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Health providers bemoan costly drug shortage

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James Neff, director of pharmacy services at Holy Cross Hospital in Fort Lauderdale, said his department went slightly over budget last year because of the drug shortage. They were usually able to obtain the necessary drugs or reasonable alternatives, but buying replacement drugs – often from compounding pharmacies instead of manufacturers – proved to be expensive. Using alternative drugs required extensive training so the staff knew how to administer them, which also added to costs, he said. One of the most difficult situations in recent years was a shortage of propofol, the preoperative drug used as an anesthetic.

"Many times we were threatened and the physicians said they would shut down the OR [operating room] unless you could get a drug," Neff said. "We never had to shut down, but we had to have some slight delays in procedures as we scrambled for medications.
"The most disturbing was the oncology medications," he said. "A patient would start a treatment and then, mid-cycle, they'd say you need six more treatments, but you can't get it. It was horrible."

In a recent survey, 43 percent of pharmacy directors told the American Society of Health-System Pharmacists (ASHSP) that cancer treatment was delayed due to the drug shortage, and 35 percent said there was moderate to very high risk of cancer patient death due to such delays or alternative therapies. When Neff was able to track down the drugs outside the hospital's contracted suppliers, each drug cost at least five times the normal price, he said.

Dr. Jeffrey Fromowitz, a dermatologist in Boca Raton, said the drug shortage has impacted both the costs and comfort of his patients. For example, the acne medication minocycline used to be available for almost no cost at Publix, but then it ran into a shortage and now an uninsured patient must pay $200 per dose, he said. For a while, doxycycline was extremely difficult to obtain, so patients who needed that particular antibiotic were given alternative, less-proven treatment plans, he said. For at least a year, Fromowitz couldn't get sodium bicarbonate to numb patients before skin cancer removal, so his patients were a lot less comfortable, he said.
"It strains relationships. There could be mistrust about why a drug isn't available," Fromowitz said. "Patients question why they can't get this medication if that's what they need. There is a perception of the inequality in the delivery of care."

Even when alternative treatments are available, using them increases the likelihood of mistakes because health providers aren't familiar with how to properly dose the other medications, said Jaime Weiner Riskin, a clinical assistant professor in Nova Southeastern University's College of Pharmacy. She previously worked for six years as a clinical coordinator at local hospitals, where managing the drug shortage, including finding the drugs, researching alternatives and training dozens of employees to dose them properly, took up a huge chunk of her time. "Financially, drug shortages have been a huge issue," Riskin said. "It's not just the cost of the drug. It could potentially effect whether a patient will go home within the next 30 days."

Having a longer length of stay and more costly treatments is a financial drain for hospitals because Medicare and Medicaid have moved away from free-for-service billing to diagnosisrelated groups (DRGs), said attorney Lee Lasris, a partner in the Davie-based Florida Health Law Center. The government payors give hospitals a predetermined fee based on the diagnosis, and expect that to cover the cost of care. If a drug shortage makes hospitals go over that cost or extends the stay beyond what was expected, it could turn into a loss for the provider, Lasris said. Should an alternative medication result in a re-admission or medical error, Medicare often won't pay for it, he added. Errors can also lead to costly lawsuits.

Doctors also have to carefully document why they selected an alternative medication in the hopes that Medicare will cover it, even if the drug isn't labeled for that use, Lasris said.
When patients get sick, it could prove costly for health providers in an accountable care organization (ACO), a shared savings program for Medicare.
Attorney Mike Segal, a partner with Broad and Cassel in Miami, said the increased costs of illness and longer hospitalization goes against ACOs' goals of reducing the cost of care, and that could deny providers their performance bonuses for reducing expenses, regardless of whether the drug shortage caused it.

"Another major cost is labor," Riskin said. "Whatever initiatives the pharmacy does to save money for the hospital, we have to stop to address drug shortages. It could take two to three days to deal with one drug shortage, so your resources are affected, as well. It's a huge financial burden." Labor expenses linked to drug shortages cost hospitals $216 million, according to a 2011 study by the University of Michigan and the ASHSP.

Feds take action

There is no single cause for the drug shortages. Supplies have been disrupted by plant closures, quality compliance problems, companies dropping product lines with thin margins, the scarcity of key ingredients and many other reasons. President Barack Obama first took action on the issue with an executive order to the U.S. Food and Drug Administration in 2011.
The FDA said in a Feb. 5 report to Congress that it prevented 140 drug shortages in the first nine months of 2013. The FDA started requiring companies to notify it when a shortage or production halt is imminent so it can seek an alternative source and warn health care providers to conserve medications. The FDA started allowing expedited reviews of generic drug applications to make up for manufacturers that were scaling back. These efforts led to a significant reduction in new drug shortages. However, many of the drugs from past years remain scarce. There were 85 drugs on the FDA's shortage list on Feb. 7, including eight for oncology.

Despite the reduction, the FDA report to Congress said the drug shortage continues to pose a real challenge to public health, especially because some of the scarce medications are for critical needs such as cancer treatment and parenteral (IV) nutrition.
The ASHSP says there are currently 231 drugs in short supply. That's larger than the FDA list because it includes drugs that manufacturers told the FDA were being put back into production, but still aren't widely available, said Cynthia Reilly, the ASHSP's director of medication safety and quality.
"We would agree the number of new shortages is down," she said. "But drugs are staying on shortage for a long time. Once a shortage occurs, it's difficult to resolve."
Some drug companies have found opportunities on the shortage list. Miami-based NextSource BioTechnology recently became the sole manufacturer of lomustine capsules to treat metastatic brain tumors and Hodgkin disease after Bristol-Myers Squibb discontinued the product. NextSource issued a statement calling for all pharmaceutical compounders to stop the unregulated production of this drug.

Compound fills void, poses some risks

The latest conundrum for hospitals and outpatient surgery centers is a shortage of the saline solution used in IV bags, which are standard for most patients. Baxter Healthcare Corp., representing 45 percent of production, shut down its plant for maintenance and the other providers haven't kept up with demand.
Neff said some hospitals are using lactate ringer solution as an alternative, but that's not always the best choice and it's becoming increasingly hard to find. No one wants to turn away patients

or make them wait because they don't have IV bags.
Neff said Holy Cross hired a compounding pharmacy to make IV bags while it renovates its pharmacy, so the hospital can make it inhouse. This outsourcing is, of course, more expensive, he said. Neff said he selected the compounding pharmacy carefully, ensuring that it had proper sterility controls and a clean record, because IV products can leave patients vulnerable to infection.

Any medication that makes a patient sick again causes inflation in health care spending and is a drain on provider resources. And the outcome can be deadly.
Compounding IV drugs has been the subject of national controversy since 2012, when pain shots made at the New England Compounding Center (NECC) caused at least 751 meningitis infections and led to deaths in 20 states, including three in Florida, according to the Centers for Disease Control and Prevention. Compounding pharmacies operate under states' pharmacy regulations, as opposed to the U.S. Food and Drug Administration's more stringent drug manufacturing rules. Florida revoked NECC's license to distribute here, although it wasn't able to inspect its facilities.

The Florida Board of Pharmacy has given pharmacies until March 1 to obtain a special permit for compounding for the first time, and recent inspections are focused on ensuring the sterility of those medications and proper documentation, Executive Director Mark Whitten said.
In November, Obama signed into law a bill on compounding pharmacy regulation that made it optional, not mandatory, for large-scale compounders to register with the FDA.
Goar Alvarez, NSU's director of pharmacy services, said the drug shortage has led many health providers to turn to compounding pharmacies for medications, especially injectables. He's concerned that some compounders don't have the highest sterility standards, especially those shipping from out of state.

Riskin said her hospitals relied on compounders before the NECC scandal, but she grew leery after she realized the IV bags sold to them were supposed to last two weeks when the normal shelf life is 24 hours. "It's very scary because in the hospital, we have very stringent stability and sterility rules,"Riskin said. "A lot of hospitals rely on compounders day-to-day. They were our last backup for the drug shortage, and now we can't rely on them."

Boca Raton family practitioner Dr. Kenneth Woliner said he's received mailers from several compounding pharmacies with state discipline records, offering to split fees with him if he refers them prescriptions, which is illegal. He developed a list of 10 quality pharmacies to refer patients. "There are rogue pharmacies that haven't been shut down because enforcement is so bad," Woliner said. "It's really hard to know if someone prepared a prescription that's potent or not."
Lasris said health providers need to take extra care in selecting compounding pharmacies because it's likely plaintiffs' attorneys would target them if patients get sick from the compounded drugs.

"If the doctor knew the compounding pharmacy had a bad record, or if another patient had a bad outcome, then that doctor could be found to be negligent," he said.

The Details: Florida board of Pharmacy reports

NW Pharmacy, Miami

- Medications were mixed in the same room construction was taking place

- The sterility of its production of injectable drugs and eye drops was in doubt as staff repeatedly
- exposed them to non-sterile surfaces, even bare hands
- Failing to test injectable medication for harmful bacteria
- Labeling medication with "beyond-use-dates" that were too long

Rejuvi Pharmaceuticals, Boca Raton

- Unclean conditions such as powder residue all over room, dirty water left in sink, dead bugs and rodent fecal matter in prescription department
- Shipped medications with wrong expiration dates
- Compounding without on-site pharmacist

SCI Medical Supply, Miami

- Animal feces on the work counters

BY THE NUMBERS

85
Drugs on FDA shortage list on Feb. 7

231
Current drugs in shortage as verified by the American Society of Health-System Pharmacists

58 percent
Portion of pharmacy directors surveyed by the Academy of Managed Care Pharmacy who said patients had at least one adverse event due to the drug shortage

55.2 percent
Portion of pharmacy directors who told AMCP that medication errors were caused by the drug shortage

49 percent
Portion of pharmacy directors who told AMCP they added staff to help manage the drug shortage

71 percent
Portion of pharmacy directors who told ASHSP there was an inadequate supply of injectable oncology drugs to treat patients

65 percent
Portion of pharmacy directors who told ASHSP that the cost to treat cancer patients increased due to the drug shortage