

Responses to Questions on CSSB 37(FIN) 4-17-17

Senator Giessel's Office

In regard to national certification: There is no “national” certification for these entities. The Drug Supply Chain Security Act mandated that all states set up their own individual licensing programs to regulate wholesalers, outsourcing facilities and 3PLs. They will set up their own criteria and standards that must be met in order for these entities to do business with Alaska pharmacies, ensuring patient safety.

There have been questions about the Verified-Accredited Wholesale Distributors (VAWD) inspection that is run through the National Association of Board of Pharmacies (NABP). This is an option for states to use for licensing distributors, however. Currently, per NABP, there are 3 states that require VAWD accreditation (Indiana, North Dakota, and Wyoming). However, there are 21 other states that recognize the VAWD.¹ We do know that it is quite expensive. Per NABP VAWD Accreditation the estimated total for the 3-year accreditation is \$7,500 and is repeated every 3-years.²

Basically the way the statute is written is that the Board could use something like the VAWD, or create their own criteria for licensure via regulation, which is what most states are doing.

Currently the national act's regulations are still being written, but the act allows states to go forward with their licensing programs, as long as the standards met or exceeded the federal guidelines.

If Alaska chose not to pass SB 37:

- Things would remain the same, and Alaskans would be at risk for being distributed contaminated drugs and possible serious outbreak
- Alaska would have no recourse to prosecute entities that were distributing or creating unsafe drugs
- Alaska would not collect the fees from these entities (likely about 400)
- The federal government would step in and regulate and Alaska would have no control over the program. This is not an option the other 48 states have found to be ideal, and they all have created their own licensing programs for wholesale distributors.
 - The Board of Pharmacy is comprised of 5 Alaska licensed pharmacist and 2 public members. We would be able to react more quickly than the federal government given the scale / size of the federal agency.
 - The Board of Pharmacy is comprised of fully qualified individuals so there is no need to give up our state control to the federal government in this regard.
 - These licensing categories are new for the federal government as well and they have not yet finalized their own regulations and have already been reviewing these since ~ 2013 and no final date in place for implementation leaving Alaska vulnerable.

¹ <https://nabp.pharmacy/programs/vawd/>

² <https://nabp.pharmacy/programs/vawd/apply/>

RE: questions on passage of the bill's effect on increased cost to the consumers?

- First, the wholesalers would pay for the cost for the inspection, and also the cost to be licensed in the state.
- Second, the price that a consumer pays for a drug is not affected by this purchasing process; rather the costs of drugs, by and large, for anyone covered under an insurance plan, is determined by contracts set by Pharmacy Benefit Managers (PBMs) contracts with insurers and plan administrators. SB 37 would have little impact if any on what the consumer will pay for the drug. The bill just ensures that the supply chain of drugs is SAFE.

Re: Where do Native Health Organizations/Pharmacies obtain their drugs? Are they inspected by someone?

The Alaska Board of Pharmacy has no authority over Native Health Organizations in general. We believe, the source of their medication supply would need to follow state and/or federal standards. However, we were able find out that the Ketchikan Native Health Center stated they receive their wholesale drugs through their VA contract with McKesson, our only state-licensed wholesale distributor in Alaska. Other clinics may use other suppliers occasionally if needed.