



Reclassification of Wholesale Distributors of Dangerous Drugs

Update 9-29-2017

On September 29, 2017, [HB 49](#) (Ohio's Biennial Budget) modifies 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.

Updated applications can be accessed here:
<http://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

The Board's licensing department has reclassified all current wholesale distributor licenses to conform with the new licensing types. Information on the reclassification was sent via email to all entities licensed as wholesale distributors prior to September 29, 2017.

If you have not received an email from the Board on or after September 29th, please contact the Board via email at: New.License@pharmacy.ohio.gov.

Fee Increases

Effective September 29, 2017, there will be increased application and service fees charged by the Board, as follows:

- Category II (no controlled substances) - \$950
- Category III (controlled substances included) - \$1,000
- Late Renewal Fee - \$300
- Verification of Licensure - \$35

NOTE: All fees above apply to initial, change and renewal applications for wholesale distributors, manufacturers, third-party logistics providers, repackagers and outsourcing facilities.

IMPORTANT: Updated rules for the new license types are currently in development. In the interim, licensees shall comply with the following:

- Wholesalers, repackagers and manufacturers shall comply with rules [4729-9-16](#) & [4729-5-11](#) and all other applicable rules of [Chapter 4729-9](#).
- Virtual wholesalers shall comply with rules [4729-9-28](#) & [4729-5-11](#) and all other applicable rules of [Chapter 4729-9](#).
- Brokers shall comply with rules [4729-9-30](#) & [4729-5-11](#) and all other applicable rules of [Chapter 4729-9](#).
- Third-party logistics providers shall comply with rule [4729-9-29](#) & [4729-5-11](#) and all other applicable rules of [Chapter 4729-9](#).
- Outsourcing facilities shall comply with rule [4729-16-02](#) & [4729-5-11](#) and all other applicable rules of [Chapter 4729-9](#).