Compelling Reasons to become USP <797> & <800> Compliant

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-01-Hospital

DATE: **October 30, 2015**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance Related to Compounding of Medications

- **October, 2015 the Department of Health & Human Services Centers for Medicare and Medicaid Services updated** the State Operations Manual (SOM) with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP) to bring them into alignment with current accepted standards of practice including United States Pharmacopeia (USP) standards; compounding of medications, particularly compounded sterile preparations and now handling of hazardous compounds
- **§482.25 Condition of Participation: Pharmaceutical Services.** The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, **warranting a Condition-level citation**
- Compounded sterile preparations (CSP's) & Hazardous Compounding may also be a source of **healthcare-associated infection**…Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for CSP's, whether they are the type of CSP that must be compounded in an aseptic pharmacy location that meets USP <797> standards for low, medium or high-level risk CSP's

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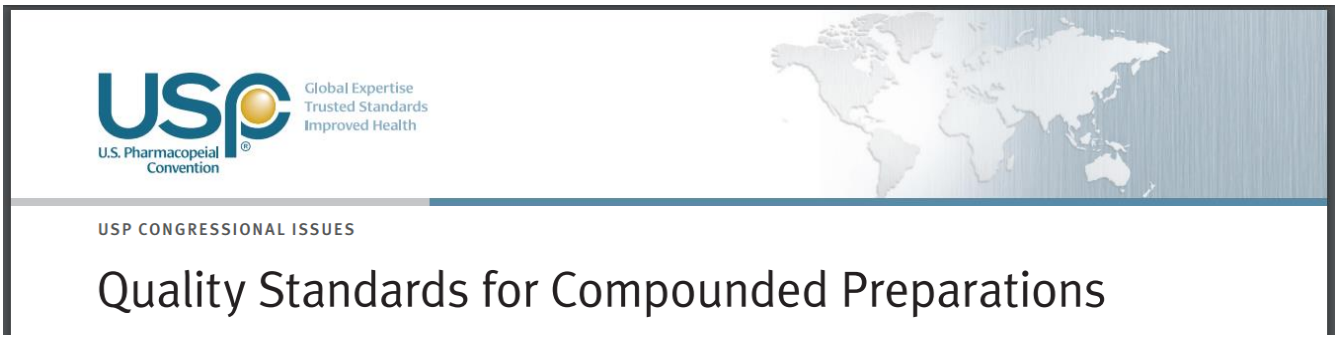
Bloomberg BNA LEGAL

States Adopt Variety of Oversight Strategies in Wake of NECC Disaster

- March 13 --In September 2012, a clinician in Tennessee reported to the Centers for Disease Control and Prevention (CDC) a case of fungal meningitis in a patient who had received an injection of a steroid produced by the New England Compounding Center (NECC) in Framingham, Mass. The CDC linked a growing number of such cases to three lots of the steroid shipped to 20 states. By the time the CDC declared the outbreak over in October 2013, 751 people in 20 states had become infected, and 64 people had died.

- Federal lawmakers questioned how such a disaster could occur, and through multiple hearings and reports, concluded that NECC appeared to have exploited a gap in regulatory authority between the federal Food and Drug Administration (FDA) and state boards of pharmacy pertaining to compounding pharmacies.



USP is a nongovernment, nonprofit scientific organization that was established almost 200 years ago. We are a trusted source of objective, science-based public standards, working through volunteer experts—helping to advance public health and ensure the quality of medicines, dietary supplements, and foods. USP's quality standards for medicines are mandatory in the U.S. and enforceable by the Food and Drug Administration (FDA).

USP has developed a growing set of standards for specific compounded preparations: these provide standardized formulas and beyond-use dates, and, like other USP standards for medicines, are enforceable in law. USP also creates timely, authoritative practice standards related to compounding.

These "chapters" help practitioners adhere to widely acknowledged, scientifically sound compounding practices. USP's compounding standards are developed and revised

through USP's Compounding Expert Committee, whose work is supported by nine FDA liaisons and two liaisons from the Centers for Disease Control (CDC).

USP compounding standards help compounding practitioners adhere to widely acknowledged, scientifically sound procedures and practices, and facilitate the delivery of consistent and good-quality prepared medicines to patients.
State Boards of Pharmacy may adopt USP compounding standards into their regulations.

What Is USP <797>?
USP 797 refers to chapter 797 "Pharmaceutical Compounding – Sterile Preparations," in the USP National Formulary. It is the first set of enforceable sterile compounding standards issued by the United States Pharmacopeia (USP). USP 797 describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded.

The standards in this chapter are intended to apply to all persons who prepare compounded sterile preparations (CSPs) and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). USP 797 requirements affect all disciplines involved in sterile compounding, including physicians, nurses, pharmacists, and pharmacy technicians.

What is USP <800>?
The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection. The new general chapter defines processes intended to minimize the exposure to hazardous drugs in healthcare settings.

General Chapter <800> was published on February 1, 2016 in the First Supplement to USP 39–NF 34.The Expert Committee approved a delayed official implementation date of July 1, 2018 to allow entities additional time to implement the standard. With the delayed official date, entities have more than two years to implement this new standard.

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Legal Considerations

Compounding is the preparation, mixing assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order or initiative based on the practitioner's relationship in the course of professional practice.

Practitioners who compound should understand their responsibility to comply with USP standards. Compounding is largely regulated by the state boards of pharmacy. A number of states have incorporated USP's compounding General Chapters into their pharmacy laws and regulations, and require conformance with these standards.