

Creating a strategy to reduce
the impact of drug shortages



Aligning with a GPO can help non-acute providers guard against operating without critical pharmaceuticals

Drug shortages are not a new problem. They have been occurring for many years. However, what used to be rare is becoming more commonplace as economics and regulation pressure pharmaceutical manufacturers. Exacerbating the problem is the increased competition for drugs among acute and non-acute health care organizations. Ambulatory surgery centers, physician practices, home health agencies, infusion centers, free-standing urgent care and emergency care centers and others find themselves at the mercy of suppliers and distributors that are often faced with the inability to ramp up production of certain drugs. So how does a non-acute provider hedge its bets and protect its patients and its bottom line from the negative impacts of drug shortages? For many, the answer has been their GPO partner.



How bad is the problem?

As consumers and health care providers are well aware, pharmaceuticals are big business. Billions of dollars are at stake each year as new drugs are introduced and patents expire on popular and profitable name-brand drugs.

The prescription drug and vaccine market is characterized by sporadic shortages of individual drugs and occasional periods during which many drugs in a class are in shortage, according to an October 2011 ASPE report issued by the Office of the Assistant Secretary for Planning and Evaluation of the Office of Science and Data Policy of the U.S. Department of Health and Human Services (HHS).

The Food and Drug Administration (FDA) reports that in 2010 there were 178 drug shortages recorded at the agency. At the time of the report from HHS through today, shortages have been concentrated in the area of sterile injectable drugs, 132 of which were in short supply in October 2011. The FDA continued to see shortages in 2011, especially those involving older sterile injectable drugs, including cancer drugs, anesthetics for surgery, drugs for emergency medicine and electrolytes for intravenous feeding.

The HHS study reported that drug shortages have had significant impacts on health care providers and patients. In June 2011, the American Society of Health-System Pharmacists (ASHP) and the American Hospital Association (AHA) released drug shortage surveys. ASHP surveyed 353 directors of pharmacy in U.S. hospitals and estimated that annual labor costs to manage shortages are approximately \$216 million nationwide. AHA found that almost 100 percent of 820 hospitals surveyed had experienced at least one drug shortage in the past six months and nearly half experienced 21 or more shortages in this period.

These shortages occurred over all treatment categories with the most acute shortages effecting surgery/anesthesia, emergency care, cardiovascular, gastrointestinal/nutrition, pain management and infectious diseases. Even more troubling, 82% of survey respondents reported that drug shortages resulted in treatment delays, 69% said patients received less effective drugs, 63% reported that patients didn't receive the recommended treatment and 35% said that patients experienced an adverse outcome.

In November 2010, the Institute for Safe Medication Practices presented results of a July–September 2010 survey of 1,800 health care practitioners, 68% of which were pharmacists. A majority reported problems with drug shortages, including the use of less desirable, often more expensive alternatives, and the potential for medication errors and poor patient outcomes.

The FDA works closely with industry, health care providers and patients to prevent and mitigate shortages of “medically necessary” medicines – those the Drug Shortage Program at FDA considers to be used to treat or prevent a serious disease or medical condition for which there is no alternative medicine available in adequate supply.

Two recent positive developments offer promising progress on the drug shortage front. The Generic Pharmaceutical Association has adopted the Accelerated Recovery Initiative approved by the Federal Trade Commission. The initiative is designed to resolve drug shortages by providing the FDA with information that will enable its staff to more efficiently and effectively accelerate the recovery of critical drugs in short supply by compiling competitively sensitive production information for manufacturers. Also, the pharmaceutical industry's positive response to the FDA's request to voluntarily provide early notification of potential supply disruptions has enabled the agency to prevent 128 possible drug shortages over a six-month period.

Why do drug shortages occur?

According to the FDA, there are many reasons for drug shortages. Perhaps most troubling is the fact that nearly half of the shortages reported in 2011 were caused by quality issues such as bacterial and mold contamination; glass, metal and fibers in vials; crystallization of the active ingredient; precipitate formation due to reaction with raw materials or containers; new impurities or degradants; equipment breakdown; and natural disasters. Nearly 20% of the shortages resulted from delays or capacity issues at the manufacturing level. Other causes identified included component problems, discontinuation of the drug, increased demand and loss of manufacturing site and raw materials.

Data collected by the FDA indicated that seven manufacturers dominated drug manufacturing. Production lines operate 24/7, often producing multiple products, leaving no leeway for problems that may arise. When problems do occur, there is no simple fix because of the complex nature of the manufacturing process. Finally, the FDA determined that one of the underlying reasons for drug shortages was a matter of economics. Was it costing more to produce the drug than it could be sold for, or was a lucrative patent set to expire, substantially reducing the drug's profitability?

What actions are health care providers taking?

Non-acute care providers can take cues from acute care organizations when it comes to anticipating and minimizing the impact of drug shortages. According to the AHA survey, some of the actions these organizations are taking include:

- Closely tracking inventory and moving stock
- Changing dispensing practices (using different dose form, compounding from a multi-dose vial instead of ready-to-use systems)
- Allocating supplies/rationing resources to those in greatest need
- Identifying and implementing alternative therapies
- Adding back-up inventory for critically necessary drug categories
- Establishing contracts with new suppliers to secure back-up sources of drugs.



The October 2011 ASPE report points out that most sterile injectable drugs, a drug class that has recently been in the shortest supply, are not purchased directly by consumers or reimbursed directly by insurance. Rather, these drugs are purchased by health care providers, generally hospitals and physician practices. But most hospitals don't purchase sterile injectable oncology drugs directly, either. These drugs are purchased through GPOs, which negotiate prices with generic manufacturers on behalf of their clients.

"Provista's and Novation's goal is to take proactive steps to help solve a critical problem facing health care providers and patients by increasing the overall availability of drugs vulnerable to shortage," explains Mitch Steiner, vice president of specialty pharmacy programs, Provista. "We are successfully advancing this strategy, and we will continue to update members throughout the year."

How GPOs can help your organization deal with drug shortages

Provista and its contracting company, Novation, have supported members' needs in the area of pharmaceutical availability thanks to an innovative, industry-leading pharmacy program. The first-in-the-industry contracting initiative proactively encourages the production of lifesaving drugs. Novation's willingness to provide financial assurances to drug manufacturers on behalf of Provista's members has encouraged increased production of critical and historically unavailable drugs. Provista, via Novation, is providing incentives for manufacturers to make more pharmaceutical product available for the entire health care industry. This is an example of the bold moves Provista is making to support and protect its members' drug supplies.

"No single entity is solely responsible for the functioning of the pharmaceutical supply chain," says Mitch Steiner, Provista's vice president of specialty pharmacy programs. "We firmly believe these drug shortages can best be addressed through collaborative efforts of all sectors of the supply chain, such as manufacturers, wholesalers, distributors, group purchasing organizations and the U.S. Food and Drug Administration. All must participate in improving our current circumstances."

Novation is working on behalf of Provista members to negotiate agreements that provide predictable demand so drug manufacturers are able to invest and allocate their resources in the most effective ways. Injecting a high degree of certainty into an equation predicated on uncertainty is already paying off with drug manufacturers beginning to increase production of several drug lines classified as being in short supply. Some are available immediately, while others will be available on a rolling basis over the next several months.

The Novation pharmacy contracts available to Provista members are offered under the NOVAPLUS® label, so members receive extra insulation in the event of future supply disruptions. Provista's and Novation's strategy is improving the inventory situation on these drugs for all providers, creating capacity as opposed to sequestering capacity.

Provista has the solutions to your drug shortage challenges.

In addition to offering innovative contracting strategies to combat potential drug shortages, Provista offers drug shortage alerts and product availability updates on a regular basis.

To learn more about Provista's pharmacy program,
contact Provista Customer Service at (888) 538-4662
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