

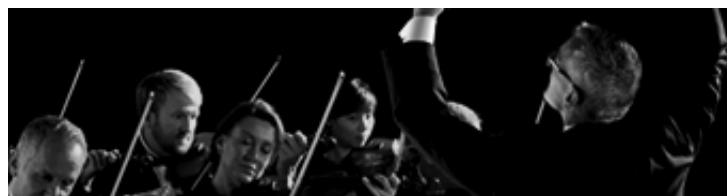
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Surmounting shortages: GPOs work creatively with manufacturers to avert drug shortfalls

By [Adam Rubenfire](#) | October 24, 2015

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When the sedative propofol was frequently in shortage between 2009 and 2014, the scarcity forced hospitals across the country to cancel surgeries as pharmacists struggled to obtain a supply.

The propofol shortage was resolved last summer and the number of new drug shortages has dropped. But there were still 190 drugs in active shortage as of the end of the third quarter of 2015, according to the American Society of Health-System Pharmacists, or ASHP. Many of the items listed in the group's drug shortage database are critical for hospitals, including pre-filled epinephrine syringes placed in cardiac crash carts and vital antibiotics such as meropenem.

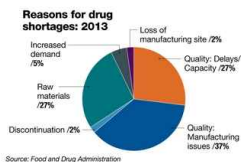
Most hospitals rely on their **group purchasing organization** to ensure steady

pharmaceutical supplies. But a shortage at a GPO's contracted manufacturers can leave the GPO and its members scrambling to find other suppliers or alternative therapies. These shortages, often caused by manufacturing capacity or quality problems, can create medical crises for patients.

Lee Perlman, president of the Greater New York Hospital Association's group purchasing arm, said such drug shortages too often have left his business unable to fulfill its core mission—ensuring predictable supplies at a predictable price to hospital customers. It's a big failure “if a patient lying in bed is waiting for operations that can't go forward because there's a drug shortage,” he said.

To facilitate a reliable pharmaceutical supply, GPOs spend a significant amount of time looking for alternative drugs and working to contract for those drugs. They use various strategies to get around shortages, such as promising manufacturers volume, forging long-term or exclusive deals, creating their own private drug labels, and even scouting out raw material suppliers to work with manufacturers on high-demand drugs.

Drug shortages are estimated to cost U.S. hospitals at least \$200 million annually because of the higher cost of substitute drugs, according to a 2010 survey from Premier, a Charlotte, N.C.-based group purchasing and performance improvement company. An ASHP report estimated that labor costs related to the shortages cost hospitals an additional \$216 million each year. These reports were released at about the same time as the drug shortage crisis hit its peak in 2011.



The **Food and Drug Administration** says the three biggest causes of shortages are delays in manufacturing or other capacity issues, quality issues in the manufacturing process, and difficulty obtaining raw materials. Most of the drugs on the ASHP shortage list are generics. Sterile injectable drugs make up a majority of drugs in shortage because only seven manufacturers account for most of the market, and the drugs are difficult to manufacture safely.

The Healthcare Supply Chain Association, the GPO trade group, has lobbied the FDA to use its regulatory power to expedite applications for new drugs that could serve as alternatives to drugs in shortage. HSCA CEO Todd Ebert said the FDA has the authority in drug shortage situations to move new drug applications to the top of the

authority in drug shortage situations to move new drug applications to the top of the pile and help alleviate shortages.

When faced with a shortage, GPOs look for alternative manufacturers, or sometimes contract for a substitute medication. But there isn't always an alternative, and drugmakers don't always want to bind themselves to a contract, said Sara Turnbow, lead pharmacist at the Minnesota Multistate Contracting Alliance for Pharmacy, a state-run GPO for government facilities.

If a GPO can't nail down a contract for an alternative manufacturer—which isn't uncommon when a drug is in shortage—it's up to hospitals to purchase the drug themselves, often from a wholesaler. Regardless, GPOs try to make sure their members know where they can get alternatives, Turnbow said. Many GPOs hold conference calls to respond to concerns from panicked hospital members during shortages. Turnbow said she discourages her members from stockpiling drugs because that can be unfair to other provider organizations.

To keep drug supplies flowing, GPOs have had to get creative, sometimes turning to contracting practices that are controversial within the industry. Many GPOs have signed contracts guaranteeing drugmakers volume—even if that means the GPO loses money when its members don't need that much supply.

Brian Romig, vice president of pharmacy services at Novation, an Irving, Texas-based GPO, said his organization's pitch to manufacturers is that, “We will give you some confidence as a supplier that our members will buy a certain amount, and we'll go at risk for that. You have the confidence to know that you can open up a line in your manufacturing facility to make a certain amount and you know you have a buyer for that.”

Perlman argues that sole-source contracting, in which a GPO contracts with only one drugmaker for a particular drug, can ensure a stable supply regardless of price. The practice offers assurance to manufacturers that there will always be a demand for their product because they won't be competing with other drugmakers. “We need to give manufacturers predictable demand at a price that they'll want to make it in, and we don't need to have five different vendors necessarily competing on price,” he said.

But other GPO executives say single-source contracting is anti-competitive and prevents providers from getting the lowest price for a drug. And if the sole-source manufacturer reports a shortage, that GPO may be left scrambling.

MH TAKEAWAYS

GPOs are promising manufacturers volume in return for steady supply, forging long-term or exclusive deals, creating private drug labels, and finding raw material suppliers to work with manufacturers on high-demand drugs.

Ron Hartmann, senior vice president of pharmacy at **MedAssets**, an Alpharetta, Ga.-based GPO and performance improvement firm, said it's best to contract with two or more manufacturers of a drug, particularly for products with a history of supply issues. Multi-source contracting provides GPO members with “the best opportunity to purchase a contracted product at a competitive price at the time of purchase,” he said.

Hartmann said some manufacturers don't want to be a GPO's sole source because it can put them financially at risk if their drug ends up in shortage. MedAssets has negotiated with a number of manufacturers who would rather be a part of a dual- or multi-sourced solution for a GPO, he said.

Some experts say longer-term contracts can help ensure a sustainable supply. Manufacturers have been asking for longer contracts, and GPOs should provide them as an incentive for manufacturers willing to promise a sustainable supply, said Bill Larkin Jr., head of pharmacy services for the Greater New York Hospital Association GPO. “Our job as GPOs is to try to create more predictability in the marketplace,” he said. “Having a long-term contract is a good thing.”

GPOs also have strengthened contractual failure-to-supply clauses, which require manufacturers to compensate healthcare providers when a shortage forces them to purchase more expensive drugs. But a 2014 American Society of Health-System Pharmacists report argued that failure-to-supply clauses have been an unreliable safeguard when all the manufacturers of a drug are reporting shortages, because the penalties don't apply when there's no alternative therapy.

Some GPOs have created private drug labels in which they contract directly with a manufacturing company to make a generic drug under their own brand name. This strategy is cheaper than buying name-brand drugs, and it gives the GPO more control over the manufacturing process if issues arise that could lead to a shortage. Such labels include Novation's Novaplus and Premier's PremierPro Rx.

Premier Chief Operating Officer Mike Alkire said private-label programs offer stability for the GPO, and the manufacturer can invest in its processes because it receives funding and assured demand from the GPO.

But MedAssets opposes the private-label approach. “We don't believe that private labels contribute to efficiency in the marketplace,” Hartmann said. MedAssets customers, he said, have expressed a preference for multiple product options, while GPOs with private labels often will only offer the drug through their private label.

Gary Freeman, vice president of pharmacy at Amerinet, a GPO that recently was acquired by Salt Lake City-based Intermountain Healthcare, said the exclusive contracts between GPOs and drugmakers that often are part and parcel of private-label arrangements raise problems from a clinical perspective. “There's an ethical problem if I have an agreement with a manufacturer that they're only going to supply me,” he said. “They may be the only manufacturer of a particular product. There are other people that need that drug.”

To address the problem of obtaining active ingredients in short supply, Premier has forged contracts connecting raw material suppliers with manufacturers to ensure that manufacturers have long-term, reliable access to safe raw materials.

One of those drugs is the antibiotic cephalosporin. Premier was approached by a manufacturer that had identified an active pharmaceutical ingredient supplier that held most of the market share for raw materials used to create the drug. The manufacturer wanted to manufacture it for the PremierPro label.

This summer, Premier signed a six-year contract with both the manufacturer and the ingredient supplier. A big benefit was enhancing transparency regarding the drug's supply chain as well as legal protections regarding the active ingredients' availability.

When a drug's supply is tight, manufacturers aren't always forthcoming with information about their active ingredient suppliers, Alkire said. Active ingredient deals ensure predictable supply but also offer Premier better access to manufacturers to help them respond to adverse events in the supply chain, he said.

The lack of transparency regarding active product ingredient suppliers and outsourced manufacturing makes it difficult to resolve shortages, said Erin Fox, director of drug information at University of Utah Health Care, Salt Lake City. She said GPOs can and

should push manufacturers to be more open about their processes so that suppliers can be held accountable.

“This is a manufacturing problem,” Fox said. “Since they're not solving this very quickly, and we're still having shortages and patient impact, (manufacturers) should have to give up some concessions around transparency, and maybe not everything gets to be proprietary.”

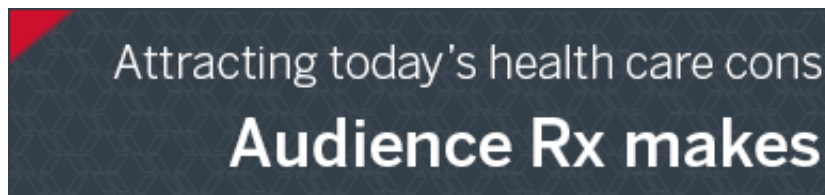
Valerie Jensen, associate director of the FDA's drug shortage staff, said her agency welcomes the work of organizations such as GPOs in bringing more transparency and credibility to the drugmaker supply chain. “Ultimately, it's the manufacturer that would need to fix whatever problem there is,” Jensen said. “But if outside groups were able to work with the companies or search out companies that have a great track record, that would prevent shortages.”

Adam Rubenfire

Adam Rubenfire covers breaking healthcare news and supply chain for Modern Healthcare. His beat responsibilities include capital equipment, group purchasing organizations, food service and general medical supplies. His work has appeared in the Wall Street Journal, Automotive News and Crain's Detroit Business. He has a bachelor's degree in organizational studies from the University of Michigan. He joined Modern Healthcare in 2014.

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