Nonsterile compounding is a common practice in retail and community pharmacies and hospitals. USP just released the revised General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations. The regulations were initially introduced in 2000 and recently published revisions further clarify the safety standards for compounded nonsterile preparations (CNSPs), such as oral and topical preparations. Regulatory bodies, like state boards of pharmacy, are expected to enforce the standards, and non-compliance could potentially result in citations. In addition to ensuring compliance with the existing chapter, review the checklist below to help as you prepare for the impact of the recent revisions. USP <795> section references are provided and key changes are emphasized.

Have you:

**Facility**
- Designated a space specifically for nonsterile compounding and ensured its conditions meet the USP <795> standards? *(Section 4)*
- Assessed capabilities and procedures for temperature monitoring in compounding and storage areas? *(Section 4.2)*
- Ensured an adequate sink is available and water sources are appropriate for cleaning and compounding? *(Section 4.3)*

**Types of CNSPs and Beyond Use Dates (BUDs)**
- Reviewed and understand the types of preparations and how to establish beyond use dates? *(Section 10)*
- Assessed the impact of changes to BUDs to your pharmacy production workflow and staffing? *(Section 10)*

**Master Formulation and Compounding Records**
- Created and/or validated Master Formulation Records for any batch compounded preparations or preparations made from nonsterile components? *(Section 11)*
- Reviewed documentation requirements for Compounding Records? *(Section 11)*

**Policies and Procedures**
- Determined if existing policies and procedures are compliant with USP <795> revisions and required components? *(Section 15)*
- Assessed hand hygiene and garbing practices for nonsterile compounding? *(Section 3)*
- Developed procedures establishing the cleaning procedures and frequency of nonsterile compounding areas and equipment? *(Sections 5 and 6.1)*
Policies and Procedures (continued)

☐ Developed procedures for management of component receipt, storage and spill cleanup? <Section 6.2>
☐ Established a quality assurance and quality control program for CNSPs, including reporting of complaints and adverse events? <Sections 12 and 14>

Staff Training and Competency

☐ Identified and provided clear expectations for a designated person to oversee compliance with all aspects of USP <795>? <Section 1.1>
☐ Reviewed your staff training and competency policies, procedures and documentation? <Section 2>
  o Proficiency must be demonstrated every 12 months for core competencies.

Hazardous Drugs

☐ Prepared for USP <800>?
  o Hazardous drug references have been removed from USP <795> and cross-referenced to USP <800>.

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