

On Your Behalf . . .

ASHP Works to Improve Sterile Compounding Practices



New USP Compounding Standard

On January 1, 2004, a new standard on compounding sterile products from the *United States Pharmacopeia* (USP) will become effective. This new standard will have the weight of federal regulations and could be enforced by state boards of pharmacy and referenced by Joint Commission on the Accreditation of Healthcare Organizations™ (JCAHO) surveyors.

USP 27 will include a new *General Tests and Assays Chapter 797, Pharmaceutical Compounding—Sterile Preparations* that replaces the *General Information Chapter 1206, Sterile Drug Products for Home Use*. This chapter will apply to all practice settings in which sterile preparations are compounded, including hospitals, ambulatory care clinics, home infusion services, and physicians' offices. The move from a General Information chapter (numbered above 1000) to a General Tests and Assays chapter (numbered below 1000) makes it enforceable by the Food and Drug Administration. For state boards of pharmacy to enforce the standards, the standards would have to be adopted by individual state legislative or regulatory actions.

Pharmacy departments that are already struggling with out-of-date facilities, the pharmacist shortage, and other resource constraints will be challenged to meet these new standards. The American Society of Health-System Pharmacists® (ASHP) has been helping pharmacists confront the challenges of sterile product compounding for decades, and it has responded to this latest development by helping to craft the new standard, conducting surveys, developing new guidance, producing training materials, and offering educational sessions on sterile compounding. ASHP staff are also working with affiliated state chapters and their state boards of pharmacy on revisions to sterile compounding statutes, regulations, and guidelines, and working with congressional staff on compounding-related studies and pending federal legislation.

ASHP and the New USP Standard

ASHP's guidance documents on sterile compounding have long been recognized by state boards of pharmacy, JCAHO, and other organizations as the standard of practice.¹⁻² Facilities that have adopted ASHP's published best practices should have little difficulty meeting the new standard. Because of their recognized expertise, ASHP members participated in the development and review of the USP chapter. ASHP members were on the USP committee responsible for its drafting and several ASHP staff and members participated in USP open hearings on the draft. ASHP also circulated copies of the first draft, published in the March/April 2002 *Pharmacopeial Forum* (PF), to the members of the ASHP USP Advisory Committee and drafters and reviewers of the *ASHP Guideline on Quality Assurance for Pharmacy-Prepared Sterile Products for comment*.³ Comments from these reviewers were compiled and forwarded to USP. The second draft, published in the May/June 2003 PF, reflected substantial acknowledgment of the ASHP's reviewer's comments.⁴

ASHP reported on the new standard in a news article in the *American Journal of Health-System Pharmacy*™, (USP publishes enforceable chapter on sterile compounding; September 15, 2003).⁵ This article included explanations and quotes from representatives of the USP, FDA, NABP, and JCAHO on the intent of the chapter, its legal status, and discussion of how the USP standards might be used by state boards of pharmacy, JCAHO surveyors, and the ASHP residency accreditation program. It also briefly covered differences between USP Chapter 797 and ASHP guidelines.

ASHP and the Status of Sterile Compounding Practice

Recent well-publicized reports of patients being harmed by compounded injectables have again raised concerns about the effectiveness of compounding practices. ASHP has supported three national surveys to determine the status of sterile compounding practice. The first in 1991, the second in 1995 to assess whether the ASHP guidelines published in 1993 improved practices, and the third in 2002, based on the 2000 revision of the ASHP guidelines.⁶⁻⁷

The preliminary results of the third survey were presented at the 2002 ASHP Midyear Clinical Meeting and the final results, **National survey of quality assurance activities for pharmacy-compounded sterile preparations**, will be published in the December 15, 2003, issue of the *American Journal of Health-System Pharmacy*. The survey found that there were some improvements, but gaps remained in levels of compliance with the ASHP guidelines. Since the ASHP guidelines and USP chapter 797 contain similar requirements, hospital pharmacies in compliance with the ASHP guidelines should find compliance with USP 797 easier.

Sterile Compounding Practice Featured at the 2003 Midyear Clinical Meeting

The session, **Compounding Sterile Preparations—Pharmacy's Dilemma** (Monday afternoon, December 8, 2003), reflects some of the content from the 2002 Midyear Clinical Meeting session, but places an emphasis on the new USP standards and ways to comply with them. The 2002 session introduced the likelihood of a new national standard from USP. That well-attended session touched on regulatory and legislative initiatives in response to public concerns about the safety of pharmacist-compounded sterile preparations, current standards at that time, the gaps between standards and actual practices, and the forthcoming standards for USP.

Presentations in 2003 review USP Chapter 797 and gaps in current practice as represented by respondents to the survey conducted in 2002, best practices for meeting the requirements in 797, engineering options for controlling the sterile compounding environment, and 797 implications for state board of pharmacy oversight of sterile compounding.

The basis for requirements in 797 and practical approaches to meeting those requirements will be presented. Statements within 797 acknowledge that the applicability of the requirements, and how they could be met during various compounding operations in any particular setting, could depend on professional judgment. Controlling the sterile compounding environment addresses determining whether a clean room or barrier-isolator would best meet the needs of various facilities given local circumstances and variables considering preparations compounded, workload, staffing, location, and structural constraints.

Copies of the session's supplemental educational materials and presentation slides will be available on the ASHP Web site.

Next Steps

The 2003 MCM session will be followed by several other activities and publications to assist hospital and health-system pharmacists meet the evolving standards. The ASHP publication, *Principles of Sterile Product Preparation*, is undergoing revision. The second edition, entitled *Principles of Compounding Sterile Preparations*, will be available late summer or fall 2004. The ASHP *Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products* will be revised, as well as the CD-ROM training resource, *Sterile Product Preparation: A Multimedia Tool*.

References

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3. United States Pharmacopeial Convention. (1206) Sterile drug products for home use. *Pharm Forum*. 2002; 28:498-534.
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5. United States Pharmacopeial Convention. (797) Pharmaceutical compounding—sterile preparations. *Pharm Forum*. 2003; 29:940-65.
6. Crawford SY, Narducci WA, Augustine SC. National survey of quality assurance activities for pharmacy-prepared sterile products in hospitals. *Am J Hosp Pharm*. 1991; 48:2398-413.
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