



Rules Update – Drug Distributors - Spring 2019

In March and April 2019, new rules governing the operation of Ohio licensed drug distributors will take effect. As a reminder, a drug distributor includes all the following license types:

- Manufacturer of dangerous drugs
- Outsourcing facility
- Third-party logistics provider
- Repackager of dangerous drugs
- Wholesale distributor of dangerous drugs, including the following classifications:
 - Broker
 - Virtual wholesaler

All rules pertaining to drug distributors will be located in division 6 of the Ohio Administrative Code. The following table provides an overview of the new rules, the rule or rules it is replacing, the rule's effective date, links to the rule text and any applicable guidance documents.

NOTE: This table includes some rules that were moved to division 6 in 2018.

Rule	Title	Effective Date	Replaces?
4729:6-1-01	Definitions.	3/1/2019	4729-9-01
4729:6-2-01	Responsible person - drug distributor.	3/1/2019	4729-5-11
4729:6-2-02	Distributor of dangerous drugs licensing and renewal.	3/1/2019	4729-9-16
4729:6-2-03	Criminal records checks.	3/1/2019	4729-9-16
4729:6-2-04	Drug distributor applications.	3/1/2019	4729-9-16
4729:6-2-05	Change in description of a distributor of dangerous drugs.	3/1/2019	4729-9-08
4729:6-2-06	Procedure for discontinuing business as a distributor of dangerous drugs.	3/1/2019	4729-9-07
4729:6-3-01	Disposal of controlled substances.	4/1/2018	4729-9-06



4729:6-3-02	Report of theft or significant loss of dangerous drugs, controlled substances, and drug documents. Guidance document available: www.pharmacy.ohio.gov/theft	3/1/2019	4729-9-15
4729:6-3-03	Inspections and corrective actions.	4/1/2018	4729-9-09
4729:6-3-04	Verification of licensure prior to sale or purchase.	3/1/2019	4729-9-12
4729:6-3-05	Suspicious order monitoring and due diligence. Effective April 30, 2019. Guidance to be issued the week of February 18, 2019.	4/30/2019	4729-9-16
4729:6-3-06	Controlled substances inventory requirements.	3/1/2019	4729-9-16
4729:6-3-07	Sales of dangerous drugs on-line.	3/1/2019	4729-9-24
4729:6-3-08	Distributor of dangerous drugs samples and complimentary supplies.	3/1/2019	4729-9-13
4729:6-4-01	Disciplinary actions.	3/1/2019	4729-9-19
4729:6-5-01	Wholesale distributors - general operations.	3/1/2019	4729-9-16
4729:6-5-02	Wholesale distributors - recordkeeping.	3/1/2019	4729-9-16
4729:6-6-01	Virtual wholesalers - general operations.	3/1/2019	4729-9-28
4729:6-7-01	Brokers - general operations.	3/1/2019	4729-9-30
4729:6-8-01	Manufacturers - general operations.	3/1/2019	4729-9-16
4729:6-8-02	Manufacturers - recordkeeping.	3/1/2019	4729-9-16
4729:6-9-01	Repackagers - general operations.	3/1/2019	4729-9-16
4729:6-9-02	Repackagers - recordkeeping.	3/1/2019	4729-9-16
4729:6-10-01	Outsourcing facilities - general operations.	3/1/2019	4729-16-02
4729:6-10-02	Outsourcing facilities - recordkeeping.	3/1/2019	4729-16-02
4729:6-11-01	Third party logistics providers - general operations.	3/1/2019	4729-9-29

4729:6-11-02	Third party logistics providers - recordkeeping.	3/1/2019	4729-9-29
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