

PHARMACY PRACTICE NEWS

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Late-Breaker
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ISMP pushes for more flexibility CMS 30-Minute Rule On Drug Administration Seen as Risk to Patients

The Centers for Medicare & Medicaid Services' (CMS) rule requiring that medications be given within 30 minutes before or after their scheduled time has prompted many health-system nurses to adopt rushed and risky workaround practices that increase the potential for serious errors, according to the Institute for Safe Medication Practices (ISMP).

ISMP and other groups, including the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association (APhA), have asked CMS to implement a more flexible approach to administration timeliness, one that retains the 30-minute rule for time-critical medications but allows others a wider dosing latitude. At least one hospital already has taken the more flexible approach to drug administration, despite the risk for being

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A Call to Action on Sterile Compounding Gains Traction

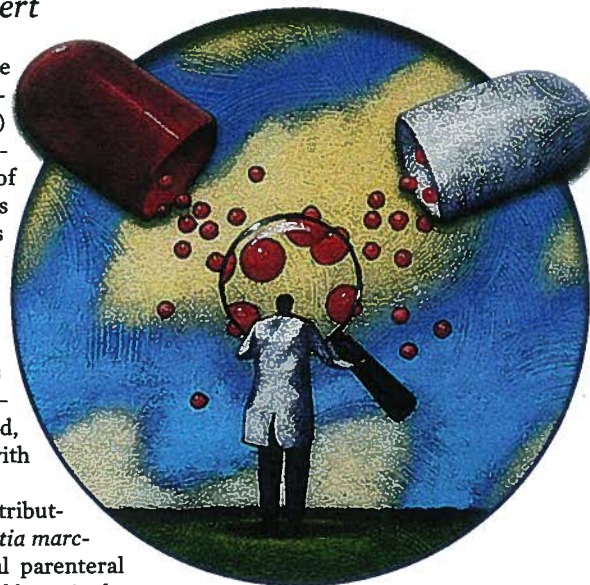
FDA, Joint Commission poised to issue new guidances following ISMP Alert

Three months ago, the Institute for Safe Medication Practices (ISMP) called on regulatory agencies to increase oversight of compounding pharmacies in the wake of nine deaths in Alabama linked to contaminated admixtures. It now appears that at least two of those agencies—the FDA and the United States Pharmacopeia (USP)—are beginning to respond, according to interviews with several top officials.

The deaths have been attributed to an outbreak of *Serratia marcescens* in outsourced total parenteral nutrition solutions shipped by a single compounding pharmacy.

In the ISMP's *Medication Safety Alert!* on the outbreak, the group recognized the importance and practicality of contracting with compounding pharmacies.

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After Heart Transplant Hospital

MEDICATION SAFETY

TPN POLICY

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But it put particular pressure on the FDA to develop a more aggressive plan for guarding against future fatalities.

“Since the early 1990s, [the] FDA has been aware of multiple problems with compounded preparations that have resulted in recalls, patient injuries and deaths,” the alert stated. “However, when we communicated with the FDA recently to discuss [the events in Alabama], no one could clearly articulate how the agency regulates compounding pharmacies.”

In response to the alert, FDA spokeswoman Shelly Burgess said that the FDA has the authority to inspect pharmacies but defers to the states with respect to routine practice. “Compounding pharmacies are regulated by federal and state laws. [The] FDA makes every effort to cooperate with states in investigating compounding pharmacies and typically defers to state authorities for the day-to-day operation of traditional pharmacy compounding,” she said.

But the FDA doesn't appear to be deferring all aspects of sterile compounding oversight. *Pharmacy Practice News* has learned that guidance from the FDA is expected to be released later this year. The FDA's Center for Drug Evaluation and Research Guidance Agenda for 2011 notes two forthcoming documents, “Good Pharmacy Compounding Practices for Sterile Drug Products” and “Outsourcer Pharmacy Operations Compliance Policy Guide” in the category “Current Good Manufacturing Practices (CGMPs)/Compliance.”

Forthcoming guidance from the Joint Commission is also anticipated, but will address sterile compounding, not out-

“Compounding pharmacies will be regulated regardless, and they will still have to meet state requirements,” he said. “If [ISMP] is mandating FDA and state board oversight, there is a problem there with resources to get out to every pharmacy and check what they are doing, what procedures they use, their quality control, etc.”

Mr. Catizone said that hospital pharmacy directors and others who determine when and how to outsource services like sterile compounding share in accountability. “If there is an error like the one in Alabama, and a hospital is contracting with a compounding pharmacy, both [the hospital and the compounding pharmacy] are going to be responsible for that error,” he said. “Whatever the standards are that the state and the hospital have set for pharmacy, the director should make sure that the contracted pharmacy meets those standards. Directors need to ask questions and remember that they are not obligated to do business with someone.”

Eric S. Kastango, MBA, RPh, FASHP, member of the 2010-2015 USP Sterile Compounding Expert Committee and president of Clinical IQ, a pharmacy consultancy in Florham Park, N.J., agrees that pharmacy directors must also step up. According to Mr. Kastango, who contributed to the ISMP alert, hospitals and pharmacy directors are responsible for their choice of outsourced services.

“Hospitals should be qualifying their vendors. They should be in contact



Scan to access ASHP Foundation's new web-based tool for evaluating vendors of sterile parenteral products.

with them, auditing them and physically visiting them to understand what they are doing, how they are doing it and why they are doing it,” he said. “A lot of pharmacists think that outsourcing limits liability when it doesn't.”

Although monitoring outsourced services can be time-consuming, labor-intensive and expensive, such oversight is one of the responsibilities of the profession, Mr. Kastango said. Likewise, pharmacists must know what they are monitoring, he added, stressing that it is important for pharmacy directors not only to understand USP Chapter <797> but to know what their state boards require of vendors, as well. “We go to vendors because they present themselves as skilled and knowledgeable, but ignorance is no excuse for breaking a law,” he said. “For you to be able to go to any vendor, you have to have confidence in what you are asking for.”

Mr. Kastango said that compounding pharmacies should provide meaningful responses to hospitals with whom they wish to work. “Ask the vendor what that vendor is doing to protect your patients and prevent an event like what happened in Alabama,” he said. “They should be forthcoming in key performance indicators in their operations. The quality control measurements can't be just a bunch of numbers meant to look important and not give you a sense of what goes on.”

According to Bona E. Benjamin, BSPHarm, director of medication-use

quality improvement at the American Society of Health-System Pharmacists (ASHP), compounding pharmacies must also back their own work. “Obviously you can't be there to watch them every day. They need to stand behind their products,” she said. “Although you need to do your due diligence in selecting the company, their best advertisement is that they can deliver the product they promised because if they can't, others can.”

Sterile compounding is an either/or proposition, Ms. Benjamin added. “There are no shortcuts in this regard. A product is either sterile or it's not,” she said. “Sterile compounding is a very high-risk procedure, given that the product is going directly into the body. It is labor-intensive, both in practice and in facilities management, and you would anticipate that this requires a high level of resources committed to education and quality control.”

Advocating for Oversight

Ms. Benjamin said that ASHP offers guidance for pharmacy directors tasked with outsourcing sterile compounding as part of its best practice recommendations. “ASHP Guidelines on Outsourcing Sterile Compounding Services” goes into detail about what to look for to make sure that a company is reputable and reliable.”

The ASHP Research and Education Foundation also offers help on the outsourcing front. Late last month, the group announced a new web-based tool for evaluating outside vendors of parenteral product preparation services. To access the tool, visit www.ashp.foundation.org/SterileProductsTool or scan the 2D bar code on this page.

Mr. Catizone encourages pharmacy directors who seek assistance to contact their state board of pharmacy, as well.

A List of Musts for Compounding Pharmacy Vendors

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Forthcoming guidance from the Joint Commission is also anticipated, but will address sterile compounding, not outsourcing practices. "In order to improve evaluation of sterile compounding, the Joint Commission is updating its surveyor guidelines in this area, taking into account revisions to USP <797>," said Paul M. Schyve, MD, the Commission's senior vice president. "Once the guidelines are updated, they will be reissued to the surveyors. Updated guidelines will also be provided to the field."

Dr. Schyve added that by policy, the Joint Commission evaluates health care organizations against standards that have gone through the Commission's own standard-setting process, "and not to standards from other organizations."

State Boards of Pharmacy Wrestling With <797>

How each state board reacts to the call for action will be up to them, said Carmen Catizone, MS, RPh, DPh, executive director of the National Association of Boards of Pharmacy in Mount Prospect, Ill. He added that state boards are already contending with implementing changes to USP Chapter <797>.

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Mr. Catizone encourages pharmacy directors who seek assistance to contact their state board of pharmacy, as well. "Most boards of pharmacy are receptive to pharmacists calling for guidance or education," he said. "In situations where a pharmacy seeks to outsource, a discussion with the state board about what the hospital should [do to monitor] quality and what the pharmacist director should look for in

compounding pharmacy would be a great starting point."

—Terri D'Arrigo

A List of Musts for Compounding Pharmacy Vendors

Health systems that are considering using outside vendors for sterile compounding solutions can glean several useful tips from ASHP guidelines on the practice. One of the ASHP's primary recommendations is to ask vendors to submit a request for proposal (RFP) that includes specific information on areas of operation that can have a direct impact on patient safety. For example, the RFPs should include:

- Assurance that all pharmacists and pharmacy technicians employed at the compounding facility are licensed as required, with verification that they are in good standing on file and available for review
- Documentation of the results of all accreditation or regulatory surveys conducted of the compounding pharmacy's sites, including copies of any significant regulatory actions brought against the facility
- Details on the facility's quality management programs, including those targeted to cleaning and validation, staff training and competency assessment
- A demonstrated commitment to continually integrating technology and knowledge to improve patient safety
- A risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities
- Assurance that the compounded medications are compatible with the client's medication administration devices (e.g., bar-code labeling, smart pumps, etc.)

For more guidelines on contracting with an outsourcing compounding pharmacy, scan the 2-D bar code on this page.

