



## Licensure as an Outsourcing Facility

Updated 6/19/2019

[Section 4729.52](#) of the Ohio Revised Code and [Chapter 4729:6-10](#) of the Ohio Administrative Code permit entities, known as outsourcing facilities, to provide non-patient specific sterile compounded drug preparations. In order for an outsourcing facility to operate and/or conduct business in the State of Ohio all of the following apply:

- The entity must be registered with the United States Food and Drug Administration as an outsourcing facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act. More information on registering as an outsourcing facility can be accessed here:  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm389118.htm>
- The outsourcing facility must be licensed as an outsourcing facility by the State of Ohio Board of Pharmacy. You will need to submit proof of registration with the FDA with your application. For more information on obtaining an outsourcing facility license, visit: <https://www.pharmacy.ohio.gov/Licensing/WDDD.aspx>

### **Q1) If an outsourcing facility dispenses patient specific drugs do they need to apply for a terminal distributor of dangerous drugs license?**

Yes. [Rule 4729:6-10-01](#) of the Ohio Administrative Code requires an outsourcing facility that dispenses patient-specific drugs to register as a terminal distributor of dangerous drugs. For more information on obtaining a terminal distributor license, visit:  
<http://www.pharmacy.ohio.gov/Licensing/TDDD.aspx>

### **Q2) Does a licensed Ohio pharmacist need to be the responsible person on an outsourcing facility license?**

Yes. An Ohio licensed pharmacist must be the responsible person on an outsourcing facility

license.

**Q3) What is the definition of an outsourcing facility?**

"Outsourcing facility" means a facility at one geographic location or address that is engaged in anticipatory compounding of sterile drugs and complies with the United States Food and Drug Administration section 503B of the Federal Food, Drug, and Cosmetic Act. More information on outsourcing facilities can be accessed here:

<https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities>

**Q4) If my company already has another type of Board of Pharmacy license (ex. wholesaler license), do I need to apply for a new license as an outsourcing facility?**

Yes. You would need a separate outsourcing facility license.

**Q5) Other than my FDA registration, do I need to submit any additional documentation with my application?**

Yes. If you were inspected by the FDA, you should include a copy of the GMP Inspection Form along with your application. Also, if applicable, any corrective actions &/or follow up inspection reports (including any Form FDA-483, WARNING letters, recalls, etc.) must be included with your application.