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STATE OF OHIO BOARD OF PHARMACY

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

Ohio Administrative Code Rule 4729-16-03 requires drugs compounded in a pharmacy to adhere to U.S. Pharmacopeial Convention (USP) Chapters 797 for sterile compounded and 795 for non-sterile compounded drugs. Additionally, all compounded prescriptions must also adhere to section 503A of the Federal Food, Drug and Cosmetic Act.

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 latest revision which became official May 1, 2011 includes categories of compounding (simple, moderate, and complex); definitions for terms (e.g., beyond-use date, hazardous drug, stability); and criteria for compounding each drug preparation (e.g., suitable compounding environment, use of appropriate equipment).

- Section 503A was added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (the Modernization Act). Section 503A describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) section 501(a)(2)(B) (concerning current good manufacturing practice); (2) section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). For more information on Section 503A, please visit: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377052.pdf

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.