

DRUG TOPICS

USP proposes new 797 standards

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Eric Kastango
world.

While most people haven't had time to digest the intricate details of the United States Pharmacopeia's proposed changes to General Chapter 797 (Pharmaceutical Compounding-Sterile Preparations), response to the protracted document has been almost universally positive.

Although the official public comment period has been set to close on Aug. 15, Diane Cousins, VP of patient safety at USP, doesn't expect final rules to be released until at least 2007. "After the public comment period, new rules require that the issue will have to go out for public comment again," she said.

In the meantime, there has been no shortage of opinions on some of the proposed changes as well as observations on how well Chapter 797 is being enforced in the real world.

"I looked on the changes as being very favorable. They were scientific as well as practical," said Ken Baker, R.Ph., JD, executive director of the Pharmacy Compounding Accreditation Board (PCAB). He lauded USP for taking into consideration not only what the experts had to say but also some of the practical considerations involved with sterile preparations.

Among the highlights of the proposed revisions: the addition of a glossary; new sections on radiopharmaceuticals, hazardous drugs, and single-dose versus multidose containers; as well as changes to the section on environmental monitoring.

Lesley Maloney, Pharm.D., ASHP director of public health and quality, noted that the newest revisions are more specific and provide more guidance. "We applaud USP for this process. They have been very open and transparent." Maloney said ASHP is in the process of formulating its official comments on the proposed revisions and expects to have them available right before USP's August deadline.

Some industry insiders consider the revisions an improvement over the previous standards, which were seen as being too lofty to achieve and bordering on best practices rather than focusing on patient safety. "USP looked at the standards and took the state boards' comments very seriously," said Carmen Catizone, R.Ph., executive director of the National Association of Boards of Pharmacy. He said NABP endorses the USP standards. "We are very comfortable going forward with the new draft." He also said NABP is recommending that the states use the standards as a way of gauging compounding practice in their states.

While the new revisions seem to clarify what was perceived as ambiguous in the previous version—published in 1994—the issue of enforceability remains a challenge. Currently, about nine state pharmacy boards require pharmacists to comply with USP Chapter 797. "Some pharmacy boards have risen to the challenge and changed their laws because they feel very strongly. Others are in the process of changing, and still others are mulling it over," said Eric Kastango, R.Ph., president/CEO of Clinical IQ, a health-care consulting company based in Florham Park, N.J., that specializes in aseptic compounding and quality systems education and training.

Kastango, who was on USP's sterile compounding committee, believes that the tide has shifted and that the regulatory authorities can no longer ignore the importance of USP Chapter 797.

NABP's Catizone noted that under most state practice acts, if there is a problem with a pharmacist, authorities are going to look at what is the standard of care, and they will point to the USP standards. "They will be enforceable from that perspective." On the other hand, he noted that detractors will argue that USP Chapter 797 is just a standard a private group has put together and that compounding could be done under a different set of standards while still achieving the same outcome.

Proponents of 797 contend that the new USP standards address the issue of patient safety. "There is enough evidence in the literature to demonstrate that patients are being hurt or killed by incorrectly prepared compounded sterile preparations," Kastango said. "We wanted to give pharmacists evidence-based recommendations on how they can be more effective in providing a sterile preparation to a patient."

In the latest revision of Chapter 797 there was a great deal of input from several organizations, including the National Institute for Occupational Safety & Health and the American Society for Microbiology. All of these expert groups, noted Kastango, gave the USP committee feedback on how to use evidence-based science to do environmental monitoring of hazardous drugs and facility design.