

SB

201

<TARGET><BILL>SB 201</BILL><SUBJECT>SB
201</SUBJECT><COMM>SFIN29</COMM></TARGET>

SENATE FINANCE COMMITTEE REPORT

DATE: 4/6/16

FURTHER:

DATE TURNED
IN TO OFFICE: _____

Finance Committee considered SENATE BILL NO. 201

SB 201-PHARMA BD & EMPLOYEES; DRUG DIST/MANUFAC

"An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy."

and recommends:

- be replaced with CS _____ (_____) Same Title New Title
- adopt previous CS _____ (_____) Same Title New Title
- attached amendment(s)
- adopt _____ Letter of Intent
- further referral to _____ Committee

Dept Abbr.	
ADM	LWF
CED	LAW
COR	LEG
EED	MVA
DEC	DNR
DFG	DPS
GOV	REV
DHS	DOT
AJS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
CED	X			1

APPROPRIATION - no fiscal note

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
<i>[Signature]</i>	MICCICHE	✓			
<i>[Signature]</i>	BISHOP	✓			
<i>[Signature]</i>	DISNEY			✓	
<i>[Signature]</i>	OLSON			✓	
<i>[Signature]</i>	Hoffman			✓	
CO-CHAIR: <i>[Signature]</i>	Relly			✓	
CO-CHAIR: <i>[Signature]</i>	MacKinnon	✓			

ALASKA STATE LEGISLATURE

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North to the Future

Senator Cathy Giessel
Senate District N

SB 201 Pharmacy Board & Employees; Drug Distribution / Manufacturing

Sponsor Statement

Passage of SB 201 will create a more secure drug supply chain by allowing for licensing and inspection of wholesale drug distributors outside of the state. Currently, Alaska is one of the few remaining states that does not license out-of-state wholesale drug distributors. With laws and regulations varying from state to state, licensing an out-of-state wholesale distributor can prove arduous. With this legislation, Alaska can take action to eliminate wholesalers looking for loopholes in the regulatory system and ensure that all out-of-state applicants seeking licensure comply with the same regulations as Alaska wholesalers.

This legislation is critical and necessary to bring Alaska into compliance with the Drug Quality Security Act (DQSA) and create a new license category for "Out-of-State Wholesale Drug Distributors. Currently, there is no authority by the Board of Pharmacy to regulate Out-of-State Wholesale Drug Distributors or third party logistic providers (3PLs). SB 201 would ensure safe delivery of controlled, non-counterfeit medications to Alaskans.

SB 201 would require that any out-of-state wholesale drug distributor or outsourcing facility follow specific guidelines including obtaining a license, authorizing inspection of the facility by a designee of the board, and appointing an agent before shipping, mailing or delivering prescription drugs to a licensee in the state or advertising in the state.

Additionally, this legislation allows the Board of Pharmacy to create a new position titled "Executive Administrator" to serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards, as well as implement board statutes and regulations, and aid in managing current licensees.

[Senator Cathy Giessel@akleg.gov](mailto:Senator_Cathy_Giessel@akleg.gov)

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SB 201 Sectional Overview

Pharmacy Board & Employees; Drug Distribution / Manufacturing

Section 1: Amends AS 08.80.030(b)

(13): Amends and allows licensing and inspection for out-of-state drug distributors and outsourcing facilities.

(14): Establishes qualifications and duties of executive administrator. Executive administrator is delegated authority in order to conduct board business.

Section 2: Amends AS 08.80.030 by adding a new subsection:

AS 08.80.030(c): Specifications for facilities, equipment, personnel, and procedures for control of drugs in compliance with the federal Drug Supply Chain Security Act.

Section 3: Amends AS 08.80.157 by adding a new subsection:

(k): Applies to wholesale drug distributors and outsourcing facilities outside the state under AS 08.80.159, regarding licensing.

Section 4: Amends AS 08.80 by adding a new section:

Sec. 08.80.159: Requires that a wholesale drug distributor or outsourcing facility have a license in Alaska before shipping, mailing, or delivering prescription drugs to a licensee in the state or before advertising in the state, that an agent must be appointed in the state, and a designee of the board must authorize inspection of the facility.

An outsourcing facility, in addition, must comply with the federal Drug Quality and Security Act of 2013. The board may require an inspection of facilities located outside of the state, approve a designee to inspect. The board shall adopt regulations to implement this section.

Section 5: Amends AS 08.80 by adding new section to Article 2:

Sec. 08.80.270: Allows the Board to create an executive administrator position. Defines the role of the executive administrator.

Section 6: Amends AS 08.80.480 by adding a new paragraph:

AS 08.80.480(37): Defines "outsourcing facility"

ALASKA STATE LEGISLATURE

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North to the Future

Senator Cathy Giessel
Senate District N

Responses to questions during SB 201 hearing SFIN 4-9-16

- 1. Would SB 201 apply to regulation of international wholesalers? (sub question..... do our AK licensees do business with wholesalers in Mexico or Canada or similar?) But even so, we can't regulate a business in another country could we?**

Alaskan pharmacies do not do business with wholesalers in Mexico or Canada since they presumably don't sell US FDA approved drugs and as such the FDA does not allow import of said drugs.

Q1. We are only able to order from US based wholesalers and Pharmaceutical companies. We have never tried to order outside those parameters because we, as Pharmacists, cannot guarantee that the medication will conform to USP (United Stated Pharmacopeia) and FDA standards for potency and efficacy for our patients. No the Alaska Board of Pharmacy has not authority in another country and limited in other states.

There is an exemption in the importation laws/regs for a doctor to obtain or use a medication on a patient by their, the patient's, request for any medication worldwide. So if I've got cancer and I've read about some tree bark concoction from Tibet that I would like to try and my doctor is willing to work with me on using it then it can be imported for me and me only. This may only apply to commercially available medications from other countries that I am not sure of. Now of course there is no way to know if the product will work but that is between me, the patient, and my doctor. As far as ordering a medication that is commercially available here in the US then my understanding is that is not allowed just because you can get it cheaper in Tijuana Mex.

2. Are internet sales regulated? Sub question - would AK licensees purchase off the internet? Are they even allowed to do that?

Alaskan Pharmacies may purchase off the internet from Wholesalers licensed in the United States and purchase FDA approved drugs. Alaskan pharmacies may not purchase and then dispense drugs from wholesalers (presumably out of the country) that are NOT FDA approved.

For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs, some which have been counterfeits directly from foreign sources for administering to patients.

These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.

I think what the above says is that there will continue to be "roque" internet wholesalers that are selling non-fda approved drugs. These entities would presumably not register with the State of Alaska. It would seem to me that it would be the intent of the bill to stop these illegal entities if they are operating in the United States.

Q2. No. We can probably find cheaper medications off the internet but again since we have no idea where these medications are coming from, country and or manufacturing facility, I don't know any Pharmacist that would do that. Again, without assurance of any compliance with USP or FDA standards we would never order from them.

Internet Sales—

1. “While the new authorities under DQSA and FDASIA help address some of the risks posed by counterfeit drugs, they will not prevent all types of illegal diversion or distribution schemes that FDA has discovered in recent years. For example, FDA has uncovered numerous instances of medical practitioners deliberately obtaining unapproved drugs—some which have been counterfeits—directly from foreign

sources for administering to patients. These laws would not prevent situations where consumers purchase drugs from rogue Internet websites or where a pharmacy purchases product from outside the legitimate supply chain and dispenses directly to a patient.”

- a. <http://www.fda.gov/NewsEvents/Testimony/ucm387449.htm> (under “Remaining Challenges” section in the article)

Now to respond to the problem of internet “pharmacies” the National Association of Boards of Pharmacy (NABP), of which every state Pharmacy Board is a member, has been working with ICANN (Internet Corporation for Assigned Names and Numbers) to obtain exclusive rights to the dot pharmacy internet protocol identifier. They obtained those rights about a year ago and for me to have the HarryRace.pharmacy domain name I’m in the process of applying to them for the rights to use that website. If I obtain that website then anyone in the world that goes to that site will know that I am a licensed pharmacy and I will only dispense genuine USP/FDA quality medications. So these sites will start to show up on the WWW shortly. I don’t know if anyone has passed all the inspections from NABP to have been issued a domain yet but when it happens I know it will be a big media splash.

International wholesalers—

1. Bulk drugs manufactured in a foreign establishment must be registered under section 501(i) of the FD&C (Food, Drug, and Cosmetic Act). They must be accompanied by a valid certificate of analysis.

As for bulk powders/drugs. We are strictly prohibited by the FDA to import these types of materials.....Thank you PHARMA. As a compounding pharmacist and working with Prescription Compounding Centers of America (PCCA) for 30 years I’ve come to understand the issues that they as importers of bulk powders have to deal with. The paperwork that is required by the FDA to import these chemicals is very onerous and getting worse by the year. Something a mom/pop shop like ours would never be able to comply with. That is why we have PCCA as our trusted wholesaler of these products, because for one thing I’ve toured the plant and I’ve seen the pallets with the drums and bags of chemicals/medications in the warehouse. I’ve seen how they handle the whole process from the product landing on their docks to the finished bottled packages that I would obtain in my pharmacy. They would then, of course, have to comply with this statute. Knowing them that will not be an issue.

Fiscal Note

State of Alaska
2016 Legislative Session

Bill Version:	SB 201
Fiscal Note Number:	1
(S) Publish Date:	4/6/2016

Identifier: SB201-DCCED-CBPL-03-25-16
 Title: PHARMA BD & EMPLOYEES;DRUG
 DIST/MANUFAC
 Sponsor: GIESSEL
 Requester: (S) Labor & Commerce

Department: Department of Commerce, Community and
 Economic Development
 Appropriation: Corporations, Business and Professional
 Licensing
 Allocation: Corporations, Business and Professional
 Licensing
 OMB Component Number: 2360

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2017 Appropriation Requested	Included in Governor's FY2017 Request	Out-Year Cost Estimates					
			FY 2017	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
OPERATING EXPENDITURES								
Personal Services	100.9		100.9	100.9	100.9	100.9	100.9	100.9
Travel	6.0		6.0	6.0	6.0	6.0	6.0	6.0
Services	12.5		10.0	10.0	10.0	10.0	10.0	10.0
Commodities	5.0							
Capital Outlay								
Grants & Benefits								
Miscellaneous								
Total Operating	124.4	0.0	116.9	116.9	116.9	116.9	116.9	116.9

Fund Source (Operating Only)

1156 Rcpt Svcs	124.4		116.9	116.9	116.9	116.9	116.9	116.9
Total	124.4	0.0	116.9	116.9	116.9	116.9	116.9	116.9

Positions

Full-time	1.0		1.0	1.0	1.0	1.0	1.0
Part-time							
Temporary							

Change in Revenues	124.4		116.9	116.9	116.9	116.9	116.9
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Estimated SUPPLEMENTAL (FY2016) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2017) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
 If yes, by what date are the regulations to be adopted, amended or repealed? 07/01/17

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By:	Janey Hovenden, Director	Phone:	(907)465-2536
Division:	Corporations, Business and Professional Licensing	Date:	03/25/2016 12:00 PM
Approved By:	Catherine Reardon, Director	Date:	03/25/16
Agency:	Division of Administrative Services, DCCED		

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2016 LEGISLATIVE SESSION

Analysis

SB201 authorizes the Board of Pharmacy to license and inspect out-of-state wholesale drug distributors and outsourcing facilities and creates an executive administrator position for the board.

Current statutes allow licensing of in-state wholesale distributors only. In November 2013, federal law was enacted under the Drug Supply Chain Security Act (DSCSA) requiring regulations for licensing of wholesale drug distributors.

SB201 further authorizes the Board to establish the qualifications and duties of an executive administrator to assist the board in complying with the new Federal regulations. Alaska currently is one of two states that do not license out-of-state wholesale distributors.

This bill will change the Board of Pharmacy licensing program by increasing the number of applications received and processed by division staff. Additional staff will be necessary to implement the additional licensing of out-of-state wholesale distributors and outsourcing facilities.

There is no expected impact on the public or private sectors in the state as the licensing will impact entities outside the State of Alaska.

The board will need to implement new regulations for the licensing and inspection of the facilities, within a time frame of nine to twelve months. The new federal regulations are extensive, requiring research by board staff to ensure regulations meet the federal requirements.

If the bill passes the following expenses will be incurred:

Personal Services: \$100.9 (one full-time permanent Executive Administrator, range 18)

Travel: \$6.0 (Executive Administrator to attend four board meetings per year)

Services: \$2.5 (legal costs to amend regulations, printing, and postage in first year)

\$10.0 (department-wide services support for one new position)

Commodities: \$5.0 (computer, office panels, office furniture and other one-time needs for one new position in first year)

Professional licensing programs within the Division of Corporations, Business and Professional Licensing are funded by Receipt Supported Services, fund source 1156 Rcpt Svcs (DGF). Licensing fees for each occupation are set per AS 08.01.065 so the total amount of revenue collected approximately equals the occupation's actual regulatory costs.



THE STATE
of **ALASKA**
GOVERNOR BILL WALKER

Department of Commerce, Community,
and Economic Development

BOARD OF PHARMACY

P.O. Box 110806
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March 25, 2016

The Honorable Senator Cathy Giessel
State Senate
State Capitol Room 427
Juneau, AK 99801-1182

Re: SB201

Dear Senator Giessel:

I am writing to express the Board of Pharmacy's strong support for passage of SB201: An Act relating to the Board of Pharmacy; relating to the licensing and inspection of certain facilities located outside the state; relating to drug supply chain security; and creating a position of executive administrator for the Board of Pharmacy.

Passage of this bill will create a more secure drug supply chain by allowing for licensing and inspection of Out-of-State Wholesale Drug Distributors shipping to Alaska. At this time, Alaska is one of the few remaining states that do not license these facilities. Our goal is to eliminate those wholesalers looking for loopholes in the regulatory system by ensuring that these out-of-state applicants are held to the same regulations that Alaska wholesalers shipping from within the state are held to.

This legislation is critical and necessary to bring Alaska in compliance DQSA (Drug Quality Security Act) as required under section 582 of the FD&C Act through the FDA. The new license category will aid in further securing the supply chain and drug distribution system at the state level. Currently, the Board of Pharmacy does not have the authority to regulate the Out-of-State Wholesale Drug Distributors or Third Party Logistic Providers.

SB201 Would require that any Out-of-State Wholesale Drug Distributor or outsourcing facility follow specific guidelines including obtaining a license, authorizing inspection of the facility by a designee of the board, and appointing an agent before shipping, mailing or delivering prescription drugs to a licensee in the state or advertising in the state.

Additionally, this legislation allow the Board of Pharmacy to create a new position titled "Executive Administrator" to serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards, as well as implement board statutes and regulations, and aid in managing current licensees. This position must be distinct from the current licensing examiner position due to the impact of increasing FDA regulations and requirements for compliance to protect the drug supply chain at the state level.

The passage of SB201 is very important to our mission of safeguarding the health and safety of Alaska's citizens.

Sincerely,
John Cotter, RPh
Chair, Alaska Board of Pharmacy

p.p. *Donna Bellino*
Donna Bellino
Licensing Examiner

db:jc



Alaska Pharmacists Association

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Soldotna*

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*Michelle Vaughn
Juneau*

*Irene Williams
Fairbanks*

March 30, 2016

Senator Cathy Giessel
Alaska State Capitol Building
Room 427
Juneau, AK 99801

Dear Senator Giessel,

On behalf of the Alaska Pharmacists Association (AKPhA), I am writing in support of the Alaska Senate Bill 201. I would like to personally thank you for introducing this piece of legislation, which is of vital importance to bring the State of Alaska into compliance with the federal requirement that all wholesalers distributing prescription drugs in our State be licensed.

AKPhA represents over 200 pharmacists and pharmacy technicians in the State of Alaska. Our mission is to preserve, promote, and lead the profession of pharmacy in Alaska. Alaska SB 201 strongly aligns with our mission, as it will ensure that our State is in line with this FDA mandate.

Again, we appreciate your efforts and leadership on this issue. Should there be anything that I, or the Alaska Pharmacists Association can do to help ensure passage of this legislation, please let me know.

Sincerely,

Tara Ruffner, Pharm D
President
Alaska Pharmacists Association

E-mail: akphrmcy@alaska.net

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