

DRUG TOPICS

Compound interest: Hospitals are making major changes to their operations to comply with USP Chapter 797

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While not on the *New York Times* Bestseller List, "USP Chapter 797, Pharmaceutical Compounding: Sterile Preparations" is a must-read for all compounding pharmacists. It took effect on Jan. 1, 2004.

The document details the procedures and requirements for compounding sterile preparations and sets standards that are applicable to all practice settings where sterile preparations are compounded. The settings include hospitals, community pharmacies, physician practices, infusion clinics, home care organizations, long-term care facilities, and satellite pharmacy locations.

JCAHO began including elements of Chapter 797 standards in its surveys on July 1, 2004. Experts say that if health facilities are not yet compliant with these standards, there are various steps they can take and tools they can use to achieve this goal.

Steps to take "The first thing people need to do is get a copy of USP 797 and then do a gap analysis so they can see where the problems are and the areas where they are lacking," advised Linda McElhiney, Pharm.D., a compounding pharmacist for three hospitals that are part of Indianapolis-based Clarian Health Partners.

Steven Aragona, R.Ph., director of pharmacy at Hackensack University Medical Center, Hackensack, N.J., said one challenge is to help pharmacists understand the regulations and what issues need to be addressed. "We understand about wanting to keep IV mixtures clean, but many pharmacy schools have not addressed some of the things that are included in 797," he said.



Aragona recommended that pharmacists attend USP 797 seminars sponsored by reputable organizations so they can bring up-to-date, reliable information back to their hospital staff. He also recommended hiring a consultant with expertise in meeting the new guidelines who can help conduct a gap analysis to isolate needed changes. "We looked at those areas in relation to the JCAHO guidelines and the dates for action and we put together an action plan," he told *Drug Topics*.

Driving home the importance of proper scrubbing and gowning to hospital employees was at the top of Aragona's action plan. "We're hitting them very hard on the importance of hand washing—not just hand washing when you go into a room, but every time you think you break aseptic technique," he said.

Pack these compounding tools Aragona also stressed that it is beneficial for a hospital to have a training program through which R.Ph.s can convey to the environmental services staff precisely what takes place in a clean room and why the room must be kept clean. "We realized that if we can't create in people's minds an expectation of what that room should look like and that it needs to be kept clean at all times, we would be fighting a losing battle," he said. He suggested that hospitals consider having environmental services dedicate specific cleaning equipment for the clean room so that dirt and grime from another area would not end up there.

Noting that Hackensack recently hired a staff developer, Aragona said, "The way we orient people has to undergo a change. Most pharmacists or techs learned to make IVs on the job. Now, when someone joins our

staff, we give them a lecture on aseptic technique."

McElhiney echoed Aragona's sentiments concerning the importance of training the housekeeping staff to follow rigorous clean room guidelines. "That was a challenge. You don't see the housekeeping staff all the time. Many times they clean at night so you don't see what they do," she said. The new regulations have also inspired McElhiney and Aragona to become more meticulous when it comes to testing their staff.

Aragona said Hackensack Medical Center is considering making its annual testing much more complicated by requiring its staff to prepare an admixture that involves the addition of more than one drug. The medical center is also considering having a system in place in which only those who are preapproved can prepare compounded drugs.

McElhiney is giving her pharmacy technicians a manual test every six months so she can make sure their aseptic technique is good. "If bacteria start growing on something they are compounding, they have to go back to the drawing board and be retrained," she said.

Aragona is concerned that nurses, who occasionally have to compound an IV in an emergency situation, be educated about 797. "We want to make sure we provide enough information to our nurses on how to safely compound something when they are not able to access the pharmacy in an emergency."

New makeovers In addition to the challenge of training employees to follow aseptic techniques, USP 797 has created the need for hospitals to undergo renovation. Noting that all of the IV rooms are undergoing major renovation at her hospitals, McElhiney said, "In the clean room, we have to put in an air system for a certain air quality. It costs several thousand dollars per hospital. In some satellite pharmacies we've had to do things in order to comply with USP."

Aragona said his hospital is undergoing similar changes. "The most challenging portion is what to do with satellite pharmacies. These small pharmacies are situated around the building in specific areas and may be handling a specific number of floors. In the past, satellite pharmacies may have had a laminar flow hood in them and prepared IVs. Now we have to figure out how we address that sort of setup."

Aragona went on to say that renovations and construction of a clean room could cost between \$100,000 and \$200,000. The renovations may include laminar flow filtering, as well as construction of the room. The latter entails special attention to the flooring, ceiling tiles, and paint needed to meet the guidelines. "There's a lot that goes into the construction of the rooms and their maintenance. It's a lot of work to get there."

Cultural shift Convincing employees to change from the way they've done things in the past is yet another obstacle in the path to complying with USP 797.

USP 797 states that employees should not wear makeup, in order to prevent bacteria from latching on to particles generated by the cosmetics. However, Aragona said, it's difficult to make employees see why they have to change something they've been doing for a long time.

"We're wrestling with all those issues. We thought if we went into the IV room and washed our hands and tried to keep the place clean, we were doing a good job. Now we learn that despite these efforts, there are other precautions we need to take," said Aragona.

McElhiney noted that any person who enters the room must practice proper gowning and scrubbing. "Even if you aren't going to be compounding in the clean room, you have to gown up and scrub if you are setting foot in there," she said.

Complying with USP 797 also entails writing standard operating procedures for tasks, monitoring the room's air, and performing sterility and pyrogen testing. "There were things we were doing before they were required, such as documenting the air temperature," McElhiney said. If the room is too hot, the drugs stored there can degrade, she explained. There were already alarms in the refrigerators that sound off to maintenance if the temperature gets too high or if the unit breaks down. Equipment has now been installed to test the room's humidity, she said.

According to JCAHO spokesman Mark Forstneger, "JCAHO is allowing reasonable time frames for implementing various aspects of 797." Queried whether any hospitals have been cited for failure to comply with any USP 797 requirement, he said. "JCAHO surveys against [its own] standards, not against USP. Although some of the standards may cross over to USP requirements, we cannot break down whether or not a hospital has been cited for any of those USP standards."

Aragona said that while USP 797 has been out for only a little more than a year, the organization is already considering revisions to the guidelines.

Eric Kastango, R.Ph., president of Clinical IQ, a Florham Park, N.J.-based consultancy firm that conducts gap analyses nationwide, has spoken at numerous seminars on USP 797. He agreed that the new guidelines are forcing pharmacists to pay attention to the importance of employee hygiene and of training staff to scrub and gown properly. "It's critical," he stressed. "It's important to recognize that pharmacists have a responsibility to compound correctly and that they need to start applying the art and science of contamination control and aseptic processing procedures that are consistent with what we expect other industries to do. We have taken for granted what it takes to do compounding correctly. It's important to make sure that the facilities where compounding pharmacists work are appropriate and that they are like an operating room. Most hospital IV rooms are storerooms that have a hood in them versus an OR that is designed to maintain a level of cleanliness."

Kastango advised hospital administrators to give pharmacists the resources they need to achieve the level of cleanliness required for patient safety. "797 is not a one-time deal. It's a lifestyle change," he concluded.