Follow protocols when using medications from compounding pharmacies

Compounding pharmacies have long been valued for their ability to tailor prescription drugs for specific patients. More recently, they have helped conserve scarce drugs by redistributing them from larger to smaller single-use vials.

For an ambulatory surgery center (ASC) that is not associated with a hospital and therefore has no access to a hospital pharmacy, a local compounding pharmacy might be the key to keeping expenses down and providing needed drugs.

However, a confluence of conditions has led to deeper scrutiny of the compounding industry and reluctance to rely on it to provide a safe alternative to mass-produced pharmaceuticals. There is another way, experts agree: ASCs can select compounding pharmacies with confidence in their safety and professionalism if managers understand those companies’ limitations and role in the pharmaceutical industry.

National outbreak
In September 2012, a patient developed fungal meningitis 19 days after receiving an epidural steroid injection at an ASC in Nashville, Tennessee. Thus began an outbreak that the Centers for Disease Control and Prevention (CDC) would soon trace to the New England Compounding Center (NECC) in Framingham, Massachusetts.

NECC had shipped more than 17,000 doses to customers in 23 states before initiating a voluntary recall. More than 14,000 patients had received injections, resulting in 55 deaths and 741 serious illnesses in 20 states, the CDC reported.

While the NECC episode was not the first distribution of contaminated drugs from a compounding pharmacy, it gained national attention and Congressional interest.

Bills now pending in the Senate and several state legislatures aim to resolve a variety of conflicting laws, Food and Drug Administration (FDA) guidelines, and court decisions regarding compounding pharmacies. “Existing standards are not always enforced,” Simpleman notes, “because there are not enough inspectors.”

An April 2013 report by Rep. Edward J. Markey (D-Mass) notes that while pharmacies, including those that compound, are regulated and certified by states, many ship products between states, including over the Internet. There is no requirement to inform the state of origin when an adverse incident occurs. Meanwhile, according to the Markey report, some compounding pharmacies have expanded their business from filling prescriptions for individuals with special medical needs to producing large quantities of drugs whose manufacture is otherwise highly regulated. Specifically, they produce sterile injectables used in connection with surgery—drugs that are among the most frequently in short supply.

Inadequate oversight
Markey has introduced the VALID Compounding Act, which would continue state oversight of traditional compounding for individuals but add FDA regulatory power for compounding pharmacies that behave as drug manufacturers, making large
quantities not tied to specific prescriptions. On May 22, 2013, the Senate Health, Education, Labor and Pensions Committee approved similar legislation. Representatives Rosa DeLauro (D-Conn) and Nita Lowey (D-New York) are sponsoring the SAFE Compounded Drugs Act, which would allow the FDA to set production standards for compounding pharmacies.

In June, the group purchasing organization Premier Inc released a survey of its health care provider members, which concluded that 90% believe the compounding industry needs both stricter laws and stronger regulatory oversight. Premier called for “clearly defining the 2 types of drug compounders—traditional compounders and compounding manufacturers—and the clarification of separate regulatory oversight and enforcement mechanisms.”

As of May 2013, states had introduced 55 new legislative proposals aimed primarily at tightening rules governing sterile production.

In the case of NECC, the company had received warnings from Massachusetts inspectors and the FDA, under its 2002 Compliance Policy Guide, which is not legally binding. Among its violations, NECC failed to follow proper sterilization procedures.

Tom Simpleman, CEO of The Fawks Company in Denver, has seen similar conditions during his career as a consultant for drug manufacturers. He recalls encountering contaminated dextrose solutions; a compounder using an incubator designed for veterinary use (“and using it wrong”); and another who diluted chemotherapy drugs to increase profits.

Use only certified pharmacies

Simpleman, who is a registered pharmacist, now helps ASCs and other nonacute facilities verify compliance with medication regulations. He says despite the errors he has observed, he has also seen many compounders meet manufacturing standards with good quality control. The best way to find one, he says, is to conduct research based on the Internet, the state board of pharmacy, and the national Pharmacy Compounding Accreditation Board (PCAB). “The PCAB inspects compounders like AAHAC [The Accreditation Association for Ambulatory Health Care] inspects ASCs,” he notes.

Simpleman’s Bible is the United States Pharmacopeia (USP). Section 797 covers preparation of sterile products. The standard is the same for every facility that makes sterile preparations, from a physician’s office to a major drug company. Therefore, he advises ASCs not to open in-house pharmacies in an effort to manage drug quality because they could get sued in the event of a mistake.

Under USP Section 797, sterile compounding requires a “clean room,” where air filters remove contaminants. Workers wear protective clothing, and the room may have positive air pressure to prevent entry of contaminants. The more ingredients a compound has, the higher its risk category and the stricter the manufacturing standards. Storage conditions also must be controlled.

Instead, he recommends working with a certified local pharmacy. The PCAB website, www.pcab.org, contains a list of accredited compounding pharmacies by state, including those newly accredited. The listings indicate whether a pharmacy may compound sterile products but do not specify the exact drugs it may prepare.

Simpleman notes that state and city pharmacy inspectors are familiar with retail practices but may not know much about compounding sterile products.

The International Academy of Compounding Pharmacists (IACP), which represents 2,700 compounding professionals, offers a Compounding Pharmacy Assessment Questionnaire on its website (visit www.iacprx.org or call 800-927-4227). IACP also offers a pharmacy locator.
The questionnaire contains detailed questions on licensing, services provided, quality controls, and testing methods.

For example, among questions to ask an out-of-state pharmacy are:

• If the pharmacy is in a different state than the purchasing institution, is the pharmacy licensed to dispense/distribute/provide medications in this state as well?
• What is the license number?
• Is the permit in good standing?

In the quality assurance category are the following:

• Does the pharmacy have a standard operating procedure (SOP) in place in case of a recall?
• Has the pharmacy had a recall in the last 24 months?
• How can a customer report problems to the pharmacy?
• Have the staff been trained and evaluated in proper aseptic technique, gowning, and clean room procedures?
• What SOPs are in place to show compliance with those procedures?

Visit and ask questions
After locating a certified compounding pharmacy, the ASC pharmacy specialist should visit it, Simpleman advises. Among things to look for is documentation: he feels “uneasy” if the paperwork is not in place, no matter how organized the rest of the facility is. The ASC representative should ask about compounding procedures, the recall process, and verification of competency. Do not reject a candidate just because of a recall, he adds.

“If somebody had a recall, it doesn’t mean they’re bad people.” However, he says it is preferable to learn that the pharmacy initiated the recall itself rather than wait for regulators to discover a problem.

According to Simpleman, if the pharmacy will be repackaging single-use medications, it must receive products directly from the wholesaler—not the ASC. Although that method is more expensive, it is also much safer. “Remember why it’s single use,” he says. “It’s not sterile. That’s a terrific medium for things to grow.”

—Paula DeJohn