

# Manufacturer

## In State:

- Anyone manufacturing prescription-only drugs in West Virginia must be licensed by the state as a manufacturer.

## Out of State:

*Traditional Manufacturer—you own the product and manufacture the product.*

*Virtual Manufacturer— you own the product, but someone else manufactures it for you on contract or otherwise at their facility.*

*Actual Manufacturer—you manufacture a product on contract or otherwise that you do not own.*

*3PL—you act as a third party shipping product that you do not own or manufacture.*

- (Traditional) If you are a drug manufacturer located outside of West Virginia, but distribute any of your product into West Virginia, either yourself or through the use of a Third-Party Logistics Provider (3PL), you must be licensed by this state as a manufacturer (in other words, if you distribute or have your product distributed into West Virginia on your behalf, you must be licensed). And your 3PL must have a 3PL distributor's license.
  - Controlled Substances: (Traditional) If controlled substances are involved you must have a controlled substances handling permit as well.
- (Virtual) If you are a drug manufacturer located outside of West Virginia, but distribute any of your product into West Virginia, either yourself or through the use of a Third-Party Logistics Provider (3PL), you must be licensed by this state as a manufacturer (in other words, if you distribute or have your product distributed into West Virginia on your behalf, you must be licensed). And your 3PL must have a 3PL distributor's license.
  - Controlled Substances: (Virtual) If you do not handle the product, then you do not have to also get the CS handling permit since you won't actually touch the product.
- (Actual) If it is manufacturing the drugs on behalf of a virtual manufacturer and it sends that product into West Virginia on behalf of the virtual manufacturer or otherwise, it must be licensed as a manufacturer.
  - Controlled Substances: (Actual) If controlled substances are involved you must have a controlled substances handling permit as well.
- (Actual) If the actual manufacturer is outside West Virginia, it does not need licensed if it never sends the product into West Virginia on your behalf (i.e., it transfers it to a 3PL or wholesaler outside of West Virginia, and it is that other entity that actually sends it into West Virginia).
- (3PL) 3PL must have a 3PL distributor's license. For any product you are shipping in on behalf of a traditional, virtual, actual manufacturer or other party who actually owns title to and control over the drug, that traditional, virtual manufacturer, actual manufacturer, or other party must be properly licensed as a manufacturer.
  - Controlled Substances: (3PL) If controlled substances are involved, the 3PL must have a controlled substances handling permit as well.