

Wholesale Drug Distributor Frequently Asked Questions (WDD FAQ's):

Rule: If an entity is physically shipping legend drugs into or within Indiana, it must be licensed as a wholesale drug distributor (WDD) and be Verified-Accredited Wholesale Distributors™ (VAWD™) certified unless its business practice is explicitly expected out of the licensure requirement by Indiana statute (i.e. manufacturer, medical gas only, animal drug only).

Q: "Our company does not physically store, possess, or ship legend drugs into Indiana. We are the NDA holder. We contract out with a manufacturer and third party logistics provider to ship our drugs into the state. Do I need a WDD license in Indiana?"

A: No. If the company does not physically ship the drugs into Indiana, it does not need a WDD license.

Q: "I'm a reverse distributor and only destroy the drugs. Do I need a WDD license?"

A: Yes. Reverse distributors need a WDD license and VAWD in Indiana (as all WDD licensees must be VAWD accredited). Reverse distributors physically handle legend drugs and therefore require licensure. Reverse distributors are also explicitly listed as WDD in Indiana statute.

Q: "Our company is a third party logistics provider in California that ships to a wholesale drug distributor in Illinois that ships to a chain drug warehouse in Indiana. Which one of us needs a license?"

A: The third party logistics provider is not required to be licensed in Indiana as the company does not physically ship drugs into the state; however, both the wholesale drug distributor and chain drug warehouse must be licensed and VAWD accredited.

Q: "Our company is a third party logistics provider that coordinates shipments from a wholesale drug distributor in Texas to a wholesale drug distributor in Michigan for shipment into Indiana and the company—on rare occasion—ships directly into Indiana. Do we need a license?"

A: Yes. Any physical shipment of legend drugs within or into Indiana requires WDD licensure.

Q: "Our company only ships medical gas and over-the-counter drugs into Indiana, but we held a WDD license in the past and we want to renew. Can we obtain a license?"

A: No. A medical gas only distributor or over-the-counter drug only distributor does not require licensure in Indiana and the Board will not issue a license to any company that is not required to be licensed.

Q: "Our company only physically ships veterinary drugs into Indiana. Do we need a WDD license?"

A: It depends. If the legend drugs may also be used for humans, your company needs a license—even if the drugs are intended for animal use. If the legend drugs are "animal use only", the company does not need a license.

Q: "Our company is a repackager for a manufacturer and we send legend drugs directly to a licensed and VAWD accredited WDD in Indiana. We only ship to one company at one location. Do we need a license?"

A: Yes. Repackagers are not exempted by statute and need a license to ship legend drugs within or into Indiana.

Q: "My company is a manufacturer and we deliver our drugs to a WDD in Indiana. We understand that we do not need a license, but we have always had one and wish to continue with licensure in Indiana. Can we obtain a license?"

A: No. A manufacturer will not be issued a license even it ships directly into Indiana, irrespective of any past licensure; however, if a manufacturer also ships legend drugs that it did not manufacture into Indiana, it must be licensed.