Wholesale Distributor, 3PLs and Limited Distributors FAQ

1. How do I know which license type I need?

a. No one knows your business better than you do. You may review Iowa Code 155A, Iowa Administrative Code 657-17, 657-42, 657-43 and Title II of the Drug Security Chain Supply Act (DSCSA). If, after reviewing the applicable laws and rules you're still unsure which license is most appropriate, please consult your attorney.

2. What are the license periods?

a. Wholesale distributor and limited distributor licenses are valid from January 1 - December 31 annually. 3PL licenses are valid from April 1 - March 31 annually.

3. Where can I find the Iowa Code that grants the Board the authority to license wholesale distributors, 3PLs and Limited Distributors?

- a. https://www.legis.iowa.gov/docs/code/155a.pdf
- 4. Where can I find the rules that govern the licensing requirements for wholesale distributors of human prescription drugs?
 - a. 657 IAC Chapter 17
- 5. Where can I find the rules that govern the licensing requirements for limited distributors?
 - a. 657 IAC Chapter 42
- 6. Where can I find the rules that govern the licensing requirements for third-party logistics providers (3PLs)?
 - a. 657 IAC Chapter 43
- 7. What are the licensing fees for licensure as a wholesale distributor or a 3PL?
 - a. The nonrefundable licensing fee is \$750 per year.

8. What are the licensing fees for licensure as a limited distributor?

a. The nonrefundable licensing fee is \$175 per year.

9. Are background checks required for licensure?

a. An FBI background check is required to be performed on the facility manager of a wholesale distributor or a 3PL. A background check for a facility manager of a limited distributor is not required.

10. How much are background checks?

a. The nonrefundable fee for a background check is \$45. This is in addition to all other licensing fees.

11. Does lowa require drug distributor accreditation for wholesale distributors and 3PLs?

- a. Yes. All new wholesale distributors and 3PLs seeking initial licensure in Iowa must provide proof of drug distributor accreditation prior to a license being issued. The Board recognizes and accepts drug distributor accreditation by:
 - National Association of Boards of Pharmacy (Drug Distributor Accreditation formerly known as VAWD),
 - National Coalition for Drug Quality and Security (Quality and Security Accreditation), or
 - Another accreditation organization which is pre-approved by the Board.
- 12. I'm a third-party logistics provider that warehouses and orchestrates the sales of non-DSCSA-covered prescription drugs and devices. Do I need a license to ship product into lowa?
 - a. Most likely, but not a 3PL license. A 3PL license is required for persons or entities providing logistical services relating to human prescription drugs. For the type of activity described here, you most likely will need a Limited Distributor license. However, if you're unsure, you should consult your attorney for an opinion.