



Reclassification of Wholesale Distributors of Dangerous Drugs

Updated 9/11/2020

On September 29, 2017, [HB 49](#) (Ohio's Biennial Budget) modified sections 4729.52 and 4729.53 of the Ohio Revised Code to create five separate license types for the manufacture and distribution of dangerous drugs, as follows:

1. "Wholesale distributor of dangerous drugs" or "wholesale distributor" means a person engaged in the sale of dangerous drugs at wholesale and includes any agent or employee of such a person authorized by the person to engage in the sale of dangerous drugs at wholesale. **NOTE: This license type will include the broker and virtual wholesaler classification types.**
2. "Manufacturer of dangerous drugs" or "manufacturer" means a person, other than a pharmacist or prescriber, who manufactures dangerous drugs and who is engaged in the sale of those dangerous drugs. **NOTE: This license type will permit the distribution of dangerous drugs at wholesale.**
3. "Third-party logistics provider" means a person that provides or coordinates warehousing or other logistics services pertaining to dangerous drugs including distribution, on behalf of a manufacturer, wholesale distributor, or terminal distributor of dangerous drugs, but does not take ownership of the drugs or have responsibility to direct the sale or disposition of the drugs.
4. "Repackager of dangerous drugs" or "repackager" means a person that repacks and relabels dangerous drugs for sale or distribution.
5. "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs and is registered as an outsourcing facility with the United States Food and Drug Administration.

NOTE: "Sale" or "sell" includes any transaction made by any person, whether as principal proprietor, agent, or employee, to do or offer to do any of the following: deliver, distribute, broker, exchange, gift or otherwise give away, or transfer, whether the transfer is by passage of title, physical movement, or both.

"Wholesale sale" and "sale at wholesale" mean any sale in which the purpose of the purchaser is to resell the article purchased or received by the purchaser.

If you currently perform more than one operation, as defined above, under the same business entity and at the same location, you **may** require an additional license. For information regarding obtaining an additional license, please send an email describing your business operations to: New.License@pharmacy.ohio.gov.

Rules

Updated rules for the new license types went into effect on March 1, 2019 and include the following chapters:

Chapter Name and Number	Applicable To:
Chapter 4729:6-1 Definitions	All drug distributors [i.e. manufacturer of dangerous drugs, outsourcing facility, thirdparty logistics provider, repackager of dangerous drugs and wholesale distributor of dangerous drugs (includes broker and virtual wholesaler)].
Chapter 4729:6-2 Licensure	All drug distributors
Chapter 4729:6-3 General Provisions	All drug distributors
Chapter 4729:6-4 Discipline	All drug distributors
Chapter 4729:6-5 Wholesale Distributors	Wholesale distributor of dangerous drugs

Chapter 4729:6-6 Virtual Wholesaler Distributors	Virtual wholesalers
Chapter 4729:6-7 Brokers	Brokers
Chapter 4729:6-8 Manufacturers	Manufacturers
Chapter 4729:6-9 Repackagers	Repackagers
Chapter 4729:6-10 Outsourcing Facilities	Outsourcing facilities
Chapter 4729:6-11 Third Party Logistics Providers	Third-party logistics providers