National Home Infusion Association

USP General Chapter <797>, Pharmaceutical Compounding-Sterile Preparations

Position Statement

Pharmacists have a crucial role in providing extemporaneously compounded sterile preparations (CSP’s) to patients and for ensuring the sterility, safety, and efficacy of these preparations.

Over the past decade, infusion pharmacies have used a wide range of resources to guide the preparation of CSP’s, including professional practice guidelines published by the American Society of Health-System Pharmacists (ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products) and the United States Pharmacopoeia (USP<1206>, “Sterile Drug Products for Home Use,”); national accreditation standards of the Joint Commission on Accreditation of Healthcare Organizations, the Accreditation Commission for Healthcare, and the Community Health Accreditation Program; and, where applicable, state laws governing pharmacy practice.

In recent years, there have been isolated published reports of patient injury and death related to improperly compounded CSP’s. These reports have prompted state, federal, and professional organizations to examine the adequacy of the current framework of standards pertaining to CSP’s. The USP convened an expert committee to consider revisions to USP <1206> that would apply to all health care practice settings and could be enforced by state boards of pharmacy. The result is the publication of USP <797>, “Pharmaceutical Compounding—Sterile Preparations,” which officially takes effect on January 1, 2004.¹

The stated intent of USP <797> is “to prevent harm and fatality to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and incorrect ingredients in CSP’s.” The introduction to USP <797> notes that “sterile compounding requires cleaner facilities, specific training and testing of personnel in principles and practices of aseptic manipulations; air quality evaluation and maintenance; and sound knowledge of sterilization and solution stability principles and practices.” The document states further that, “injections for administration into the vascular and central nervous systems pose the greatest risk of harm from nonsterility and large errors in ingredients.”

NHIA supports the general concepts of the practices and standards for CSP’s described in USP <797> and supports the use of the standard as a tool for approaching good CSP practices. However, USP <797> does not provide explicit guidance on compounding CSP’s. For even the most experienced infusion pharmacists, the document raises more questions than it answers, and there will be many ways to comply. The standards are not structured in a manner that facilitates implementation by pharmacists or interpretation by state boards of pharmacy, which will be responsible for enforcing the standards at their discretion. It is important to note that the USP itself has no regulatory enforcement authority over the practice of pharmacy, pharmacists, or pharmacies.

NHIA is committed to compiling areas of question and concern related to USP <797> and working with USP and other appropriate organizations to clarify these issues. NHIA is also committed to providing ongoing education and information for members, state boards of pharmacy, and others regarding appropriate implementation of CSP standards in the infusion pharmacy sector.

In addition, NHIA strongly encourages its membership to do the following:

- Review current operations against state board of pharmacy regulations and requirements relative to CSP’s to identify possible areas of noncompliance or deficiencies.
- Contact state boards of pharmacy to determine if the board is aware of <797> and that it goes into effect on January 1, 2004. Inquire how the board interprets the Chapter, and whether the board plans to enforce the requirements.

It is the ultimate responsibility for all personnel who prepare CSP’s to understand these fundamental practices and precautions, develop and implement appropriate procedures, and continually evaluate their procedures and the quality of final CSP’s to prevent harm and fatality to patients treated with CSP’s.

**Reference:**