



## Drugs Compounded in a Pharmacy Must Adhere to the U.S. Pharmacopeia Convention Chapters 795 & 797

**Updated 2-3-2018**

[Rule 4729-16-03](#) of the Ohio Administrative Code requires drugs compounded in a pharmacy to adhere to U.S. Pharmacopeia Convention (USP) Chapters 797 for sterile compounded and 795 for non-sterile compounded drugs.

The Board is committed ensuring proper oversight of compounded drugs. Therefore, drugs compounded in a pharmacy must meet the following standards:

- <797> Pharmaceutical Compounding—Sterile Preparations—This General Chapter provides procedures and requirements for compounding sterile preparations. General Chapter <797> describes conditions and practices to prevent harm to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in intended strength, unintended chemical and physical contaminants, and ingredients of inappropriate quality in compounded sterile preparations.
- <795> Pharmaceutical Compounding—Nonsterile Preparations: This General Chapter provides guidance on applying good compounding practices in the preparation of nonsterile compounded formulations for dispensing and/or administration to humans or animals.

The State of Ohio Board of Pharmacy is committed to educating compounding pharmacies on compliance with the changes to this rule. If you have any questions or concerns, please contact your local Compliance Specialist or contact the Board directly at 614-466-4143.

