



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



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

<b>4729:6-11-02</b>	<a href="#">Third party logistics providers - recordkeeping.</a>	3/1/2019	<a href="#">4729-9-29</a>
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