

STATE OF ALASKA

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

ALASKA BOARD OF PHARMACY



March 7, 2019

Anchorage

Board Packet

PUBLIC

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	03/01/2023
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

STATE CAPITOL
P.O. Box 110001
Juneau, AK 99811-0001
907-465-3500



550 West Seventh Avenue, Suite 1700
Anchorage, AK 99501
907-269-7450

Governor Michael J. Dunleavy
STATE OF ALASKA

January 8, 2019

Mr. Leif Holm
167 Santa Claus Lane
North Pole, AK 99705

Dear Mr. Holm,

I am pleased you have accepted re-appointment to the Board of Pharmacy and appreciate your willingness to continue serving Alaska in this important capacity.

The willingness of Alaskans like you to volunteer your expertise and perspective as public policy is shaped and implemented is crucial for a healthy Alaska. Thank you for continuing to give your time and talents to serve the people of Alaska.

Sincerely,

A handwritten signature in blue ink, appearing to read "Michael J. Dunleavy".

Michael J. Dunleavy
Governor



ALASKA BOARD OF PHARMACY MEETING TENTATIVE AGENDA

MARCH 7, 2019 (DAY 1)

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

Board Members:

Richard Holt,
PharmD, MBA
(Chair)

Leif Holm, *PharmD*
(Vice Chair)

James Henderson,
RPh

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

Upcoming Meetings:

TBD

Meeting Details

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

Meeting Start Time: 9:00 AM Alaskan Standard Time

Meeting Start Date: 3/7/2019

Meeting End Time: 4:30 PM Alaskan Standard Time

Meeting End Date: 3/7/2019

Meeting Location: Robert Atwood Building, 550 W 7th Ave, ACC 102 (ANCHORAGE)
or the State Office Building, 9th Floor, 333 Willoughby Ave, Commissioner's Conference
Room (JUNEAU)

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 - 9:10 a.m. Ethics Disclosures
- IV. Agenda Item #4 - 9:15 a.m. Public Comment
- V. Agenda Item #5 - 9:25 a.m. PDMP Update
 - A. Board of Pharmacy Data Report
 - B. PDMP 2019 Legislative Report (Draft)

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(Vice Chair)

James Henderson,
RPh

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

**Upcoming
Meetings:**

TBD

- C. BJA's Enhanced Programmatic Desk Review (EPDR)
- D. CDC Grant Opportunity - "Overdose Data to Action"
- E. Military Health System (New, December 2018)
- VI. Agenda Item #6 - 10:00 a.m. Conference and Meeting Updates
 - A. Controlled Substance Advisory Committee (Lana Bell)
 - B. Alaska Pharmacists Association Annual Meeting (Rich Holt)
- VII. Agenda Item #7 - 10:30 a.m. Investigative Report
- VIII. Agenda Item # 8 - 10:45 a.m. New Business
 - A. NABP - NPDB - Adverse Action Reporting
 - B. Skilled Nursing Facilities
(From November 30th, 2018 Agenda)
 - C. Controlled Substance Issue
 - 1. January 23rd Letter to Pharmacists
 - 2. January 25th Media Release
 - 3. February 5th Patient Handout
 - 4. Feedback
 - D. IHS - Pharmacist-in-Charge License Requirement
 - E. Proposed Rule - Partial Fill Schedule II / Quantity Prescribed Field
 - F. Transfer of Unfilled Controlled Substances
- IX. Agenda Item #9 - 11:45 p.m. Lunch
- X. Agenda Item #10 - 12:45 p.m. Correspondence
 - A. NACDS - Lis Houchen
 - B. NABP Proposed Resolutions
 - C. NABP MPJE Workshop
 - D. NABP Annual Meeting
 - E. Automated Dispensing
 - F. Unlicensed Practice
 - G. Prescription Adaptation - Dennis McAllister
- XI. Agenda Item #11 - 1:30 p.m. Division Update/Budget Report (tentative)
 - A. FY19 1st Quarter
 - B. FY19 2nd Quarter

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James Henderson,
RPh

Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

**Upcoming
Meetings:**

TBD

XII. Agenda Item #12 - 2:00 p.m. Old Business

A. OMRO

1. OMRO Application
2. OMRO Denial Documents
3. DCCED Proposal for Action - No Objection
4. ALJ - Proposed Decision
5. OMRO Proposal for Action

B. Continuing Education Audit

1. Pharmacists
2. Technicians

XIII. Agenda Item #13 - 2:45 p.m. Board Business

A. Review Applications

1. Technician - Rochelle Sakar (Tabled)
2. Technician - Andrew Hammer-Licka - 143549
3. Technician - Lisa Speckels - 142213
4. Pharmacist - Dana Alkire - 143317 (Items Pending)
5. Pharmacist - Chelsea Gwinn - 142825 (Items Pending)
6. Pharmacist - Robert Harrison - 131407 (Complete)
7. Drug Room - Alpine Surgery Center - 143793
8. Out-of-State Pharmacy - Biologics - 143645
9. Out-of-State Pharmacy - Biologics - 143646

B. Review Failed Quorum Applications

1. Pharmacist - Yibo Sun - 142885 (Items Pending)
2. Pharmacist - Fred Cazeau - 142926 (Items Pending)
3. Pharmacist - Katie Schumacher - 123169 (Items Pending)
4. Pharmacist - Michael Anczak - 131480 (Items Pending)
5. Facility - Coram CVS - 142465 (name change to "Geneva Woods Infusion Pharmacy" on 02/27/19 prior to issuance)
 - a. Correspondence regarding DBA name change
 - b. Amendment for DBA name change

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Lana Bell, *RPh*

Phil Sanders, *RPh*

Tammy Lindemuth,
Public Member

Sharon Long, *Public*
Member

**Upcoming
Meetings:**

TBD

6. Facility - Northwest Compounders - 141407
7. Facility - Airgas USA, LLC - 143078
8. Facility - Airgas USA, LLC - 143084
9. Facility - Airgas USA, LLC - 143088
10. Facility - Airgas USA, LLC - 143090
11. Facility - Airgas USA, LLC - 143055
12. Facility - Airgas USA, LLC - 143023
13. CPA - PHAR384
14. CPA - PHAR393
15. CPA - PHAR480
16. CPA - PHAR388
17. CPA - PHAR389
18. CPA - PHAR387

C. Applications & Forms Update

D. 2019 Annual Report

- XIV. Agenda Item #14 - 4:25 p.m. Review Lost/Stolen Rx
 - A. Safeway Pharmacy #1820 (#120100)
- XV. Agenda Item #15 - 4:30 p.m. Recess until March 8th

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

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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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March 3, 2019

Richard Holt, BS Pharm, PharmD, MBA
Chair, Alaska Board of Pharmacy
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
P. O. Box 110806
Juneau, AK 99811-0806

Dr. Holt and Honorable Members of the Alaska State Board of Pharmacy:

On behalf of the members of the National Association of Chain Drug Stores (NACDS), we are writing to the Alaska Board of Pharmacy regarding problems that Alaska pharmacists are having in creating and renewing their online Prescription Drug Monitoring Program (PDMP) accounts. We have received numerous complaints that pharmacists are having technical difficulties setting up and/or renewing their accounts and are unable to receive assistance from state authorities operating the PDMP.

Pursuant, to AS 17.30.200, Alaska pharmacists are required to register an account with the PDMP. However, if pharmacists are unable to create or renew their accounts, they cannot be registered with the Alaska PDMP and cannot, when appropriate, access the PDMP to determine whether a controlled substance should be dispensed to a given patient.

Based on reports that we have received, pharmacists contacting state officials for assistance with PDMP accounts are met with a voicemail greeting indicating that there is an 8 to 10-week backlog for new PDMP account creations and a 10 to 14-week backlog for PDMP account renewals. Pharmacists are extremely concerned. They recognize the value for them to voluntarily check the PDMP before dispensing controlled substances. At the same time, they question how they are supposed to comply with the law, when there are two to three-month delays, where they cannot comply with Alaska's law due to no fault of their own.

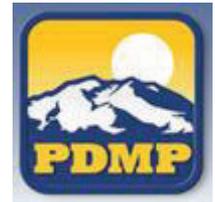
In conclusion, Alaska pharmacists are ready and willing to comply with Alaska's PDMP law. However, they require guidance from the Board as to how they should handle situations wherein they attempt to create a PDMP account or renew an account but cannot do so due to technical difficulties and a two to three-month backlog for assistance from state officials. We thank you for your attention to our concerns and look forward to further guidance.

Sincerely,

Lis Houchen
lhouchen@nacds.org

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 January 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.

Updates and Imminent changes:

- 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>
- Enhancement features of interest include Clinical Alerts, NarxCare, and the Compliance Module.
- 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

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 January 31, 2019, there are a total of 7,070 registered users, 972 of which are registered using the ‘Pharmacist’ role and 40 are registered using the ‘Pharmacist-in-Charge’ role (Figure 1). 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 14%, 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

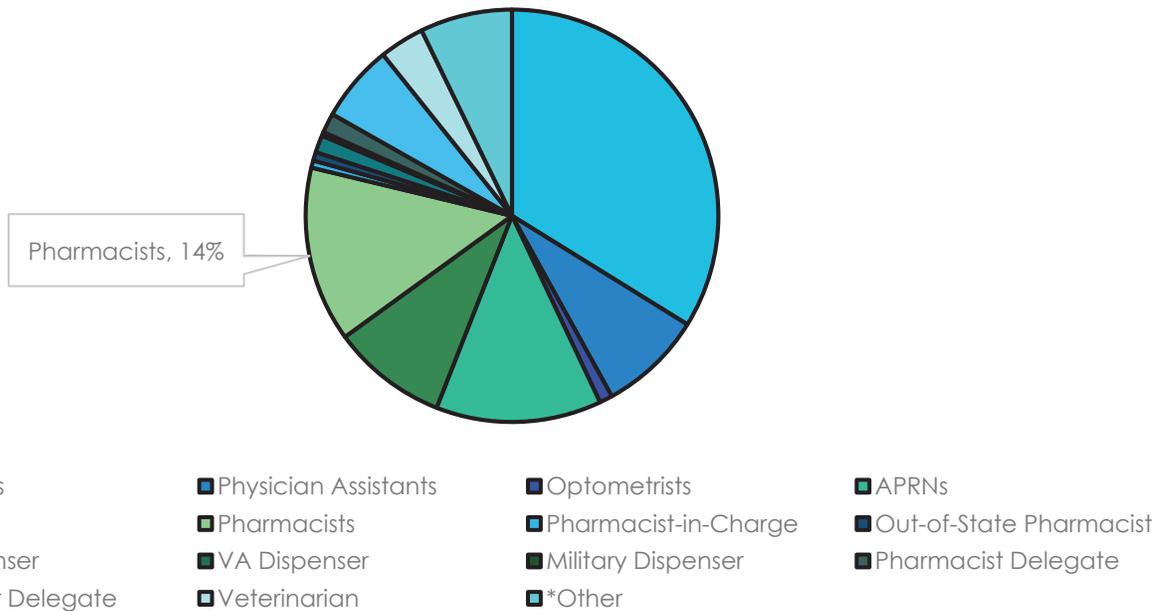


Figure 1 A. The Pharmacists user role category comprises 14% of actively registered users. A breakdown of additional pharmacy-related registrations are included in Figure 1 C. *Other includes admin, medical residents with prescriptive authority, medical examiner/coroner, medical interns, and medical residents.

Registration Trend (Cumulative): Pharmacists

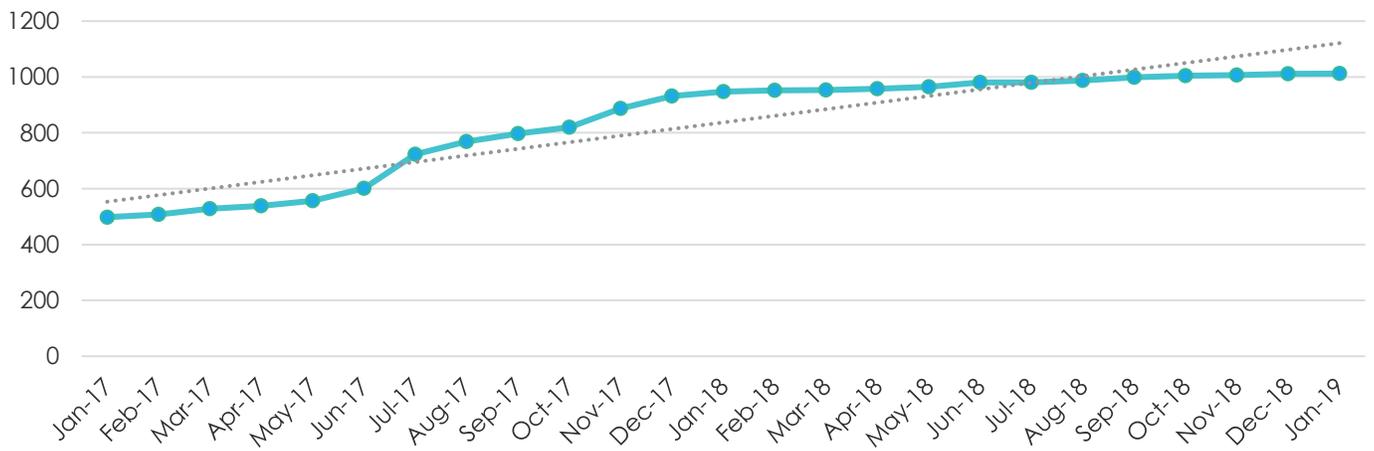


Figure 1 B. The PDMP registration trend for pharmacists from 2017 to 2018 reflects a steady increase over time. The base registration count at by the end of 2016 was 494 pharmacists.

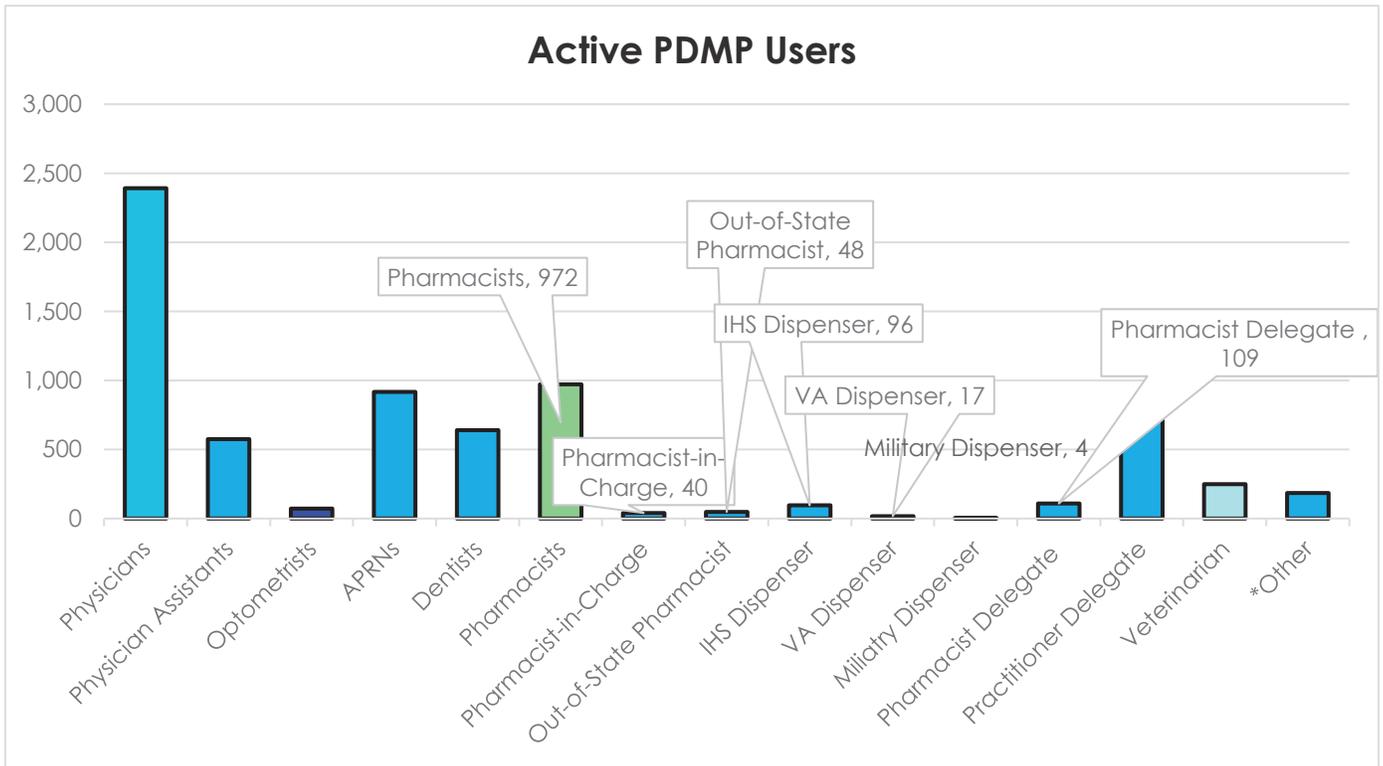


Figure 1 C. A breakdown of pharmacy-related user roles.

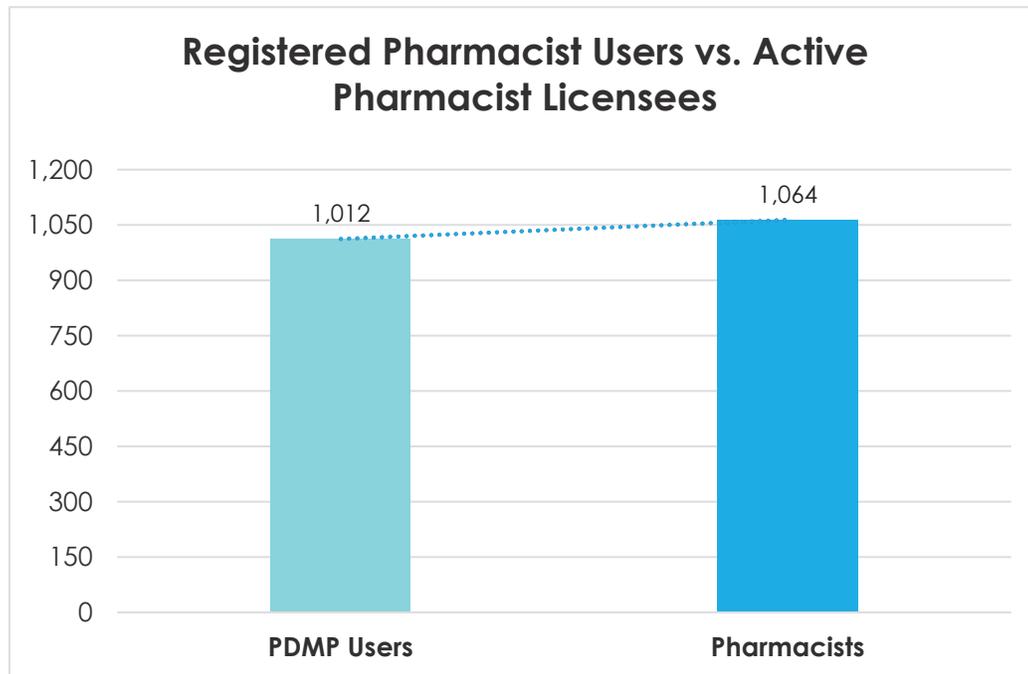


Figure 2. The proportion of licensed pharmacists to registered PDMP users (pharmacists and pharmacist-in-charge user roles; excludes out-of-state pharmacists). This represents a compliance rate of 93%, meaning only 7% of licensees potentially required to register are not yet registered or are registered under a federal user role category. When considering VA, IHS, and Military dispenser users (n=117), this compliance rate increases to 106% and may be inclusive of IHS 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	TBD

Figure 3. Threshold reports are generated every three months. The last report generated for 09-01 to 12-01 resulted in 40 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 AWARe platform.

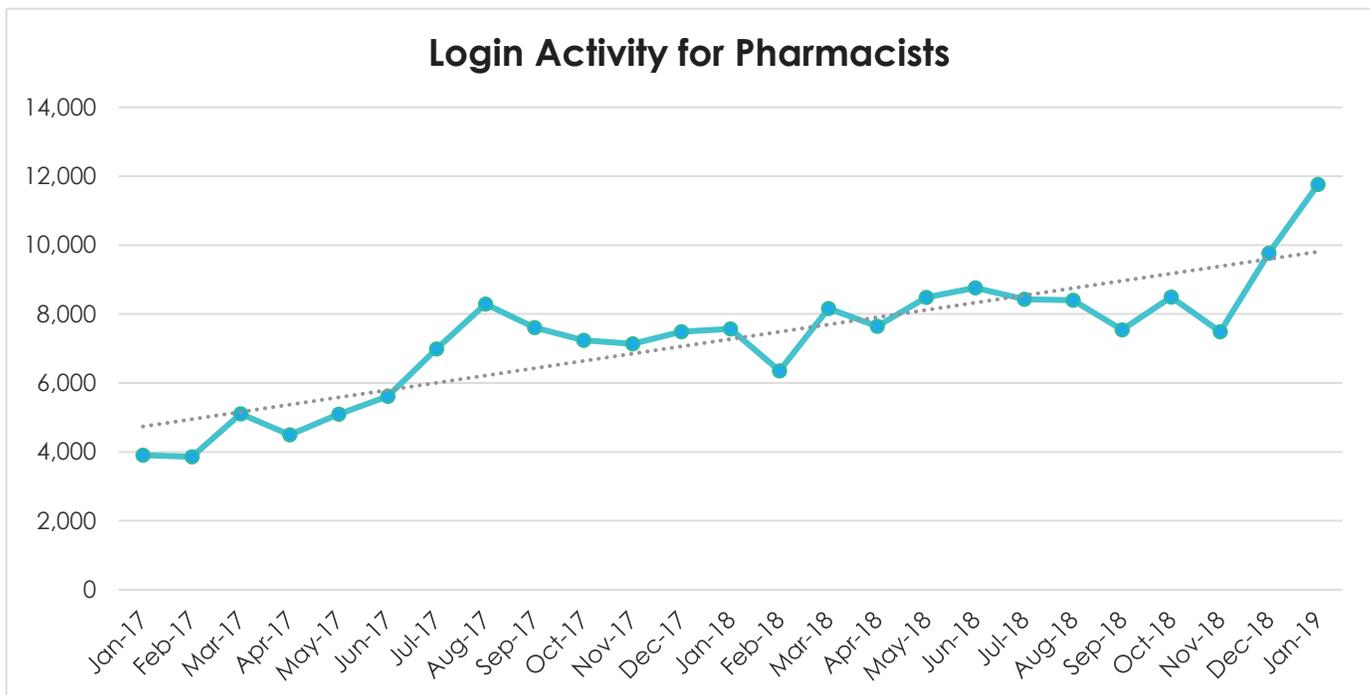


Figure 4. Pharmacists are not required to login to check patient prescription history, however, this graph shows that pharmacists are maximizing efforts to prevent doctor shopping of controlled substance prescriptions.

Patient Prescription History Query Activity for Pharmacists

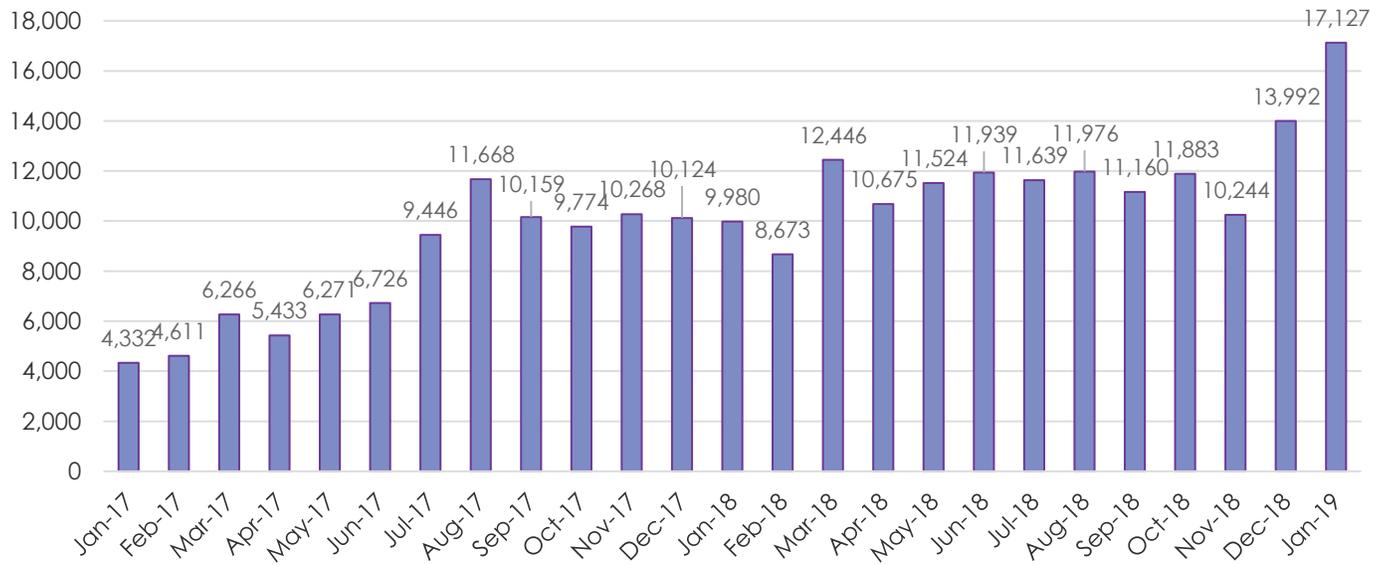


Figure 5. Pharmacists are not required to login to check patient prescription history, however, consistent with login activity trends, pharmacists are consulting the PDMP when dispensing medications.

Adjusted Login Activity by Profession (2018)

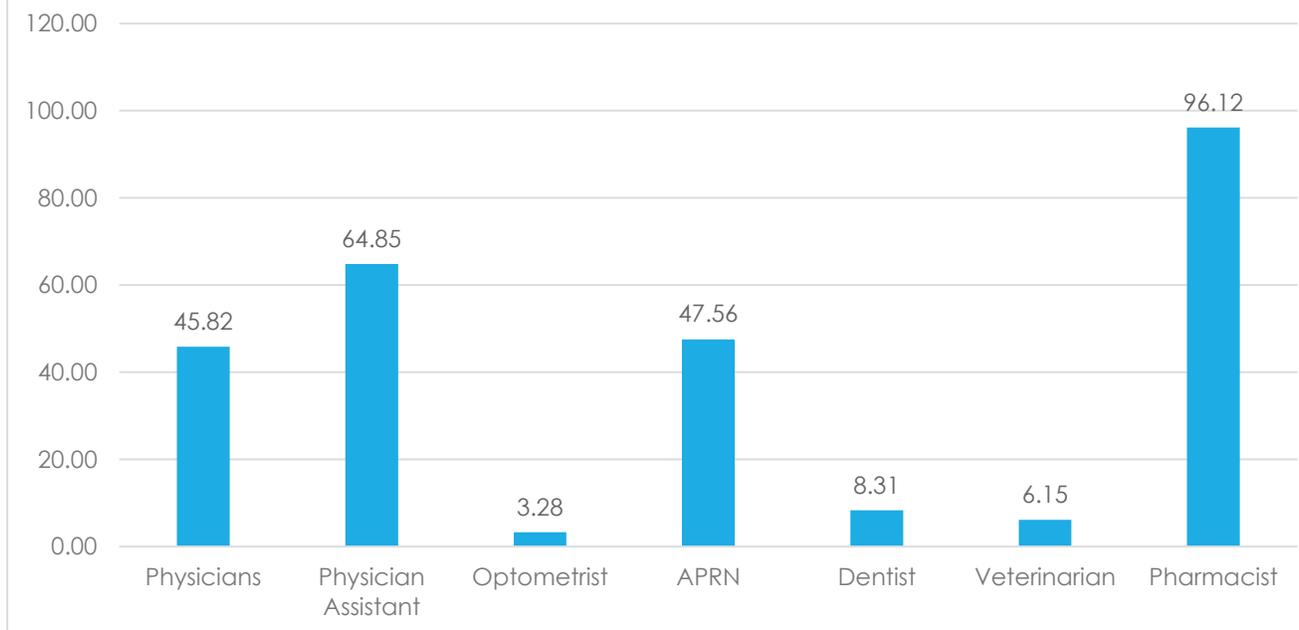


Figure 5. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest login rate adjusted by the number of registered users in their profession. The average login per one pharmacist is 96 times a year. Optometrists have the lowest login rate per at 3 logins per year per optometrist.

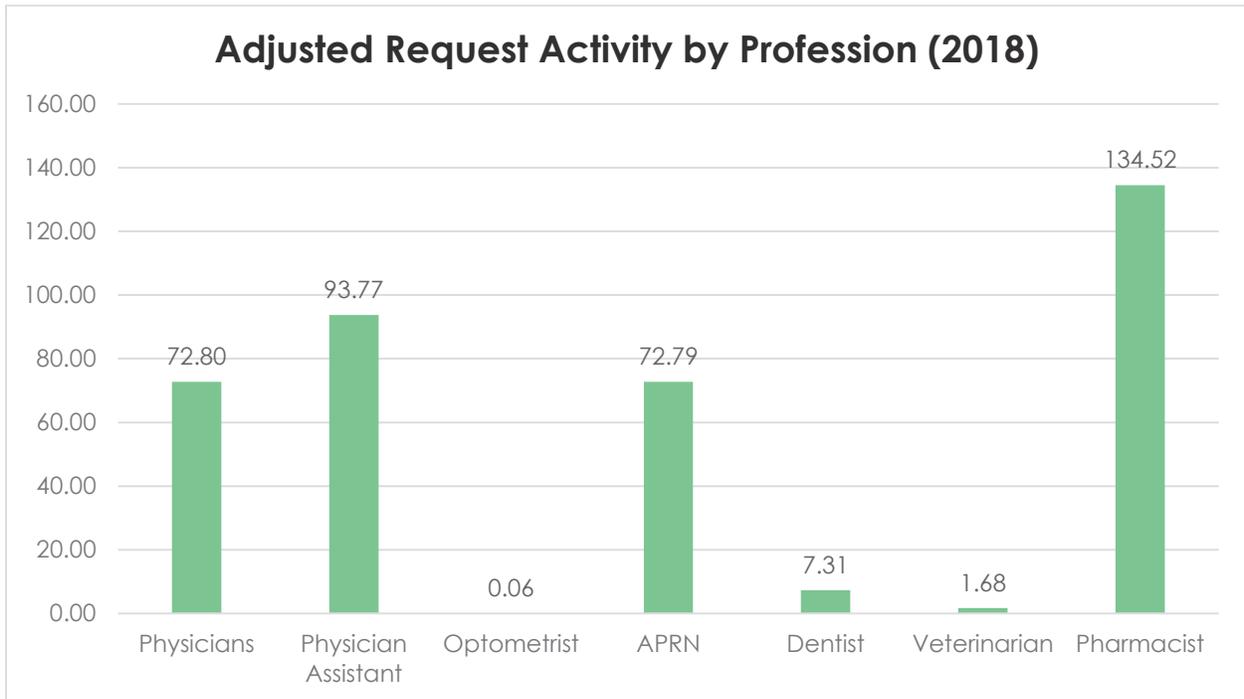


Figure 6. Adjusted by registered user count. Of mandatory professions required to register with the PDMP, pharmacists are the only providers not required to login to view patient prescription history; however, they have the highest patient request activity adjusted by the number of registered users in their profession. The average login per one pharmacist is 134 times a year. Optometrists have the lowest login rate per at less than one logins per year per optometrist.

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 6, below.

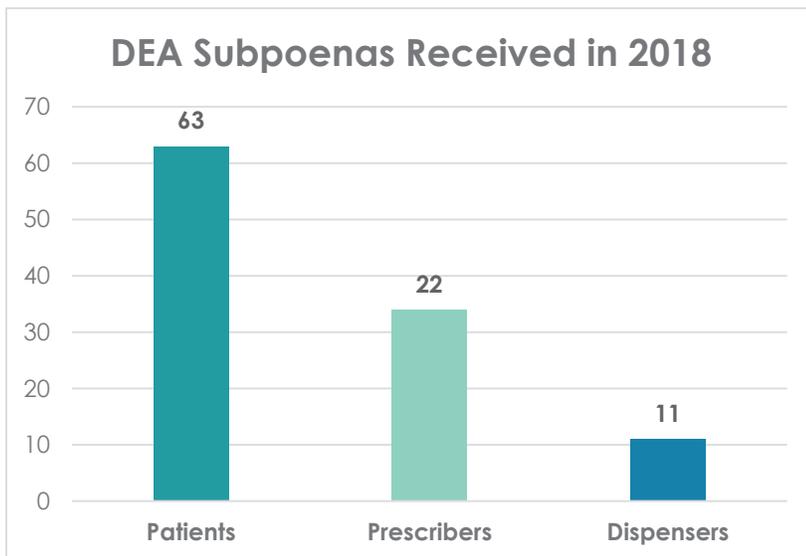


Figure 6. The PDMP manager has responded to 100% of the DEA subpoenas received in 2018. So far in 2019, the PDMP manager has responded to 23 subpoenas and will respond to 3 pending subpoenas before the deadline on March 10th.

Figure 7 captures the number of delinquent pharmacies through January 2019. Reporting is required daily per AS 17.30.200(b) and 12 AAC 52.865(b).

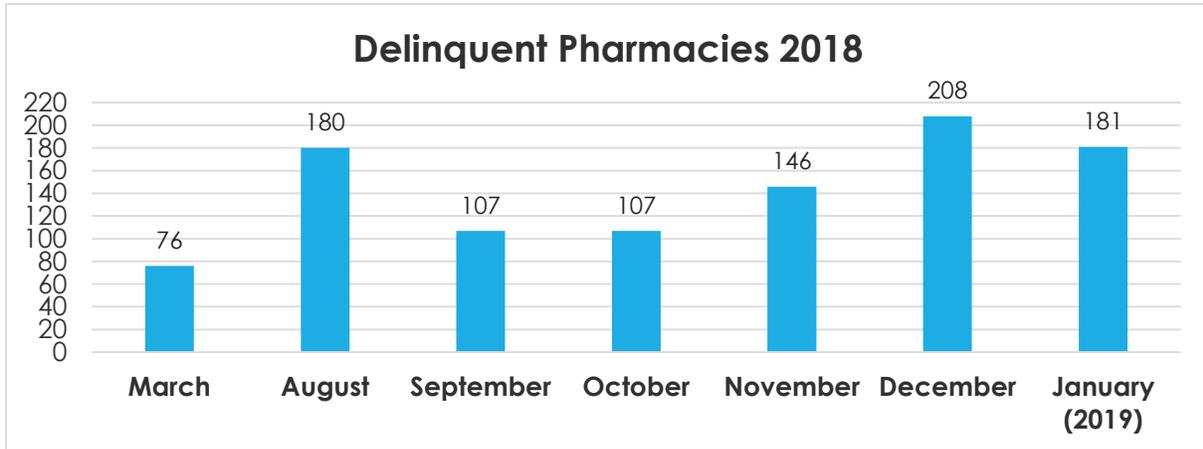


Figure 7. The number of delinquent pharmacies has more than doubled since the last compliance report. Pharmacies will be contacted via mail to correct reporting gaps. This also includes delinquent prescribers required to be reporting daily.

The following data (Figures 8 through 10) represents information not specific to any given profession and provides a general summary of PDMP trends as recorded in the controlled substance prescription database.

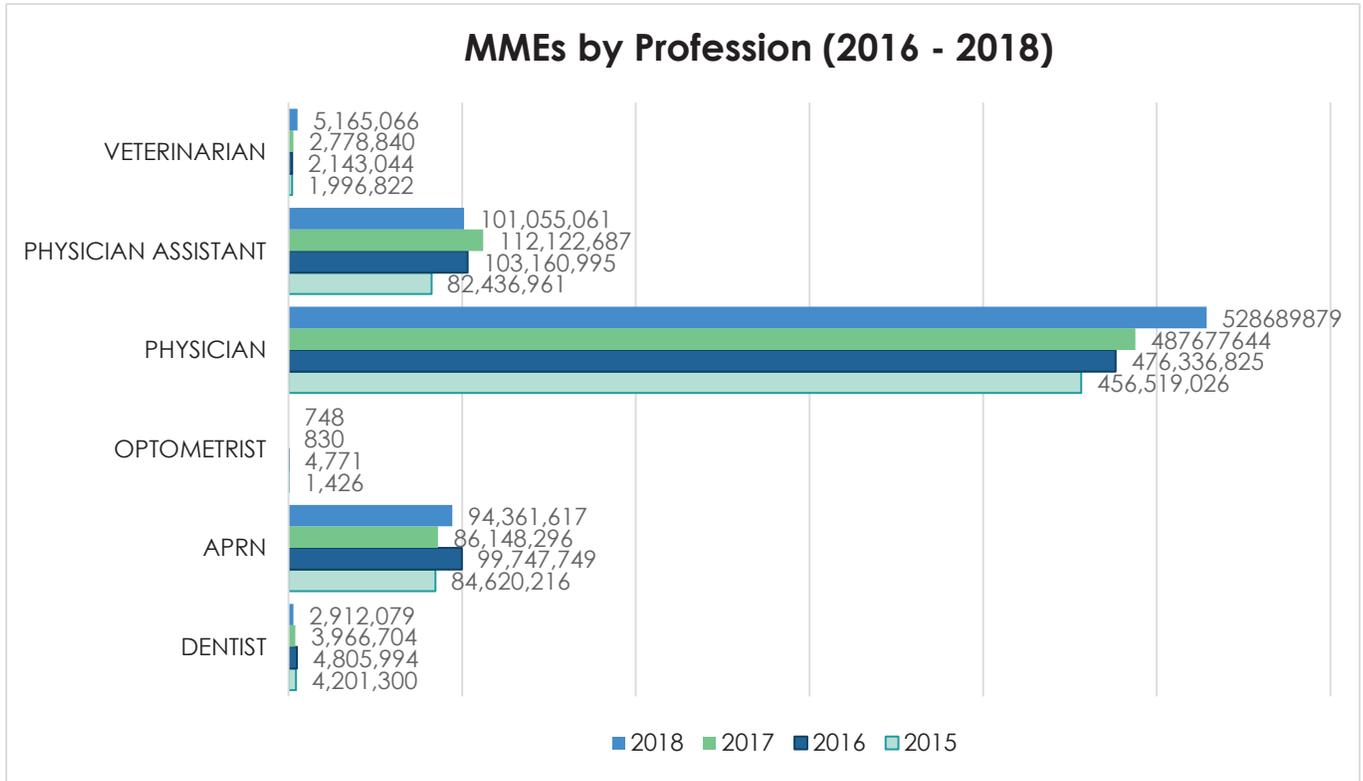


Figure 8. Total MMEs dispensed from 2015 - 2018.

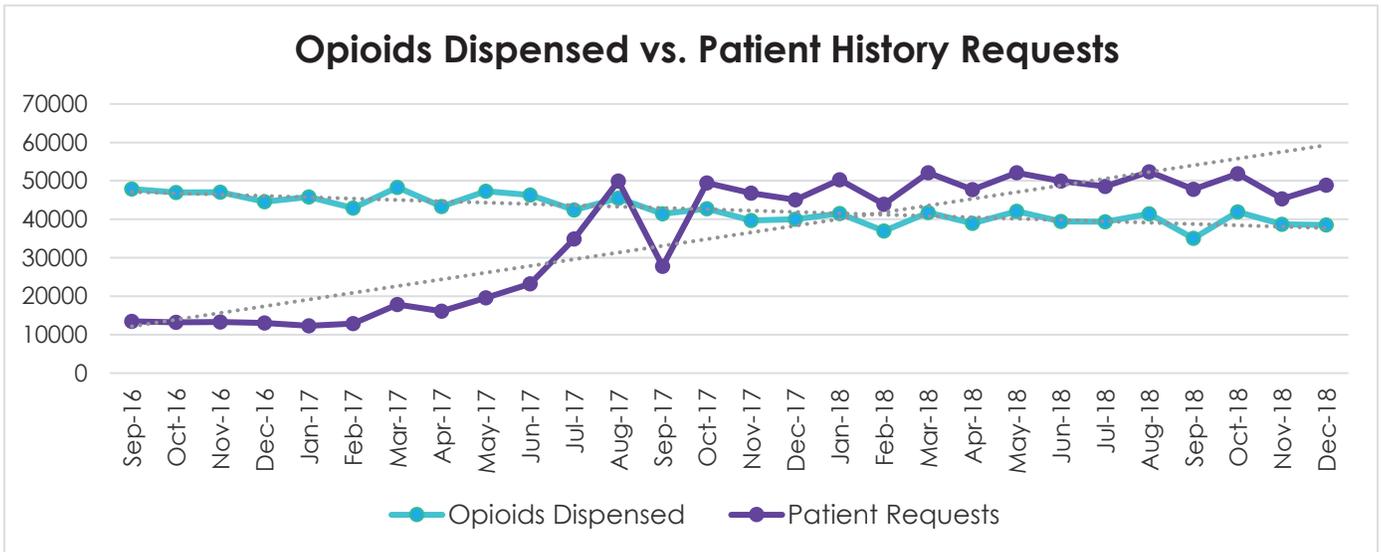


Figure 10. This graph shows the upward trend of patient prescription history requests in the PDMP, suggesting an inverse relationship between overall opioid dispensing in the state. The decrease in opioid dispensations may also be attributed to other factors, including prescriptive policies and salience of increased state-wide monitoring of prescribing practices as reflected in individual prescriber report cards.

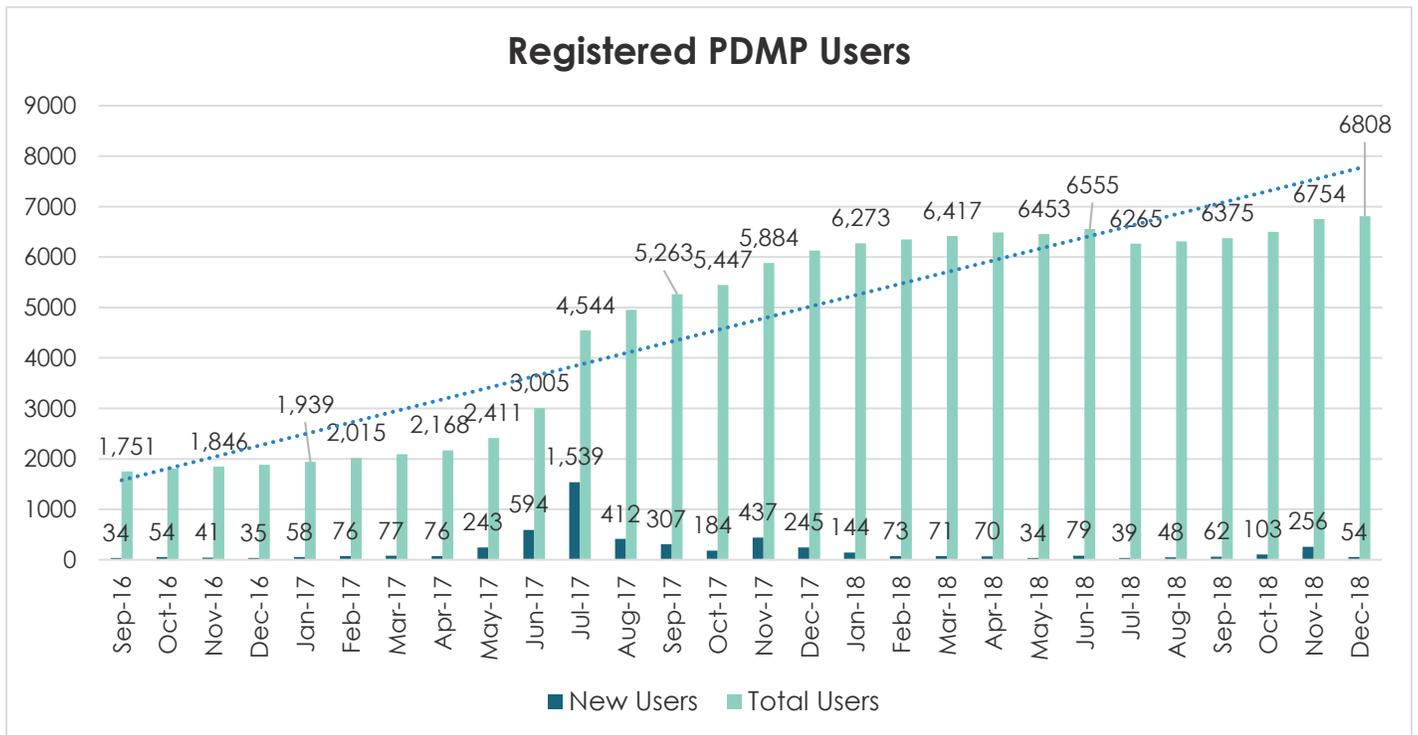


Figure 4. Registered users have steadily increased following mandatory registration.



U.S. Department of Justice
Office of Justice Programs

Bureau of Justice Assistance

Washington, D.C. 20531

January 30, 2019

Jay C Butler
Chief Medical Officer and Director
State of Alaska, Department of Health and Social Services
PO Box 110635
Juneau, Alaska-99811

RE:
2017-PM-BX-0006, State of Alaska, Department of Health and Social Services

Dear Jay C Butler,

This letter is to confirm that the U.S. Department of Justice, Office of Justice Programs (OJP), BJA will conduct an Enhanced Programmatic Desk Review (EPDR) of AK DEPT OF HEALTH AND SOC SRVS scheduled for February 13, 2019 beginning at 1:00PM EST. The date of this EPDR were confirmed with Andy Jones, Director via andy.jones@alaska.gov on January 18, 2019. The EPDR will include a review of the programmatic, financial, and administrative activities related to the awards listed above.

This EPDR is part of OJP's federally-mandated requirement (see Uniform Guidance 2 C.F.R. § 200) to conduct grant monitoring and oversight of the financial, administrative, and programmatic activities of grantees. The focus of the EPDR will be to assess and ensure compliance with the regulations, terms, and conditions for each grant under review, examine the programmatic progress of each grant, validate information that has been reported, and provide technical assistance for grant management requirements.

Activities during the EPDR will include observation of grant program activities and discussion of programmatic progress, as well as a review of the award file, grantee policies and procedures, expenditure documents, performance measurement data collection and validation, and other documentation. **To assist with this effort, please ensure that all key personnel are available to answer any questions I may have during the EPDR.**

OJP requires that grantees provide selected documentation in order to determine the organization's compliance with the terms and conditions of the grant(s). Some of this documentation must be provided in advance, to support planning for the EPDR. **Please provide the following documents (as applicable) electronically via email to Wendy Rose Wendy.Rose@ojp.usdoj.gov by February 11, 2019:**

FINANCIAL:

- Financial system report with the expenditure amounts for each approved budget category cumulative through the end of the last fiscal quarter (general ledger and budget to actual)
- Written explanation of process used to complete the quarterly Federal Financial Report (FFR). The explanation should address the following elements:
 - How the financial system report is used to report amounts on the quarterly FFR
 - How grant costs are accounted for separately from other grants/projects
 - How the chart of accounts maps to DOJ budget categories
 - How subrecipient expenditures are compiled into the FFR, if applicable
- Supporting documentation for any cash or in-kind matches, trust fund accounts, and/or interest allocated to grant account(s)

ADMINISTRATIVE:

- List of all key personnel as described in the grant application, including grant-funded personnel, consultants, and contractors (name, title, assigned projects, date of hire, current salary, and fringe benefit costs)
- Organization chart
- Written explanations for the following, as applicable (if not included in policies and procedures manual):
 - Process to track and maintain property and equipment
 - Process to apply payroll costs to the grant
 - Overtime approval process
 - Procurement process for vendors, contractors, and consultants including the process in place to ensure that contracts are not awarded to contractors or individuals on the Lists of Parties Excluded from Federal Procurement and Non-procurement Programs (found on SAM.gov)
- Most recent inventory records
- List of all conferences held, the amount expended for each conference, approved conference request forms, and post reports submitted
- List of all subrecipients, the amount of funds disbursed to each subrecipient, as well as expenditures incurred by each subrecipient, as of the most recent quarter ended

On the day of the EPDR, please make the following documents (as applicable) available for review and possible collection. Additional documents may be requested and collected as necessary.

FINANCIAL:

- Supporting documentation for a sample of expenditures to be selected from the financial system report during the EPDR

ADMINISTRATIVE:

- Award file
- Policies and procedures manual to include, as applicable:
 - Grant accounting to include procedures for financial management
 - Cash management
 - Procurement
 - Travel
 - Inventory controls
 - Personnel/time and attendance
 - Sub-recipient monitoring
 - Sub-recipient award process
 - Conference costs
- Voucher packages for major purchases
- Timesheets for grant-funded employees - one timesheet per person selected by the grant manager for the last three pay periods for employees
- Supporting documentation for costs and services of consultants
- Supporting documentation for sole source contracts
- Supporting documentation for subrecipient award process including pre-award, post-award monitoring, and closeout
- Subrecipient monitoring plan
- Subrecipient EPDR and/or desk review reports
- Privacy certificates
- Institutional Review Board approval documentation

PROGRAMMATIC:

- Evidence that services/activities described in progress reports have been completed
- Evidence to support the performance measurement data reported to OJP

If you have any questions or concerns regarding the requested documentation, or if there are issues or questions you would like to address during the EPDR, please contact me at Wendy.Rose@ojp.usdoj.gov or (202) 514-7842.

Thank you in advance for your assistance. I look forward to meeting with you and your staff.

Sincerely,

Wendy Rose
Grant Program Specialists
BJA
Office of Justice Programs
U.S. Department of Justice

cc:

Andy Jones



CDC-RFA-CE19-1904
Overdose Data to Action
Department of Health and Human Services
Centers for Disease Control - NCIPC

GENERAL INFORMATION

Document Type:	Grants Notice
Funding Opportunity Number:	CDC-RFA-CE19-1904
Funding Opportunity Title:	Overdose Data to Action
Opportunity Category:	Discretionary
Opportunity Category Explanation:	
Funding Instrument Type:	Cooperative Agreement
Category of Funding Activity:	Health
Category Explanation:	
Expected Number of Awards:	78
CFDA Number(s):	93.136 -- Injury Prevention and Control Research and State and Community Based Programs
Cost Sharing or Matching Requirement:	No
Version:	Synopsis 3
Posted Date:	Feb 01, 2019
Last Updated Date:	Feb 08, 2019
Original Closing Date for Applications:	May 02, 2019 Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.
Current Closing Date for Applications:	May 02, 2019 Electronically submitted applications must be submitted no later than 11:59 p.m., ET, on the listed application due date.
Archive Date:	Jun 01, 2019
Estimated Total Program Funding:	\$840,000,000
Award Ceiling:	\$7,100,000
Award Floor:	\$550,000

ELIGIBILITY

Eligible Applicants:	State governments County governments City or township governments
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Additional Information on Eligibility:

ADDITIONAL INFORMATION

Agency Name:

Centers for Disease Control - NCIPC

Description:

The complex and changing nature of the opioid overdose epidemic highlights the need for an interdisciplinary, comprehensive, and cohesive public health approach. States, territories, and local partners need access to complete and timely data on prescribing, and on nonfatal and fatal drug overdoses to understand the scope, direction, and contours of the epidemic. They also need the tools and resources to then use data to inform and target their prevention and response efforts. This NOFO integrates work funded through three previous CDC funding opportunities: Prescription Drug Overdose Prevention for States (CDC-RFA-CE15-1501), Data Driven Prevention Initiative (CDC-RFA-CE16-1606) and Enhanced State Surveillance of Opioid-Involved Morbidity and Mortality (CDC-RFA-CE16-1608). This three year funding opportunity will continue work focused on: increasing comprehensiveness and timeliness of surveillance data; building state and local capacity for public health programs determined to be promising based on research evidence; making Prescription Drug Monitoring Programs (PDMPs) easier to use and access; and working with health systems, insurers, and communities to improve opioid prescribing. It adds new work focused on linkages to care and other areas of innovation supported by evidence-based practice.

Link to Additional Information: .**Grantor Contact Information:**

If you have difficulty accessing the full announcement electronically, please contact:

Reshma Mahendra
zep0@cdc.gov

Grants Policy



OPIOID DATA TO ACTION FUNDING OPPORTUNITY

SURVEILLANCE

Required

Morbidity
(Select 1 of 4 options)

- ED Tier 1: Report every 2 weeks (\$250,000 per year)
- ED Tier 2: Report every month (\$215,000 per year)
- ED Tier 3: Report every quarter (\$115,000 per year)
- ED Tier 4: Planning year then report every quarter (\$90,000 per year)

Mortality
(Select 1 of 3 options)

- SUDORS Tier 1: Report w/6-12 month lag (SUDORS Base + \$75,000)
- SUDORS Tier 2: Report w/8-14 month lag (SUDORS Base + \$25,000)
- SUDORS Tier 3: Planning year then report at least every w/8-14 month lag (SUDORS Base)

Surveillance Innovation Project

Optional

- Rapid Opioid Overdose Death Collection (< 1 month from date of death)** (Additional funds of \$200,000 per year)
- Additional quarterly reporting of billing ICD-10-CM codes for all ED visit** (Additional funds of \$50,000 per year)

PREVENTION

Required

PDMP
(Select one)

- PDMP Base: Improved PDMP functionality
- PDMP Base + Expanded: Improved PDMP functionality and intra- & inter-state interoperability (Additional funds of \$250,000)

State & Local Integration

(20% of prevention budget required to go local to communities)

Linkages to Care

Providers & Health Systems Support

Optional

- Public Safety Partnerships**
- Empowering Individuals**
- Prevention Innovation Project**
- Peer-to-Peer Learning Coordinator** (Additional funds of \$250,000)

CSAC Update

(March 7 – 8, 2019)

As the current CSAC Chairperson, I, Lana Bell, give the following update to the Alaska Board of Pharmacy:

- The committee is mandated to meet twice each year and can be attended by the public
- The Board of Pharmacy (BoP) Chair is now also Chair of the CSAC who must establish the agenda and is responsible for setting meetings
- The CSAC chair position can be delegated by the Chair of the board to another BoP board member
- There is currently no plan for the next meeting and no new information on support and resources to schedule and administer the meeting, write meeting minutes, and maintain the CSAC website content
- The CSAC is statutorily housed and managed by the Department of Law, however, it is the current understanding that there is disinterest in continuing to engage in administrative tasks associated with the committee



Current Members

(Note, Lana Bell is now the Chairperson)

Aspen, Sandra (Cordova)
Public

Bell, Lana (Anchorage)
President of Board of Pharmacy/Designee
*Chairperson

Butler, Jay (Juneau)
Commissioner of Health and Social Services/Designee

Coile, Leonard (Palmer)
Public

Greenstreet, Andrew (Anchorage)
Commissioner of Department of Public Safety/Designee

Henderson, Robert (Anchorage)
Attorney General/Designee

Putney, Timothy (Kodiak)
Peace Officer

Stinson, Jr., Lawrence (Anchorage)
Physician

von Hafften, Jr., Alexander (Anchorage)
Psychiatrist

The Controlled Substances Advisory Committee (CSAC), created under the authority of [AS 11.71.100](#), is an advisory board made up of various subject-matter experts in the field of controlled substances, with expertise in medicine, law enforcement, and citizenry. The CSAC is charged with advising the Governor of the need to add, delete, or reschedule substances under Alaska law, and with evaluating the effectiveness of current programs, budget and appropriations, enforcement policies and procedures, treatment, counseling, and regulations regarding controlled substances and to further make recommendations to the Governor, Alaska Court System and Legislature based upon their findings.

The committee consists of 9 members: the Attorney General or the Attorney General's designee; the Commissioner of Health and Social Services or the Commissioner's designee; the Commissioner of Public Safety or the Commissioner's designee; the President of the Board of Pharmacy or the designee of the President who shall also be a member of the Board of Pharmacy; a peace officer appointed by the Governor after consultation with the Alaska Association of Chiefs of Police; a physician appointed by the Governor; a psychiatrist appointed by the Governor; and two individuals appointed by the Governor.

Members of the Controlled Substances Advisory Committee are appointed by the Governor or the respective state commissioner. See [AS 11.71.100](#). Board members are also identified on [State of Alaska Boards and Commissions website](#).



Alaska Pharmacists Association 53rd Annual Convention

February 8-10, 2019, Sheraton Anchorage

Schedule Updated: 1/28/19

All Sessions Are Accredited For Both Pharmacists and Technicians.

Friday, February 8, 2019

7:30 am-6:00pm OPTIONAL Separate Registration Required	APhA Medication Therapy Management Services Certificate Program Trainers: Cathy Arnatt, Kathryn Sawyer & Sara Supe <i>Provided in partnership with the AK Dept of Health & Social Services</i> Susitna	AzPhA Immunization Certificate Program Trainers: Holly Van Lew & Aimee Young Yukon
8:00 am – Noon Separate Registration Required	Acute Care/Hospital Practice Advancement Initiative (PAI) Workshop Kuskokwim East/West Facilitators Vanessa Freitag & Brook DesRivieres Appetizer Reception for attendees at close of program	
NOON	AKPhA Convention Registration Open Howard Rock Ballroom Lobby, 2nd Floor	
1:00 - 2:00 pm	Major Depressive Disorder: I Got The Blues Heidi Brainerd & Jennifer Pangalangan Howard Rock B	
1:30 – 4:00 pm	Exhibit Area Check-In and Set Up Howard Rock Foyer & A	
2:15 – 3:15 pm	Diabetes and Cardiovascular Disease Risk Reduction Brittany Keener & Judy Thompson Howard Rock B	
3:15 – 3:30 pm	Coffee Break	
3:30 – 4:30 pm	Incorporating Technology and Regulatory Readiness Anne Marie Bott & Ashley Schaber Howard Rock B	

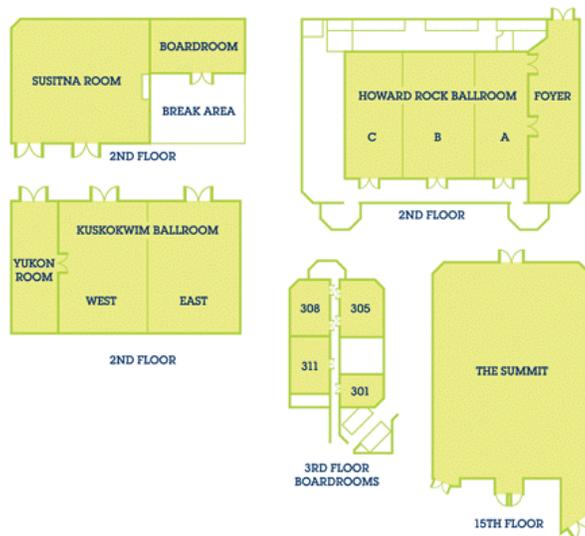
Saturday, February 9, 2019

7:00 am	Registration Open Howard Rock Ballroom Lobby, 2nd Floor Scholarship Silent Auction Open Staged at entrance to Ballroom B/C	
7:00 -8:00 am	Buffet Breakfast with Exhibitors Howard Rock Ballroom A & Foyer	
8:00 - 9:30 am	Pharmacist Billing for Cognitive Pharmacy Services: Barriers and Opportunities Andrew Hibbard Howard Rock B	Backcountry Medicine—Hypothermia Management Deb Ajango Howard Rock C
9:45 - 10:45 am	Simplifying HIV Treatment Now and in the Future David Hachey Howard Rock B	Ebola Vaccine Clinical Trials 9:45-10:15am Holly Van Lew Kuskokwim East
		Podium Poster Presentations Michelle Bai, Corrie Black, Matthew Begay-Bruno, Hannah Fjeld Howard Rock C
10:45 – 11:00 am	Coffee Break Howard Rock A & Foyer	
11:00 am - Noon	2019 Legislative & Government Affairs Update Barry Christensen & Dirk White Howard Rock B	Assessing Renal Function For Pharmacists: What you didn't know you didn't know Tom Wadsworth Howard Rock C
Noon - 1:30 pm	Lunch with Exhibitors Howard Rock A & Foyer	
12:30 - 1:00 pm	Poster Presentations Atrium	
1:30 – 3:00 pm	DEA Update Ricardo Quintero Howard Rock B	From NOACs to DOACs: The Ongoing Evolution of Blocking the Common Pathway Dominique Lauten Howard Rock C
		Managing Hepatitis C Virus and Diabetes: The Impact of a Cure Florin Iacob Howard Rock C
3:00 – 4:00 pm	Helping Our Patients Breathe: Asthma & COPD Primer for the Pharmacy Team Christopher Chong Howard Rock B	
4:00 – 4:30 pm	Dessert Social & Coffee Break with Exhibitors Sponsor: AmerisourceBergen <i>Scholarship Silent Auction Closes</i> Howard Rock A & Foyer	

4:30 pm	Exhibit Area Teardown		
4:30 – 5:30 pm	Project Management for Health Care Professionals Kathryn Sawyer	Howard Rock B	Cannabis: Uprooting the Pharmacology Megan Dorsey & Francis Balmes Howard Rock C
5:30 - 7:00 pm	AKPhA Awards Reception & Pharmacy Jeopardy Game <i>Game provided in partnership with the UAA/ISU Doctor of Pharmacy Program</i> Entertainment: Flat Baroque		The Summit Room, 15th Floor Sponsor: PickPoint

Sunday, February 10, 2019

7:00 am	Registration Open Howard Rock Ballroom Lobby, 2nd Floor		
7:00 – 8:00 am	AKPhA Academy of Health-System Pharmacy Breakfast Meeting		Susitna
7:00 - 8:00 am	Continental Breakfast Howard Rock A & Foyer		
7:15 - 8:00 am	Prayer Gathering	Kuskokwim West	AKPhA New Board Orientation Yukon
8:00 - 9:30 am	Hot Off the Press: New ACC-AHA Cholesterol Guidelines Joseph Saseen	Howard Rock B	Curve your Enthusiasm: Using AUC:MIC Dosing to Optimize Vancomycin Dosing Ryan Stevens Howard Rock C
9:45 - 10:45 am	AK Connect! - Round Table CE Session Moderators Michelle Locke & Ashley Schaber Howard Rock A & Foyer		
10:45 – 11:00 am	Coffee Break Howard Rock A & Foyer		
11:00 am - Noon	Board of Pharmacy Update Rich Holt & Leif Holm Howard Rock A & Foyer		
Noon - 1:00 pm	Lunch—AKPhA Business Meeting & Committee Discussions Howard Rock A & Foyer		
1:10 - 2:10 pm	Budding Therapies: Medical Cannabis and Its Uses Vivian Nguyen & Mariah Cadavos Howard Rock B	Points of Dispensing in Public Health Emergencies Karie Hawk, CJ Kim, John Duffy Kuskokwim East	Oh The Choices—Safely Navigating the World of OTC Medications Amy Paul Howard Rock C
2:15 - 3:15 pm	SETMuPP - Transforming Pharmacy Practice Tom Wadsworth & Renee Robinson	Howard Rock B	Immunization Update Rosalyn Singleton & Matt Bobo Howard Rock C
3:15 - 3:30 pm	Coffee Break Howard Rock A & Foyer		
3:30 - 4:30 pm	IV Sterile Compounding, Risks & Safety Scarlett Eckert Howard Rock B	Rash Decisions—Approaches for Antibiotic-associated Hypersensitivity Reactions Matthew Begay-Bruno & Adrienne Tveit Howard Rock C	
4:45 - 5:45 pm	AKPhA Board of Directors Meeting Yukon		



From: [Zimmerman, Marilyn A \(CED\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: NABP / NPDB authorized agent
Date: Thursday, December 20, 2018 8:00:36 AM
Attachments: [NABP-NPDB agent info.pdf](#)

Laura:

I pulled this up several months ago but did not have time back then to look at this. Finally getting around to it. I am attaching information about NABP as the Board of Pharmacy's authorized agent for NPDB, which means we would only have to report to NABP and not to NPDB (NABP would do that for the board). The Board of Nursing has a program similar to this and it is working really well. I'm just sending this along to you to see if this is something you and your board might want to consider.

Please let me know if you have any questions.

Please note I will be out of the office from December 25, 2018, through January 8, 2019. Happy holidays!

Best regards,

Marilyn Zimmerman, RP

Paralegal II

Division of Corporations, Business and Professional Licensing

Alaska Department of Commerce, Community, and Economic Development

PO Box 110806

Juneau, AK 99811-0806

Phone: (907) 465-1673

marilyn.zimmerman@alaska.gov

Fax: (907) 465-2974

Please note I do not have a direct fax line. Sending documents via email will bring them to my attention sooner.

Disclaimer: This message may contain confidential or privileged information and is intended only for the use of the addressee named herein. The documents attached to this email are considered legal documents. If you are not the intended recipient of this message, you are hereby notified that you must not use, copy, disclose, or take any action based on this message or information herein. If you have received this message in error, please advise the sender immediately and delete this message. Thank you for your consideration.



NABP
National Association of
Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: Executive Officer – _____ Board of Pharmacy

RE: Letter of Agreement – Clearinghouse and NPDB

The National Practitioner Databank (NPDB) was established pursuant to the Health Insurance Portability and Accountability Act of 1996 (Act).

As NABP collects and provides essentially the same data through the NABP Clearinghouse program, the Association offers to report final adverse actions to NPDB as the authorized agent of those boards of pharmacy who wish to engage such services. The reporting will be provided at no charge to participating boards and will be made under the terms and conditions of this Letter of Agreement.

The primary responsibility for reporting adverse actions to the NPDB within the required time limits rests with the boards. Boards are responsible for the information submitted to NABP, including its accuracy and completeness. NPDB officials advise that reports that are submitted with insufficient information will be rejected and emphasize the necessity for full compliance.

References to the Code of Federal Regulations are set forth below to help the Board and Board Counsel in determining the information that must be supplied to the NPDB and the time restrictions for submitting the data.

The Board agrees that:

1. It will timely submit to NABP all final adverse actions as defined in the Act and rules (45 CFR Section 60.1, et seq) along with the accompanying data as required under the Act and rules (see, in particular, 45 CFR, part 60, Sections 60.1, 60.2, 60.3, 60.5, and 60.9).
2. It will submit to NABP all reporting errors, omissions, revisions, and whether the action is on appeal (45 CFR, part 60, Section 60.6).

NABP will:

1. Submit to the NPDB in a timely manner, under the electronic format required by NPDB, the information submitted by the Board.
2. Advise the Board of any rejections of reports when so advised by NPDB.
3. Be the liaison between NPDB and the Board to help the Board successfully complete all submission requirements for the NPDB compliance audits.

In consideration of NABP providing our Board services through the NABP Clearinghouse program and/or acting as the Board agent in regard to the NPDB, the Board authorizes NABP to use the data submitted under this Letter of Agreement in programs of the Association in furtherance of NABP's purposes to aid boards of pharmacy in carrying out their duties and responsibilities to protect the public health and welfare. This includes, but is not limited to, the use of this data in regard to the maintenance of the NABP Clearinghouse used by the boards for the purpose of determining eligibility for licensure transfer.

The _____ Board of Pharmacy hereby designates NABP as its authorized agent for purposes of reporting final adverse actions to the NPDB and agrees to abide by the terms and conditions of this letter and applicable law.

Title

Date

Carmen A. Catizone
Executive Director/Secretary

Date

How to Designate an Authorized Agent

Health care organizations can give another organization (an "authorized agent") permission to query and report to the NPDB on their behalf. To establish an authorized agent relationship, both the health care organization and the agent must be properly registered with the NPDB and have a mutually-written agreement in effect prior to the authorized agent's querying or reporting.

To establish an agent relationship, the account administrator must follow these steps:

Sign in to the NPDB as the administrator.

On the [Select an Option](#) page, select **Administrator Options**.

Select an Option

SELECT AN OPTION

NATIONAL PRACTITIONER DATA BANK
NPDB

Services

Query

New query responses **12**

Report

Maintenance

Administrator Options

View Data Bank Correspondence

Update User Account

View Billing History

On the Administrator Options page, select **Maintain Agent Information**.

On the Authorized Agents page, select **Add**.

Complete the form on the [Designate Authorized Agent](#) page.

Designate Authorized Agent

DESIGNATE AUTHORIZED AGENT



Complete this form to select an authorized agent who can query and/or report on your behalf. Specify (1) the last four digits of the agent's Data Bank Identification Number, (2) the Agent Organization Name, City, State, ZIP Code, and Country (if applicable), (3) whether to allow the agent to query or report, (4) whether query and/or report responses will be routed to the agent or the entity, and (5) whether the agent's or the entity's EFT account will be charged when EFT is the method of payment used for a query submission. Once the data provided here is validated, you will be instructed to print the Agent Designation Request for your records. This document will serve as the sole record of your request.

[Help ?](#)

OMB # 0915-0126 expiration date 03/31/18

Public Burden Statement. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0126. Public reporting burden for this collection of information is estimated to average 15 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10C-031, Rockville, Maryland, 20857.

AGENT INFORMATION

Data Bank Identification Number
(last 4 digits):

Agent Organization Name:

City:

State:

CHOOSE ONE FROM LIST

ZIP Code:

Country (if U.S., leave blank):

Certify the information, and select **Continue**; follow the instructions on the Agent Designation Status page and select **Continue**.

Print or save the formatted copy of the Agent Designation Request and keep as part of your records.

Notify the agent's account administrator. Instruct the administrator to sign into the NPDB and accept the request.

Note: Upon sign in, the agent's account administrator receives an alert stating that electronic correspondence is available.

If the agent accepts the designation, the Agent Designation Status page appears. Click to view the Agent Designation Response. Print or save the response and keep it with your records. Once a request is accepted, the agent can begin querying or reporting on the health care organization's behalf.

If the agent rejects the request, he or she is asked to provide a reason for the rejection, which is sent to the initiating organization.

The health care organization's account administrator receives electronic correspondence through the IQRS, stating that the request is rejected or approved.

About Multiple Organizations

Although authorized agents can represent multiple organizations, they cannot use the same query response on behalf of more than one organization. Information received from the NPDB must not be shared between multiple organizations. If two organizations wish to query on the same practitioner, by the same agent, the agent must query the NPDB separately on behalf of each organization.

Quick Links

[About Authorized Agents](#)

[How to Find an Authorized Agent](#)

[NPDB Guidebook, Chapter B Eligible Entities: Those Who May Report and Query on Behalf of Eligible Entities, Authorized Agents](#)

mandatory fields must be completed. Therefore, it is important that complete data be submitted to the NABP Clearinghouse so that it can then be passed to and accepted by NPDB. See the data submission requirements document for more information on data requirements.

NPDB requires that actions be reported within 30 days of the date the action was taken; therefore, timely reports to the Clearinghouse are extremely important if your board designates NABP as its reporting agent. Using the NABP e-Profile Connect helps speed up the process for transmitting data to NABP and also enables NABP to more quickly process and transmit the required data to NPDB. All information reported is confidential and not available to the general public.

How to Authorize NABP as the Reporting Agent

If your board of pharmacy is ready to designate NABP as its NPDB reporting agent, you must do the following:

- 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.

For further information on designating NABP as your board's reporting agent, contact **Customer Service**.

[Download the Letter of Agreement to Authorize NABP as Your NPDB Reporting Agent](#)



January 23, 2019

Dear Pharmacists,

The Board of Pharmacy has had an influx of communication concerning patients not able to get controlled substance prescriptions filled for various reasons, even when signs of forgery or fraudulence were not presented.

As a result of the increased “refusals to fill,” the board is issuing the following guidance and reminders regarding the practice of pharmacy and dispensing of control substances:

1. Pharmacists must use reasonable knowledge, skill, and professional judgment when evaluating whether to fill a prescription. Extreme caution should be used when deciding not to fill a prescription. A patient who suddenly discontinues a chronic medication may experience negative health consequences;
2. Part of being a licensed healthcare professional is that you put the patient first. This means that if a pharmacist has any concern regarding a prescription, they should attempt to have a professional conversation with the practitioner to resolve those concerns and not simply refuse the prescription. Being a healthcare professional also means that you use your medication expertise during that dialogue in offering advice on potential alternatives, changes in the prescription strength, directions etc. Simply refusing to fill a prescription without trying to resolve the concern may call into question the knowledge, skill or judgment of the pharmacist and may be deemed unprofessional conduct;
3. Controlled substance prescriptions are not a “bartering” mechanism. In other words, a pharmacist should not tell a patient that they have refused to fill a prescription and then explain that if they go to a pain specialist to get the same prescription then they will reconsider filling it. Again, this may call into question the knowledge, skill or judgment of the pharmacist;
4. Yes, there is an opioid crisis. However, this should in no way alter our professional approach to treatment of patients in end-of-life or palliative care situations. Again, the fundamentals of using our professional judgment, skill and knowledge of treatments plays an integral role in who we are as professionals. Refusing to fill prescriptions for these patients without a solid medical reason may call into question whether the pharmacist is informed of current professional practice in the treatment of these medical cases.
5. If a prescription is refused, there should be sound professional reasons for doing so. Each patient is a unique medical case and should be treated independently as such. Making blanket decisions regarding dispensing of controlled substances may call into question the motivation of the pharmacist and how they are using their knowledge, skill or judgment to best serve the public.

As a professional reminder, failing to practice pharmacy using reasonable knowledge, skill, competence, and safety for the public may result in disciplinary actions under Alaska statute and regulation. These laws are:

AS 08.80.261 DISCIPLINARY ACTIONS

(a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable, ...

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices; or ...

(E) other factors determined by the board;

(14) engaged in unprofessional conduct, as defined in regulations of the board.

12 AAC 52.920 DISCIPLINARY GUIDELINES

(a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075; ...

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(b) The board will, in its discretion, revoke a license if the licensee ...

(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;

(5) is professionally incompetent if the incompetence results in a significant risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee ...

(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

We all acknowledge that Alaska is in the midst of an opioid crisis. While there are published guidelines and literature to assist all healthcare professionals in up to date approaches and recommendations for medical treatments per diagnosis, do not confuse guidelines with law; they are not the same thing.

Pharmacists have an obligation and responsibility under Title 21 Code of Federal Regulations 1306.04(a), and a pharmacist may use professional judgment to refuse filling a prescription. However, how an individual pharmacist approaches that particular situation is unique and can be complex. The Board of Pharmacy does not recommend refusing prescriptions without first trying to resolve your concerns with the prescribing practitioner as the primary member of the healthcare team. Patients may also serve as a basic source of information to understand some aspects of their treatment; do not rule them out in your dialogue.

If in doubt, we always recommend partnering with the prescribing practitioner. We are all licensed healthcare professionals and have a duty to use our knowledge, skill, and judgment to improve patient outcomes and keep them safe.

Professionally,



Richard Holt, BS Pharm, PharmD, MBA
Chair, Alaska Board of Pharmacy

Julie Anderson
Commissioner

www.Commerce.Alaska.Gov



Department of Commerce,
Community, and
Economic Development

Anchorage, Alaska

STATE OF ALASKA

PRESS RELEASE

For Immediate Release

19-003

URGENT NOTICE: PHARMACIES URGED TO CONSULT PHYSICIAN BEFORE REFUSING THEIR PATIENT'S OPIOID PRESCRIPTION

Friday, January 25, 2019 (Anchorage)- Managing the opioid epidemic is a key priority when ensuring the safety of all Alaskans. The State of Alaska urges pharmacies to work closely with prescribers to provide appropriate care for their patients, including dispensing of opioids.

"As we work to address the epidemic, it is important that we maintain a balanced approach in our response by continuing to focus on over prescribing and illicit substance use" says Andy Jones, Director for the Office of Substance Misuse and Addiction Prevention. "We must ensure Alaskans who are working with their healthcare providers and following treatment guidelines receive the necessary medications needed to manage various chronic health conditions."

Recent federal legislation (21 CFR §1306.04(a)) provides more tools to strike this balance; it does not inhibit practitioners' ability to prescribe controlled substances to patients. "State law places the treatment of pain in the prescriber's hands," says Sara Chambers, director of the Division of Corporations, Business and Professional Licensing. "The prescribing practitioner has full authority to make a diagnosis and determine the appropriate course of treatment, including dosage and quantity of a controlled substance. The patient's best interests must come first, and pharmacists are valued partners in the healthcare team; however, **they are not prescribers and should not refuse to fill a valid prescription without first consulting the prescribing practitioner.**"

Under the new federal legislation, the Drug Enforcement Authority (DEA) recognizes "the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." A pharmacist may use professional judgment to refuse filling a prescription.

Richard Holt, Pharm. D and chairman of the Alaska Board of Pharmacy (within the Department of Commerce, Community, and Economic Development), encourages pharmacists to follow a proactive and professional method of evaluating dispensation to patients. "The Board of Pharmacy does not recommend refusing prescriptions without first trying to resolve concerns with the prescribing practitioner as the primary member of the healthcare team," says Holt. "We are all licensed healthcare professionals and have a duty to use our knowledge, skill, and judgment to improve patient outcomes and keep them safe."

Questions about prescribing and dispensing controlled substances may be directed to Sara Chambers, director of the Division of Corporations, Business and Professional Licensing, at

sara.chambers@alaska.gov or 907-465-2144. Additional information regarding controlled substance prescribing is available online at pdmp.alaska.gov.

Questions regarding opioid addiction may be directed to Andy Jones, director of the Office of Substance Misuse and Prevention at osmap@alaska.gov or 907-334-2602. Resources on opioid misuse are available online at opioids.alaska.gov.

###

Media Contact: Assistant Commissioner [Shawn Williams](#) (907) 269-8159

FREQUENTLY ASKED QUESTIONS ABOUT CONTROLLED SUBSTANCE PRESCRIPTIONS

Can a pharmacist ask a patient or prescriber about my medical condition and treatments?

Yes. Pharmacists are trained, allowed, and obligated to ask both patients and prescribers questions about any prescription. This may include any inquiry about previous medications or other attempts to treat the condition for which the prescription is being presented. This is not a violation of the Health Insurance Portability and Accountability Act (HIPAA).

What law authorizes a pharmacist to ask questions regarding my controlled substance prescription?

Title 21 of Code of Federal Regulations, Section 1306.04(a) obligates a pharmacist to make sure that all controlled substance prescriptions are being dispensed “in the usual course of medical treatment.” Therefore, a pharmacist may need to gather further information by communicating with the patient’s prescriber.

What if I or my prescriber do not want to answer questions from the pharmacist?

If a pharmacist cannot obtain adequate information from either the patient or prescriber’s office to answer their questions or address their concerns, then they are obligated to refuse to fill the prescription.

What resources may a pharmacist use to evaluate whether a prescription meets the “usual course of medical treatment?”

- the prescriber’s office to gather more information about the condition and treatment
- the Prescription Drug Monitoring Program or other software that helps analyze dangerous combinations and dosages
- board of pharmacy statutes and regulations, and published medical literature
- the medication package insert
- published information / guidelines from the Drug Enforcement Administration (DEA), Food and Drug Administration (FDA) or Centers for Disease Control (CDC)

What other criteria does a pharmacist evaluate for a controlled substance prescription?

- other aspects of a control substance prescription that a pharmacist may evaluate prior to dispensing may include multiple individuals presenting prescriptions for the same drugs in the same quantities from the same doctor
- individuals presenting prescriptions for controlled substances known to be highly abused
- individuals paying high prices for controlled substances (a DEA “red flag”)
- individuals residing long distances from the pharmacy or passing multiple pharmacies to get a prescription filled. These are known as possible “red flags” by the DEA and require that pharmacists evaluate prior to dispensing the prescription.
- This is not an all-inclusive list and is meant to provide examples of what pharmacists may evaluate. You can find more information about this at: https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2013/march_2013/carter.pdf

May a pharmacy request my identification for a controlled substance prescription?

Yes. The DEA provides pharmacists with guidelines to confirm a patient’s identity before filling a legitimate prescription.

Can a pharmacist refuse to fill my prescription?

Yes. If a pharmacist receives a prescription that does not meet the federal regulation above, they are allowed and obligated to refuse the prescription. In addition, if a pharmacist believes that any prescription is written for a medication, strength, direction, or combination that is not safe, then the pharmacist is obligated to refuse to fill the prescription. The Alaska Board of Pharmacy encourages pharmacists to work with the prescribing practitioner to resolve concerns prior to refusing to fill.

What happens after a pharmacist refuses to fill a prescription?

The pharmacist should return the prescription to the customer allowing him/her to bring it to another pharmacy of their choice. If it was an electronic prescription sent directly to the pharmacy, the prescriber will need to send the prescription to another pharmacy of the patient’s choice. The patient is also encouraged to consult with the prescribing practitioner.

Individuals who would like to file a complaint—and can **cite clearly** the reason for the complaint by referencing applicable statutes and regulations of the corresponding prescribing and/or dispensing board—can fill out a Request for Contact form. The form can be found at the following link: <https://www.commerce.alaska.gov/web/cbpl/Investigations.aspx>.

Alaska, Use Your Judgement, But Call First. . .

Thank you to the State Board of Alaska for their commitment to me and how I practice pharmacy in the Last Frontier. Without communications such as this, I would have begun to think I was doing my job improperly. Now I know. I know how busy you are and appreciate your taking the time out of your schedule to hold me personally responsible for refusing to fill prescriptions. I find it odd that you didn't pop in to discuss the matter personally with me so I may have been able to share some insight from my location. I know, you're busy and the citizens of the state have the loudest voice.

Let me tell you a secret. It is our licenses on the line every day. It took years of training to achieve it and we shall not throw them away thanks to a veiled threat made by my State Board.

Seriously. Do you really believe we have not been exercising our professional judgement until this point? You say "We all acknowledge that Alaska is in the midst of an opioid crisis."

How did we get here? By pharmacists filling everything unquestioningly or by us refusing to fill everything unquestioningly or by prescribers overprescribing and expecting pharmacists to fill everything? I wonder. . .

I take issue with this statement as well: "Yes, there is an opioid crisis. However, this should in no way alter our professional approach to treatment of patients in end-of-life or palliative care situations. Again, the fundamentals of using our professional judgment, skill and knowledge of treatments plays an integral role in who we are as professionals. Refusing to fill prescriptions for these patients without a solid medical reason may call into question whether the pharmacist is informed of current professional practice in the treatment of these medical cases."

This begs the question, Are you generalizing about ALL refutations to fill opioids or just "end-of-life or palliative care situations"? Your opening statement makes it appear as if you are chastising us for "refusals to fill". Period. But this sentence is misleading.

If I am to understand this letter and its intent correctly, pharmacists are trying to limit the opioids dispensed. That's good, right?

Until citizens complain. Oh. I get it. That's bad.

Opioid control good until patients complain. Then Pharmacists bad.

Honestly, did you really write this next bullet point?

"3. Controlled substance prescriptions are not a 'bartering' mechanism. In other words, a pharmacist should not tell a patient that they have refused to fill a prescription and then explain that if they go to a pain specialist to get the same prescription then they will reconsider filling it. Again, this may call into question the knowledge, skill or judgment of the pharmacist."

I don't like how you worded it but seriously, if the prescriber is ignoring our requests to get a patient into a Pain Management practice and insists on making therapeutic changes that are outside his area of expertise, then this is a good way to help the patient. (Yes, I have used my professional judgement to reach this point.)

Just out of curiosity, what has been done to empower the Medical Board to investigate bad prescribers?

I'm sure all of those pharmacists with whom you spoke, prior to the writing and distribution of this acerbic letter, would have at least one example each of a provider who is locally recognized as a bad egg. I'm also certain you could find cases where your professionally practicing pharmacist abided by your second point: "This means that if a pharmacist has any concern regarding a prescription, they should attempt to have a professional conversation with the practitioner to resolve those concerns and not simply refuse the prescription.", only to be rebuffed or threatened by said prescriber or office.

Since we are all making assumptions here, I am going to go out on a limb and assume you sent a similarly worded and threatening letter to the State's Prescribers. It is only fair since we are all on the same team. I am in fact positive that your bullet points resembled these:

1. Prescribers must use reasonable knowledge, skill, and professional judgment when evaluating

whether to write a prescription. Extreme caution should be used when deciding to write a prescription.

2. Part of being a licensed healthcare professional is that you put the patient first. This means that if a pharmacist has any concern regarding a prescription, and they should attempt to have a professional conversation with you, the practitioner, to resolve those concerns you should immediately avail yourself to address their concerns and listen intently. Pharmacists being healthcare professionals also means that they have medication expertise to provide during that dialogue in offering advice on potential alternatives, changes in the prescription strength, directions etc. Simply refusing to listen to a pharmacist without trying to resolve the concern may call into question the knowledge, skill or judgment of the prescriber and may be deemed unprofessional conduct.

3. As a professional reminder, failing to practice medicine using reasonable knowledge, skill, competence, and safety for the public may result in disciplinary actions under Alaska statute and regulation. Know when a patient's therapy is outside your range of practice and when to refer them to pain management or another professional with more expertise.

4. If in doubt, we always recommend partnering with the patient's pharmacist. Feel free to call her and discuss your patients. We are all licensed healthcare professionals and have a duty to use our knowledge, skill, and judgment to improve patient outcomes and keep them safe.

Don't forget to also attach the relevant laws of Alaska governing the medical practitioners so they can feel threatened.

In summary, I would like to see the letter you sent to the Medical Practitioners about their prescribing habits and how you are strongly encouraging (or threatening, as you did to the pharmacists) them to work cooperatively with the pharmacists in charge of the patients of Alaska.

I would like to see how you are handling complaints of the pharmacists against rogue prescribers.

I would like to see an outline for how investigations are to be carried out against prescribers and their prescribing habits.

In order to be valid, a prescription must be issued for a legitimate purpose.

In order to be filled, it is my duty to verify this.

If I cannot verify it, I don't have to fill it.

(Because prescribers are so apt to get on the phone and say "oops, you got me, that was a bad one, let's change/cancel it, shall we?!")

Thank you,

A pharmacist who will continue to advocate for appropriate therapy and dosing for my patients (even if that means refusing to fill a prescription)

From: [m horgan](#)
To: [Board of Pharmacy \(CED sponsored\)](#)
Cc: [Chambers, Sara C \(CED\)](#); [HssDphOsmap \(HSS sponsored\)](#); [Anderson, Julie B \(CED\)](#); [Brenda.L.Hackett2@usdoj.com](#); [Nay, Nasruk W \(DPS\)](#)
Subject: Fw: A Pharmacist Response to BOP Letter
Date: Tuesday, February 5, 2019 3:53:24 AM
Attachments: [Form Letter to the Board.docx](#)

Hello

Please take a moment to read the enclosed letter. Pharmacists in Alaska are in a very tough situation. This letter sheds some light on our perspective. If we can all get on the same page, we can make a difference on the opioid crisis in our state. Thank you for your time.

Please find attached a letter that has been drafted in cooperation with several pharmacists in response to the letter sent to all of us from Richard Holt, Chair of the Alaska Board of Pharmacy. It is our hope that you will use this letter as inspiration to send your feelings to the board about perceptions of how this letter affects our practice. You may use this letter in whole, word for word, in part, or write a letter of your own. Our hope is to show that we are all jointly, and individually, affected by the letter from the board. Below, you will find email addresses you may find useful. We hope to have an overwhelming response and showing of solidarity from Alaska pharmacists.

Please forward this on to as many pharmacists in the state as you can!

Thank you,

Shelly Thompson
Michelle Smith
Jeremy Daube
Kim Frazee

BoardOfPharmacy@alaska.gov

Sara.chambers@alaska.gov

Andy Jones, Director for the Office of Substance Misuse and Addiction Prevention osmap@alaska.gov

Michael J. Dunleavy – apparently we are unable to email the governor directly

Julie Anderson, Commissioner of Department of Commerce, Community and Economic Development Julie.anderson@alaska.gov

Laura Carrillo – where the original letter originated – laura.carrillo@alaska.gov
attorney.general@alaska.gov

Brenda Hackett - US Dept of Justice – Drug Enforcement Administration – Brenda.L.Hackett2@usdoj.com

Department of Public Safety - Alaska State Troopers – Statewide Drug Enforcement Unit – Nasruk
Nay nasruk.nay@alaska.gov

Thank you

Melissa Page

January 26, 2019

To The Alaska Board of Pharmacy:

In response to the letter to pharmacists dated January 23, 2019, we have concerns regarding the intent and purpose of said letter.

While we agree with the points presented in the letter, we have deep concerns regarding the potential consequences it may have on the profession of pharmacy's reputation, image of trustworthiness, and the respect given to us by other healthcare professionals.

In response to point number 1:

Using "reasonable knowledge, skill and professional judgment when evaluating whether to fill a prescription" is the standard to which pharmacists subscribe. Decisions to fill or refuse controlled substances both have consequences. Just as refusing to fill risks negative health consequences, filling prescriptions that fall well outside of nationally accepted guidelines also risks negative health consequences for patients.

Therefore, extreme caution is also of utmost importance when we are presented with controlled substance prescriptions that fall well outside of national and state guidelines. Omitting this point from your letter may negatively impact the ability of pharmacists to reach common ground with some prescribers and patients.

In response to point number 2:

We appreciate that you acknowledge pharmacists have "medication expertise" and have knowledge and experience that can provide value during dialogues with prescribers regarding "potential alternatives, changes in the prescription strength, directions, etc." Open communication should include resolving concerns that pharmacists may have regarding risk versus benefit assessments, quality of life assessments, tried and failed therapies, and alternative treatments in addition to clearing of other potential red flags. However, we have concerns regarding your statement that "simply refusing to fill a prescription without trying to resolve that concern may call into question the knowledge, skill or judgment of the pharmacist and may be deemed unprofessional conduct." It is never a "simple" decision to refuse to fill a prescription. In some cases, the provider will not communicate openly with the pharmacist regarding their reasoning in prescribing control medications in doses that fall outside of accepted guidelines. When this occurs, a pharmacist with the patient's best interest in mind, has the professional corresponding responsibility to not fill the prescription.

In response to point number 3:

While all licensed prescribers have training in pain management, pain specialists should have further knowledge, skills, training and tools to better manage patients on high dose opioids or when opioids are used in combination with other medications that may increase patient risk. Therefore in rare cases when

patients need pain medication in doses or combinations that fall outside of accepted guidelines, a referral to a pain specialist, guided by legitimate and authorized research, who is equipped to assess the patient's risk versus benefit is a reasonable recommendation. In these instances, a dialogue before filling is needed to ascertain as to how the patient got to where they are and what the plan is for future treatment. While it is true that prescribers have "full authority" in the course of treatment, pharmacists also have a corresponding responsibility and will be held responsible in the event that a prescription causing harm is filled.

In response to point number 4:

As pharmacists, we recognize that palliative care, advanced cancer, and end of life care do have different guidelines that require a pharmacist to exercise compassion while continuing to practice our profession at the highest level with care and safety being dual desirable outcomes. Pharmacists must still use professional knowledge, skills and judgment to assess each prescription individually.

In response to point number 5:

"Sound professional reasons" for refusing to fill a prescription, may include state and national guidelines. In the absence of Alaska having state controlled substance guidelines, many pharmacists refer to Washington and Oregon guidelines as well as CDC guidelines for direction. We understand that guidelines are not law, however they are there to consolidate generally accepted practices and are written and adapted through cooperation between multiple health care professions. Therefore, using them to help guide prescribing and dispensing of controlled medications is a reasonable and prudent choice. While some patients' needs may fall outside these guidelines, this should be a rare occurrence.

We find the third to last paragraph disconcerting:

"While there are published guidelines and literature... do not confuse guidelines with law; they are not the same thing." This statement diminishes the significance of national and state guidelines as a baseline for guiding prescribers and pharmacists on what is appropriate. This is concerning because Title 21 Code of Federal Regulations 1306.04(a) outlines that those that fill a prescription have a corresponding responsibility with the prescriber in the dispensing of medications. The law specifically states "a prescription not issued in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of the law...and the person knowingly filling such a prescription...shall be subject to penalties." We purport that published guidelines are legitimate and authorized research. Furthermore, we sincerely hope that in the near future the State of Alaska will establish and publish guidelines for the prescribing and dispensing of controlled substance medications that have been compiled through the collaboration of healthcare professional across many modalities. This would go a long way in enabling pharmacists and prescribers to work together effectively.

Formal letters from the Board of Pharmacy hold significant weight in pharmacist, provider, and public opinion. The Board's previous letter, while acknowledging pharmacists' right under federal law to refuse to fill, does so only after threat of disciplinary action to the pharmacist. It is imperative that patients,

prescribers, and pharmacists understand pharmacists' role and duty in filling prescriptions, clearing red flags, and refusing unsafe prescriptions. Therefore, we sincerely hope the Board will put careful consideration and thought into a public response and clarification surrounding the concerns of professional pharmacists within the state.

From: [Carrillo, Laura N \(CED\)](#)
To: "[Jacquelyn May](#)"
Subject: RE: Letter to Pharmacists
Date: Monday, January 28, 2019 1:22:00 PM

Thank you for your feedback. I'll forward this to the board for their review.

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: Jacquelyn May [mailto:jemay71@hotmail.com]
Sent: Thursday, January 24, 2019 4:01 PM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Subject: Fw: Letter to Pharmacists

From: Jacquelyn May
Sent: Thursday, January 24, 2019 3:23 PM
To: holt.richard@alaska.gov,
Subject: Letter to Pharmacists

Dr. Mr. Holt and esteemed Board Members,

As Pharmacist-in-Charge at Bernie's Pharmacy, I appreciate your letter of today. I would like to alert the Board that pharmacies are experiencing disturbances within the health care system from an entity that the state licenses and that is the wholesalers. We recently had contract issues with Amerisource Bergen that forced us to seek an injunction against them which was successful. That only gave us temporary relief to the end of our contract and forced us to find other resources. The reason that they used to terminate our contract is that they no longer felt comfortable with our percentage of controlled substance purchasing. This is in spite of the fact that we have been subject to extensive DEA auditing two years ago and were found to be in full compliance. We also went through a full inspection from Amerisource Bergen's own private inspection team with no issues. Amerisource Bergen could not actually cite any wrong doing on our part at all, but it was made clear that this was a move they were making to improve their own public image.

The State Board of Pharmacy may wonder why a contract issue between a pharmacy and a wholesaler is of any interest to them and normally I would say that it has none. But, given that we are a pharmacy in good standing with the State of Alaska and the Federal Government, it is frustrating to have our ability to practice pharmacy subverted by companies that themselves admit that they are unqualified to get involved in the clinical aspects of patient care. By restricting our ability to purchase controlled substances, they have effectively inserted themselves into the health care system in a very destructive way.

We have another wholesaler that we are dealing with, but they also will not allow us to purchase controlled substances yet also citing their fear of the DEA and public perception of the opioid crisis. This has forced our patients to go to other pharmacies to try to get their medication. We notified our patients well in advance of this disruption and educated them about the issues they might experience. Nothing prepared us for the sheer numbers of patients that were turned away by other pharmacies, treated callously and made to feel disrespected. Many of these patients were also told that they would only be able to fill their controlled medications if they transferred their entire profile from our pharmacy to theirs. All of these events have been frustrating and hard on our pharmacy, but ultimately the biggest worry is for our patients.

Pharmacists are seeing their professional judgment impeded by the corporate policies of big chains and now wholesalers as well? These are all entities that receive licensure through the State of Alaska. Perhaps they need to be included in your scrutiny as well.

Again, I cannot emphasize enough how much your letter is respected and appreciated. It gives me some relief to know that Alaska patients are being heard. We at Bernie's Pharmacy have been advocating on their behalf with our Senators, Representative, Governor and whoever else will listen, so I can only hope that this is the beginning of a much needed dialogue. I am happy to help in any way that I can.

Respectfully submitted,

Jacquelyn May
Pharmacist in Charge, Bernie's Pharmacy

From: [Carrillo, Laura N \(CED\)](#)
To: ["nhall@bbahc.org"](mailto:nhall@bbahc.org)
Cc: [Thompson, Norman H \(CED\)](#)
Subject: FW: IHS Pharmacy - PIC license in AK required?
Date: Wednesday, January 23, 2019 10:30:00 AM

Hi Mr. Hall,

Please see the below correspondence from our board chair addressing the question you had on licensure requirements for PICs.

Thank you,

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

From: Richard Holt [mailto:dokholt@mac.com]
Sent: Wednesday, January 23, 2019 2:17 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Thompson, Norman H (CED) <norman.thompson@alaska.gov>
Subject: Re: IHS Pharmacy - PIC license in AK required?

Yes, it was also my understanding that if they were licensed by us then they must adhere to our statutes and regulations. Once licensed and our jurisdiction I don't see how they would be able to "cherry pick" what regulations to follow.

Also, it states in 08.80.345: "a licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment." Pharmacist is defined in statute AS 08.80.480(22) as "... currently licensed by this state ..".

Therefore, since the pharmacy is licensed by us the statute says the pharmacist (and hence the pharmacist-in-charge) has to be licensed by this state.

Hope that helps

Thanks,
Rich

Sent from my iPhone

On Jan 22, 2019, at 5:58 PM, Carrillo, Laura N (CED) <laura.carrillo@alaska.gov> wrote:

Hi Rich,

I got a call from an IHS pharmacy looking into changing their PIC, but the prospective PIC's pharmacist license is in Colorado and not here. My interpretation is that since this IHS pharmacy has an in-state pharmacy license, they're now obligated to comply with all of our statutes/regulations. Does this apply to their employees as well? Can we require a federally-employed pharmacist working for an Alaskan-licensed pharmacy to obtain an Alaska pharmacist license? AS 08.80.330 doesn't state they must be licensed in our state, but I believe that's the intent of the language since it refers to in-state pharmacies.

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



**Bristol Bay Area
Health Corporation**
6000 Kanakanak Road
P.O. Box 130
Dillingham, AK 99576
(907) 842-5201
(800) 478-5201
FAX (907) 842-9354
www.bbahc.org

*Bristol Bay Area
Health Corporation is
a tribal organization
representing 28 villages in
Southwest Alaska:*

Aleknagik
Chignik Bay
Chignik Lagoon
Chignik Lake
Clark's Point
Dillingham
Egegik
Ekuk
Ekwok
Goodnews Bay
Ivanof Bay
Kanatak
King Salmon
Knugank
Koliganek
Levelock
Manokotak
Naknek
New Stuyahok
Perryville
Pilot Point
Platinum
Port Heiden
Portage Creek
South Naknek
Togiak
Twin Hills
Ugashik

January 24, 2019

Richard Holt, PharmD, MBA
Chair
Alaska Board of Pharmacy
P.O. Box 110806
Juneau, AK 99811-0806
BoardOfPharmacy@Alaska.Gov

RE: Pharmacist-in-Charge at Kanakanak Hospital

Dear Dr. Holt,

I write on behalf of Bristol Bay Area Health Corporation (BBAHC) regarding the Pharmacist-in-Charge (PIC) requirement for the pharmacy at Kanakanak Hospital in Dillingham, AK. As you know, our staff have been in contact with Laura Carrillo, MPH, Executive Administrator for the Board of Pharmacy regarding whether the pharmacy can have a PIC with an out-of-state license.

As a result of our review of state and federal statutes, the enclosed/attached 2012 Alaska Attorney General Memorandum "Re: License Requirements for Individual Pharmacists Working/or Tribal Health Programs of the Alaska Attorney General,"¹ and past precedent by the Alaska Board of Pharmacy, we believe that an out-of-state licensed pharmacist can serve as the PIC. We are writing to request clarification.

As you know, the Kanakanak Hospital is operating as a federal facility. It is operated by BBAHC on behalf of Indian Health Services (IHS) pursuant to a Compact under the Indian Self-Determination and Education Assistance Act of 1975 (ISDEAA).² Under federal law and Alaska statute, federal facilities are not required to have state licenses. However, the pharmacy obtained a state license around 1984, and

¹ Office of the Attorney General State of Alaska, Memorandum *Re: License Requirements for Individual Pharmacists Working/or Tribal Health Programs*, AGO No. AN2009102500 (April 17, 2012), 2012 WL 1515178. This opinion is also posted on the State of Alaska Department of Commerce, Community and Economic Development website under the Frequently Asked Questions for the Board of Pharmacy "License Requirements for Individual Pharmacists Working for Tribal Health Programs" https://www.commerce.alaska.gov/web/Portals/5/pub/PHA_Legal_Opinion_2012_4.pdf ("2012 AG Memo").

² See, e.g., Compact, Art. I, § 2(d) ("This Compact and Funding Agreement shall transfer to signatory Tribes ... the responsibility for the programs, activities, functions and services of the Indian Health Service included in the Funding Agreement."); BBAHC Funding Agreement § 3 ("BBAHC agrees to administer the Kanakanak Service Unit of the IHS, a tribally operated Service Unit of the IHS "); 25 U.S.C. § 5385 (PFSAs eligible for inclusion in funding agreements include those carried out by IHS under specified federal laws, plus other federal laws enacted for the benefit of Indians because of their status as Indians).

currently has Alaska License Number PHAR345, expiration date 6/30/2020. With this state license, the Board of Pharmacy has recently said the Hospital must have a PIC with an Alaska license. This position is not consistent with the Board's previous position on this question. It is also not consistent with the law.

First, there is no explicit requirement in the Alaska statutes related to pharmacy licensing that says the PIC must have an Alaska license.³

Second, the Board's recent analysis to determine requirements for the PIC is contradicted by the State's Attorney General's analysis in 2012. As you have asserted, A.S. 08.80.345 says "a licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment."⁴ Because the definition of Pharmacist in AS 08.80.480(22), "means an individual currently licensed by this state," therefore the PIC must be licensed in-state.⁵ However, as stated by the Alaska Attorney General, Section 221 of the Indian Health Care Improvement Act (IHCIA) preempts Alaska's professional licensing requirements.⁶ Section 221 states as follows:

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.

Accordingly, the individuals are able to work at the Kakanak Hospital as "pharmacists" with out-of-state licenses. Thus, this should also apply to the requirements for the PIC, which is defined as "a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy's personnel."⁷ Pursuant to Section 221, the PIC would be required to have a pharmacy license, and the Board of Pharmacy would be able to verify the out-of-state license is valid before proceeding.⁸

Further, this conclusion is supported by the Alaska Board of Pharmacy's past practices with BBAHC. In reviewing past correspondence between BBAHC and the

³ See, e.g., A.S. 08.80.330. See also, 12 AAC 52.020(c) ("An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200").

⁴ Email from Richard Holt to Carrillo, Laura N, Subject: "Re: IHS Pharmacy - PIC license in AK required?", January 23, 2019 (on file).

⁵ *Id.*

⁶ 2012 AG Memo.

⁷ AS 08.80.480(23).

⁸ 2012 AG Memo.

Alaska Board of Pharmacy, in response to a question from one of BBAHC's previous PICs, Mary K. Vellucci, Licensing Examiner stated that, "[a]t a federal facility, a pharmacist who is not licensed in AK can be the PIC."⁹ This email was sent shortly after the Alaska Attorney General memo on pharmacist licenses. For several years after, BBAHC had PICs who were licensed out of Alaska.

The Board approved the out-of-state when it reissued the pharmacy license and included the out-of-state license number and State issued on the Wallet cards provided. For example, Robert May was the named Pharmacy Manager from May 2012 until October 1, 2012 and is listed on the pharmacy license as the PIC. His license was issued by Nevada. Amy Whisler was interim Pharmacy Manager on several occasions. She was appointed PIC on October 11, 2012, with a North Carolina license, and is listed on the Kananak Hospital Pharmacy License effective on November 7, 2012. On November 14, 2013, Anthony Rampersand filed the Change of Pharmacy Manager form, with a New York license. He is listed on the Pharmacy License as PIC effective November 26, 2013.

In summary, while BBAHC currently has an Alaska-licensed pharmacist to serve as the PIC, this does not change the law or existing precedent allowing us to have a PIC with an out-of-state pharmacist license.

We look forward to receiving from you a confirmation that you agree with our analysis of the issue. Please let me know if you have any questions.

Sincerely,



Robert Clark
President/CEO

cc: Geoff Strommer, Esq.
Barbara Simpson Kraft, Esq.
Elizabeth P. Hodes, Esq.

Enc: 1) Office of the Attorney General State of Alaska, Memorandum Re: License Requirements for Individual Pharmacists Working/or Tribal Health Programs, AGO No. AN2009102500 (April 17, 2012).
2) Email from Mary K. Vellucci, Alaska Board of Pharmacy, to Amy Whisler, BBAHC, May 16, 2012.

⁹ Email from Mary K. Vellucci, Licensing Examiner, Alaska Board of Pharmacy, to Amy Whisler, BBAHC, May 16, 2012.

STATE OF ALASKA

SEAN PARNELL, GOVERNOR

DEPARTMENT OF LAW

OFFICE OF THE ATTORNEY GENERAL

1031 WEST 4TH AVENUE, SUITE 200
ANCHORAGE, ALASKA 99501-1994
PHONE: (907)269-5100
FAX: (907)276-3697

April 17, 2012

Richard C. Holm, Chair
Board of Pharmacy
P.O. Box 110806
Juneau, AK 99811-0806

Re: License requirements for individual pharmacists working for tribal health programs, AGO No. AN2009102500

Dear Mr. Holm:

You have asked whether Alaska professional licensing requirements apply to pharmacists working for Alaska Native tribal health programs. As explained in the following opinion, because of a federal law enacted in March 2010, pharmacists employed by tribal health programs do not need to be licensed in Alaska as long as they are licensed in another state. This federal law, sometimes called Section 221, reads:

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. 450 et seq.).¹

Section 221 expressly preempts—i.e., overrides—state licensing requirements for a pharmacist who qualifies for the exemption.²

The conclusion that pharmacists employed by tribal health programs are exempt from Alaska licensing requirements relies entirely on the existence of Section 221. Section 221 was enacted along with the Patient Protection and Affordable Care Act (PPACA). PPACA has been challenged in multiple lawsuits, and the U.S. Supreme

¹ 25 U.S.C. § 1621t.

² See subsection III(A) of opinion.

Court may ultimately decide that it is unconstitutional. If the court strikes down all of PPACA, including the Indian health provisions, Section 221 will no longer be the law and the analysis of the licensing question will change. As of the date of this opinion, however, Section 221 is in effect.

To qualify for a Section 221 exemption, a pharmacist must be employed by a tribal health program operating under an Indian Self-Determination and Education Assistance Act (ISDEAA) agreement between the federal Indian Health Service (IHS) and a tribal organization. The exemption applies only to a pharmacist with a current, valid out-of-state license. The licensing exemption only applies during time spent working for the tribal health program—if a pharmacist wishes to “moonlight” working elsewhere, an Alaska license is required.³ A pharmacist who works for a tribal health program as a contractor rather than a regular employee may be entitled to the exemption, but this will depend on the specific facts of the situation.⁴

The Board may require a pharmacist to provide proof of out-of-state licensure and tribal health program employment status before recognizing a Section 221 licensing exemption.⁵ Licensing boards who need help determining whether a particular person in a specific factual scenario qualifies for a Section 221 exemption should contact the Department of Law.

Section 221 does not prevent state licensing boards from exercising authority over their own licensees. A tribal pharmacist who holds an Alaska license is still subject to discipline by the Board.⁶

Finally, as the Department of Law concluded in 2005 with regard to dental health aides,⁷ federally certified community health aides do not have to obtain pharmacist or pharmacy technician licenses even if they are performing pharmacy-related functions as

³ *Id.*

⁴ *See* subsection III(B) of opinion.

⁵ *See* subsection III(C) of opinion.

⁶ *See* subsection III(D) of opinion.

⁷ *See* 2005 Inf. Op. Att’y Gen. (Sept. 8; 663-05-0152), 2005 WL 2300398 (Alaska A.G.).

long as they are acting within their scope of practice.⁸ Requiring community health aides to obtain state professional licenses would pose an obstacle to the federal community health aide program, which is intended to increase health services in remote areas through the use of paraprofessional aides. This conclusion does not depend on Section 221 and would not be affected if PPACA were struck down.

OPINION

I. INTRODUCTION

You have asked whether Alaska professional licensing requirements apply to individual pharmacists working for Alaska Native tribal health programs. Because of an express federal statutory exemption enacted in March 2010, pharmacists employed by tribal health programs that are operated under Indian Self-Determination and Education Assistance Act (ISDEAA) agreements need not obtain Alaska licenses as long as they are validly licensed in another state.⁹ Additionally, as the Department of Law previously determined with regard to dental health aides,¹⁰ federally certified community health aides need not be state licensed even if they are performing pharmacy-related functions as long as they are acting within their scope of practice.

II. FACTUAL OVERVIEW OF ALASKA NATIVE HEALTH CARE

The federal government recognizes itself as having special obligations towards Native Americans and Alaska Natives, including providing them with health care.¹¹ Historically, federal agencies like the Bureau of Indian Affairs (BIA) and later the Indian Health Service (IHS) directly administered Indian health care services in Alaska and elsewhere. Federal employees are generally not subject to state professional licensing

⁸ See section IV of opinion.

⁹ 25 U.S.C. § 1621t.

¹⁰ 2005 Inf. Op. Att’y Gen. (Sept. 8; 663-05-0152), 2005 WL 2300398 (Alaska A.G.) (hereinafter, “2005 AG opinion.”).

¹¹ See 25 U.S.C. § 1601(1) (“Federal health services to maintain and improve the health of the Indians are consonant with and required by the Federal Government’s historical and unique legal relationship with, and resulting responsibility to, the American Indian people”).

requirements such as those contained in Alaska's Pharmacy Act.¹² The IHS has its own pharmacy standards and requires its pharmacists to have a current license from any state.¹³

However, since the passage of the ISDEAA in 1975,¹⁴ tribal groups¹⁵ in many areas have taken over administration of Indian health care services. The ISDEAA entitles tribal groups to enter into agreements with the federal government under which they receive federal funding to provide services to Native Americans and Alaska Natives, such as health care, that a federal agency like the IHS would otherwise provide.¹⁶ The purpose of the ISDEAA is to give tribal groups more control over Indian services, helping tailor

¹² See 1992 Inf. Op. Atty. Gen. 149 (March 31; 663-91-0104), 1992 WL 564898 (Alaska A.G.) at n.1 (recognizing licensing exemption for federal employees); see also *Sperry v. Florida*, 373 U.S. 379, 385 (1963) ("A State may not enforce licensing requirements which, though valid in the absence of federal regulation, give 'the State's licensing board a virtual power of review over the federal determination' that a person or agency is qualified and entitled to perform certain functions," and may not enforce requirements "which impose upon the performance of activity sanctioned by federal license additional conditions not contemplated by Congress."); *Johnson v. Maryland*, 254 U.S. 51, 57 (1920) (holding that a state could not require the driver of a United States Postal truck to obtain a state driver's license in order to perform his federal job); *United States v. Virginia*, 139 F.3d 984, 987-88 (4th Cir. 1998) (holding that a state could not require private investigators under contract with the FBI to obtain state private investigator licenses); *Taylor v. United States*, 821 F.2d 1428, 1431-32 (9th Cir. 1987) (noting that a state could not require Army hospital personnel to be licensed under state law).

¹³ See IHS Manual, Part 3, Chapter 7.2B(1)(b) ("All pharmacists delivering pharmaceutical care to American Indians/Alaska Natives shall be currently licensed by at least one of the fifty State boards of pharmacy in the United States.").

¹⁴ 25 U.S.C. § 450 et seq.

¹⁵ For simplicity, this opinion uses the term "tribal group" as an all-inclusive term to refer to a tribe, Alaska Native village, tribal health care organization, or inter-tribal consortium.

¹⁶ *Cherokee Nation of Oklahoma v. Leavitt*, 543 U.S. 631, 634 (2005).

programs to better fit community needs.¹⁷ A tribal group providing health care services under an ISDEAA agreement is not bound by IHS internal agency guidelines, policies and manuals unless it expressly agrees to be bound.¹⁸

Thus, now that Indian health care services are increasingly controlled by tribal groups rather than by the federal government, the question naturally arises whether tribal health care professionals are subject to state licensing requirements or are exempt from those requirements like the IHS employees they've replaced. This section provides a brief overview of the tribal health system as background for the analysis of this question.

A. The Indian Self-Determination and Education Assistance Act (ISDEAA)

A tribal group that wants to take control of Indian health care services may enter into a "self-determination contract" under Title I of the ISDEAA or a "self-governance compact" under Title V of the ISDEAA.¹⁹ The federal government must accept a tribal group's Title I contract proposal or provide written findings detailing why the proposal is unacceptable under specified statutory criteria.²⁰ Title V compacts give tribal groups

¹⁷ See 25 U.S.C. § 450a(b) (committing to a policy "which will permit an orderly transition from the Federal domination of programs for, and services to, Indians to effective and meaningful participation by the Indian people in the planning, conduct, and administration of those programs and services").

¹⁸ 25 U.S.C. § 458aaa-16(e); 25 U.S.C. § 4501 (sample contract at (b)(11)); 42 C.F.R. § 137.5.

¹⁹ Title V was added to the ISDEAA in 2000 by Public Law 106-260, 114 Stat. 711 and is codified to 25 U.S.C. §458aaa-25 U.S.C. §458aaa-18. Title V made permanent a demonstration project authorized by Title III of the ISDEAA. H.R. Rep. No. 106-477 at 16 (1999), *reprinted in* 2000 U.S.C.C.A.N. 573, 574.

²⁰ 25 U.S.C. § 450f(a)(2), (4).

more control over the structuring of programs than Title I contracts,²¹ but have more stringent eligibility requirements.²²

A tribal group that has entered an ISDEAA contract or compact must negotiate a funding agreement with the IHS detailing the services it will provide and the federal funds it will receive. In order to allow a transfer of control without a reduction in services or a transfer of the financial burden of providing services, the ISDEAA requires the federal government to provide tribal groups with the same level of funding that the IHS would have received if it were providing services directly, plus funds to cover reasonable overhead costs.²³ To further reduce the potential financial burden on tribal groups that take over IHS functions, the federal government provides coverage under the Federal Tort Claims Act (FTCA) for personal injury suits arising out of the performance of services under ISDEAA contracts and compacts.²⁴

B. The ISDEAA in Alaska

In Alaska, 99% of IHS funding has been transferred to tribal control under ISDEAA contracts, compacts, and funding agreements, and the IHS no longer provides any direct health services. According to the IHS, as of December 2011, 25 tribal groups operate health programs in Alaska under Title V, and 14 do so under Title I. The Title V groups are signatories to the Alaska Tribal Health Compact, the umbrella Title V

²¹ See 25 U.S.C. §458aaa-5(e) (under Title V, tribal groups may redesign programs and re-direct funding “in any manner which the Indian tribe deems . . . best,” so long as eligible persons receive care).

²² See 25 C.F.R. § 1000.17 (requiring, among other things, a “demonstration of financial stability and financial management capability for the previous 3 fiscal years”).

²³ 25 U.S.C. §450j-1(a)(1); 25 U.S.C. §458aaa-15(a) (making section 450j-1(a)(1) applicable to Title V compacts).

²⁴ 25 U.S.C. § 450f(d); 25 U.S.C. § 458aaa-15(a) (making section 450f(d) applicable to Title V IHS compacts); see *Snyder v. Navajo Nation*, 382 F.3d 892, 897 (9th Cir. 2004) (“Congress wanted to limit the liability of tribes that agreed to these arrangements. Congress therefore provided that the United States would subject itself to suit . . . for torts of tribal employees hired and acting pursuant to such self-determination contracts under the ISDEAA.”).

compact for all of Alaska developed in 1994.²⁵ Each signatory to the Compact negotiates its own funding agreements with the IHS. The Compact is revised periodically to account for changes in law, new signatories, and other amendments.

C. Tribal health care providers

Health professionals working for tribal programs may be tribal group employees, federal employees, or contractors.

The IHS is authorized to hire health professionals under “personal services contracts” rather than through normal federal hiring processes.²⁶ A personal services contract is supposed to be “characterized by the employer-employee relationship it creates between the Government and the contractor’s personnel.”²⁷ The Alaska Area IHS used to enter into numerous personal service contracts to send health professionals to work for tribal health care programs in Alaska under nominal federal supervision. The IHS required these health professionals to be licensed in some state, but did not require them to have an Alaska license. The IHS took the position that these health professionals were essentially federal employees and thus exempt from state licensing requirements. Recruiting out-of-state health professionals to come to Alaska is easier if they do not need an Alaska license.

Since 2010, the Alaska Area IHS reports that it has stopped sending health professionals to work for tribal health care programs under personal services contracts. Relying on a new provision of federal law discussed below, the IHS now takes the position that health professionals that are hired directly by tribal groups are exempt from state licensing requirements as long as they are licensed in some state. Thus, the IHS believes there is no longer any need for it to serve as a hiring intermediary.

Some people working for tribal health programs in remote areas in Alaska are paraprofessionals who are not licensed in traditional health professions such as pharmacy. They are called “community health aides.”²⁸ Community health aides are certified under

²⁵ See IHS website, <http://www.ihs.gov/facilitieservices/areaoffices/alaska/> (last visited March 15, 2012).

²⁶ 25 U.S.C. § 1638c.

²⁷ 48 C.F.R. 37.104(a).

²⁸ 25 U.S.C. § 1616l.

a special federal program.²⁹ In 2005, the Department of Law concluded that Alaska licensing laws otherwise applicable to dental hygienists do not apply to dental health aides certified under the federal community health aide program.³⁰

D. Alaska licensing law

In Alaska, health professionals, including pharmacists, are licensed by professional licensing boards supported by the Department of Commerce, Community, and Economic Development, such as the Board of Pharmacy, the State Medical Board, and the Board of Nursing. The licensing statutes and regulations applied by these boards generally specify that federal employees are exempt from their reach.³¹ But no existing Alaska statutory or regulatory provision specifically exempts tribal health professionals from any of Alaska's professional licensing requirements.

III. TRIBAL HEALTH PROFESSIONALS

In March 2010, the Indian Health Care Improvement Reauthorization and Extension Act was enacted into law as part of the Patient Protection and Affordable Care

²⁹ 25 U.S.C. § 1616l(b).

³⁰ 2005 AG opinion.

³¹ See AS 08.64.370 (1) (exemption from medical licensing requirements for "officers in the regular medical service of the armed services of the United States or the United States Public Health Service while in the discharge of their official duties"); AS 08.68.800(a)(1) (exemption for "a qualified nurse licensed in another state employed by the United States government or a bureau, or agency, or division of the United States government while in the discharge of official duties"); AS 08.36.350 (exemption for "a dentist in the employ of the United States Public Health Service, United States Department of Veterans Affairs, Alaska Native Service, or other agency of the federal government, in the discharge of official duties").

Act (PPACA).³² It included a new provision, often referred to as Section 221, creating an explicit exemption from state licensing requirements:

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. 450 et seq.).³³

The term “health profession” is defined to include “pharmacy.”³⁴ Thus, Section 221 purports to exempt from state licensing requirements any pharmacist with an out-of-state license who is “employed by” a “tribal health program” with an ISDEAA agreement.

The legislative history of Section 221³⁵ suggests that Congress enacted it to help tribal health programs attract out-of-state personnel by extending to tribal health

³² Pub. L. No. 111-148 at § 10221, 124 Stat. 119 (2010). PPACA incorporated by reference and enacted into law (with several amendments) S. 1790, the Indian Health Care Improvement Reauthorization and Extension Act of 2009 “as reported by the Committee on Indian Affairs of the Senate in December 2009.” PPACA has been challenged in multiple lawsuits, and the U.S. Supreme Court heard oral argument on the law’s constitutionality in March 2012. *See Dep’t of Health & Human Services v. Florida*, 132 S. Ct. 604 (2011) (granting certiorari). Although the S. 1790 Indian health provisions are not at issue in these lawsuits, they would be struck down in the event that the court holds PPACA unconstitutional and further concludes that the unconstitutional provisions cannot be severed from the remainder of the law. That result would change the analysis of the licensing issue.

³³ S. 1790 at § 134 (codified at 25 U.S.C. § 1621t).

³⁴ 25 U.S.C. § 1603(10) (“The term ‘health profession’ means allopathic medicine, family medicine, internal medicine, pediatrics, geriatric medicine, obstetrics and gynecology, podiatric medicine, nursing, public health nursing, dentistry, psychiatry, osteopathy, optometry, pharmacy, psychology, public health, social work, marriage and family therapy, chiropractic medicine, environmental health and engineering, an allied health profession, or any other health profession.”).

professionals the same license portability enjoyed by IHS employees.³⁶ Congress recognized that tribal health programs have difficulty filling positions and hoped to make these positions more attractive.³⁷

A. Section 221 preempts state licensing requirements.

The Supremacy Clause of the U.S. Constitution dictates that federal law is the supreme law of the land.³⁸ Thus, federal law can preempt—i.e., override—state law.³⁹ Section 221 expressly exempts certain people from state licensing requirements. This

³⁵ Section 221 was included within many different bills seeking to reauthorize the Indian Health Care Improvement Act that were introduced every year from 1999 until 2010. Section 221’s text remained largely unchanged throughout this process; the legislative history of prior versions of the bill is thus relevant to its interpretation.

³⁶ S. Rep. No. 110–197 at 12 (2007) (“The Committee has been made aware of the need to increase the number of licensed health professionals in the Indian health system and included provisions in S. 1200 to address that need. S. 1200 provides for portability of current licenses for tribal health professionals consistent with other Federal health licensing provisions.”); S. Rep. No. 109–222 at 14 (2006) (“The Committee has been made aware of the need to increase the number of licensed health professionals in the Indian health system and included provisions in S. 1057 to address that need. S. 1057 provides for portability of current licenses for tribal health professionals consistent with other Federal health licensing provisions.”); H.R. Rep. No. 108–791(I) at 89 (2004) (“The new IHCIA section 221 extends the right enjoyed by IHS to exempt from licensing requirements in the state which the Indian health program is carried out, so long as the provider is licensed in at least one other state.”); S. Rep. No. 108–411 at 22 (2004) (noting that Section 221 “extends similar current authority for the IHS to tribal health programs”).

³⁷ S. Rep. No. 108–411 at 10 (2004) (stating purpose “to ensure an adequate supply of health professionals to the IHS, tribal and urban Indian health programs.”); *see* 154 Cong. Rec. S1150-02, S1154 (daily ed. Feb. 26, 2008) (comments of Sen. Russell Feingold) (“Recruiting talented and dedicated professionals to serve in IHS facilities, whether urban or rural, is a key challenge facing many tribal communities . . .”).

³⁸ U.S. Const. art. VI, cl. 2.

³⁹ *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654 (1995).

clear Congressional statement is sufficient to preempt state law.⁴⁰ Thus, pharmacists who are covered by the Section 221 exemption need not obtain Alaska licenses.

In a preemption analysis, Congress's intent "is the ultimate touchstone"—in other words, the main question is whether Congress intended a statute to override state law.⁴¹ There are several different types of preemption.⁴² Sometimes it is difficult to figure out whether federal law preempts state law because Congress has not clearly stated its intent. A court may find that Congress has implicitly preempted state law because the state and federal laws cannot effectively coexist—this is known as "implied" preemption.

But where the text of a federal statute explicitly announces that it overrides state law, Congress's intent is clear and no complex analysis is necessary. This is known as "express" preemption. Section 221 is an example of express preemption. Section 221 expressly declares that that certain health professionals "shall be exempt" from state licensing requirements. This language is not susceptible to alternative interpretations that leave room for state licensing law. Section 221's clear preemptive language is reinforced

⁴⁰ Only a valid federal law that is within Congress's constitutional power can preempt state law. See Laurence H. Tribe, *American Constitutional Law*, § 6-28 ("So long as Congress acts within an area delegated to it, the preemption of conflicting state or local action . . . flow[s] directly from the substantive source of whatever power Congress is exercising, coupled with the Supremacy Clause."). The federal government's power to exempt the off-reservation activities of tribal entities from state law is not without limits.

⁴¹ *Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996)).

⁴² See *Allen v. State, Dep't of Health & Soc. Servs., Div. of Pub. Assistance*, 203 P.3d 1155, 1162-64 (Alaska 2009) (summarizing types of federal preemption).

by statements in the legislative history acknowledging that it would preempt state law.⁴³ Accordingly, Section 221 expressly preempts state licensing requirements for the health professionals it covers.

B. Scope of the Section 221 licensing exemption

The logical next question is the extent of Section 221's preemption of state law—i.e., who is covered by the licensing exemption, and under what circumstances? Under the terms of Section 221, in order to qualify for the exemption a person must: (1) be a “licensed health professional” who is “licensed in any State” and (2) be “employed by a tribal health program.”⁴⁴ Some aspects of these requirements are easy to interpret. For instance, the term “tribal health program” is specifically defined in statute to mean a health program operated by a tribal group under an ISDEAA agreement with the IHS.⁴⁵

⁴³ See 150 Cong. Rec. S12052-02, S12055 (Dec. 8, 2004) (Congressional Budget Office cost estimate noting that Section 221 “would preempt state licensing laws in cases where a health care professional is licensed in one state but is performing services in another state under a funding agreement in a tribal health program”); H.R. Rep. No. 109–661(I) at 131 (2006) (noting that Section 221 “would preempt state licensing laws in cases where a health care professional is licensed in one state but is performing services in another state under a contract or compact with a tribal health program”); H.R. Rep. No. 109–661(I) at 132 (2006) (noting that the 2006 version of the bill containing Section 221 was “not intended to preempt any State, local or tribal law other than State licensing laws in certain cases where a health care professional is licensed in one State but is performing services in another State under a contract or compact with a tribal health program”); S. Rep. No. 110–197 at 88 (2007) (noting that Section 221 “would preempt state licensing laws in cases where a health care professional is licensed in one state but is performing services in another state under a contract or compact with a tribal health program”). Cf. 154 Cong. Rec. S993-08, S997 (daily ed. Feb. 14, 2008) (Senator Coburn proposes an amendment “[t]o ensure tribal members have access to the highest levels of quality and safety,” which would have deleted Section 221 and replaced it with the language “Nothing in this Act preempts any State requirement regarding licensing of any health care personnel.”).

⁴⁴ 25 U.S.C. § 1621t.

⁴⁵ 25 U.S.C. § 1603(25) (“The term ‘tribal health program’ means an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the [Indian Health] Service through, or provided for in, a contract or compact with the Service under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.).”).

But Section 221 may contain ambiguities, and it has not been around long enough to have been thoroughly interpreted by courts or government agencies. This subsection provides some guidelines that may be helpful in determining the applicability of Section 221 in borderline cases.

First, the legislative history suggests that Section 221 was intended to put tribal health professionals on similar footing to IHS health professionals with regard to state licensing requirements.⁴⁶ An IHS pharmacist must hold a current, valid state license, but it need not be from the state in which she is practicing.⁴⁷ If questions arise regarding the scope of the Section 221 exemption, it may be useful to look at the details of the licensing requirements that the IHS imposes on its own personnel.

In addition, consulting the scope of FTCA coverage for tribal health professionals may be instructive. The federal government extends FTCA liability coverage to tribal health programs and their employees.⁴⁸ FTCA coverage is not directly related to Section 221 or state licensing requirements. But by providing a legal remedy for a patient who is injured by a negligent tribal health professional, FTCA coverage provides some protection for patients even if the tribal health professional is not subject to the oversight of the local state licensing board due to Section 221. Because FTCA coverage provides some protection for patients where Section 221 has removed the protection of local state

⁴⁶ See sources cited, *supra* note 36.

⁴⁷ See U.S. Dep't of Health and Human Servs., Public Health Servs., *Commissioned Corps Instruction, "Category Specific Appointment Standards"* at 3 ¶6-1.a.(1) (May 6, 2011) (available at http://dcp.psc.gov/ECCIS/documents/CCI2_3_1_03.pdf) (detailing qualifications for an IHS pharmacist who is a member of the Public Health Service Commissioned Corps); IHS Manual 3-7.2(B)(1)(b) (June 26, 1995) (available at http://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p3c7) (detailing qualifications for an IHS pharmacist hired through the civil service system). The pharmacy section of the IHS Manual states that "Pharmacists hired directly by tribes or tribal organizations pursuant to [the ISDEAA] are subject to licensure requirements of the State in which their practice is located." IHS Manual 3-7.2(B)(1)(b) (June 26, 1995) (available at http://www.ihs.gov/ihm/index.cfm?module=dsp_ihm_pc_p3c7). However, this manual section has not been updated since the enactment of Section 221 and appears to have been superseded.

⁴⁸ 25 U.S.C. § 450f (d); 25 U.S.C. § 458aaa-15(a) (making section 450f(d) applicable to Title V IHS compacts).

oversight, it may make sense to consult the boundaries of FTCA coverage when determining the boundaries of Section 221. FTCA coverage generally extends to tribal health program employees and tribal personal services contractors while they are performing services under an ISDEAA agreement.⁴⁹ It may not cover an independent contractor for a tribal health program or services that are not provided under an ISDEAA agreement.⁵⁰

These considerations may help answer some questions regarding the scope of Section 221. For example, is a health professional who works for a tribal health program covered by the Section 221 exemption while “moonlighting” for a non-tribal employer? The considerations outlined above suggest that she is not. An IHS employee who moonlights is not exempt from state licensing requirements when performing a non-federal job, because the federal exemption is tied to the federal job. Similarly, the Section 221 exemption should be considered tied to the tribal health program and its ISDEAA agreement. This conclusion is also supported by the fact that FTCA coverage does not extend to work performed outside the scope of an ISDEAA agreement.⁵¹ Thus, if a tribal health professional wishes to provide services outside the scope of an ISDEAA agreement, she must obtain an Alaska license.

Other questions regarding the scope of Section 221 may need to be decided based on specific facts. For example, determining whether Section 221 covers a tribal health professional who works as a contractor rather than a regular tribal health program employee may require an examination of the contract at issue. If the contract is akin to a federal personal services contract—which creates a relationship very similar to a traditional employer/employee relationship⁵²—the Section 221 exemption might apply, but if the contract creates an independent contractor relationship, the exemption would

⁴⁹ 25 U.S.C. § 450f (d); 25 C.F.R. § 900.193; 25 C.F.R. § 900.192; 25 C.F.R. § 900.206.

⁵⁰ 25 U.S.C. § 450f (d); 25 C.F.R. § 900.189; 25 C.F.R. § 900.195; 25 C.F.R. § 900.183(b)(4); *see, e.g., Wooten v. Hudson*, 71 F. Supp. 2d 1149, 1154 (E.D. Okla. 1999) (holding that physician was covered by FTCA during hours he worked for tribal health program but not during hours he worked for private company); *Tsosie v. United States*, 452 F.3d 1161, 1167 (10th Cir. 2006) (holding that independent contractor physician was not covered by FTCA).

⁵¹ 25 U.S.C. § 450f (d).

⁵² 48 C.F.R. § 37.104(a).

probably not apply. This distinction is suggested by the fact that personal services contractors are supervised in the same manner as employees⁵³ and the fact that the FTCA generally covers personal services contractors⁵⁴ but not independent contractors.⁵⁵ A licensing board presented with a contractor for a tribal health program claiming a Section 221 exemption should examine the relevant contract in consultation with the Department of Law.

Other specific fact situations might reveal further questions regarding the scope of Section 221. Licensing boards who need help determining whether a particular person is entitled to a Section 221 exemption should contact the Department of Law.

C. A state licensing board may require proof of a tribal health professional's entitlement to a Section 221 exemption.

State licensing boards aren't completely without authority over tribal health professionals because tribal health professionals are not federal employees. If a tribal health professional does not meet the requirements of Section 221, she is subject to the licensing requirements of the state in which she is practicing. Accordingly, state licensing boards may require tribal health professionals to provide proof of out-of-state licensure and employment by a tribal health program before recognizing the exemption. Boards may use this residual authority to ensure that nobody is engaging in unlicensed practice by checking to make sure out-of-state licenses are current and valid. A board may cease recognizing a Section 221 exemption if a person's out-of-state license is suspended or revoked. Taking these actions would not interfere with federal law—indeed, it would support federal law by enforcing Section 221's policy determination that all tribal health professionals should have a license from a state.

⁵³ Cf. 48 C.F.R. § 37.104(c)(2) (providing that in determining whether a contract is a federal personal services contract, “[e]ach contract arrangement must be judged in the light of its own facts and circumstances, the key question always being: Will the Government exercise relatively continuous supervision and control over the contractor personnel performing the contract?”).

⁵⁴ 25 U.S.C. § 450f (d); *see also* 25 C.F.R. § 900.193.

⁵⁵ *See* sources cited *supra* note 50.

D. A state licensing board may discipline a tribal health professional who holds an Alaska license.

Although Section 221 means that a tribal health professional working in Alaska may not need to have an Alaska license, it does not mean that one who *does* hold an Alaska license is exempt from the requirements of that license. Even federal employees who hold Alaska licenses must comply with the terms of their licenses or face discipline. Indeed, the federal government has chosen to rely on the state licensing boards by requiring that federal and tribal health professionals be licensed by a state board, rather than by creating a federal professional licensing scheme. A state board's enforcement of its standards against its licensees who are federal or tribal employees does not obstruct any federal purpose—indeed, it furthers federal purposes by ensuring that the state licenses on which the federal government relies properly signal their holders' qualifications. Thus, federal law does not preempt a state board's power to discipline one of its own licensees when that licensee works for a tribal health program.

IV. COMMUNITY HEALTH AIDES

Community health aides are paraprofessionals who work in remote clinics and are not licensed in traditional health professions.⁵⁶ They are certified under a federal program that has operated in Alaska for many years.⁵⁷ As is the case with dental health aides,⁵⁸ as long as community health aides are acting within their scope of practice authorized by federal law, they need not comply with state professional licensing requirements, including those found in Alaska's Pharmacy Act.

Congress has directed the IHS to “provide[] for the training of Alaska Natives as health aides or community health practitioners” and “use[] those aides or practitioners in the provision of health care, health promotion, and disease prevention services to Alaska Natives living in villages in rural Alaska.”⁵⁹ Congress instructed the IHS to create a training curriculum and certification board for community health aides with an eye

⁵⁶ 25 U.S.C. § 1616l.

⁵⁷ 25 U.S.C. § 1616l(b); *see also* CHAP website, <http://www.akchap.org/html/about-chap.html> (last visited March 15, 2012) (history of community health aide program).

⁵⁸ 2005 AG opinion.

⁵⁹ 25 U.S.C. § 1616l(a).

toward meeting Congress's Indian health goals.⁶⁰ The Community Health Aide Program Certification Board, established under this law,⁶¹ sets standards and certifies community health aides and practitioners, dental health aides, and behavioral health aides and practitioners.⁶² Each type of community health aide is subject to specific training and education requirements and has a scope of practice set forth in the Community Health Aide Program Certification Board Standards and Procedures.⁶³ The Alaska Community Health Aide/Practitioner Manual sets detailed guidelines and protocols that community health aides must follow.⁶⁴

In 2005, the Department of Law issued an opinion concluding that Alaska licensing laws otherwise applicable to dental hygienists do not apply to dental health aides certified under this federal program.⁶⁵ The opinion observed that one objective of the community health aide program "is to provide dental care to Alaska Natives through paraprofessionals because there are too few dentists and hygienists available to provide those services in remote areas."⁶⁶ The opinion noted that "[i]f federal dental health aides are forced to comply with state law before they can lawfully provide dental treatment, the congressional purpose to increase dental treatment in remote areas through the use of paraprofessional aides will be defeated."⁶⁷ The opinion reasoned that application of state law to dental health aides would "stand as an obstacle to Congress' objective to provide dental treatment to Alaska Natives by using non-dentist, non-hygienist

⁶⁰ 25 U.S.C. § 16161(a), (b)(2)(C), (b)(3).

⁶¹ 25 U.S.C. § 16161(b)(3).

⁶² Community Health Aide Program Certification Board Standards and Procedures at pg. 1 (amended June 19, 2008) (available at http://www.akchap.org/resources/chap_library/CHAPCB_App_Docs_BHA/CHAPCB_Standards__Procedures__Amended__06-19-08_final.pdf).

⁶³ *Id.*

⁶⁴ Alaska Community Health Aide/Practitioner Manual (2006 edition).

⁶⁵ 2005 AG opinion.

⁶⁶ *Id.* at *6.

⁶⁷ *Id.*

paraprofessionals.”⁶⁸ The opinion thus concluded that 25 U.S.C. § 16161 implicitly preempts state law.⁶⁹

The state superior court agreed with this analysis, rejecting a challenge brought by a group of dentists.⁷⁰ The superior court explained:

It is clear that Congress intended to circumvent state licensing laws and have the community health aides trained, certified, and supervised under a separate federal statutory scheme. To find otherwise would deem the legislation, in which Congress specifically directs the Secretary to create and implement the Community Health Aide Program for Alaska, entirely futile and unnecessary; it is unlikely that Congress would be so careless.⁷¹

Although the 2005 attorney general opinion and 2006 superior court opinion specifically addressed only dental licensing requirements, the same analysis applies to pharmacist and pharmacy technician licensing requirements that would pose an obstacle to the federal community health aide program. Federal law provides that community health aides should be instructed on “efficient and effective management of clinic pharmacies.”⁷² Requiring a community health aide to obtain an Alaska pharmacist license before performing these duties would obstruct the federal program because such a license requires a college degree and other advanced qualifications that community health aides are unlikely to have.⁷³ The requirements for a pharmacy technician license are not as stringent,⁷⁴ but requiring health aides to become licensed pharmacy technicians could nonetheless pose an obstacle to the federal program because Alaska law restricts what a

⁶⁸ *Id.*

⁶⁹ *Id.* at *7.

⁷⁰ Order, *Alaska Dental Society v. State of Alaska*, Case No. 3AN-06-04797CI (Alaska Super. Ct., June 27, 2006) (hereinafter, “2006 order”).

⁷¹ *Id.* at 18.

⁷² 25 U.S.C. § 16161(b)(2)(B).

⁷³ AS 08.80.110.

⁷⁴ See 12 AAC 52.140 (requiring a high school education, fluency in English, and a clean criminal history).

pharmacy technician may do.⁷⁵ Moreover, imposing state requirements on top of the requirements created by the federal program could be seen as interfering with federal purposes even if those requirements are not very difficult to meet. Accordingly, the Pharmacy Act does not prevent community health aides from performing services within their federally certified scope of practice, even if those services would normally require state licensure.

Nonetheless, although community health aides may provide some medication-related services, they have a limited scope of practice. The Community Health Aide Manual provides detailed descriptions of everything community health aides are certified to do. If a community health aide goes beyond the scope of her federal certification, she is not exempt from state law.

V. CONCLUSION

Because Section 221 expressly preempts state law, pharmacists working for tribal health programs under ISDEAA agreements need not obtain Alaska licenses as long as they are validly licensed in another state. The Board of Pharmacy may require a tribal pharmacist who is not licensed in Alaska to provide proof of entitlement to a Section 221 exemption.

Additionally, federally certified community health aides need not obtain pharmacist or pharmacy technician licenses as long as they are acting within their scope of practice under federal law.

Sincerely,

MICHAEL C. GERAGHTY
ATTORNEY GENERAL

By: 
Laura Fox
Assistant Attorney General

⁷⁵ 12 AAC 52.230.

R 345

Vellucci, Mary K (CED)

From: Vellucci, Mary K (CED)
Sent: Wednesday, May 16, 2012 2:30 PM
To: Amy R. Whisler
Subject: RE: Changes in Dillingham

Your comments are noted and will be filed in the pharmacy's record with the Change in PICs. At a federal facility, a pharmacist who is not licensed in AK can be the PIC.

If there is anything else, reply to let me know.

Mary Kay Vellucci
Licensing Examiner, AK Board of Pharmacy
Div. of Corporations, Business and Professional Licensing
PO Box 110806; Juneau AK 99811-0806
Ph: (907) 465-2589 Fax: (907) 465-2489
mary.kay.vellucci@alaska.gov

-----Original Message-----

From: Amy R. Whisler [<mailto:awhisler@bbahc.org>]
Sent: Tuesday, May 15, 2012 12:06 PM
To: Vellucci, Mary K (CED)
Subject: RE: Changes in Dillingham

Mary Kay,

Thank you for your help with this. I know you are very busy and I do understand and appreciate any help you can provide.

I am listed as the Pharmacist Intern's sponsor and at this point probably will continue unless if it needs to be the Pharmacist-in-Charge. Also, I tried to look in the regulations to be sure a pharmacist can be the PIC if they are not yet licensed in AK. I was unable to find any information so I was hoping you could address this.

We will get that PIC change form sent into you as you attached in your last email. I did send one in earlier this month when I was filling in. The following is the schedule of acting (interim) managers in the last few months:

Rene Lucha (interim) 01/30/12 to 02/24/12
Amy Whisler (interim) 02/25/12 to 03/25/12
Suzanne Alexander (interim) 03/26/12 to 04/18/12
Amy Whisler (interim) 04/18/12 to 05/08/12
Robert May (permanent) 05/08/12 to present

Thank you again Mary Kay. I appreciate your help.

Amy

-----Original Message-----

From: Vellucci, Mary K (CED) [<mailto:mary.kay.vellucci@alaska.gov>]
Sent: Wednesday, May 09, 2012 7:32 AM
To: Amy R. Whisler
Subject: RE: Changes in Dillingham

Please write a list of the acting PICs (including effective dates) since Bob Ward vacated the position, complete a Change in Pharmacy Manager (revised version attached) for Robert May and attach it to a copy of this print out. In the future, please notify the division as the changes occur.

****You need to determine if you have any interns coming in who have their supervising pharmacist identified on the Declarations of Sponsorship as someone who is no longer employed with you. If so, complete a new Declaration of Sponsorship for them and submit with the items above. Normally I would offer to assist you with this. However, I am in the middle of renewals (3,000 licenses), the class of 2012 is eager to get licensed, it's the end of fiscal year, board business etc. As you know, this is a one-woman show here at the Alaska board .**

Thank you for letting us know about your circumstances and good luck.

Mary Kay Vellucci

Licensing Examiner, AK Board of Pharmacy Div. of Corporations, Business and Professional Licensing PO Box 110806; Juneau AK 99811-0806

Ph: (907) 465-2589 Fax: (907) 465-2489 mary.kay.vellucci@alaska.gov

-----Original Message-----

From: Amy R. Whisler [<mailto:awhisler@bbahc.org>]

Sent: Tuesday, May 08, 2012 6:00 PM

To: Vellucci, Mary K (CED)

Subject: Changes in Dillingham

Mary Kay,

As you probably know, the Dillingham pharmacy has undergone several changes in the last several months. These changes include pharmacy managers or pharmacists-in-charge, as well as staff pharmacists. To get through the transition, we had several different acting pharmacy managers. As of today, we now have a permanent pharmacist manager, Robert May. Most of the changes were pretty sudden so we have had a difficult time keeping up with notifying you as each change happened. I can send you a history of the acting managers during the last few months if you would like. I do apologize for not being able to keep up.

Robert has moved here from the lower 48 and is licensed in states other than AK as of now. He is planning on taking the AK MPJE and getting licensed in AK. This is an Indian Health Service related facility so I believe he has some time to obtain the AK license. But, in the interim, I was wondering what needs to be done on our part, if anything, in addition to filling out the change in PIC license.

Your help would be most appreciated.

Thank you,

Amy

From: [Carrillo, Laura N \(CED\)](#)
To: "Richard Holt"
Subject: FW: D.O Notice of Proposed Rulemaking (federal) - Partial Fill Schedule II / Quantity Prescribed field (460-ET)
Date: Monday, February 4, 2019 11:07:00 AM

Hi Rich,

Please see below regarding an opportunity to comment on partial fills for scheduled II drugs.

Comments can be made through: <https://www.regulations.gov/searchResults?rpp=25&po=0&s=partial%2Bfill&fp=true&ns=true> under the title, "Administrative Simplification; Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 National Council for Prescription Drug Programs D.O Standard."

If you'd like, I can add this to our board packet

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: Narus, Erin Y (HSS)
Sent: Monday, February 4, 2019 10:00 AM
To: Carrillo, Laura N (CED) <laura.carrillo@alaska.gov>
Cc: Semling, Charles P (HSS) <charles.semaling@alaska.gov>; Goslin, Julius P (HSS) <jpgoslin@alaska.gov>; Jones, Andy M (HSS) <andy.jones@alaska.gov>
Subject: Fw: D.O Notice of Proposed Rulemaking (federal) - Partial Fill Schedule II / Quantity Prescribed field (460-ET)

Laura,

We wanted to make you aware of this opportunity to comment on proposed federal rules around claims submittal for partial filling of Schedule II drugs.

<https://www.govinfo.gov/content/pkg/FR-2019-01-31/pdf/2019-00554.pdf>

We will be watching these rules through the NPRM process and will provide additional information if the rule becomes codified at the federal level. This could be useful information for pharmacists following CARA (Pub. L. 114-198; enacted 7/22/16).

DEA information on reform of 21 CFR 1306.13 may be found here (Regulation Identifier No. 1117-AB45); NPRM anticipated in FFY2019:
<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201810&RIN=1117-AB4>
<https://www.govinfo.gov/content/pkg/FR-2018-11-16/pdf/2018-24084.pdf> (pg. 57902-57904)

Since I don't have an email for Rich, could you please share with him and the Board?

Hope you are doing well.

Best regards,
Erin

Erin Narus, PharmD, RPh
Div. Health Care Services, Medicaid
907.334.2425
DSM: erin.narus@hss.soa.directak.net

From: Centers for Medicare & Medicaid Services <cmslists@subscriptions.cms.hhs.gov>
Sent: Monday, February 4, 2019 5:59 AM
To: Narus, Erin Y (HSS)
Subject: D.0 Notice of Proposed Rulemaking

centers for medicare and medicaid services



administrative simplification



D.0 Notice of Proposed Rulemaking

The Department of Health and Human Services (HHS) [announces](#) the Notice of Proposed Rulemaking (NPRM) CMS-0055-P that was recently published in the Federal Register. This NPRM proposes to modify the requirements for the use of the

Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs (NCPDP) by requiring HIPAA covered entities to use the Quantity Prescribed field (460-ET) for retail pharmacy transactions for Schedule II drugs.

This modification would enable covered entities using the HIPAA retail pharmacy transaction to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill. We believe this modification is necessary, particularly in light of the fact that the opioid crisis is a nationwide public health emergency, and the modification, if adopted, would further the Administration’s efforts to address the crisis.

There is a 60-day public comment period for this rule, which closes on April 1, 2019. We encourage our stakeholders to read this [proposed rule](#) and submit comments, as these will assist us in preparing the final rule.

Read the full [Information Bulletin](#) on the [Go-to-Info page](#) for more information.

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(2) An eligible veteran who receives urgent care under paragraph (b)(5)(iii) of this section or urgent care consisting solely of an immunization against influenza (flu shot) is not subject to a copayment under paragraph (d)(1) of this section.

(3) If an eligible veteran would be required to pay more than one copayment under this section, or a copayment under this section and a copayment under § 17.108 or § 17.111, on the same day, the eligible veteran will only be charged the higher copayment.

[FR Doc. 2019-00277 Filed 1-30-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 162

[CMS-0055-P]

RIN 0938-AT52

Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard

AGENCY: Office of the Secretary, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would adopt a modification to the requirements for the use of the Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, National Council for Prescription Drug Programs by requiring covered entities to use the Quantity Prescribed (460-ET) field for retail pharmacy transactions for Schedule II drugs. The modification would enable covered entities to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, in the HIPAA retail pharmacy transactions. We believe this modification is important to ensure information is available to help prevent impermissible refills of Schedule II drugs, which would help to address the public health concerns associated with prescription drug abuse in the United States.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. April 1, 2019.

ADDRESSES: In commenting, please refer to file code CMS-0055-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0055-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-0055-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

Geanelle G. Herring, (410) 786-4466. Daniel Kalwa, (410) 786-1352. Angelo Pardo, (410) 786-1836.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments.

I. Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of the Department of Health and Human Services (HHS) to adopt standards for electronic health care administrative transactions conducted between health care providers, health plans, and health care clearinghouses. In January 2009 (74 FR 3295), the Secretary adopted the National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide,

Version D, Release 0, August 2007 (hereinafter referred to as Version D.0) for the following retail pharmacy transactions: Health care claims or equivalent encounter information; referral certification and authorization; and coordination of benefits. As discussed later, a technical issue with Version D.0 necessitates a modification of the requirements for the use of this standard.

A. Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills

The HHS Office of the Inspector General (OIG) conducted a study of Medicare Part D payments for Schedule II drugs that were billed as refills in 2009. Schedule II drugs are of particular interest to regulators because of the public health issues associated with their use and the potential for misuse and abuse. Schedule II drugs are defined, in part, by the Controlled Substances Act (CSA) as those with a high potential for abuse, with use potentially leading to severe psychological or physical dependence (21 U.S.C. 812(b)(2)). The CSA prohibits the refilling of Schedule II drugs; however, in some cases partial fills are permissible. Partial fills of Schedule II drugs were previously allowed only in limited circumstances, including where a pharmacist had less quantity on hand than the prescribed amount of medication, the prescription was for a patient in a LTC facility, or a patient had a terminal illness.¹

Based on the data from the study, the HHS OIG issued a report in September 2012 titled “Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills,” which analyzed all of the 2009 program year prescription drug event (PDE) records for refills of Schedule II drugs.² The OIG analyzed 20.1 million records for Schedule II drugs and identified refills according to the numeric values in a particular data field—the Fill Number (403-D3)³ field. The OIG concluded that the Medicare Part D program had inappropriately paid \$25 million for 397,203 Schedule II drug refills and that long-term care

¹ The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to the NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by CARA.

² Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>

³ National Council of Prescription Drug Programs (NCPDP) Telecommunication Standard Implementation Guide, Version D, Release 0, August 2007, defines the Fill Number Field as “403-D3”.

(LTC) facility pharmacies billed for 75 percent of such refills. OIG stated that the Medicare Part D plan sponsors should not have paid for those drugs because federal law prohibits Schedule II drug refills, and concluded that “[p]aying for such drugs raises public health concerns and may contribute to the diverting of controlled substances and their being resold on the street.”⁴

PDE records are claim summary records submitted by prescription drug plan sponsors to CMS for every prescription filled by a provider for a Medicare Part D beneficiary. PDE records contain data elements from prescription drug claims. One of those data elements is the Fill Number (403–D3) field. The Version D.0 implementation specifications require that a “0” be entered in that field for a new prescription and that the number be sequentially increased by 1 for each refill. For purposes of its report, the OIG methodology specified that any value greater than zero is considered a refill.⁵ Accordingly, where it found the value in the Fill Number (403–D3) field in a PDE record to be greater than zero, the OIG concluded that the PDE record was a refill for a Schedule II drug, though it acknowledged, given the fact that LTC facility pharmacies were allowed to dispense partial fills (where less than the full amount prescribed is dispensed) for Schedule II drugs under certain conditions, that it was possible some LTC facility pharmacies may have incorrectly billed partial fills of these drugs as refills.

In its written response to the OIG report,⁶ the Centers for Medicare & Medicaid Services (CMS) noted its concern that the OIG’s strict interpretation of PDE data did not support the OIG’s findings. CMS believed that the OIG’s findings were based in part on a misinterpretation of Schedule II drug partial fills dispensed to LTC facility residents as refills. The NCPDP maintains a work group, known as WG9 Government Programs Medicare Part D FAQ Task Group (hereinafter referred to as Task Group), designed to guide federal pharmacy programs on NCPDP standards. CMS made an inquiry to the Task Group, noting that although the OIG report appeared to misinterpret partial fills dispensed to patients in LTC facility pharmacies as

refills, it was not aware of any means by which such a pharmacy could distinguish partial fills of a controlled substance prescription for billing purposes without using the Fill Number (403–D3) field. This inquiry resulted in NCPDP submitting Designated Standard Maintenance Organization (DSMO) change request #1182⁷ to update the pharmacy standard.

In August 17, 2000 **Federal Register** (65 FR 50312), we published a final rule titled “Health Insurance Reform: Standards for Electronic Transactions” in which the Secretary adopted procedures to maintain existing HIPAA standards, modify existing HIPAA standards, and adopt new HIPAA standards. This August 2000 final rule also established a new category of organization, entitled “Designated Standard Maintenance Organization (DSMO).” DSMOs which are accredited by the American National Standards Institute (ANSI), are responsible for maintaining the standards adopted under HIPAA and are required to receive and process change requests proposals for new standards or the modification of existing standards. Individuals, entities and organizations that believe an adopted standard requires modification may submit change requests to the appropriate DSMO. The change request must be accompanied by a documented business case that supports the recommendation. The DSMO, through committee structure, will then review the request and notify the appropriate Standard Development Organization, in this case, whether it approves or rejects the modification request. Approved recommendations are then forwarded to National Committee of Vital Health Statistics (NCVHS) by the DSMO. NCVHS reviews the recommendation and, through its own committee structure, determines whether or not to formally recommend adoption of the modification by the Secretary of HHS.

DSMO change request #1182, was done in response to CMS request to the Task Group if there was a way to appropriately use the current NCPDP D.0 standard to distinguish partial fills of a controlled substance prescription from refills in LTC facility pharmacy claims. The Task Group replied in a letter⁸ to CMS advising that the Version D.0 implementation specification does not support the OIG’s findings regarding the use of the Fill Number (403–D3) field, further stating that the industry

uses the Fill Number (403–D3) field to represent the fill number (that is, the amount actually dispensed) and not necessarily the refill number. The Task Group indicated it would work on a clarification to avoid further misinterpretation, advising CMS that the NCPDP would recommend changes to the standard to allow Version D.0 to specify the conditional use of the Quantity Prescribed (460–ET) field, which is not used in the claim billing transaction, to indicate the actual quantity prescribed in the transmission of the claim, which would make data available to validate whether there are inappropriate fills in excess of the quantity prescribed. The NCPDP effected this change in its November 2012 publication of Version D.0, which required the use of the Quantity Prescribed (460–ET) field when claims for Schedule II drugs are submitted to Medicare Part D. NCPDP’s modification to the standard addressed Medicare Part D only, therefore HHS has not adopted the 2012 version because it is limited to Medicare Part D only. Therefore, HIPAA covered entities may not use it to remain in compliance with HIPAA. HHS believes that by modifying the requirements for the use of the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007, all covered entities, not just entities submitting Medicare Part D transactions, to clearly distinguish whether a prescription is a “partial fill,” where less than the full amount prescribed is dispensed, or a refill, in the HIPAA retail pharmacy transactions.

B. National Committee on Vital and Health Statistics (NCVHS) Recommendation

The National Committee on Vital and Health Statistics (NCVHS) was established by statute in 1949; it serves as an advisory committee to the Secretary and is statutorily conferred a significant role in the Secretary’s adoption and modification of HIPAA standards. On June 21, 2013, the NCVHS wrote to the Secretary that it agreed with the NCPDP’s recommended plan to allow Version D.0 to specify the conditional use of the Quantity Prescribed (460–ET) field in a republished Version D.0 with an explanation in the Editorial Corrections section and a change to the Version D.0 Editorial Document.⁹ The NCVHS indicated that with this change, “data will be available to validate whether or

⁴ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 13 <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

⁵ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 6 <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

⁶ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, page 17 <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

⁷ https://www.ncdp.org/NCPDP/media/pdf/OESS_request_20121115.pdf.

⁸ https://www.ncdp.org/NCPDP/media/pdf/OESS_request_20121115.pdf.

⁹ To review the recommendation, see <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/1306211t1.pdf>.

not there are inappropriate fills in excess of the quantity prescribed, a concern raised in a September, 2012 report from the HHS Office of the Inspector General.” In light of the opioid crisis, HHS believes in the importance of a targeted modification of the Version D.0 standard, to ensure the availability of data to indicate whether Schedule II drugs are being inappropriately filled, and we are proposing requirements for the use of Version D.0 to specify that covered entities must treat the Quantity Prescribed (460–ET) field as required for retail pharmacy transactions.

C. Congressional and Administration Actions in Response to the Opioid Crisis

During the last decade the nation has experienced worsening issues with opioid addiction and overdose deaths, prompting various Congressional and Administration actions. For example, the Comprehensive Addiction and Recovery Act (CARA) (Pub. L. 114–198) was enacted on July 22, 2016, and amended the CSA to allow a pharmacist to partially fill a prescription for a Schedule II controlled substance if: (1) Such partial fills are not prohibited by state law; (2) a partial fill is requested by the patient or prescribing practitioner; and (3) the total quantity dispensed in a partial fill does not exceed the quantity prescribed. Partial fills of Schedule II drugs were previously allowed only in limited circumstances, including where a pharmacist had less quantity on hand than the prescribed amount of medication, the prescription was for a patient in a LTC facility, or a patient had a terminal illness.¹⁰

We believe CARA’s implementation will yield an upsurge of partial refills, which supports the need for this proposed modification. That view is echoed in a May 31, 2017 letter the NCPDP sent to the DEA, which said “[w]ith implementation of the CARA partial Fill Provision, the potential exists for a significant increase in the number of occurrences of a prescription for a Schedule II controlled substance being partially filled.”

At the President’s direction, the Secretary of HHS declared a nationwide public health emergency to address the opioids crisis on October 26, 2017.¹¹ The President also declared a

nationwide public health emergency pertaining to the opioid crisis and directed the heads of executive departments and agencies to use all lawful means to exercise all appropriate emergency and other relevant authorities to reduce the number of deaths and minimize the devastation the drug demand and opioid crisis inflicts upon American communities. To address the crisis, HHS also announced a 5-Point Strategy calling for better: (1) Addiction prevention, treatment, and recovery services; (2) data; (3) pain management; (4) targeting of overdose reversing drugs; and (5) research.¹² The requirements proposed in this rule would support one of HHS’s top opioid strategic priorities calling for better data, which could ultimately result in reduced drug supply.

II. Provisions of the Proposed Regulations

A. Proposed Modification to the Requirements for Use of the Telecommunication Standard Implementation Guide Version D, Release 0 (Version D.0), August 2007, NCPDP

As discussed earlier, covered entities inconsistently reflect partial fills and fill numbers in the HIPAA retail pharmacy transactions that utilize Version D.0 because the currently adopted Version D.0 does not permit covered entities to use the Quantity Prescribed (460–ET) field. As a result, stakeholders cannot reliably discern from transactions data when a Schedule II drug has been partially filled or refilled. To remedy this problem, we are proposing to require, under the circumstances explained later, the Quantity Prescribed (460–ET) field in the August 2007 Version D.0 (the version currently adopted by HHS) to be treated as required. These changes would enable covered entities to clearly distinguish partial fills and fill numbers in the HIPAA retail pharmacy transactions, which would support and improve the Administration’s and the health care industry’s data collection and research efforts by, among other things, enabling policymakers, health care researchers, and other health care stakeholders that monitor the volume of opioids billed to health plans across the country to correctly identify partial fills in claims and prior authorization transactions. By facilitating accurate assessments, policymakers would be able to establish more effective controls and other measures to prevent inappropriate, or

even illegal, prescribing of Schedule II drugs.

In this proposed rule, we would require the Quantity Prescribed (460–ET) field in the August 2007 Version D.0 to be treated as a required field where the transmission uses the August 2007 Version D.0 standard for a Schedule II drug for the following three transactions: (1) Health care claims or equivalent encounter information; (2) referral certification and authorization; and (3) coordination of benefits. We would modify the regulations at §§ 162.1102, 162.1302, and 162.1802 to apply the new requirements. To ensure that the proposed definition of “Schedule II drugs” mirrors the DEA definition, we would specify that the term has the same meaning as the definition of that term at 21 CFR 1308.12.

To be clear, our proposal *would not* modify the presently adopted Version D.0 in any way. Rather, it would require covered entities to treat a field in Version D.0 differently than the Version D.0 implementation specification requires. We further want to make clear that this proposal also *does not* propose to adopt the 2012 publication of Version D.0. There, the NCPDP changed the Quantity Prescribed (460–ET) field designation from “not used” to “situational,” and the situational circumstance is “[r]equired for all Medicare Part D claims for drugs dispensed as Schedule II. May be used by trading partner agreement for claims for drugs dispensed as Schedule II only.” By applying only to transactions involving Medicare Part D claims, the 2012 publication would not cover a huge swath of HIPAA covered entities and therefore we believe our proposal would yield much greater benefit than if we were to adopt that 2012 publication.

We also note that the NCPDP has issued a subsequent publication, the October 2017 Telecommunication Standard Implementation Guide, Version F2 (Version F2), where, among many other unrelated changes, it revised the situational circumstance to specify an even broader use of the Quantity Prescribed (460–ET) field as “required only if the claim is for a controlled substance or for other products as required by law; otherwise, not available for use.” We note that although the NCVHS on May 17, 2018 recommended adoption of Version F2 to the Secretary, we are not presently proposing to adopt it because, it would delay the ability for covered entities to accurately capture partial fills of Schedule II drugs. In addition, given the many other significant changes it would

¹⁰ The Drug Enforcement Agency (DEA) indicated in a July 2017 letter to the NCPDP that it was currently promulgating proposed rulemaking to address the changes to 21 CFR 1306.13 (which concerns partial fills of prescriptions for Schedule II controlled substances) made by CARA.

¹¹ <https://www.hhs.gov/sites/default/files/opioid%20PHE%20Declaration-no-sig.pdf>.

¹² <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

require of covered entities, we believe it requires further evaluation. We are, however, committed to continuing to work with stakeholders to update as appropriate the HIPAA standards used for retail pharmacy transactions, and we are carefully considering the NCVHS's recommendation.

In addition, given the public health emergency caused by the opioid crisis and the urgent need to find ways to yield data and information to help combat it, we believe it is more appropriate for us to take this narrow, targeted approach that would not be overly burdensome to covered entities and can be accomplished quickly.

B. Compliance Date

We propose to revise § 162.1102 to reflect that covered entities would be required to be in compliance with the modification to the requirements for the use of Version D.0 in retail pharmacy transactions 180 days after the effective date of the final rule.

We believe these proposed requirements are a modification to an implementation specification, which is defined at 45 CFR 160.103 as a specific requirement or instruction for implementing a standard. Section 1175(b)(2) of the Act specifies that the compliance date for a modification to a standard or implementation specification cannot be sooner than 180 days after the date the modification is adopted. A modification is considered to be "adopted" on the date it becomes effective in the **Federal Register**, which in this case would be 60 days after its publication in the **Federal Register**. Because we believe it is important for this modification to be implemented as soon as statutorily permissible, we are proposing that covered entities would be required to comply with the modification 180 days after the date the modification is adopted in a final rule (to be clear, this would be 240 days following the date of publication of a final rule).

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We would consider all

comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we would respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

Covered entities inconsistently reflect partial fills and fill numbers for Schedule II drugs in retail pharmacy transactions that utilize Version D.0 because Version D.0 does not permit covered entities to use the Quantity Prescribed (460–ET) field. As a result, stakeholders cannot reliably discern from transactions data when a Schedule II drug has been partially filled or refilled. To help understand the economic burden of this issue, we refer back to the previously mentioned 2012 OIG report which estimates that pharmacies inaccurately billed \$25 million worth of partial fills as refills in 2009 paid by the Medicare Part D program. The OIG also expressed concerns about the possibility of these inappropriately dispensed Schedule II drugs being resold on the street.¹³ As noted previously, CMS noted its concern that the OIG's strict

interpretation of PDE data did not support the OIG's findings. CMS believed that the OIG's findings were based in part on a misinterpretation of Schedule II drug partial fills dispensed to LTC facility residents as refills, however, these findings are helpful as a starting point for this estimate. The White House Council of Economic Advisers estimates that opioids abuse exacted a cost of \$504 billion in 2015 and contributed to a significant number of prescription and illicit drug overdose deaths.¹⁴ Furthermore, and as previously discussed, the Secretary declared a public health emergency to combat the opioid crisis.

For this analysis we leverage the historical cost and benefit data from the study conducted to support the Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards proposed and final rules (73 FR 49742 and 74 FR 3295, 3296, respectively) (hereinafter referenced as the study). The impact analysis for this proposed rule utilizes the historical cost estimates derived from the study across covered entities. The final estimate provided an overall cost of \$38 million to fully implement the then-new requirements of the 2007 Version D.0 for chain pharmacies (73 FR 49772). Since this is a very narrow, targeted modification that is limited to requiring covered entities to use the Quantity Prescribed (460–ET) field of the already adopted Version D.0, we anticipate the aggregate costs to be minimal. We expect minor system and implementation expenses, which would consist of modifying software configurations, updating business processes, and minimal personnel training. We further believe the investments to adopt this modification and update existing systems have the same cost variables as the adoption of this current D.0 version. We used these same considerations from the January 16, 2009 final rule (74 FR 3296), to formulate our assumptions on implementing system upgrades, and staff training costs. While it is difficult to determine aggregate costs across the industry, we believe system costs for this modification would require limited IT resources, training, and changes to business processes, and have estimated that this modification would cost between 1 to 5 percent of the original estimated cost, or between \$380,000 and \$1,900,000. The study also estimated a maximum upgrade fee cost of \$1.08 million per year for independent pharmacies (73 FR 49772). This results

¹³ Inappropriate Medicare Part D Payments for Schedule II Drugs Billed as Refills, <https://oig.hhs.gov/oei/reports/oei-02-09-00605.asp>.

¹⁴ <https://www.whitehouse.gov/opioids/>.

in an estimated cost for this modification of \$10,800 to \$54,000 per year in service fees across all independent pharmacies.

Pharmacies would benefit from using the Quantity Prescribed (460-ET) field because it would facilitate better monitoring of Schedule II drugs for over- or inappropriate prescribing. By virtue of this more robust data that we believe could be used to help avoid audits and incorrect payments, we estimate that large pharmacy chains could save up to \$500,000 per year, while, while smaller chains could save approximately \$100,000 per chain. Therefore, this could yield a total 10-year benefit of up to \$10 million, and that does not account for the value of the time pharmacists and pharmacy technician staff who process these claims also might save.

We believe health plans and their associated pharmacy benefit managers (PBMs) would also incur minimal cost since most have existing hardware and software platforms capable of using this field with their current technology and networks. Thus, we expect this modification to have a similarly minimal cost impact of between 1 and 5 percent of the original implementation costs. The study originally estimated the total cost to implement the 2007 Version D.0 for plans and PBMs to be a maximum of \$10.6 million for the industry (73 FR 49773). Thus, we estimate that the total cost for this modification for health plans and PBMs to be between \$106,000 and \$530,000.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A RIA must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule. We anticipate that the Quantity Prescribed (460-ET) field requirements would result in a reduction of overprescribing and inappropriate prescribing of Schedule II drugs, and also reinforce our commitment to lowering overall health care costs by reducing administrative burden and improving the quality of health care.

The RFA requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we

estimate the great majority of retail pharmacies are small businesses as defined by the Small Business Administration's (SBA) definition of having revenues of less than \$7.5 million to \$38.5 million in any 1 year. The SBA defines a size threshold in terms of annual revenues for pharmacies as \$27.5 million; we estimate that 95 percent of retail pharmacies have revenues below \$27.5 million or are nonprofit organizations and are therefore considered small entities. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities because the Quantity Prescribed (460-ET) field requirements are a minor modification for covered entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we continue to define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately \$150 million. We believe this proposed rule would have no consequential effect on state, local, or tribal governments or on the private sector in excess of that threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We believe that since this proposed rule would not impose substantial costs on state or local governments, the

requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This proposed rule is expected to be an E.O. 13771 regulatory action. Details on the estimated costs of this proposed rule can be found in the rule's economic analysis.

We have assessed the anticipated costs and benefits of this proposed rule and estimate that it would reduce operating costs for standard pharmacy transactions, remove inefficiencies and ambiguities, and facilitate better monitoring of Schedule II drugs.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

45 CFR Part 162

Administrative practice and procedures, electronic transactions, health facilities, health insurance, hospitals, incorporation by reference, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 162 as set forth below:

PART 162—ADMINISTRATIVE REQUIREMENTS

- 1. The authority citation for part 162 continues to read as follows:

Authority: Secs. 1171 through 1180 of the Social Security Act (42 U.S.C. 1320d-1320d-9), as added by sec. 262 of Pub. L. 104-191, 110 Stat. 2021-2031, sec. 105 of Pub. L. 110-233, 122 Stat. 881-922, and sec. 264 of Pub. L. 104-191, 110 Stat. 2033-2034 (42 U.S.C. 1320d-2(note), and secs. 1104 and 10109 of Pub. L. 111-148, 124 Stat. 146-154 and 915-917.

- 2. Section 162.1102 is amended by adding paragraph (d) to read as follows:

§ 162.1102 Standards for health care claims or equivalent encounter information transaction.

* * * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], the Quantity Prescribed (460-ET) field must be treated as required where the

transmission meets both of the following:

(1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

■ 3. Section 162.1302 is amended by adding paragraph (d) to read as follows:

§ 162.1302 Standards for referral certification and authorization transaction.

* * * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE AFTER PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], the Quantity Prescribed (460-ET) field must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

■ 4. Section 162.1802 is amended by adding paragraph (d) to read as follows:

§ 162.1802 Standards for coordination of benefits information transaction.

* * * * *

(d) For the period on and after [DATE 180 DAYS AFTER THE PUBLICATION OF THE FINAL RULE IN THE **Federal Register**], the Quantity Prescribed (460-ET) field must be treated as required where the transmission meets both of the following:

(1) Is for a Schedule II drug, as defined and updated in 21 CFR 1308.12.

(2) Uses the standard identified in paragraph (b)(2)(i) of this section.

Dated: December 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019-00554 Filed 1-30-19; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 18-314; FCC 18-165]

Further Streamlining FCC Rules Governing Satellite Services

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (FCC) proposes to create a new, optional, unified license to include both space stations and earth stations operating in a geostationary-satellite orbit, fixed-satellite service satellite network; and to

repeal or modify unnecessarily burdensome rules governing satellite services, such as annual reporting requirements.

DATES: Comments are due March 18, 2019. Reply comments are due April 16, 2019.

ADDRESSES: You may submit comments, identified by IB Docket No. 18-314, by any of the following methods:

- *FCC website:* <http://apps.fcc.gov/ecfs>. Follow the instructions for submitting comments.

- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Clay DeCell, 202-418-0803.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking (NPRM), FCC 18-165, adopted and released November 15, 2018. The full text of the NPRM is available online at <https://docs.fcc.gov/public/attachments/FCC-18-165A1.pdf>. The NPRM is also available for inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW, Room CY-A257, Washington, DC 20554. To request materials in accessible formats for people with disabilities, send an email to FCC504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (TTY).

Comment Filing Requirements

Interested parties may file comments and reply comments on or before the dates indicated in the **DATES** section above. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).

- *Electronic Filers.* Comments may be filed electronically using the internet by accessing the ECFS, <http://apps.fcc.gov/ecfs>.

- *Paper Filers.* Parties who file by paper must include an original and one copy of each filing.

Filings may be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th Street SW, Room TW-A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of before entering the building.

- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.

- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington DC 20554.

- *Persons with Disabilities.* To request materials in accessible formats for persons with disabilities (braille, large print, electronic files, audio format), or to request reasonable accommodations for filing comments (accessible format documents, sign language interpreters, CART, etc.), send an email to FCC504@fcc.gov or call 202-418-0530 (voice) or 202-418-0432 (TTY).

Ex Parte Presentations

Pursuant to 47 CFR 1.1200(a), this proceeding will be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with 47 CFR

TOPIC: Discuss transfer of unfilled controlled substance prescription

Applicable sections: 12 AAC 52.480

12 AAC 52.480. LABELING. One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

- (1) name, address, and phone number of the dispensing pharmacy;
- (2) unique identification number of the prescription drug order;
- (3) date the prescription drug order is dispensed;
- (4) initials of the dispensing pharmacist;
- (5) name of the prescribing practitioner;
- (6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;
- (7) directions for use;
- (8) quantity dispensed;
- (9) appropriate ancillary instructions or cautions;
- (10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";
- (11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner; and
- (12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent.

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER. (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.

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner.

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or by means of facsimile between pharmacies without limitation up to the number of originally authorized refills.

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

- (1) if transferred verbally, the transfer shall be communicated directly between two licensed pharmacists;
 - (2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);
 - (3) the pharmacist transferring the prescription drug order information shall record the following information:
 - (A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;
 - (B) the name of the pharmacist receiving the prescription drug order information;
 - (C) the name of the pharmacist transferring the prescription drug order information; and
 - (D) the date of the transfer;
 - (4) the pharmacist receiving the transferred prescription drug order information shall record the following information:
 - (A) the original date of issue and date of dispensing, if different from the date of issue;
 - (B) the original prescription drug order number and the number of refills authorized on the original prescription drug order;
 - (C) the number of valid refills remaining and the date of the last refill;
 - (D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and
 - (E) the name of the pharmacist transferring the prescription drug order information; and
 - (5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further refills.
- (e) A pharmacy using an automated data processing system shall meet the same requirements for a manual prescription drug order transfer listed in (d) of this section.
- (f) If two or more pharmacies use a common electronic database for prescription record keeping, prescription drug orders may be refilled at any of the pharmacies using the common electronic database if provisions are made
- (1) for an audit trail that documents the location of each filling; and
 - (2) to ensure that the number of authorized refills is not exceeded.

Authority: AS 08.80.005 AS 08.80.030



NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

February 27, 2019

Richard Holt, BS Pharm, PharmD, MBA
Chair, Alaska Board of Pharmacy
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
P. O. Box 110806
Juneau, AK 99811-0806

Dr. Holt and Honorable Members of the Alaska State Board of Pharmacy:

On behalf of the members of the National Association of Chain Drug Stores (NACDS), I am writing in response to the Board of Pharmacy's (Board) letter dated January 23, 2019 and the subsequent "Frequently Asked Questions About Controlled Substance Prescriptions" document regarding pharmacists dispensing of opioids. In Alaska, our members operate 72 pharmacies, with nearly 250 pharmacists, employ 6,200 full and part-time employees, and pay \$ 10.7 million in state taxes.

Pharmacies are on the frontlines of the opioid epidemic. Every day, pharmacists face a moment of truth when presented with an opioid prescription, making decisions as a provider of patient care and as part of the solution to the drug abuse crisis. Based on these experiences, the chain pharmacy community is committed to pursuing strategies addressing the opioid crisis that prevent misuse and abuse of prescription medications while maintaining access to needed therapies. Pharmacies are committed to ensuring that patients with legitimate chronic and other non-acute pain (like cancer pain) have access to needed pain medications. Accordingly, we want to assure the Board that our pharmacists are conducting due diligence in meeting the needs of their patients, while at the same time, recognizing their corresponding responsibility to help ensure that opioids are being dispensed only for legitimate medical purposes.

Our pharmacists fully recognize their legal obligation under 21 CFR 1306.04(a) which establishes that while a prescription for a controlled substance must be issued for a legitimate medical purpose by the prescriber and "the responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, ... a corresponding responsibility rests with the pharmacist who fills the prescription." In layman's terms, the regulation states that the pharmacist shares an obligation with the practitioner who issued the prescription (but without having actually conducted a medical examination of the patient) and must exercise professional judgment.

As federal and state law contemplates, Alaskan pharmacists attempt to work with prescribers to ensure legitimate pain patients receive their medicines, while drug seekers fail in their efforts. Many pharmacists have attempted to communicate directly with prescribers on behalf of patients and have been met with no response or a delayed response from the prescriber, making it extremely difficult to verify the legitimacy of the prescription. In a number of recently reported cases, prescribers are simply handing the Board's letter to their patients and telling them to convey it to the pharmacist should they meet any resistance in having their prescription filled.

This situation has become increasingly difficult in and around the Anchorage area, where patients are seeking alternative pharmacies to obtain legitimate controlled substance prescriptions, causing an increase in demand of controlled substances for nearby pharmacies. This increase in demand of controlled substances has caused shortages for some pharmacies and has hindered their ability to care for their existing customers, let alone new customers.

Pharmacists are concerned that there is a misperception that pharmacy refusals to fill certain prescriptions in Alaska are being done arbitrarily and capriciously. As the Board has requested that each patient be assessed individually, we respectfully ask the Board and the Division of Corporations, Business, and Professional Licensing to also assess each patient "complaint" on its individual merit and not assume that these pharmacy refusals are blanket refusals.

We appreciate the recent development and posting of the FAQ's on the respective prescriber and pharmacy websites, which we understand is also accessible via the prescription drug monitoring program. We respectfully ask the Division to proactively encourage the Boards of Medicine and Nursing to send the FAQ's to each of their respective licensees.

It appears as though the number of complaints from patients has abated in the past several weeks, due in large part to the work done by the Board. Nonetheless, we believe that the publicity of this situation will yield additional complaints in the coming weeks that could potentially be avoided with increased FAQ education and communication to prescribers. While we certainly recognize that some complaints may be legitimate grievances of denied access to pain medications, we remain concerned that some patient complaints stem from a misunderstanding or lack of knowledge as to current Alaska statutory restrictions on dispensing of opioids, as well as the dual obligation of pharmacists to ensure that legitimate pain patients receive their medications, while denying illegitimate drug seekers access to those same drugs. Ongoing patient and provider education is necessary to help ensure that the patient complaints being addressed are solely those coming from legitimate pain patients who are not receiving the opioid drugs that they need and whose access has been denied.

The members of NACDS stand ready to work with the Board, the Division and anyone else necessary to ensure patient safety and patient access to needed prescriptions, the prevention of opioid addiction, and the education of patients and prescribers regarding the legal obligations of pharmacists when dispensing opioids.

Sincerely,

A handwritten signature in black ink that reads "Lis Houchen". The signature is written in a cursive, flowing style.

Lis Houchen

lhouchen@nacds.org



NABP
National Association of
Boards of Pharmacy
www.nabp.pharmacy

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F) 847/375-1114

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: February 14, 2019
RE: Proposed Resolutions, NABP 115th Annual Meeting, May 16-18, 2019, Minneapolis, MN

Attached you will find a copy of the resolutions that NABP has received since the 114th Annual Meeting through February 8, 2019. We hope that you will have the opportunity to discuss the resolutions with your board so as to assist your voting delegate during the consideration of the resolutions at the 115th Annual Meeting in Minneapolis, MN.

Although we encourage you to share these resolutions with your board members, we strongly ask that these resolutions **not** be released to the press or any third parties at this time. Please remember that the NABP Committee on Resolutions has not yet reviewed the resolutions. The resolutions are presented exactly as we received them at the NABP office. The resolutions do **not** represent any official position of the Association or position advocated by NABP. The language and subject matter contained in the resolutions is solely the product of the entities that submitted them.

As you may know, any active member board, district, or committee of the Association may submit resolutions. All resolutions submitted in writing to the Association at least 20 days prior to the date of the Annual Meeting (April 26, 2019) shall be presented at the Annual Meeting for consideration. Resolutions not presented within such time limitations may be presented to the NABP Registration/Information Desk during the Annual Meeting by 8 AM on Thursday, May 16, 2019, and will be considered for adoption by the Association upon the affirmative vote of three-fourths of those Association members present and constituting a quorum.

The Committee on Resolutions will meet the morning of Thursday, May 16, 2019, during the Annual Meeting to review the resolutions. At that time, and with the consent of the submitter, changes may be made to ensure that the resolutions do not conflict with the purposes of NABP or create any adverse legal consequences. Each revised resolution will be presented to the membership for discussion and consideration at the 115th Annual Meeting.

If you have any questions, please feel free to contact us at ExecOffice@nabp.pharmacy.

Attachment

Resolutions Passed at 2018 District Meetings

District 1

Resolution #1 (Co-supported by District 2 & District 4)

Whereas, FDA recalls of products prepared in 503B facilities are inconsistent with the procedures of FDA recalls of manufactured products and

Whereas, state boards of pharmacy lack adequate direction from the FDA on how to appropriately respond to such recalls;

Therefore be it resolved that NABP contact the FDA and request that the recall procedures for products prepared in 503B facilities be clarified and standardized in accordance with the recall procedures for manufactured products.

Resolution #2 (Co-supported by District 4)

Whereas Virtual Manufacturers are becoming more common;

Whereas Virtual Manufacturing is an entity that does not actually manufacture a drug;

Whereas most state boards of pharmacy license manufacturers;

Whereas most state boards of pharmacy do not have the resources to appropriately review and license all the various subcontractors;

Therefore, be it resolved that NABP create a task force to explore the creation of a national validation to assist state boards of pharmacy with licensing such entities comparable to the VAWD program.

Resolution #3 (Co-supported by District 2 & District 4)

Whereas de-prescribing is a component of the practice of pharmacy and;

Whereas de-prescribing is defined as the process of tapering, stopping, discontinuing, or withdrawing drugs, with the goal of managing and improving outcomes.

Therefore be it resolved that NABP work with interested stakeholders, including but not limited to HHS, NCPDP, and the Tri-Regulator Collaborative, to develop the appropriate standards and functionality within e-prescribing software and systems to more fully operationalize existing functions such as "cancel Rx" so as to avoid duplicative or inappropriate prescribing and medication therapy.

Resolution #4

Whereas, the delivery of medications to patients and shipment of medications to reverse distributors is delegated to delivery services and

Whereas, the delivery services and their employees are not licensed with the appropriate state board(s) of pharmacy and

Whereas, when medications are lost or reported missing in transit while in the possession of the delivery services and

Whereas, state boards of pharmacy do not license such entities or employees lack the regulatory and enforcement authority to address and correct the lost of medications and threat to the public health

Therefore be it resolved that NABP form a Task Force to evaluate the issue of documentation of the custody of the drugs transported by delivery services and services' employees.

Resolution #5

Whereas, the patient care responsibilities of pharmacists are increasing and resulting in positive patient outcomes and

Whereas, a critical component to the pharmacist's increasing patient care responsibilities is appropriate and competent support by technicians and

Whereas, the state boards of pharmacy, through NABP and the NAPLEX, assess the competence of individuals seeking licensure to practice pharmacy;

Therefore be it resolved that the state boards of pharmacy support NABP in developing a Task Force on the position of a national licensure examination to assess the competence of individuals seeking to be licensed as technicians.

District 5

Resolution #1

Whereas, Dispensing of prescriptions for Veterinary patients is a growing service that is provided by pharmacies

Whereas, State Boards of Pharmacy are tasked with governing the dispensing of prescriptions by pharmacies

Whereas, Variability in how pharmacies issue prescriptions for Veterinary patients exists and, furthermore, this variability can lead to issues in reporting of these prescriptions when required by the state's prescription drug monitoring program

Whereas, Standardization of prescription records minimizes the potential for error and allows for consistent levels of care to be delivered to the public

Therefore be it resolved that NABP convene a task force to explore and develop best practice standards for the issuance of prescriptions for non-human patients for its member states to consider using.

District 6

Resolution #1: Changes to the Model Act for FDA-approved ingestible event markers

WHEREAS, new and evolving technology and devices are essential to the enhancement of pharmacy and patient care services; and

WHEREAS, patients have adapted and rely on technology and devices that track biometrics to improve their overall health and well-being; and

WHEREAS, state boards of pharmacy regulate the practice of pharmacy and the use of prescription drugs and devices, as well as the use of technology in pharmacy practice; and

WHEREAS, an ingestible event marker is a prescription device approved by the United States Food and Drug Administration (FDA) used to record time-stamped, patient-logged events that links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device; and

WHEREAS, the co-encapsulation of prescription ingestible event markers with prescription medications is distinct from compounding and from medication adherence packaging; and

WHEREAS, the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act) does not address the packaging of prescription ingestible event markers with prescription medications;

THEREFORE BE IT RESOLVED that NABP amend the Model Act to address the new FDA category of ingestible event markers as prescription devices, and allow pharmacists to package a prescription medication and a prescription ingestible event marker within a customized ingestible event medication adherence package in lieu of pharmacists separately dispensing the prescriptions to patients.

District 7

Resolution #1 (Co-supported by District 6)

WHEREAS boards of pharmacy receive information regarding perceptions of workload, working conditions, and resources related to the provision of patient care and public safety;

WHEREAS the information is primarily anecdotal or subjective survey data of pharmacists perceptions;

WHEREAS boards of pharmacy require objective data to substantiate the impact on patient safety and determine the appropriate action;

Therefore be it resolved, that NABP request the Pharmacist Workforce Center or its partner organizations conduct an analysis to provide objective data to determine the impact of workload, working conditions, and related topics on substantiated patient safety outcomes.

Resolution #2 (Co-supported by District 6 & District 8)

WHEREAS, the practice of pharmacy continues to evolve toward direct patient care; and

WHEREAS, the practice of pharmacy has included pharmacists performing patient assessments and initiating, modifying, or discontinuing drug therapy for four decades in some states; and

WHEREAS, pharmacists are currently making diagnoses for minor ailments and self-limiting conditions and have done so since the 1990's in some states; and

WHEREAS, published literature continues to demonstrate optimal patient outcomes are achieved when pharmacists are involved in the assessment, diagnosis, and treatment of many acute and chronic conditions; and

WHEREAS, states are increasingly enabling pharmacists to prescribe for various conditions and medication classes; and

WHEREAS, schools of pharmacy are currently teaching the building blocks of patient assessment, diagnosis, point-of-care tests, prescribing, and other related concepts.

THEREFORE BE IT RESOLVED that NABP send a letter to the American Council for Pharmacy Education (ACPE) to more formally codify in its standards an expectation that schools prepare each graduate, upon entry into the profession, with skills related to patient assessment, diagnosis, prescribing, and related competencies such as proper documentation, consistent current medical standards of care, as part of the next update to the ACPE Accreditation Standards.

THEREFORE BE IT RESOLVED that NABP update the Model Act regarding the definition of the "practice of pharmacy" to further recognize the role pharmacists are currently playing in practice with respect to assessment, diagnosis, and prescribing.

District 8

Resolution #1

WHEREAS the Food and Drug Administration, as required by the Drug Quality and Security Act, has released a draft standard Memorandum of Understanding for individual states to enter into with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate. And

WHEREAS the long standing, generally accepted definition of distribution does not include the act of patient specific dispensing. And

WHEREAS in the current draft MOU, the Food and Drug Administration has deviated from the long standing, generally accepted definition of distribution by including the act of patient specific dispensing. And

WHEREAS the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, August 2018 states: "Distribute" or "Distribution" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include to Dispense or Administer. Therefore,

BE IT RESOLVED THAT the National Association of Boards of Pharmacy will not support a Memorandum of Understanding in which the term distribution includes the act of dispensing.



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TO: EXECUTIVE OFFICERS – MPJE PARTICIPATING STATES, MPJE Item Writers,
MPJE Review Committee

FROM: Maureen Garrity, Competency Assessment Director

DATE: January 3, 2019

RE: MPJE Item Development Workshop – March 13-15, 2019

The National Association of Boards of Pharmacy® (NABP®) will host the Multistate Pharmacy Jurisprudence Examination® (MPJE®) Item Development Workshop on March 13-15, 2019, at NABP Headquarters in Mount Prospect, IL. The item development process is a collaborative effort, and NABP encourages all MPJE participating states to attend this important workshop.

The tentative meeting schedule is (all times are CDT):

Wednesday, March 13: Arrive in Chicago, IL, by 3 PM and check in at the Hilton Northbrook Hotel desk

- Shuttle to NABP Headquarters in Mt Prospect, IL
- Item authoring training session: 3:30 - 4:45 PM (Group dinner to follow)

Thursday, March 14: 8:30 AM - 4 PM Item writing (Dinner on your own)

Friday, March 15: 8:30 AM - 3 PM Item writing

NABP will reimburse approved expenses (travel, food, and lodging) for up to two participants from each state to attend the workshop. However, NABP may need to limit the attendance from any jurisdiction to one participant in the event of space limitations. If your state board is unable to send a representative, the writing assignment will need to be completed remotely. Full details including content areas to be targeted and logistics will be provided at a later date to the designated item writers who will write remotely.

Please provide contact information on the response form for the individuals who will attend the workshop on site, or for those who will complete the state assignment remotely. The NABP Meeting Services department will forward travel and hotel information approximately six weeks prior to the meeting once NABP has secured the names of the attendees.

January 3, 2019

Page 2

If you have any questions or comments, please contact Anne Woolridge, competency assessment supervising coordinator, at awoolridge@nabp.pharmacy or 847/391-4534, or Maureen Garrity at mgarrity@nabp.pharmacy or 847/391-4596.

2019 MPJE Item Development

Please indicate your state’s commitment to the 2019 MPJE item development assignment by indicating either attendance at the workshop taking place March 13-15, 2019, **or** remote participation. This form is in a fillable format. It requires Adobe Reader 6.0 or higher. Open the file, add the information, and click “yes” to save the changes. Please email this form to MPJE@nabp.pharmacy no later than **Friday, February 1, 2019**.

State Board: _____

Attending the MPJE workshop at NABP Headquarters on March 13-15, 2019.

NOT attending; will complete the assignment remotely.

MPJE Item Writer Contact Information

Please provide the contact information for the individuals who will attend the MPJE Workshop **or** will be completing the writing assignment remotely.

Item Writer: _____

Phone: _____

Email: _____

Item Writer: _____

Phone: _____

Email: _____



NABP

National Association of
Boards of Pharmacy

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TO: EXECUTIVE OFFICERS – ACTIVE MEMBER STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: January 7, 2019
RE: Official Delegate Certificate for NABP's 115th Annual Meeting, May 16-18, 2019,
Minneapolis, MN

NABP BYLAWS - ARTICLE I, Section 3. – Credentialing Delegates

Each active and associate member shall furnish credentials for the delegate and alternate delegates of the board to the Annual Meeting of this Association on a blank furnished by the Executive Director/Secretary and returned to the Association in accordance with policies set forth by the Executive Committee.

In accordance with the above stated bylaw, attached is your 2019 delegate certificate form. We ask that you list the name of the person who will serve as the official delegate for your board and the name of the person(s) who will serve as the official alternate delegate(s).

The official delegate is the voting delegate and is responsible for voting at the Association's business sessions and transmitting your board's position on all matters brought before the convention. Each active member board of pharmacy in good standing represented at the Annual Meeting shall have one vote. No voting by proxy shall be permitted.

Only current pharmacy board members or chief administrative officers qualify to serve as delegates or alternate delegates. However, all NABP members, active and associate, may participate in the discussions during the business sessions.

All official voting delegates will be identified by a special **red** ribbon attached to their badge. Alternate delegates will be identified by a **white** ribbon and will be authorized to act and vote for the official delegate (in his or her absence) if so authorized in writing and official recognition of this fact is conveyed to the chair.

In previous years, the voting delegate from each state was eligible to receive a grant from NABP to offset some travel expenses to attend the Annual Meeting. Effective in 2012, one affiliated member from each active member board of pharmacy may be eligible to receive the grant, whether or not they are assigned as the state's voting delegate. Additional information on the designation of the Annual Meeting travel grant recipient will be provided under separate cover.

EXECUTIVE OFFICERS – ACTIVE MEMBER STATE BOARDS OF PHARMACY

January 7, 2019

Page 2

Annual Meeting rules and procedures that apply to voting delegates, (including procedures for elections, change of delegate during the meeting, etc) will be forwarded to all delegates prior to the meeting. Additionally, applicable rules will be announced at the start of each business session at the Annual Meeting. *Robert's Rules of Order*, current edition, and the *NABP Constitution and Bylaws* will be in effect for the business sessions.

I am looking forward to a successful convention in Minneapolis and working with your board in furthering the objectives of the Association. Please mail the completed delegate certificate to Lisa Janso at NABP Headquarters or scan and email to ExecOffice@nabp.pharmacy.

Attachment: Active Member Boards Delegate Certificate

National Association of Boards of Pharmacy
OFFICIAL DELEGATE CERTIFICATE – ACTIVE MEMBER BOARDS

The Constitution of the National Association of Boards of Pharmacy states:

ARTICLE II - PURPOSE

The purpose of the Association is to provide for interstate transfer in pharmacist licensure, based upon a uniform minimum standard of pharmacist education and uniform legislation; and to improve the standards of pharmacist education, licensure, and practice by cooperating with State, National, and International Governmental Agencies and Associations having similar objectives.

ARTICLE III - MEMBERSHIP, VOTING AND DISTRICTS

Section 1.

(a) The members of this Association shall be the boards of pharmacy (or similar pharmacy licensing agency) of the individual States, the District of Columbia, the Territories and Commonwealths of the United States, the individual provinces of the Dominion of Canada, and such other jurisdictions that apply to join the Association and are approved, from time to time, by the Executive Committee. The members shall consist of active and associate members.

(b) Applications for membership shall be submitted to the Executive Director/Secretary. New member boards may be admitted to the Association at any meeting of the Executive Committee by an affirmative vote of two-thirds (2/3) of the total members of the Executive Committee entitled to vote.

(c) Active member boards shall be those member boards that have formally approved the Constitution and Bylaws of the Association, and that require the use of the NABP Clearinghouse for all candidates for the purpose of transferring licensure both into and out of the state as provided by the Bylaws of this Association.

(d) Associate member boards shall be those member boards not classified as active member boards.

(e) Any individual who is a member or administrative officer of an active or associate member board of the Association shall be an affiliated member of the Association and shall continue to be an affiliated member hereof, although such person is no longer actively participating on such board, so long as such person has not been convicted of an offense involving moral turpitude or violation of pharmacy, liquor, or drug laws and so long as such board is a member in good standing with this Association.

Section 3.

(a) Each active member board of pharmacy in good standing which is represented at the Annual Meeting shall have one vote on each issue put to a vote of the active member boards at the Annual Meeting of this Association. *The vote shall be cast by an individual currently serving as a member or as the administrative officer (as defined in Article III, Section 1) of an active member board of this Association who shall be recognized at the Annual Meeting as the official delegate of said active member board. No voting by proxy shall be permitted.*

The Bylaws of the National Association of Boards of Pharmacy states:

ARTICLE I

Section 3. Credentialing Delegates

Each active and associate member board shall furnish credentials for the delegate and alternate delegates of the board to the Annual Meeting of this Association on a blank furnished by the Executive Director/Secretary and returned to the Association in accordance with policies set forth by the Executive Committee.

Execution of this certificate by an active member state shall be deemed acceptance by the board of pharmacy of the Constitution and Bylaws of NABP and a continuing commitment to permit the transfer of pharmaceutical licensure as provided under the terms and conditions of the Bylaws in conformance with the statutes and regulations of such active member state.

Failure to pay membership dues to NABP within thirty (30) days from the date of invoice will jeopardize the good standing of the Board and will nullify an Active Member Board's right to vote at the Annual Meeting (Article III, Section 3(a), NABP Constitution above).

TO: NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

FROM: _____ BOARD OF PHARMACY

This is to certify that (name of official voting delegate) _____ has been duly appointed as a delegate and is hereby authorized and empowered to act for the _____ Board of Pharmacy at the Annual Meeting of the National Association of Boards of Pharmacy, to be held at the Minneapolis Marriott City Center in Minneapolis, MN, May 16-18, 2019.

This is to certify that (name of alternate delegate(s)) 1) _____,
2) _____, 3) _____ are authorized to act and vote for the official delegate (in his/her absence) if authorized by him/her and official recognition of this fact is conveyed to the Chair and recognized officials.

Attest:

Chief Executive Officer/Secretary

Seal

Date



NABPF

National Association of Boards
of Pharmacy Foundation

www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056

T) 847/391-4406

F) 847/375-1114

TO: EXECUTIVE OFFICERS – ACTIVE MEMBER STATE BOARDS OF PHARMACY
FROM: Carmen A. Catizone, Executive Director/Secretary
DATE: January 7, 2019
RE: Annual Meeting Travel Grant Program for NABP's 115th Annual Meeting, May 16-18, 2019, Minneapolis, MN

The National Association of Boards of Pharmacy Foundation (NABPF) is pleased to continue the Annual Meeting Travel Grant Program for NABP members needing financial assistance to attend NABP Annual Meetings. NABP feels that it is essential for boards of pharmacy to participate in Annual Meetings because during this time NABP's member boards of pharmacy will vote upon Association resolutions, select Executive Committee officers and members, and present and discuss information on current issues facing pharmacy regulators.

For the past 115 years, the mission of NABP has been to aid and support pharmacy regulators in creating standards that protect the public health. NABP realizes that budget constraints can prevent state boards of pharmacy from sending representatives to meetings, so the Annual Meeting Travel Grant Program will reimburse the board's designee **up to \$1,500** in travel fees to defray expenses such as airfare, hotel rooms, meals, taxis, parking, and tips. Grant monies do not include Annual Meeting registration fees. Monies are limited and grants are available on a first-come, first-served basis. Please note that the NABPF Annual Meeting Travel Grant reimbursement policy requires individuals to pay for all airfare, meals, hotel accommodations, and other meeting costs up front, and submit an expense report and original receipts to NABPF after the Annual Meeting in order to receive reimbursement.

One individual per active member board of pharmacy is eligible to receive the grant. **Though the individual awarded the travel grant need not be the board of pharmacy's voting delegate, his or her board of pharmacy must have a voting delegate in attendance at the Annual Meeting to vote during all applicable business sessions in order to receive reimbursement.**

The chief administrative officer of the board must complete the attached form to apply for the travel grant, or to request the grant be awarded to a current board member from his or her state. NABPF must receive all applications before the 115th Annual Meeting, May 16-18, 2019, Minneapolis, MN. NABPF will inform applicants whether or not they have qualified for a grant, and at that time provide them with more detailed instructions on procedures for reimbursement.

For more information, please contact Lisa Janso at 847/391-4462. We request that you complete the attached document and return via email to ExecOffice@nabp.pharmacy prior to the Annual Meeting.

Attachment: Annual Meeting Travel Grant Application



NABPF
 National Association of Boards
 of Pharmacy Foundation
www.nabp.pharmacy

1600 Feehanville Drive
 Mount Prospect, IL 60056
 T) 847/391-4406
 F) 847/375-1114

NABPF Annual Meeting Travel Grant Application

Thank you for applying for the NABPF Annual Meeting Travel Grant Program. To be considered for the grant, please complete this application and send it to NABP Headquarters before the 115th Annual Meeting, which will be held May 16-18, 2019, in Minneapolis, MN. The Travel Grant Program will reimburse travel expenses (according to NABPF’s travel reimbursement policy) up to \$1,500. **The individual named below will receive reimbursement for their travel expenses only if their state board of pharmacy’s voting delegate is present at all Annual Meeting business sessions.**

_____ Date

Board of Pharmacy _____

Grant Recipient Name _____ Grant Recipient Title _____

Grant Recipient Term Expiration Date on Board of Pharmacy _____

Grant Recipient Email Address _____

Executive Officer Name (please print) _____

Executive Officer Signature (enter initials if submitting electronic copy) _____

Executive Officer Email Address _____

Contact Person/Title
 (if different from Executive Officer) _____

Return completed form to:

Email: ExecOffice@nabp.pharmacy

Mail:
 NABP Foundation
 Attn: Lisa Janso, Annual Meeting Travel Grant Program
 1600 Feehanville Drive
 Mount Prospect, IL 60056

FOR INTERNAL USE ONLY
Date received ____ - ____ -2019
Grant approved _____ denied _____
Comments: _____

From: [Kevin Rew](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: Re: Questions about Automated
Date: Friday, February 1, 2019 3:48:31 PM

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 information is available.

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

From: Kevin Rew <krew@medifriendrx.com>

Sent: Tuesday, December 4, 2018 1:36 PM

To: Carrillo, Laura N (CED)

Subject: Fwd: Questions about Automated

Hi Laura,

This is the email I sent to Jun, asking questions about automated dispensing.

Thank you for your guidance!

Sincerely,
Kevin

----- Forwarded message -----

From: **Kevin Rew** <krew@medifriendrx.com>

Date: Tue, Dec 4, 2018 at 2:26 PM

Subject: Questions about Automated

To: <jun.maiquis@alaska.gov>

Hello,

Please forgive the "full assault" of a voicemail and email in rapid succession. I thought this would be a better forum to pose my question.

As quick background, 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. 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; and
2. On pharmacy premises, for access by patients who do not wish to wait in line.

In either case, the ADDS would be owned and operated by the pharmacy.

I know that Alaska has rules permitting telepharmacy. These rules aren't an exact fit for this situation because the ADDS would be situated in medical clinics.

Can you please tell me whether the Board of Pharmacy has granted any variances or is contemplating rules changes that would accommodate the use of ADDS that this pharmacy wants? Perhaps we could approach the Board with a request.

Many thanks for your assistance and guidance!

Sincerely,
Kevin Rew

--



Kevin Rew
General Counsel and COO

1999 Harrison St., Suite 1530
Oakland, CA 94612
o: 510.770.6343
f: 512.233.5828
e: krew@medifriendrx.com
w medifriendrx.com

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f: 512.233.5828

e: krew@medifriendrx.com

w: medifriendrx.com

From: [Zinn, Sher K \(CED\)](#)
To: [Carrillo, Laura N \(CED\)](#)
Subject: Unlicensed pharmacist at Walgreens
Date: Friday, February 1, 2019 10:37:13 AM

Found this article about an unlicensed pharmacist working at CA Walgreens for years before being caught. How did that happen?

<https://sanfrancisco.cbslocal.com/2019/01/30/woman-poses-as-walgreens-pharmacist-for-years-hands-out-750k-prescriptions/>

Sher Zinn
Regulations Specialist
State of Alaska
Dept. of Commerce
Corp., Business & Professional Licensing
Phone- 907-465-1049
fax- 907-465-2974
sher.zinn@alaska.gov

February 27, 2019

Alaska State Board of Pharmacy

Dear Colleagues,

I am writing to ask you and your Board to consider proposing legislation or rule, as appropriate for your jurisdiction, regarding the ability of pharmacists to use their professional judgment to adapt prescriptions, while still meeting the intent of the prescriber. In the high velocity pace of practice, there are omissions or changes a pharmacist can make on an unclear prescription without contacting the prescriber.

In the early years of my career, this practice was commonplace and accepted by prescribers and pharmacists. With the advent of third party payers and subsequent audits and payment recoupment, the practice has all but disappeared. The result is a disruptive practice of having to contact prescribers, in order to clarify thereby delaying delivery of a filled prescription to the patient and creating an environment of frustration for all involved.

The Idaho Board of Pharmacy has recently adopted a rule titled Prescription Adaptation that codifies the ability of a pharmacist to make minor adjustments in a prescription while meeting the intent of the prescriber without additional contact. Additionally the Washington Pharmacy Quality Assurance Commission has a working draft of an Adaptation rule and the Arizona State Board of Pharmacy is considering proposing a similar rule. Washington amended the original Idaho language with the added statement of prescriber intent.

The rule language in the Washington draft:

XXX Prescription Drug Orders: Adaptation.

- (1) A pharmacist using professional judgement may change the quantity, dosage, dosage form, or direction of medication dispensed if it meets the intent of the prescriber.
- (2) A pharmacist may complete missing information on a prescription if there is sufficient evidence to support the change.
- (3) A pharmacist may extend a maintenance drug for the limited quantity necessary to coordinate a patient's refills in medication synchronization program.
- (4) A pharmacist who adapts a prescription in accordance with these rules must document the adaptation in the patient's record.

We believe this to be a common sense solution to a very frustrating issue for both prescribers and pharmacists. It will also give the pharmacist a defense during audits if they document their actions accordingly. This is an issue that all of pharmacy can agree on and unite behind a single voice.

Please contact me for questions or further clarification. Please share if the Board will be interested in pursuing this initiative. We encourage your support and action on this concept, and look forward to working with you going forward.

Cordially,

Dennis McAllister R.Ph., FASHP
602-513-2759
dennis_mcallister@express-scripts.com

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Board of Pharmacy
Schedule of Revenues and Expenditures

	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18	FY 19 1st QTR
Licensing Revenue	\$ 500,238	\$ 159,341	\$ 673,100	\$ 269,646	\$ 802,230	\$ 208,755	\$ 801,317	\$ 63,290
Allowable Third Party Reimbursement	-	-	1,701	-	-	3,256	210	-
Total Revenue	500,238	159,341	674,801	269,646	802,230	212,011	801,527	63,290
Direct Expenditures								
Personal Services	162,493	158,574	182,280	164,266	225,050	215,674	273,406	47,540
Travel	15,713	18,850	24,054	24,548	16,676	11,119	13,704	80
Contractual	19,799	11,798	24,633	9,149	14,812	41,331	21,960	57
Supplies	1,385	365	69	90	111	519	-	-
Equipment	-	-	-	-	-	-	-	-
Total Direct Expenditures	199,390	189,587	231,036	198,053	256,649	268,643	309,070	47,677
Indirect Expenditures*	213,722	228,785	197,912	145,863	192,296	222,916	259,680	64,920
Total Expenses	413,112	418,372	428,948	343,916	448,945	491,559	568,750	112,597
Annual Surplus (Deficit)	87,126	(259,031)	245,853	(74,270)	353,285	(279,548)	232,777	(49,307)
Beginning Cumulative Surplus (Deficit)	201,801	288,927	29,896	275,749	201,479	554,764	275,216	507,993
Ending Cumulative Surplus (Deficit)	\$ 288,927	\$ 29,896	\$ 275,749	\$ 201,479	\$ 554,764	\$ 275,216	\$ 507,993	\$ 458,686

** For the first three quarters, indirect costs are based on the prior fiscal year's total indirect amount on a percent of year completed basis. The 4th quarter board reports reflect the current year's actual indirect expenses allocated to the boards.
Biennium July 1, 2018 — June 30, 2020
FY14 Fee Increase

Appropriation	(All)
AL Sub Unit	(All)
AL Task Code	PHA1

Sum of Expenditures		Object Type Code			Grand Total
Object Code	Object Name	1000	2000	3000	
1011	Regular Compensation	26,599.32			26,599.32
1023	Leave Taken	3,318.93			3,318.93
1028	Alaska Supplemental Benefit	1,837.82			1,837.82
1029	Public Employee's Retirement System Defined Benefits	2,027.70			2,027.70
1030	Public Employee's Retirement System Defined Contribution	1,088.87			1,088.87
1034	Public Employee's Retirement System Defined Cont Health Reim	848.39			848.39
1035	Public Employee's Retirement Sys Defined Cont Retiree Medical	194.53			194.53
1037	Public Employee's Retirement Sys Defined Benefit Unfnd Liab	2,422.44			2,422.44
1039	Unemployment Insurance	97.80			97.80
1040	Group Health Insurance	7,265.47			7,265.47
1041	Basic Life and Travel	11.07			11.07
1042	Worker's Compensation Insurance	296.13			296.13
1047	Leave Cash In Employer Charge	691.17			691.17
1048	Terminal Leave Employer Charge	359.37			359.37
1053	Medicare Tax	417.46			417.46
1077	ASEA Legal Trust	40.84			40.84
1079	ASEA Injury Leave Usage	11.33			11.33
1080	SU Legal Trst	11.21			11.21
2000	In-State Employee Airfare			-	-
2001	In-State Employee Surface Transportation			-	-
2002	In-State Employee Lodging			-	-
2003	In-State Employee Meals and Incidentals			-	-
2009	In-State Non-Employee Taxable Per Diem			80.00	80.00
3001	Test Monitor/Proctor				-
3046	Advertising				37.12
3057	Structure, Infrastructure and Land - Rentals/Leases				19.38
3069	Commission Sales				-
Grand Total		47,539.85		80.00	56.50
					47,676.35

Board of Pharmacy
Schedule of Revenues and Expenditures

	FY 12	FY 13	FY 14	FY 15	FY 16	FY 17	FY 18	FY 19 1st & 2nd Qtr
Licensing Revenue	\$ 500,238	\$ 159,341	\$ 673,100	\$ 269,646	\$ 802,230	\$ 208,755	\$ 801,317	\$ 105,295
Allowable Third Party Reimbursement	-	-	1,701	-	-	3,256	210	73
Total Revenue	500,238	159,341	674,801	269,646	802,230	212,011	801,527	105,368
Direct Expenditures								
Personal Services	162,493	158,574	182,280	164,266	225,050	215,674	273,406	109,870
Travel	15,713	18,850	24,054	24,548	16,676	11,119	13,704	3,775
Contractual	19,799	11,798	24,633	9,149	14,812	41,331	21,960	6,436
Supplies	1,385	365	69	90	111	519	-	-
Equipment	-	-	-	-	-	-	-	-
Total Direct Expenditures	199,390	189,587	231,036	198,053	256,649	268,643	309,070	120,081
Indirect Expenditures*	213,722	228,785	197,912	145,863	192,296	222,916	259,680	129,840
Total Expenses	413,112	418,372	428,948	343,916	448,945	491,559	568,750	249,921
Annual Surplus (Deficit)	87,126	(259,031)	245,853	(74,270)	353,285	(279,548)	232,777	(144,553)
Beginning Cumulative Surplus (Deficit)	201,801	288,927	29,896	275,749	201,479	554,764	275,216	507,993
Ending Cumulative Surplus (Deficit)	\$ 288,927	\$ 29,896	\$ 275,749	\$ 201,479	\$ 554,764	\$ 275,216	\$ 507,993	\$ 363,440

** For the first three quarters, indirect costs are based on the prior fiscal year's total indirect amount on a percent of year completed basis. The 4th quarter board reports reflect the current year's actual indirect expenses allocated to the boards.

Appropriation (All)
 AL Sub Unit (All)
 PL Task Code PHA1

Object Code	Object Name	Object Type Code			Grand Total
		1000	2000	3000	
1011	Regular Compensation	56,125.19			56,125.19
1014	Overtime	40.64			40.64
1023	Leave Taken	11,041.76			11,041.76
1028	Alaska Supplemental Benefit	4,128.93			4,128.93
1029	Public Employee's Retirement System Defined Benefits	3,880.35			3,880.35
1030	Public Employee's Retirement System Defined Contribution	2,607.68			2,607.68
1034	Public Employee's Retirement Sys Defined Cont Health Reim	2,075.32			2,075.32
1035	Public Employee's Retirement Sys Defined Cont Retiree Medical	466.07			466.07
1037	Public Employee's Retirement Sys Defined Benefit Unfnd Liab	5,757.22			5,757.22
1039	Unemployment Insurance	218.29			218.29
1040	Group Health Insurance	19,410.61			19,410.61
1041	Basic Life and Travel	29.55			29.55
1042	Worker's Compensation Insurance	662.81			662.81
1047	Leave Cash In Employer Charge	1,551.84			1,551.84
1048	Terminal Leave Employer Charge	806.18			806.18
1053	Medicare Tax	934.86			934.86
1077	ASEA Legal Trust	103.51			103.51
1079	ASEA Injury Leave Usage	11.33			11.33
1080	SU Legal Trst	17.37			17.37
2000	In-State Employee Airfare		446.41		446.41
2001	In-State Employee Surface Transportation		37.48		37.48
2002	In-State Employee Lodging		458.00		458.00
2003	In-State Employee Meals and Incidentals		150.00		150.00
2005	In-State Non-Employee Airfare		421.70		421.70
2007	In-State Non-Employee Lodging		1,374.00		1,374.00
2008	In-State Non-Employee Meals and Incidentals		450.00		450.00
2009	In-State Non-Employee Taxable Per Diem		144.00		144.00
2010	In-State Non-Employee Non-Taxable Reimbursement		56.50		56.50
2020	Out-State Non-Employee Meals and Incidentals		189.00		189.00
2022	Out-State Non-Employee Non-Taxable Reimbursement		48.00		48.00
3001	Test Monitor/Proctor				-
3035	Long Distance		55.05		55.05
3036	Local/Equipment Charges		245.07		245.07
3045	Postage		57.34		57.34
3046	Advertising		113.35		113.35
3057	Structure, Infrastructure and Land - Rentals/Leases		39.95		39.95
3069	Commission Sales		67.00		67.00
3088	Inter-Agency Legal		4,774.51		4,774.51
3094	Inter-Agency Hearing/Mediation		1,083.50		1,083.50
Grand Total		109,869.51	3,775.09	6,435.77	120,080.37

Board of Pharmacy Applications and Forms Update

(As of February 22, 2019)

Application	Form #	Summary of Changes	Rationale	Status
Pharmacist	08-4032	<ul style="list-style-type: none"> • Added emergency permit application • Added military instructions • Added temporary and emergency permit fees • Added PDMP section to attestation and acknowledgement page • Updated verification of work experience page (to include work and internship hrs) • Updated affidavit of internship hours or experience page (reflecting updated regulations regarding 1500 hrs) • Removed obsolete instructions related to NABP testing 	Align with board and centralized statutes and regulations	Complete 01/24/19 and currently posted to website
Pharmacy	08-4082	<ul style="list-style-type: none"> • Added PDMP language for registration and reporting requirements • Appended self-inspection report • Updated to modern format 	Outdated application (last revised in 2014)	Submitted to regulations specialist 02/21/19
Wholesale Drug Distributor	08-1466	<ul style="list-style-type: none"> • Added sections for out-of-state wholesale drug distributors and outsourcing facilities 	Statute will take effect on July 1, 2019	Draft in-progress
Pharmacy Self-Inspection Report	08-4150	<ul style="list-style-type: none"> • Updated layout and enabled form interaction • Updated sections to reflect updated regulations • Replaced “expiration date” with “beyond use date” 	Align with updated board regulations	Complete 01/23/2019 and currently posted to website

Annual Report

Fiscal Year 2019

ALASKA BOARD OF PHARMACY



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

**Division of Corporations, Business
and Professional Licensing**

This annual performance report is presented in accordance with
Alaska statute AS 08.01.070(10).

Its purpose is to report the accomplishments, activities, and the
past and present needs of the licensing program.

**ALASKA BOARD OF PHARMACY
FY 2019 Annual Report**

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**ALASKA BOARD OF PHARMACY
FY 2019 Annual Report**

Identification of the Board

Board Member	Duty Station	Date Appointed	Term Expires
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020

**ALASKA BOARD OF PHARMACY
FY 2019 Annual Report**

Identification of the Board (continued)

Board Member	Duty Station	Date Appointed	Term Expires
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020

**ALASKA BOARD OF PHARMACY
FY 2019 Annual Report**

Identification of Staff

Insert Name Here – Licensing Examiner

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Insert Name Here – Licensing Examiner

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Insert Name Here – Licensing Examiner

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Insert Name Here – Licensing Examiner

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**ALASKA BOARD OF PHARMACY
FY 2019 Annual Report**

Narrative Statement

FY 2019 Narrative Statement (continued)

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Budget Recommendations for FY 2020

The Budget Recommendations section anticipates the board’s fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as “other” so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Budget Recommendations for FY 2020

The Budget Recommendations section anticipates the board’s fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as “other” so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

Board Meeting Date	Location	# Board	# Staff
<input type="checkbox"/> Airfare:			\$0.00
<input type="checkbox"/> Hotel:			\$0.00
<input type="checkbox"/> Ground:			\$0.00
<input type="checkbox"/> Other:			\$0.00
Total Estimated Cost:			\$0.00

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Budget Recommendations for FY 2020 (continued)

Travel Required to Perform Examinations

Not applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

<input type="checkbox"/> Airfare:	\$0.00
<input type="checkbox"/> Hotel:	\$0.00
<input type="checkbox"/> Ground:	\$0.00
<input type="checkbox"/> Conference:	\$0.00
<input type="checkbox"/> Other:	\$0.00

Describe "Other" (break out all sections):

Total Estimated Cost: \$0.00

Out-of-State Meetings and Additional In-State Travel (Rank in order of importance)

#1 Rank in Importance or Not Applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				

Net Total: \$0.00 \$0.00 \$0.00 \$0.00

Out-of-State Meetings and Additional In-State Travel

#2 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

Out-of-State Meetings and Additional In-State Travel

#3 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

Out-of-State Meetings and Additional In-State Travel

#4 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

Out-of-State Meetings and Additional In-State Travel

#5 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

Out-of-State Meetings and Additional In-State Travel

#6 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

Out-of-State Meetings and Additional In-State Travel

#7 Rank in Importance

Date	Location	# Board	# Staff	
Description of meeting and its role in supporting the mission of the Board:				
Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
<input type="checkbox"/> Airfare:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Hotel:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Ground:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Conference:	\$0.00	\$0.00	\$0.00	\$0.00
<input type="checkbox"/> Other	\$0.00	\$0.00	\$0.00	\$0.00
Describe "Other" (break out all sections):				
Net Total:	\$0.00	\$0.00	\$0.00	\$0.00

ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report

Budget Recommendations for FY 2020 (continued)

Non-Travel Budget Requests

- Not Applicable Resources Examinations
 Membership Training Other

Product or Service	Provider	Cost Per Event
		\$0.00

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

- Not Applicable Resources Examinations
 Membership Training Other

Product or Service	Provider	Cost Per Event
		\$0.00

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

- Not Applicable Resources Examinations
 Membership Training Other

Product or Service	Provider	Cost Per Event
		\$0.00

Description of item and its role in supporting the mission of the Board:

ALASKA BOARD OF PHARMACY

Fiscal Year 2019 Annual Report

Budget Recommendations for FY 2020 (continued)

Other Items with a Fiscal Impact		Cost Per Event:	\$0.00
<input type="checkbox"/> Not Applicable		Number of Events:	0
Product or Service	Provider	Total Cost	
		\$0.00	
Description of item and its role in supporting the mission of the Board:			

Other Items with a Fiscal Impact		Cost Per Event:	\$0.00
<input type="checkbox"/> Not Applicable		Number of Events:	0
Product or Service	Provider	Total Cost	
		\$0.00	
Description of item and its role in supporting the mission of the Board:			

Other Items with a Fiscal Impact		Cost Per Event:	\$0.00
<input type="checkbox"/> Not Applicable		Number of Events:	0
Product or Service	Provider	Total Cost	
		\$0.00	
Description of item and its role in supporting the mission of the Board:			

ALASKA BOARD OF PHARMACY

Fiscal Year 2019 Annual Report

Budget Recommendations for FY 2020 (continued)

Other Items with a Fiscal Impact	Cost Per Event:	\$0.00
<input type="checkbox"/> Not Applicable	Number of Events:	0
Product or Service	Provider	Total Cost
		\$0.00
Description of item and its role in supporting the mission of the Board:		

Other Items with a Fiscal Impact	Cost Per Event:	\$0.00
<input type="checkbox"/> Not Applicable	Number of Events:	0
Product or Service	Provider	Total Cost
		\$0.00
Description of item and its role in supporting the mission of the Board:		

Summary of FY 2020 Fiscal Requests	
Board Meetings and Teleconferences:	\$0.00
Travel for Exams:	\$0.00
Out-of-State and Additional In-State Travel:	\$0.00
Dues, Memberships, Resources, Training:	\$0.00
Total Potential Third-Party Offsets:	-\$0.00
Other:	\$0.00
Total Requested:	\$0.00

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Legislation Recommendations Proposed Legislation for FY 2020

No Recommendations

The Board has no recommendations for proposed legislation at this time.

Recommendations

The Board has the following recommendations for proposed legislation:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Regulation Recommendations Proposed Legislation for FY 2020

No Recommendations

The Board has no recommendations for proposed regulations at this time.

Recommendations

The Board has the following recommendations for proposed regulations:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Goals and Objectives

Part I

FY 2019's goals and objectives, and how they were met:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Goals and Objectives (continued)

Part I (continued)

FY 2019's goals and objectives, and how they were met:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Goals and Objectives

Part II

FY 2020's goals and objectives, and proposed methods to achieve them.

Describe any strengths, weaknesses, opportunities, threats and required resources:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Goals and Objectives (continued)

Part II (continued)

FY 2020's goals and objectives, and proposed methods to achieve them.

Describe any strengths, weaknesses, opportunities, threats and required resources:

**ALASKA BOARD OF PHARMACY
Fiscal Year 2019 Annual Report**

Sunset Audit Recommendations

**Date of Last Legislative Audit:
Board Sunset Date:**

Audit Recommendation:

Action Taken:

Next Steps:

Date Completed:

Audit Recommendation:

Action Taken:

Next Steps:

Date Completed:

Sunset Audit Recommendations (continued)

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Sunset Audit Recommendations (continued)

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal regulations require registrants to submit a detailed report of any theft or loss of controlled substances to the Drug Enforcement Administration. This form is filled out consistent with your entries in the fields on the previous pages. You should print this form and save it for your records. This form was submitted through the Internet, please do NOT send a copy to DEA.

OMB
APPROVAL No.
1117-0001
Expires
9/30/2017

1. Name and Address of Registrant CARR-GOTTSTEIN FOODS, CO. 3033 VINTAGE BLVD SAFEWAY PHARMACY #1820 JUNEAU, AK 99801	2. Phone No. When Submitted Amendment Key / Date Submitted 18EGLK5X4DIB / 02-26-2019 17:18:14
--	--

3. DEA Registration Number BC4343517	4. Date of Theft / Loss Feb 20, 2019 Amendment # 0	5. Registrant's Principal Business CHAIN PHARMACY
--	---	---

6. Registrant's County JUNEAU	7. Theft Reported to Police? No	8. Name and Phone of Police Dept.
---	---	--

9. Number of Thefts / Losses Registrant Has Experienced in Past 24 Months? 3	10. Type of Theft / Loss Other - Unknown
--	--

11. Killed / Injured Due to Armed Robbery	12. (Purchase) Value of Controlled Substances \$1.00	13. Pharmaceuticals or Merchandise Taken? No
--	--	--

14. The following applies when Type of Theft / Loss (Box 10) is "Lost In Transit":

A. Name of Common Carrier	B. Name of Consignee	C. Consignee's DEA Registration Number
D. Did the Customer Receive the Carton?	E. Was Carton Tampered With?	F. Theft or Loss From This Same Carrier in the Past

15. What identifying marks, symbols or price codes were on the labels of these containers that would assist in identifying them?

16. Numbers of Official Controlled Substances Order Forms (DEA-222)

17. What security measures have been taken to prevent future theft / loss?
 Pharmacist double counts on all controls, verification of back count, random inventory audits.

18. Comments

19. Filer Name, Title, Phone:
 Brighton Patch, Pharmacist (907)523-2060

The following is a list of the controlled substances that were lost or stolen:

NDC Number	Trade Name	Dosage Str.	Quantity Lost/Stolen
65862096901	ESZOPICLONE 3 MG TABLET	3 MG	30 EA