

CSSB 37(FIN)_{vsn N} Fact Sheet

Pharma Board & Employees; Drug Distribution / Manufacturing

CSSB 37(FIN) brings Alaska into compliance with the Federal law:

Drug Supply Chain Security Act of 2013 created a new license category for “Out-Of-State Wholesale Drug Distributors.” The Drug Quality Security Act established in 2013 was an act of both chambers of Congress to strengthen the ability to provide oversight of large scale drug compounders.

- Currently, the Alaska Board of Pharmacy has no authority to regulate Out-of-State Wholesale Drug Distributors and SB 37 would give them this tool.
- Alaska is one of four states that does not license out-of-state wholesale drug distributors, allowing unscrupulous companies to find loopholes in the regulatory system.
- To protect Alaskans, this bill would ensure that out-of-state applicants seeking licensure must comply with the same regulations as Alaska wholesalers.
- **Is there a problem?** In 2012, contaminated medications were distributed which resulted in the deaths of people from meningitis: In 2012 a nationwide fungal meningitis outbreak resulting in 751 patients in 20 states being diagnosed and 64 patients in 9 states dying was linked to a compounding facility in Massachusetts. It was found that the employees were producing medications in an unsafe manner in insanitary conditions and allowing these medications to be shipped out anyway. This tragedy highlighted the dangers of unregulated, large scale compounders.
- SB 37 ensures confidence that your prescriptions are pure, sanitary and safe. Passage of this bill would create a more secure drug supply chain and ensure that Alaskans are receiving non-counterfeit, unadulterated medications.
- When a pharmacy, doctor or hospital in Alaska orders supplies of prescription medications, they may go to the one wholesale distributor in Alaska(McKesson) but they may also order from one of hundreds of others in the Lower 48.
- Oversight of distributors’ shipping medications into the state is of utmost concern due to the increase in prescription drug counterfeiting.

- This bill would require any out-of-state drug distributor or outsourcing facility to follow specific guidelines including :
 1. obtaining a license in Alaska
 2. authorizing inspection by a designee of the board
(paid for by the wholesaler, not the state, could be a third-party inspector or DEA or FDA, whoever the state may contract with to do the inspection)
 3. appointing an agent before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state. (this is because they need a “person” to be the responsible party for subpoenas, citing for infraction or filing suit in case of problem.)
- An outsourcing facility must comply with the Drug Quality and Security Act (DQSA) of 2013.
(An “outsourcing facility” is defined in the bill as a facility in one geographical location that is engaged in the compounding of sterile drugs for a facility at another geographical location.)
- Division of Corporations, Business and Professional Licensing estimates that registering/regulating these drug wholesalers equates to approximately 400 new licensees.

SB 37 creates an “Executive Administrator” position for the Alaska Board of Pharmacy. This board has ever-increasing responsibilities under several healthcare reform bills and opioid response legislation we have passed recently. It will allow them more capacity to respond more quickly to issues and concerns, manage the licensing of new wholesalers, implement statutes and regulations and manage the multiple new responsibilities of the Board relating to the PDMP.

Until now, they have relied on the Division of Corporations, Businesses and Professional Licensing for day-to-day operations assistance.

This position will be paid with the fees supplied by the wholesale drug distributor licensees along with current licensee fees.

(Fund Source: Receipt Services, no General Funds)

~Sen. Giessel office jmc