USP 795 and 797 UPDATES

On November 1, 2022, United States Pharmacopeia (USP) published revisions to their pharmaceutical compounding standards chapter 795 (nonsterile preparations) and 797 (sterile preparations) with an anticipated implementation date of November 1, 2023, for both.

The following presentation is a broad comparison of the major differences between the currently implemented guidelines and the 2022 revisions. The presentation is not meant to be a comprehensive guide for implementation for the revisions.

USP 797 and 795 presentation

The amendments to 201 KAR 2:076 became effective on October 25, 2023. The amendments reflect the adoption by the Board of the 2022 revisions for USP 797 and USP 795 standards and include USP 800 as it relates to compounding.

Highlights of the regulation include:

• The addition of the Designated Person (definition and responsibilities).

• Definitions for “essential copy of a commercially available drug product" and “hazardous drug" and rules regarding both terms.

• The addition of a flavoring will not be considered compounding if the additive is non-expired, inert, nonallergenic, produces no effect other than the instillation or modification of flavor and is not greater than five (5) percent of the drug product's total volume.

• The dispensing of compounded preparations for veterinary use shall follow the requirements of 201 KAR 2:311.

• Verification of a compounded preparation shall be completed by a pharmacist after the preparation of the compound and prior to dispensing to the patient.

• Enforcement Discretion: Effective January 1, 2026 the board shall enforce the 2022 revisions. Until January 1, 2026 the board shall enforce the 2014 revision of USP 795 and the 2008 revision of USP 797, and the board shall not enforce USP 800.

• Until January 1, 2026 at the request of a permit holder the board may inspect pursuant to the 2022 revision standards.