

Department of Commerce, Community, and Economic Development

BOARD OF PHARMACY

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March 6, 2017

The Honorable Dan Saddler House of Representatives State Capitol Room 513 Juneau, AK 99801-1182

Re: HB 9

Dear Representative Saddler:

I am writing to express the Board of Pharmacy's strong support for passage of HB 9: 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 Out-of-State Wholesale Drug Distributors, Third Party Logistic Providers, or 503b Outsourcing Facilities.

HB 9 would require that any Out-of-State Wholesale Drug Distributor, Third Party Logistic Provider, or 503b 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 will 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 HB 9 is very important to our mission of safeguarding the health and safety of Alaska's citizens.

Sincerely, Leif Holm, PharmD Chair, Alaska Board of Pharmacy

p.p. Donna Bellino Licensing Examiner