

Annual Report

Fiscal Year 2016

BOARD OF PHARMACY



**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.

**BOARD OF PHARMACY
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Identification of the Board

Board Member	Date Appointed	Term Expires
Board Chair John Cotter, RPh	Sep 01, 2011	Mar 01, 2017
Vice Chair Leif Holm, PharmD	Mar 01, 2015	Mar 01, 2019
Secretary/Public Member Anne Gruening	Mar 01, 2010	Mar 01, 2018
Pharmacist Rich Holt, PharmD	Mar 01, 2016	Mar 01, 2020
Pharmacist Phil Sanders, RPh	Mar 01, 2016	Mar 01, 2020
Pharmacist Lana Bell, RPh	May 31, 2016	Mar 01, 2018
Public Member Taryl Giessel	Mar 22, 2013	Mar 01, 2017

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Identification of Staff

Donna Bellino – Licensing Examiner

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2589

Sher Zinn – Records and Licensing Supervisor

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
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(907) 465-2550

Brian Howes – Investigator III

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
550 W 7th Avenue
Anchorage, Alaska 99501
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Jun Maiquis – Regulations Specialist

Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
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Narrative Statement

Include an overview of the board's activity, industry trends in licensure, public protection challenges, and other information useful to Alaska stakeholders in understanding your work during FY16.

The Board held four meetings during FY 2016 as follows:

- August 13-14, 2015, Anchorage
- November 12-13, 2015, Anchorage
- February 11-23, 2016, Anchorage
- May 5-6, 2016, Anchorage

Board Members during 2015:

- Lana Bell, Pharmacist, Anchorage (term expires 3/2018)
- Anne Gruening, Public Member, Secretary, Juneau (term expires 3/2018)
- Taryl Giessel, Public Member, Eagle River (term expires 3/2017)
- John Cotter, Pharmacist., Chair, Fairbanks (term expires 3/2017)
- Leif Holm, Pharmacist, Vice-Chair, North Pole (term expires 3/2019)
- Richard Holt, Pharmacist, Wasilla (term expired 3/2020)
- Phil Sanders, Pharmacist. Soldotna (term expires 3/2020)

Board Member with membership ending in 2015:

- Lori DeVito, Pharmacist, Soldotna (term ended 3/2016)
- CJ Kim, Pharmacist, Anchorage (term ended 3/2016)
- William Altland, Pharmacist., Craig (term ended 5/2016)

Sher Zinn is the Records & Licensing Supervisor. Brian Howes serves as the Board Investigator, based in Anchorage.

Regulation Projects: The Board is continuing to work on regulation projects related to the Prescription Drug Monitoring Program. Regulations will be driven by the requirement in SB74. The Board began regulations for the definition of sterile compounding standards, emergency preparedness, and with the passage of SB71 that law on August 9th, 2015 the board will develop standards for pharmacists to administer vaccines and related emergency medications without a collaborative plan with a physician. With the passage of SB23 the board is developing regulations for pharmacist dispensing of naloxone for treatment of opioid overdose.

A regulation requiring Board recognition of the federal license exemptions for licensees practicing in a Tribal Health program unless they have notified the Board that they are practicing under another license in accordance with section 221 of 25 U.S.C. & 162lt (Patient Protection and Affordable Care Act, 2010).

Controlled Substance Prescription Database (aka Prescription Drug Monitoring Program or PDMP) (**12 AAC.52.855 – 12 AAC 52.895**) – The PDMP was mandated by the Alaska Legislature in 2008. The primary purpose of the PDMP is to create a database that records all dispensed controlled substances. This allows prescribers and pharmacists to identify, through secure methods, patients who are “doctor shopping” and/or prescribers who are over-prescribing. The program has proved very valuable to many prescribers and pharmacists within Alaska. With the passage of SB74 there will be changes in the reporting and access to the program. In summary, mandatory reporting will increase to weekly (previously monthly), mandatory PDMP review before prescribing, mandatory registration for prescribers, increase access through delegation and authorization for access to the AK Medicaid program, Alaska Medical Examiner and DHSS.

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Narrative Statement

RECOMMENDATIONS FOR PROPOSED LEGISLATION:

Out-of-State Wholesale Distributors – Alaska is now the only state that does not license out-of-state wholesale drug distributors. This shortcoming is an important concern, especially since the passage of the DQSA (Drug Quality Security Act) in November of 2013. This law now requires “Track and Trace” from the state in which the wholesale distributor is located and/or ships from and into the state in which the drugs are shipped into.

Oversight of distributors shipping drugs into Alaska is a primary concern due to the increase of prescription drug counterfeiting and the utilization of Automatic Dispensing Systems, which are currently unregulated and are often serviced from outside of the state. Currently the Board does not have the authority to regulate Wholesale Drug Distributors or Third Party Logistic Providers, and would like to introduce a bill to the legislature to add a new section AS 08.80.159 Registration of Wholesale Distributors. This legislation would not have any negative cost issues and would help to assure the safe delivery of controlled, non-counterfeit medications to Alaska residents, and prevent other parties from circumventing Alaska laws to obtain products they currently are not licensed to handle, prescribe, or distribute. SB 201 did not pass this last legislative period. The Board will continue to make this a high priority and will re-introduce draft legislation for the 2017 legislative session.

DQSA now allows an entity that compounds sterile drugs to register as a 503b outsourcing facility. Section 503b specifies that an outsourcing facility may only compound with a bulk drug substance which appears on an FDA-established list of bulk drug substances for which there is a clinical need or which are on the FDA’s drug shortage list.

Pharmacy Audit Bill: Pharmacy Audit Bills before the State House and Senate did not pass. The Alaska Pharmacist Association will introduce again for the 2017 legislative session. The Board strongly supports the Association’s efforts regarding this legislation, and would encourage the Legislature for its passage in next session. A majority of other states already have enacted this.

RECOMMENDATIONS FOR REGULATION PROJECTS, FY 2015:

- Sterile Compounding Standards
- Emergency Preparedness (In-process)
- Standards for Pharmacist Immunizations (in process)
- Inspections of In-state/Out-of-State Pharmacies for use with NABP’s VPP (Verified Pharmacy Program)
- Federal licensure exemptions for persons who practice in an Alaska tribal health programs
- Standards for dispensing Naloxone for treatment of opioid overdose (in process)

NATIONAL ASSOCIATION OF BOARDS OF PHARMACY:

The Board of Pharmacy continues to participate in the process of keeping current the pools of questions for the law exam given to pharmacists prior to licensing in Alaska. This is a formal exam called the Multi-State Pharmacy Jurisprudence Examination (MPJE), operated by NABP, which requires an Alaska pool of questions to be reviewed annually and new questions added. Each year two Board members are required to travel to NABP headquarters in Illinois, to review test questions, and then approve or delete questions and add others. If Board members are unable to attend due to scheduling conflicts they may participate remotely. The Board will determine which two members will attend during FY 2017.

LICENSING ACTIONS:

The Board conducted reviews of licensing issues as presented by the Board investigator and paralegal and actions were passed as warranted.

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Budget Recommendations for FY 2017

Board Meeting Date	Location	# Board	# Staff
August 18-19,2016	Anchorage	6	1
	<input checked="" type="checkbox"/> Airfare:		\$1,100.00
	<input checked="" type="checkbox"/> Hotel:		\$1,946.00
	<input checked="" type="checkbox"/> Ground:		\$800.00
	<input checked="" type="checkbox"/> Other:		\$1,100.00
Total Estimated Cost:			\$4,946.00

Board Meeting Date	Location	# Board	# Staff
November 17-18, 2016	Anchorage	7	1
	<input checked="" type="checkbox"/> Airfare:		\$1,100.00
	<input checked="" type="checkbox"/> Hotel:		\$1,400.00
	<input checked="" type="checkbox"/> Ground:		\$800.00
	<input checked="" type="checkbox"/> Other: MIE		\$824.00
Total Estimated Cost:			\$4,124.00

Board Meeting Date	Location	# Board	# Staff
February 2017	TBD	7	1
	<input checked="" type="checkbox"/> Airfare:		\$1,100.00
	<input checked="" type="checkbox"/> Hotel:		\$1,550.00
	<input checked="" type="checkbox"/> Ground:		\$450.00
	<input checked="" type="checkbox"/> Other: MIE		\$650.00
Total Estimated Cost:			\$3,750.00

Board Meeting Date	Location	# Board	# Staff
May 2017	TBD	7	1
	<input checked="" type="checkbox"/> Airfare:		\$1,200.00
	<input checked="" type="checkbox"/> Hotel:		\$1,500.00
	<input checked="" type="checkbox"/> Ground:		\$820.00
	<input checked="" type="checkbox"/> Other:		\$824.00
Total Estimated Cost:			\$4,344.00

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Budget Recommendations for FY 2017 (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

Total Estimated Cost: **\$0.00**

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

Not Applicable

Date	Location	# Board	# Staff
May 20, 2017	Orlando, FL	1	0

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

NABP 113th Annual Meeting is in important for the Board of Pharmacy to attend to keep up with is going on at the national level and a chance to meet and talk with other state boards.

<input checked="" type="checkbox"/> Airfare:	\$1,000.00
<input checked="" type="checkbox"/> Hotel:	\$500.00
<input type="checkbox"/> Ground:	\$0.00
<input type="checkbox"/> Conference:	\$0.00
<input type="checkbox"/> Other:	\$0.00
<input checked="" type="checkbox"/> Direct Third-Party Offset:	\$1,500.00
<input type="checkbox"/> Reimbursed Third-Party Offset:	\$0.00

Net Total Estimated Cost: **\$0.00**

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Budget Recommendations for FY 2017 (continued)

Out-of-State Meetings and Additional In-State Travel MPJE WRITING WORKSHOP

Not Applicable

Date	Location	# Board	# Staff
TBD	Mt. Prospect, IL	1	1

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

Board/Staff attend to make sure pool of questions for the Alaska MPJE exam are current and up to date for pharmacist applicants applying to become licensed in Alaska. Each state is responsible for questions.

<input checked="" type="checkbox"/> Airfare:	\$2,000.00
<input checked="" type="checkbox"/> Hotel:	\$1,000.00
<input type="checkbox"/> Ground:	\$0.00
<input type="checkbox"/> Conference:	\$0.00
<input type="checkbox"/> Other:	\$0.00
<input checked="" type="checkbox"/> Direct Third-Party Offset:	\$1,500.00
<input type="checkbox"/> Reimbursed Third-Party Offset:	\$0.00

Net Total Estimated Cost: \$1,500.00

Out-of-State Meetings and Additional In-State Travel INTERACTIVE EXECUTIVE FORUM

Not Applicable

Date	Location	# Board	# Staff
Oct 04, 2016	Rosemont, IL	0	1

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

This meeting allows for the opportunity to liaise with other state boards and work on specific issues to state boards of pharmacy.

<input checked="" type="checkbox"/> Airfare:	\$1,000.00
<input checked="" type="checkbox"/> Hotel:	\$500.00
<input type="checkbox"/> Ground:	\$0.00
<input type="checkbox"/> Conference:	\$0.00
<input type="checkbox"/> Other:	\$0.00
<input checked="" type="checkbox"/> Direct Third-Party Offset:	\$1500.00
<input type="checkbox"/> Reimbursed Third-Party Offset:	\$0.00

Net Total Estimated Cost: \$0.00

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Budget Recommendations for FY 2017 (continued)

Non-Travel Budget Requests

- Not Applicable Resources Examinations
 Membership Training Other

Product or Service	Provider	Cost Per Event
NABP Annual Membership	NABP	\$250.00

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

NABP membership is the national organization for pharmacists and allows access to their portals that are needed for testing authorization, VPP Inspections and CPE monitor verification. infomratond

Other Items with a Fiscal Impact

- Not Applicable

Product or Service	Provider	Cost Per Event
Newsletter	NABP	\$250.00

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

AK State newsletter would be the primary way of communicating with licensees and colleagues changes, current Board activity, and other related matters that are important to AK licensees and NABP.

Summary of FY 2017 Fiscal Requests

Board Meetings	\$17,164.00
Travel for Exams	\$0.00
Out-of-State and Additional In-State Travel	\$6000.00
Dues, Memberships, Resources, Training, Teleconferences	\$250.00
Total Potential Third-Party Offsets	\$4500.00
Other:	\$250.00
Total Requested:	\$19,164.00

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Recommendations for Proposed Legislation for FY 2017

- No Recommendations**
The Board has no recommendations for proposed legislation at this time.

- Recommendations**
The Board has the following recommendations for proposed legislation:

Reintroduce Legislation that would provide statutory authority to license out-of-state wholesale drug distributors, Third Party Logistic providers, and 503b outsourcing manufacturers. Also Included in this legislation would be the authority for the Board of Pharmacy to hire an Executive Administrator.

The Alaska Board of Pharmacy will also support the reintroduction of legislation introduced by the Alaska Pharmacist Association that did not get passed during the 2016 legislative session, i.e. Pharmacy Audit Bill.

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Regulation Recommendations for FY 2017

No Recommendations

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

Recommendations

The Board has the following recommendations for proposed regulations:

Regulations currently in process and to be finalized in FY2017:

- 1) Emergency Preparedness – The Board of Pharmacy has submitted a regulation project that would provide regulations and direction for pharmacy professionals to follow in the event of a declared emergency.
- 2) Pharmacy Intern – 12 AAC 52.020(b)(3)(A) – Amend (A) to read “enrolled” in a college or pharmacy.
- 3) Pharmacist Administered vaccinations – Passage of SB71 now allows pharmacists to administer immunizations without a collaborative practice agreement
- 4) SB23 Naloxone – Dispensing of opioid overdose drugs by a Pharmacists
- 5) SB74 Medicaid/Telehealth/PDMP – establish/update regulations as a result of the passage

Regulations development and review that the BOP is researching and working on:

- 1) Sterile compounding – Revise current sterile compounding standards to be aligned with USP797 and NABP VPP inspections.
- 2) Out-of-State Pharmacy Inspections – Identify how Alaska can participate in the Multi-State inspection form being developed by NABP

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Goals and Objectives

Part I

FY 2016's goals and objectives, and how they were met:

Board of Pharmacy Mission:

To promote, preserve, and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.

The Board of Pharmacy goals and Objectives remain fluid and the Board tries to meet its goals and objectives in a proactive manners. It is always the Board's goal of getting legislation introduced, and it is the Board's continued hope that the legislative and regulation work done in FY 2016 will be reintroduced and move forward in 2017.

Goals and Objectives for FY 2016

- 1) The Board will continue to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.
- 2) The Board will work to introduce legislation for authority to license out-of-state wholesale drug distributors and third party logistic providers. With the increase in licensing categories, applicants, and federal oversight the Board has identified the need for additional resources and will seek statutory authority to employ an executive administrator for the Board of Pharmacy.
- 3) The Board will continue to provide input and comment on any proposed legislation/regulations involving medications or pharmaceutical care.
- 4) The Board will continue to promote effective patient counseling by licensees.
- 5) The Boards will continue to assess and evaluate the Multi-State Pharmacy Jurisprudence Examination (MPJE).
- 6) The Board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.
- 7) The Board will continue to assess and evaluate the licensing of Pharmacy Technicians.
- 8) The Board will continue its affiliation with NABP and send one member to the District 7 NABP meeting, and two members to the annual NABP meeting.
- 9) The Board will continue to evaluate the impact of current regulations and the need for new regulations.
- 10) The Board will assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and support continued funding and enhancement for the PDMP (Prescription Drug Monitoring Program).
- 11) The Board will monitor, assess, evaluate and modify the Alaska Prescription Drug Monitoring Programs based on the best interest of the public and profession.

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Goals and Objectives

Part II

FY 2017's goals and objectives, and proposed methods to achieve them.

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

Board of Pharmacy Mission:

To promote, preserve, and protect the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.

The Board of Pharmacy goals and Objectives remain fluid and the Board tries to meet its goals and objectives in a proactive manners. It is always the Board's goal of getting legislation introduced, and it is the Board's continued hope that the legislative and regulation work done in FY 2016 will be reintroduced and move forward in 2017.

Goals and Objectives for FY 2017

- 1) The Board will continue to promote, preserve the public health, safety and welfare by and through the effective control and regulation of the practice of pharmacy.
- 2) The Board will continue to provide input and comment on any proposed legislation/regulation involving medications or pharmaceutical care.
- 3) The Board will continue to promote effective patient counseling by licensees.
- 4) The Board will continue to assess evaluate the Multi-State Pharmacy Jurisprudence Examination (MPJE).
- 5) The Board will continue to assess and evaluate the Jurisprudence practice exam and its effectiveness as a learning tool for interns.
- 6) The Board will continue to assess and evaluate the licensing of Pharmacy Technicians including certification.
- 7) The Board will continue its affiliation with NABP and send one member to the Annual NABP meeting.
- 8) The Board will continue to evaluate the impact of current regulations and assess the need for new regulations.
- 9) The Board will continue to monitor its progress of standards and regulations provided for the independent administration by a pharmacist of vaccines and related emergency medications.
- 10) The Board will draft regulations, protocols and an advisory statement for the BOP website regarding SB23 Naloxone and the dispensing of opioid overdose drugs by a pharmacist.
- 11) The Board will assess and manage the impact of SB74 to the Board of Pharmacy and implement the necessary actions items the bill requires regarding fee setting, required reporting, and the impact of the newly created PDMP Coordinator position.
- 12) The Board will assess and evaluate the continued growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and continued support for funding the Alaska Prescription Drug Monitoring Program.

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Sunset Audit Recommendations

Date of Last Legislative Audit: 11/9/2012
Board Sunset Date: 6/30/2018

Audit Recommendation: The Board should improve Collaborative Practice Agreements in accordance with regulations.

Action Taken: The process for review and approval was modified to include a check list for each agreement submitted. The check list is based on the Collaborative Practice regulations.

Next Steps: The Board reviewed the checklist and concurred that its implementation has helped to ensure ongoing compliance.

Date Completed:

Audit Recommendation: DCCED's Professional Licensing Administrative Officer should improve administrative support

Action Taken: Recommendation was addressed internally.

Next Steps: Recommendation was addressed internally.

Date Completed:

Sunset Audit Recommendations (continued)

Audit Recommendation:	Board of Pharmacy and staff, with the office of the Governor, should work together to increase the pool qualified applicants available for Board appointment to ensure full representation.
Action Taken:	Since recommendation has been made, the Board of Pharmacy has been a full Board until the resignation of a public member in April 2012. The vacancy was filled and the Board has seven members consisting of five pharmacists and two public members.
Next Steps:	
Date Completed:	