - (iv) A crime of moral turpitude as defined in section [4776.10](#) of the Revised Code.

If the responsible person on the application has any of the disciplinary actions or criminal convictions listed on the previous page and is seeking approval from the Board, please provide a request by the responsible person that includes a detailed account (including date, place, circumstances, and disposition of the matter) and

copies of relevant documents (such as court pleadings or orders, or other agency orders/dispositions) with this application.

The Responsible Person statement must be signed (**wet ink – NO COPIES**) and dated by the individual who will be responsible for compliance with all state and federal laws, regulations, and rules regulating the operation of a WDDD license.

The Responsible Person is also responsible for ensuring that the application is true, correct and complete.

I HEREBY AGREE to and assume the responsibility for compliance with all state and federal laws, regulations, and rules regulating the operation of a wholesale distributor of dangerous drugs for the applicant pursuant to rule 4729-5-11 of the Ohio Administrative Code.

I HEREBY CERTIFY that I, or personnel employed in the wholesale distribution of dangerous drugs, have the appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

FURTHER, I HEREBY AGREE that, if licensed, communications from the Board may be directed to me, and notices and citations provided for in section 4729.56 of the Revised Code may be served upon me, and shall constitute proper service upon and notice to the registered wholesale distributor of dangerous drugs for all purposes under sections 4729.51 to 4729.61 of the Revised Code. I also understand that if and when this business is discontinued that a "Written Notice of Discontinuing Business" form must be provided to the State of Ohio Board of Pharmacy as required in Rule 4729-9-07 of the Ohio Administrative Code.

I DECLARE UNDER PENALTIES OF FALSIFICATION AS SET FORTH IN CHAPTERS 2921., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE THAT I AM AUTHORIZED TO PURSUE THIS APPLICATION ON BEHALF OF THE ENTITY LISTED IN THIS APPLICATION AND THAT THIS APPLICATION IS **TRUE, CORRECT, AND COMPLETE**. I HEREBY ACKNOWLEDGE THAT IF THE LICENSE APPLIED FOR IS GRANTED, THE LICENSE-HOLDER SHALL SUBMIT TO THE JURISDICTION OF THE STATE OF OHIO BOARD OF PHARMACY AND TO THE LAWS OF THIS STATE FOR THE PURPOSE OF ENFORCEMENT OF CHAPTERS 2925., 3715., 3719. AND 4729. OF THE OHIO REVISED CODE AND ALL RELATED LAWS AND RULES.

SIGNATURE of Responsible Person	Date Signed	PRINT OR TYPE NAME
Phone (include area code)	E-mail Address	
Date of Birth (MM/DD/YYYY)	Social Security Number	
Professional License Number (if applicable)	State of Licensure (if applicable)	

**COMPLETION OF THIS FORM IS REQUIRED BY O.R.C. SECTION 4729.52
MAXIMUM PENALTY: DENIAL OF LICENSE**

CRIMINAL RECORDS CHECK REQUIREMENTS

BACKGROUND CHECKS MAY TAKE UP TO 10 WEEKS TO PROCESS

Failure to follow these instructions will delay the processing of your application.

Pursuant to [rule 4729-9-28 of the Administrative Code](#), a new wholesale distributor of dangerous drug license with a virtual wholesale distributor classification will not be issued until the following submit fingerprints to the Ohio Bureau of Criminal Identification and Investigation (BCI&I) for a BCI&I and FBI criminal records check:

- (a) The responsible person (RP) on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and
- (b) The following persons based upon the wholesale distributor's business type:
 - (i) All partners of a partnership;
 - (ii) The sole proprietor of a sole proprietorship;
 - (iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;
 - (iv) The agency director of a government agency.

DO NOT submit your application until your owners or, if incorporated, the officers and the responsible person have completed their fingerprint process.

Criminal records check may be submitted in one of two ways:

1. In Ohio, submit your electronic fingerprint impressions at a WebCheck provider which must be located in Ohio. WebCheck provider locations can be found by visiting: <http://www.ohioattorneygeneral.gov/backgroundcheck>
2. If owners/officers are out of state, you may request the number of fingerprint cards needed (each owner/officer will need two – one for BCI&I, one for FBI) from the Board and take to your local law enforcement agency to submit ink fingerprint impressions.

To obtain fingerprint cards, fill out the [Fingerprint Card Request Form](#) and email it to WDDD@pharmacy.ohio.gov or order from the Ohio Attorney General's Office by visiting: <http://www.ohioattorneygeneral.gov/backgroundcheck>

All fingerprint cards and 2 checks (totals to be determined by # of owners/officers/RP x \$22.00 and # of owners/officers/RP x \$24.00), both written to "Treasurer, State of Ohio" need mailed to:

**Bureau of Criminal Identification and Investigation
P.O. Box 365
London, OH 43140**

Note: **Do NOT** mail your fingerprints to the Board. We will not forward to Ohio BCI&I nor return them to you. You will need to have them redone and the processing of your license will be delayed.

Direct that the results be sent directly to:

State of Ohio Board of Pharmacy 77 S. High Street, 17th Floor Columbus, Ohio 43215

Reason for fingerprinting: Ohio Revised Code Section 4729.071 for Licensing.

Agency Code: 1AB002

REMINDERS:

- Fingerprints of all owners or, if incorporated, the officers and the responsible person must be done before applying. Be sure to indicate all individuals that are subject to fingerprinting on #17 of the application.
- The procedure for obtaining a change, correction, or updating of an FBI identification record are set forth in Title 28, C.F.R., § 16.34. You may also obtain a copy of your results by contacting the BCI office where you submitted your test. For your convenience, the BCI phone number is 1-877-224-0043 (Option 7).



**NON-RESIDENT LICENSURE INQUIRY AFFIDAVIT
(NON-OHIO APPLICANTS ONLY)**

Part I – Non-Licensure Requirement – To be completed by applicant for Ohio licensure and verified by state licensing authority.
If licensure is required in home state, leave blank and complete remaining portions of affidavit.

Name of Ohio Applicant
Physical Address (Street, City, State, Zip Code)
I hereby attest that by checking this box, the applicant is not required to obtain a license to conduct any operations relating to the distribution of prescription drugs by the applicant’s home state licensing authority. <input type="checkbox"/>
The company on the Ohio application provided the above information. Please correct the information, directly above or on the reverse of this form, if your records indicate any discrepancies.

If Part I of this affidavit is correct, skip Parts II & III and complete Part IV of the affidavit.

Part II – Applicant Information – To be completed by the applicant for Ohio licensure and verified by state licensing authority.

Name of Ohio Applicant		
Physical Address (Street, City, State, Zip Code)		
Type of Operation	License Number	Type of License
Date Licensed Issued	Expiration Date	
The company on the Ohio application provided the above information. Please correct the information, directly above or on the reverse of this form, if your records indicate any discrepancies.		

Part III – Non-Resident Licensure Information – To be completed by state licensing authority.

1. Does this license authorize the distribution of prescription drugs within your state?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2. To the best of your knowledge, and with information known at this time, do you have any reason to believe that the license issued by your state licensing authority will be suspended, revoked or not renewed at any time during the next two years? (If yes, please explain on a separate sheet)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3. To the best of your knowledge, has the company been denied a permit to distribute prescription drugs in your state, or any other state? (If yes, please explain on a separate sheet)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4. To the best of your knowledge, has the company's license, which authorizes the distribution of prescription drugs in your state, or any other state, been the subject of any disciplinary action? (If yes, please explain on a separate sheet)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5. To the best of your knowledge, has the company (owners, officers, or managers-in-charge) been convicted under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain on a separate sheet)	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Part IV – State Licensing Authority Certification – To be completed by state licensing authority.

Name (Please Print)	Title	State
Signature	SEAL	
Date of Signature		

This form may be submitted with the application or may be mailed separately by the state licensing authority to:

State of Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus OH 43215

From: [Cover, William](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: RE: 3PLs - FDA national license requirements
Date: Tuesday, October 15, 2019 4:56:10 AM
Attachments: [image001.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)
[image006.png](#)
[image007.png](#)
[NABP Distributor Services AK BOP 10.15.19.pptx](#)

Laura: I have spoken to our internal staff related to your recent rules set and compliance with the DSCSA. The NABP Distributor Inspection program and VAWD program have both been developed and modified to harmonize with the federal law. Once final standards are published by the FDA NABP will certainly work to update these programs to be in concert with the DSCSA. Your recent rules and use of these NABP programs will not put your board out of compliance with the federal law. I do caution that creating a self-inspection process would cause the board to have to ensure it meets these standards or would be in violation of the DSCSA. Additionally, allowing nonresident wholesale distributors to submit a self-inspection report for licensure has been discontinued in most states as this provides a potential loop hole for facilities to misrepresent their compliance with the federal law.

The attached PowerPoint deck provides additional detail on the programs related to drug distribution. As we discussed I am interested in coming to your November meeting to discuss these programs in more detail and be open to questions the board might have. Please let me know additional meeting details so that I can make travel arrangements. Thank you.

Best regards, Bill

Bill Cover BSP Pharm, RPh
Member Relations and Government Affairs Director
Phone: 224-565-5694

National Association of Boards of Pharmacy

1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy | wcover@nabp.pharmacy



From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Wednesday, October 9, 2019 6:10 PM
To: Cover, William <wcover@nabp.pharmacy>
Subject: 3PLs - FDA national license requirements

Hi Bill,

Thanks again for your time today. Here's the information on the FDA's licensing requirements for states. I believe what it's saying is that our licensing regulations can't be less stringent than the FDAs, that they can be *more* stringent, so long as they're not duplicative or inconsistent with federal regulations. See below and page 19 of the attached slides:

Direct link: <https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act>

(b) Wholesale Distributor and Third-Party Logistics Provider Standards.--

“(1) In general.--Beginning on the date of enactment of the Drug Supply Chain Security Act, no State or political subdivision of a State may establish or continue any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure that are inconsistent with, less stringent than, directly related to, or covered by the standards and requirements applicable under section 503(e) (as amended by such Act), in the case of a wholesale distributor, or section 584, in the case of a third-party logistics provider.

I look forward to seeing the slide deck for NABP's wholesale drug distributor inspection program and putting you down on our agenda to present on this.

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: [Kevin Rew](#)
To: [Carrillo, Laura N \(CED\)](#)
Cc: [Thompson, Norman H \(CED\)](#)
Subject: Re: Questions about Automated
Date: Friday, March 15, 2019 3:26:53 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[180924 \(MedifriendRx Legislation\) SB1_1447 FINAL.pdf](#)
[180921 \(MedifriendRx Legislation\) AB 2037 FINAL.pdf](#)

Hi Laura, this is great news, thank you!

I have attached the two bills that were passed and signed into law in September

Here's why there were two bills:

- California had a patchwork of rules and regulations on automated dispensing.
- With respect to outpatient dispensing, and speaking in general terms, those rules allowed pharmacies to place a kiosk adjacent to the secured pharmacy space and to dispense refills (only) from those kiosks, and they allowed community clinics that are licensed to dispense medicine to install a kiosk for dispensing under that clinic license. I don't know of any community clinics that took advantage of those abilities, I suppose because of the costs and regulatory burdens. Our goal was to allow for outpatient dispensing at clinics, under a pharmacy license.
- Our own business at the time was establishing and operating onsite pharmacies in community clinics, particularly clinics that are covered entities under the federal 340B program. Because the California Board initially had reservations, we initiated legislation that would allow for outpatient automated dispensing in that same 340B environment, where there are the greatest numbers of underserved patients. This could serve as a test market, if you will, and give the Board some experience and data. We were confident that the Board and/or the Legislature would later expand the use of automated dispensing.
- Eventually, and after our bill had been introduced, the Board decided to clean up the patchwork and sponsored its own bill. That bill was to allow automated dispensing even in for-profit health centers.
- We decided to keep both bills, and we worked with the Board to coordinate them. The resulting two bills allow for automated dispensing under the pharmacy license in the 340B settings only until July 1, 2019, and opens up the market more broadly after that.

Here's a summary of how automated dispensing is monitored, at least with our kiosks:

- In California, the kiosk is attached to the license of the pharmacy that operates it, which is responsible for compliance with all applicable rules and regulations.
- A pharmacy in California may attach up to 15 kiosks to its license.
- The kiosk is stocked with medications that come from the distributor in unit of use packaging. The medications are placed into a loading bin. The kiosk removes the medications one by one, reads the bar codes and photographs them, and slots them. The bar code information and photographs are sent to the pharmacist, who can verify everything that was placed in the kiosk against invoices.
- Each kiosk has an audio/visual screen and connection to the pharmacist.

- The patient experience at the kiosk screen is in every way possible identical to the patient experience at the pharmacy window, including, for example, identifying themselves.
- Upon receiving a prescription to route to a kiosk (we use e-prescribing only), the pharmacist causes the machine to pull the medication, read the bar codes again and send photos, for verification that it is the correct medication.
- Upon verification and of course checking patient history, the pharmacist requests consultation with the patient.
- After consultation, the pharmacist causes the kiosk to label the medication and receives photo images to confirm that the label is proper, and then causes the kiosk to release the medication.
- The kiosk keeps a perpetual inventory of all medications in and out.

I'm very grateful for your email and, if helpful, I'd love to come to your June 5-6 meeting and to answer any further questions in the meantime.

Sincerely,
Kevin Rew

Kevin Rew
General Counsel & COO



O 510.770.6343
M 512.317.9313
W www.medifriendrx.com
A 1999 Harrison Street, Suite 1530
Oakland, CA 94612



IMPORTANT: The contents of this email and any attachments are confidential. They are intended for the named recipient(s) only. If you have received this email by mistake, please notify the sender immediately and do not disclose the contents to anyone or make copies thereof.

From: "Carrillo, Laura N (CED)" <laura.carrillo@alaska.gov>
Date: Thursday, March 14, 2019 at 5:02 PM
To: Kevin Rew <krew@medifriendrx.com>
Cc: "Thompson, Norman H (CED)" <norman.thompson@alaska.gov>
Subject: RE: Questions about Automated

Hi Kevin,

The board reviewed your correspondence during their meeting last week and have requested the following information:

- Copy of California's law related to automated dispensing
- Summary of how automated dispensing is monitored

Their next meeting is June 5th and 6th, at which time they can address this issue again, given you provide the requested information.

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: Kevin Rew [mailto:krew@medifriendrx.com]
Sent: Friday, February 1, 2019 3:48 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Re: Questions about Automated

Laura,

Thanks for the feedback!

My company has developed an automated drug dispensing device (ADDS) designed for use in outpatient settings. The ADDS is designed to hold "unit of use" containers of drugs, meaning that each bottle contains a 30-day supply of the medication (or perhaps 90 days). A pharmacist controls every step of the dispensing process and caused the ADDS to label the medication as he or she provides the patient consultation.

We are in discussion with an owner/operator of a large number of pharmacies in Alaska. That operator is interested using ADDS in two potential settings:

1. Onsite at outpatient clinics, to guarantee that the patient leaves the clinic with the first prescription in hand (the primary interest); and
2. On pharmacy premises, for access by patients who do not wish to wait in line for refills.

In either case, the ADDS would be operated remotely by the pharmacy and even in the clinic setting, there would be a medical assistant or perhaps a pharmacy technician to

interface with the machine with the patient. (This pharmacy is not currently interested in self-service user interface at clinics.)

In a prior email, you said that you would forward the topic to the Board chair for possible inclusion in the next meeting, recognizing that the NABP favors automated dispensing to reach underserved populations.

Our two questions would be:

A. Given that Alaska statutes do not currently contemplate automated dispensing, would the Board consider approving a pilot project to prove the concept in Alaska? If so, how would we proceed with that request?

B. More generally, is the Board receptive to automated dispensing such that rules or legislative changes would be considered?

I'll add that we just spearheaded an effort in California to bring automated dispensing to outpatient settings under the license of the operating pharmacy, resulting in a new law that has expanded the permissible uses. We would like the opportunity to work with the Alaska Board in bringing automated dispensing systems to the state.

Thank you!

Sincerely,
Kevin Rew

On Fri, Feb 1, 2019 at 4:02 PM Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Hi Kevin,

We don't have approval for our March 7th and 8th meeting, which is why it isn't posted yet. Could you put your questions in writing please?

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

On Feb 1, 2019, at 2:57 PM, Kevin Rew <krew@medifriendrx.com> wrote:

Hi Laura,

I've just checked your website and couldn't tell whether a Board of Pharmacy meeting has been scheduled. Has one? I'd like to keep tabs on agenda items and, if possible, talk to someone about automated dispensing. Our potential pharmacy partner is very interested in extending the reach of their pharmacies to underserved communities with this option.

Thank you,
Kevin Rew

On Wed, Dec 5, 2018 at 4:00 PM Kevin Rew <krew@medifriendrx.com> wrote:

Thank you, Laura!

The pharmacy owner we're talking to is very interested in bringing this service to Alaska. I'd love to listen to and/or participate in discussions of the issue, and to work with you on pilot programs or rules/legislation. I'm sure that the presentation would be one made jointly by my company and the Alaska pharmacy operator.

As a bit of further background, I worked with the California Board of Pharmacy and the legislature for almost two years, resulting in legislation that was signed by our Governor on September 21, 2018, bringing pharmacy-licensed automated dispensing to California. Prior law allowed for very limited use. Another approach would be similar to rules that became effective in Idaho in July 2018. That state is working hard to solve the problem of access to pharmacy services by remote populations and the rules are very inviting.

I hope to work with you!

Sincerely,
Kevin Rew

On Wed, Dec 5, 2018 at 3:37 PM Carrillo, Laura N (CED)
<laura.carrillo@alaska.gov> wrote:

Hi Kevin,

Thank you for your inquiry. At this time, I don't see that we address automated dispensing systems explicitly in our statutes and regulations; however, I do know the NABP supports this in their model acts. I'll forward this to our board chair for potential discussion at our next board meeting, which is yet to be scheduled and will follow-up as new



September 24, 2019

Robert J. Clark, President/CEO
Bristol Bay Area Health Corporation
6000 Kakanak Road
P.O. Box 130
Dillingham, AK 99576

Dear Mr. Clark,

This letter is in response to your follow-up correspondence dated August 12, 2019 to the Alaska Board of Pharmacy through executive administrator, Laura Carrillo, related to state licensure requirements for pharmacists-in-charge (PIC) of licensed pharmacies operating under a Native Health Organization. The following response is being provided based on an August 20, 2019 legal opinion provided by attorney, Harriet Dinegar-Milks, to the question of whether a pharmacist for an Alaska-licensed Indian Health Service (IHS) pharmacy can appoint a PIC who does not hold a license under AS 08.80.

Att'y Dinegar-Milks opines that pharmacies operating under the Indian Self-Determination and Education Assistance Act (ISDEAA), or an IHS pharmacy, can employ a non-licensed PIC. This is supported by a formal Attorney General Opinion dated April 17, 2012, which concluded that federal law preempts state licensing requirements for pharmacists who are employed by tribal health programs. 2012 Op. Alaska Att'y Gen. (April 17) (AGO AN2009102500) at pp. 12-13. The federal law, referred to as Section 221, says:

"Licensed health professionals employed by a tribal health program shall be exempt, if licensed in any State, from the licensing requirements of the State in which the tribal health program performs the services described in the contract or compact of the tribal health program under the Indian Self-Determination and Education Assistance Act." 25 U.S.C. §1621t.

Please allow this documentation to serve as a formal response and as acknowledgment that the pharmacy board cannot require a tribal pharmacy, even if the pharmacy is licensed or registered under AS 08.80, to be staffed by an Alaska-licensed pharmacist. Furthermore, it is the understanding of the board that requiring licensure would frustrate the purpose of the federal law, which is to facilitate staffing of native health care facilities by opening employment to licensees from other states.

Sincerely,

A handwritten signature in blue ink that reads "Richard Holt".

Rich Holt, Chair
Alaska Board of Pharmacy

cc: Laura Carrillo, Executive Administrator
Sara Chambers, Division Director
Sharon Walsh, Deputy Director



Alaska Board of Pharmacy

Published to promote compliance of pharmacy and drug law

PO Box 110806 • Juneau, AK 99811-0806

Clarifications Made to Changes on a Class II Prescription

As stated in the last *Newsletter* there is a contradiction in Drug Enforcement Administration's (DEA) stance on what can be changed on a Class II prescription. DEA responded to this contradiction with a "Dear Colleague" letter dated October 15, 2008, by Joseph T. Rannazzisi, deputy assistant administrator, deputy chief of operations, Office of Diversion Control, acknowledging that DEA's written guidance documents are in conflict and a cause for confusion. DEA goes on to state that it plans to resolve this matter through future rulemaking. However, "until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber." As of March 2009, this is the official stance of DEA according to the Liaison and Policy Section, Office of Diversion Control, DEA. A copy of the letter can be found online at www.asep.com/advocacy/federal_upload/DEA_Letter%20on%20prescription%20changes.II.pdf

Since the Alaska Board of Pharmacy had no official stance on what can be changed on a Class II prescription, the last Alaska Board of Pharmacy *Newsletter* made the following clarification.

A pharmacist can modify or add the following information to Schedule II prescriptions after oral consultation with the prescribing practitioner (not his agent):

- ◆ Date of issue – may be added but not changed
- ◆ Patient's address
- ◆ Drug strength
- ◆ Drug dosage form
- ◆ Drug quantity – may be modified in conjunction with change in strength only, but not to exceed the original total dosage prescribed
- ◆ Directions for use

A pharmacist may never change the name of the drug (except to generic), name of the patient, or the signature of the practitioner.

Since federal law trumps state law, this clarification will be in place until DEA clarifies their rules.

Pharmacy Vending Machines

Many pharmacies have had multiple phone calls from patients requesting refills and transfers of prescriptions that were originally dispensed from pharmaceutical vending machines. These

vending machines have been popping up around the state in various doctor offices and clinics. These machines are Prescription Medication Dispensers that have a variety of medications prepackaged within. After entry of information from a doctor or agent the patient's insurance is charged and the prescription is labeled and dispensed like a can of pop.

There has been much question to the validity of these machines. Regulations clearly state a facility or provider cannot legally represent themselves as having a pharmacy or pharmacist based solely on the presence of a pharmaceutical vending machine.

It is also noted that the Securities and Exchange Commission (SEC) states a physician cannot "refer to him/herself for financial gain." The use of pharmaceutical vending machines in a physician's office is an infraction of this SEC regulation.

There are several illegalities resulting from the use of pharmaceutical vending machines and numerous questionable practices related to their use. Clinics and facilities with these devices are to cease and desist from continued statutory violations.

Job Shadowing

The Board was extremely pleased with the quantity and quality of public comments received on the topic of job shadowing. Each comment was reviewed in its entirety and the proposed regulations were created with your comments in mind. The Board's objectives were to streamline the paperwork, account for how job shadowing was being utilized by school systems and higher education, address public comments, and clarify Health Insurance Portability and Accountability Act obligations in the proposed regulations. Thank you for your interaction and participation in this process.

July 2010

The *Alaska Board of Pharmacy News* is published by the Alaska Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc. to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

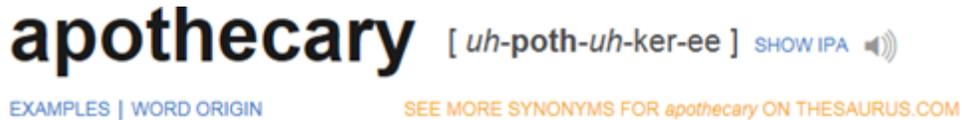
Mary Kay Vellucci - State News Editor
Carmen A. Catzone, MS, RPh, DPh - National News Editor
& Executive Editor
Larissa Doucette - Communications Manager

From: [Fagerstrom, Kathryn E \(CED\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: RE: "Apothecary"
Date: Wednesday, May 8, 2019 1:58:41 PM
Attachments: [image001.png](#)
[image004.png](#)

Hi Laura,
My apologies for the delay in responding to your email.

There are currently 8 active business licenses that contain the word "apothecary".

I concur that "apothecary" implies there is a pharmacist on location.



noun, plural a·poth·e·car·ies.

- 1 a druggist; a pharmacist.
- 2 a pharmacy or drugstore.
- 3 (especially in England and Ireland) a druggist licensed to prescribe medicine.

I understand the statutes that Brian provided; however I am concerned if the interpretation on "other similar title" is too broad to include the word "apothecary" since it is not similar to the very specifically restricted words/titles given. Apothecary implies they are engaging in business activity that requires a PHA on site but does not contain any of the restricted words/titles.

Section 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," 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.

I think this warrants further discussion on if above statute may apply to words that imply PHA activity and how BL may respond to this.

Thank you,

Kathryn E. Fagerstrom

Records & Licensing Supervisor for Corporations & Business Licensing Sections

Alaska Division of Corporations, Business and Professional Licensing commerce.alaska.gov/web/cbpl

Corporations Section www.Corporations.Alaska.Gov

Business Licensing Section www.BusinessLicensing.Alaska.Gov

P.O. Box 110806, Juneau, AK 99811-0806

Phone: (907) 465-2427

Fax: (907) 465-2974

From: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Sent: Tuesday, April 02, 2019 9:54 AM
To: Fagerstrom, Kathryn E (CED) <kathryn.fagerstrom@alaska.gov>
Subject: FW: "Apothecary"

Hi Kathy,

There's recently been concern over businesses that are not licensed by the board of pharmacy using the term, "apothecary", since it's potentially a violation of AS 08.80.420 (certain advertisements prohibited). Brian sent me an email, below, letting me know of two business licenses issued containing this term. We may need to screen these carefully when businesses are wanting to use this term, since the board of pharmacy specifically prohibits this. In the mean time, would you let me (or Brian and Sonia) know how we should proceed with the below businesses who have used this term?

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: Howes, Brian K (CED)
Sent: Tuesday, April 2, 2019 9:09 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Lipker, Sonia L (CED) <sonia.lipker@alaska.gov>
Subject: RE: "Apothecary"

Laura,

Business Licensing just recently issued these licenses (among others), are they on the same page as the Board? May be you could reach out to them...

2084529	MARY JANE'S APOTHECARY	DOUGLAS TURNER
<u>3/22/2019</u>	<u>12/31/2020</u>	
1113004	SPINNING MOON APOTHECARY	SPINNING MOON APOTHECARY LLC
<u>2/3/2019</u>	<u>12/31/2019</u>	

Section 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," 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.

Diagnosis and Management of Concussion: A Position Statement of the Current Alaska State Board of Chiropractic Examiners

Author: Brian E. Larson, D.C., DACBSP®

Current Board Members:

Brian Larson, D.C., DACBSP®, Chair

John Wayne Aderhold, Public Member

James Morris, D.C.

Jeffrey Reinhardt, D.C.

Jonathan Vito, D.C.

Thomas Bay, Licensing Examiner

Reviewed, amended, and approved: September 28, 2018

As to the qualification of Chiropractic Physicians (Chiropractors) to diagnose and manage concussions in all populations, considering the recent change of statute recognizing chiropractic physicians are qualified to administer school preparticipation physical examinations, the Alaska State Board of Chiropractic Examiners responds:

DEFINITION:

Concussion is an area of sports medicine that is in continual evolution, from definition to diagnosis, treatment, and return to play guidelines. The general components of defining concussions include the following elements of a mild traumatic injury to the brain:

1. Trauma induced, whether direct blow to the head or indirect force transmitted through the body to the head;
2. Immediate or near immediate display of physical or neurological dysfunction;
3. Symptoms are transient;
4. Results in a graded set of clinical symptoms that may or may not involve loss of consciousness (LOC);
5. A functional disturbance rather than a structural injury;
6. Resolution of symptoms typically follows a sequential course of varying duration in time;

7. The signs and symptoms cannot be attributed to an alternative causation such as mental disease, medication, or mechanical injury to the neck, ears, and/or eyes.

Alaska Law

Alaska Statute 14.30.142... states:

(c) A student who is suspected of having sustained a concussion during a practice or game shall be immediately removed from the practice or game.

(d) A student who has been removed from participation in a practice or game for suspicion of concussion may not return to participation in practice or game play until the student has been evaluated and cleared for participation in writing by an athletic trainer or other qualified person who has received training, as verified in writing or electronically by the qualified person, in the evaluation and management of concussions. In the subsection, "qualified person" means either a

(1) health care provider who is licensed in the state or exempt from licensure under state law; or

(2) person who is acting at the direction and under the supervision of a physician who is licensed in the state or exempt from licensure under AS 08.64.370(1), (2), or (4).

(e) A person who conducts an evaluation under (d) of this section and who is not paid for conducting the evaluation may not be held liable for civil damages resulting from an act or omission during the evaluation, except that the person may be held liable for reckless or intentional misconduct and for gross negligence.

This law pertains to children and adolescents under legal age in Alaska.

Qualifications to Diagnose, Manage, and Make Return-to-Play (RTP) Decisions

The Alaska Student Activities Association (ASAA), a private non-profit organization (PNP), is recognized by the Alaska Legislature, and acts as the general governing body for high school activities and sports in Alaska. As such, the ASAA recognizes advanced qualifications in sports medicine obtained by chiropractic physicians holding DACBSP® and CCSP® certifications of the American Chiropractic Board of Sports Physicians® (ACBSP®) as qualified to Diagnose, Manage, and make RTP decisions relating to student athletes falling under ASAA jurisdiction. This board applauds that recognition.

Other governing bodies for various ages and sports (school districts, PNPs, etc.) typically default to ASAA Guideline for Concussions.

This board puts forth that chiropractic physicians licensed in Alaska *may* be qualified to diagnose, manage, and make RTP decisions with appropriate and ongoing training specifically related to the science of concussion. Additionally, this board holds forth that any health care provider licensed in Alaska, regardless of endpoint of education, is

equally unqualified to diagnose, manage, or make RTP decisions without the same level of current and ongoing concussion-specific training.

Concussion is a rapidly changing science. Several methods of evaluating and managing concussions, once held as standards, are now defunct. Several concepts and conditions related to concussions are now questioned, and much recent research held as proof of diagnosis is now recognized as flawed or presumptive. Concussion is not a science that can be learned once in professional training and filed away for the remainder of a professional career. Remaining constant in the field of concussion requires dedicated, ongoing, and relentless training.

This board sets forth current certification of the online CDC training Heads Up! On Concussion for Professionals (approximately 2 hours) and the ACBSP® Concussion Registry (ACR) (approximately 12.5 hours), with passing scores on the associated minimum competency examinations, as the standard of training for qualification to access, manage, and make RTP decisions related to concussed individuals of all populations in Alaska. We challenge all other professional boards to review the afore outlined materials and make such recommendations and qualifications to their respective members for the benefit and protection of the people of Alaska.

In review of the preceding material, the Alaska Board of Chiropractic Examiners finds that Chiropractic Physicians, properly licensed in Alaska, holding current DACBSP® and CCSP® certificates from the ACBSP®, as well as Alaska specialty-licensed Chiropractic Sports Physicians, Certified Chiropractic Sports Physicians, and Chiropractic Physicians who possess current CDC and ACR certificates are qualified and recommended to diagnose, manage, and make return-to-play or work decisions related to concussions.

This board requests that the Alaska Student Activities Association, as well as other health care professional boards, respect the findings and recommendation of this board.

Chiropractic physicians participating in concussion management are required to produce current (within 2 years) CDC and ACR certificates, upon request of patients or regulatory officials of the State of Alaska. Failure to do so constitutes a scope of practice violation and is subject to discipline.

From: [Debbie Mack](#)
Subject: FW: Kiosks
Date: Tuesday, April 23, 2019 2:04:55 PM
Attachments: [attachment 1.pdf](#)

I am looking for clarity around whether or not automated will-call bins/ pick up machines, (“pick up kiosks”) are allowed in your state. The type of machine that I am talking about is one that would be at or near the pharmacy inside of a Walmart store which would serve as a secure place for holding prescriptions which have already been filled, verified, bagged, and are ready for pickup by the patient or patient’s agent. The prescriptions would be placed in the machine at the patient’s request for pickup either during or after pharmacy hours. The machine would have a phone available to call into the pharmacy or to a pharmacist at another Walmart Pharmacy (after hours) with access to the patient profile for purposes of consultation.

Walmart considered deploying this type of machine in our pharmacies back in 2007-2008 and later decided not to move forward with the project. We appeared in person before nearly every Board of Pharmacy and many approved without having regulations, many approved after writing regulations, and some approved pilot programs. A few states did not approve the machines due to conflicting statutes/regulations. Because our previous research is very old, I would like to refresh our database of states where this type of machine is allowed.

Please see the attachment for a sample of the type of pick up kiosk in questions.

It would be most helpful if you wouldn’t mind answering the questions below so that I know whether or not we can add these machines to one or more pharmacies in the state:

Does your state allow the use of “pick up kiosks” (YES / NO)?

If YES:

Must the pick up kiosk be built into the wall of the pharmacy so that the loading of the machine occurs inside the footprint of the licensed pharmacy?

May the pick-up kiosk be free standing, but adjacent to the licensed pharmacy space?

May the pick-up kiosk be free standing, at any location within the Walmart store?

Can the pick-up kiosk be used to deliver both legend drugs AND controlled substances? (Or ONLY legend drugs?)

Can the pick-up kiosk be used to deliver both new AND refill prescriptions? (Or ONLY refills?)

Can the pick-up kiosk be used to deliver prescriptions for afterhours pickup?

Thank you in advance for taking the time to answer the above questions.

Thanks

Debbie

Debbie Mack, RPh, CHC, CCEP, Sr. Director, U.S. Ethics & Compliance

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