

Group Purchasing Organizations (GPOs) Work to Maintain Access to Product Supply for America's Health Care Providers

**A publication of the Healthcare Supply Chain Association (HSCA) with research
and compilation of findings by Avalere Health**

Executive Summary

The prescription drug market has been plagued by an increase in drug shortages over the past five years.¹ Class-wide shortages, particularly for oncology products, have triggered concerns that some patients may not have access to life-saving prescription medicine. Consequently, treatment may be delayed or a more expensive therapeutic substitute may be used that may be less clinically effective, thus compromising patient care.

The nationally recognized University of Utah Drug Information Service (DIS) that tracks drug shortages reported 267 shortages as of the end of 2011, surpassing 2010's total of 211. Many of the drugs in short supply are generic sterile injectables used for cancer, emergency medicine, anesthesia, and electrolyte replacements.² A 2011 survey by the American Society of Health-System Pharmacists (ASHP) and the American Hospital Association (AHA) reported that nearly all of the 820 hospitals surveyed experienced at least one shortage over the past six months and almost half reported 21 or more drugs in short supply.³ Shortages cost U.S. hospitals an estimated \$200 million annually through the purchase of more expensive generic or therapeutic substitutes.⁴

Group purchasing organizations (GPOs) play a vital role in assisting hospitals to limit the impact of drug shortages and to ensure the least possible disruption to patient care by prompt and safe migration to alternative products, where possible. Specifically, GPOs track data on drug shortages to stay abreast of the topic, strategize with their members when there is a potential for drug supply disruption, and communicate with manufacturers and distributors to foresee any problems. Moreover, GPOs help their members lessen the exposure to drug shortages by evaluating manufacturer's reliability when sourcing and awarding contracts and in assisting them to establish best practice purchasing procedures.

The GPO industry supports the recent regulatory and legislative activities aimed at solving the drug shortage problems. As an industry, we are committed to mitigating this public health crisis. Collectively, we have identified several areas where GPOs can play an important role in helping to mitigate the patient access issues inherent in the drug shortage crisis.

¹ Assistant Secretary for Planning and Evaluation, Office of Science Policy, U.S. Department of Health and Human Services. "Economic Analysis of the Causes of Drug Shortages." October 2011.

² FDA. "Drug Safety and Availability: Drug Shortages." <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm> (accessed Nov 4, 2011).

³ Kaakeh R, Sweet BV, Reilly C, Bush C, DeLoach S, Higgins B, Clark AM, Stevenson J. Impact of drug shortages on U.S. health systems. *American Journal of Health-System Pharmacy*. 2011;68:e13-e21.

http://www.ajhp.org/site/DrugShortages.pdf?fm_preview=1

⁴ "Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis," March 2011.

- 1) The GPO industry is committed to working with manufacturers to ensure appropriate supply of products and encourage the distributors to provide a pedigree of products to providers.
- 2) The GPO industry is committed to working with our supplier partners to communicate product demands from our provider members. By communicating this information to manufacturers in a timely fashion, manufacturers should have more advance notice about demand to assist in planning for production capacity.
- 3) The GPO industry is committed to alerting our members of potential access issues. Modes of communication include webinars, conferences, newsletters and electronic alerts as issues warrant.

In addition to our market-based efforts, we call on all relevant stakeholders to work with us to address the drug shortage crisis. The GPO industry has identified specific recommendations that aim to reduce drug shortages through the following means:

Improving the Food and Drug Administration's (FDA) approval and regulatory processes

- Require collaboration between the FDA Center for Drug Evaluation Research (CDER) and the Drug Enforcement Agency to increase manufacturing production quotas related to controlled substances during drug shortages
- Maintain the appropriate resources necessary to ensure timely responses to market entry and production issues
- Institute an accelerated approval process for new sources of supply or manufacturing for items listed as being in short supply
- Improve FDA regulatory violation process

Adopting early notification systems and public communication

- Provide GPOs with early, advanced warning of potential drug shortages and/or notable increases in product demand
- Enact proposed legislation to mandate early warning of drug discontinuation or shortages by manufacturers
- Strengthen current FDA six-month notification rule
- Develop a broader definition of how the FDA defines "medically-necessary" drugs
- Improve FDA website to enhance communication
- Establish protocols for the allocation and release of products that are either anticipated to be or unexpectedly in shortage by their manufacturer and their authorized distributors to minimize speculative purchasing and hoarding of lifesaving and critical care products.
- Improve FDA regulatory violation process

Current State of the U.S. Prescription Drug Shortages

The prescription drug market has been plagued by an increase in drug shortages over the past five years.⁵ Therapeutic class-wide shortages, particularly for oncology products, have triggered concerns that some patients may not have access to life-saving prescription medicine. Consequently, treatment may be delayed or a more expensive therapeutic substitute may be used that may be less clinically effective, thus compromising patient care.

The Food and Drug Administration (FDA) currently tracks drug shortages through the Drug Shortage Program (DSP).⁶ The number of drug shortages recognized by the FDA has steadily increased since 2006 when 56 drugs were in short supply. In 2010, the FDA reported 178 drug shortages. The DSP drug shortage list is not fully comprehensive, so the FDA is likely to be underestimating the true magnitude of the drug shortage problem. The DSP drug shortage list primarily tracks shortages of medically necessary products and relies on the information provided voluntarily by manufacturers and distributors. The nationally recognized University of Utah Drug Information Service (DIS) that tracks drug shortages reported 267 as of the end of 2011, surpassing 2010's total of 211. Many of the drugs in short supply are generic sterile injectables used for cancer, emergency medicine, anesthesia, and electrolyte replacements.⁷

⁵ Assistant Secretary for Planning and Evaluation, Office of Science Policy, U.S. Department of Health and Human Services. "Economic Analysis of the Causes of Drug Shortages." October 2011.

⁶ FDA defines a shortage as any time the total supply of all clinically interchangeable versions of a drug are inadequate to meet the current or projected demand.

⁷ FDA. "Drug Safety and Availability: Drug Shortages." <http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm> (accessed Nov 4, 2011).

In 2011 the American Society of Health-System Pharmacists (ASHP) and the American Hospital Association (AHA) conducted a survey to determine the depth and effect of current shortages and reported that nearly all of the 820 hospitals surveyed experienced at least one shortage over the past six months and almost half reported 21 or more drugs in short supply.⁸ Shortages cost U.S. hospitals an estimated \$200 million annually through the purchase of more expensive generic or therapeutic substitutes.⁹ The ASHP estimates that annual labor expenses to manage drug shortages cost approximately \$216 million nationwide.¹⁰ The Institute for Safe Medication Practices (ISMP) reported that a majority of 1,800 healthcare practitioners they surveyed in late 2010 indicated problems related to drug shortages, and 35 percent of the healthcare practitioners reported an error in connection with the drug shortage, which could have led to patient harm.¹¹

Potential Causes of the Drug Shortages

Drug shortages are indicative of many different complex issues including regulatory shortcomings, quality issues, and shortages of raw materials as well as economic limitations in the drug market.

The FDA protects the manufacturing integrity of products through the Current Good Manufacturing Processes (cGMPs), which are applied to all firms that manufacture and store pharmaceuticals in the United States. The cGMPs are enforced via routine inspections and compliance issues discovered often may result in temporary closures of facilities. This interruption in production can cause long-term shortages as other manufacturing facilities or manufacturers are unable to increase supply to meet existing demand. In fact, 54 percent of the current shortages of sterile injectable drugs are linked to serious quality problems from some of the largest manufacturers.¹²

Contributing to this problem is that only a few manufacturers supply a given product.¹³ For instance, generic manufacturers produce approximately half of all sterile injectable oncology drugs in the US; a large portion of this market is comprised of only seven generic manufacturers. When a supplier experiences a manufacturing problem or discontinues production, other manufacturers are not always able to compensate with additional supply and this creates a ripple effect on the entire delivery system.

⁸ Kaakeh R, Sweet BV, Reilly C, Bush C, DeLoach S, Higgins B, Clark AM, Stevenson J. Impact of drug shortages on U.S. health systems. *American Journal of Health-System Pharmacy*. 2011;68:e13-e21.

http://www.ajhp.org/site/DrugShortages.pdf?fm_preview=1

⁹ "Navigating Drug Shortages in American Healthcare: A Premier Healthcare Alliance Analysis," March 2011.

¹⁰ Ibid.

¹¹ Institute for Safe Medication Practices. "National Survey on Drug Shortages Reveal Serious Impact on Patient Safety." September 2010. <http://www.ismp.org/pressroom/PR20100923.pdf>

¹² Assistant Secretary for Planning and Evaluation, HHS. "Economic Analysis of the Causes of Drug Shortages." October 2011.

¹³ IMS Institute for Healthcare Informatics. "Drug Shortages: A Closer Look at Products, Suppliers and Volume Volatility," November 2011.

In general, shortages and surpluses in markets can be avoided when product prices are able to adapt to changes in supply and demand. Shortages are more common in markets where pricing does not respond quickly enough to changes. In fact, the Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) partially attributes the current drug shortage to the limitations in the prescription drug market. According to its recent report, price responsiveness for prescription drugs is low in the short and long run.¹⁴ ASPE also suggests that it can take years for manufacturers to increase their current capacity to keep pace with demand, and they are unable to easily adapt the volumes they produce to account for an increase in demand. It is worth noting that GPO contracts, rather than adding complexity to this equation, provide hospitals and other health care providers with the certainty required to fulfill their business planning requirements in order to deliver clinical services to patients. These same contracts also offer an appropriate amount of flexibility that allows for changes to be made when necessary including adjustments to pricing provisions to reflect market conditions.

Prescription Drug Supply Chain

Sterile injectables are a relatively small portion of the prescription drug market, but this class of drugs accounted for 74 percent of all shortages in 2010.¹⁵ In general, sterile injectables are purchased by hospitals and physician offices that administer the injection and then receive payment from the payer for both the drug and the administration of the drug.

GPOs are similar to cooperatives in that they leverage the collective purchasing power of health care providers to negotiate discounts with manufacturers, distributors and other vendors for an array of medical supplies, capital equipment, and service contracts. A manufacturer receives economies of scale in return for their collaborative efforts with GPOs. By representing purchasing needs of their members and clients, GPOs are situated on the demand side of the drug supply chain but never take actual possession of the product. Nearly every U.S. hospital utilizes a GPO to realize savings and supply chain efficiencies and many belong to multiple GPOs.¹⁶ In most cases, hospitals and health systems purchase drugs through wholesalers based upon the price negotiated by the GPO.

¹⁴ Assistant Secretary for Planning and Evaluation, HHS. "Economic Analysis of the Causes of Drug Shortages." October 2011.

¹⁵ Assistant Secretary for Planning and Evaluation, Office of Science Policy, U.S. Department of Health and Human Services. "Economic Analysis of the Causes of Drug Shortages." October 2011.

¹⁶ Healthcare Supply Chain Association. *A Primer on Group Purchasing Organizations*, http://www.supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf (accessed November 2, 2011).

The GPO mission is to contract for those products and services, including drugs, that are essential to the operation of hospitals and other health care facilities. Through these contract negotiations, GPOs work to obtain the best value for their members and clients including the lowest possible price for a reliable and safe supply of goods and services. Hospitals use GPO-contracted prices voluntarily—each drug purchase is ultimately made by the hospital or health care provider. As a result, they have the ability to pick and choose among multiple options when purchasing these drugs. GPOs negotiate with some of the largest and most sophisticated international companies in the world, firms that routinely satisfy shareholder expectations by demonstrating their ability to successfully navigate within the marketplace and earn a return on investment.

GPOs offer providers supply chain efficiencies and cost savings

GPOs serve as a trusted partner to hospitals and other health care providers by negotiating contracts that they can use when purchasing essential supplies. Negotiated prices in GPO contracts are between extremely knowledgeable parties and are highly dynamic in that manufacturers are able to adjust pricing based on normal market conditions, such as manufacturing capacity, raw material availability, and competitive suppliers.¹⁷ GPOs manage thousands of price adjustments annually. While GPOs are naturally concerned about the need to control health care costs and strive to negotiate the best price possible for hospitals and other health care providers their first and foremost priority is to find and contract for the supplies themselves at a reasonable price.

When purchasing through GPO contracts, providers can yield savings of 10 to 15 percent compared to purchasing on their own in the supply chain market.¹⁸ GPOs do not purchase or take ownership of products; rather they develop and negotiate competitive contract pricing. Importantly, a wholesaler/distributor, who maintains the pedigree of a product, takes ownership of the medical products and then sells the drugs to the GPO members at the GPO negotiated price.

¹⁷ Typically, GPO contracts with suppliers contain clauses that allow for the termination of the agreement with proper notice. For example, contracts may state the following: “either Party may terminate this Agreement at any time for any reason whatsoever by delivering not less than ninety (90) days’ prior written notice thereof to the other Party”.

¹⁸Healthcare Supply Chain Association. *A Primer on Group Purchasing Organizations*, http://www.supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf (accessed November 2, 2011).

GPOs often have multi-year contracts with manufacturers to secure the best prices and availability for hospitals. The manufacturers then use this commitment of volume to forecast manufacturing quantities. “Failure to supply” clauses are also common in the arrangements between suppliers and GPOs. A failure to supply clause is designed to ensure that a supplier will honor its contract to provide a given drug at a given price. Should a hospital need to purchase product from another supplier at a higher price because the contracted supplier is unable to honor its obligations, the GPO contract's failure to supply language is used to ensure that the hospital is made whole. These clauses require the contracted supplier to reimburse the hospital for the additional cost it incurred obtaining the product from another supplier. However, this clause only applies when an alternate source is available. And, unfortunately, it does not ensure product availability.

The HHS has suggested that GPOs might develop failure to supply contract language that would apply to all drugs in shortage, whether available from another source or not. This is, of course, a worthwhile aspiration. Given, however, the current market conditions in which many drugs are simply not available from any source, such voluntary provisions would become less, not more viable in contract negotiations. GPOs negotiate strenuously to include failure to supply clauses that will protect the hospitals and health systems they serve but these clauses are often met with resistance. It is highly unlikely manufacturers would agree to clauses that contain additional penalties in the event the drug is unavailable even from another source.

GPOs offer value-added services

In addition to providing reduced prices for medical supplies, GPOs serve as a strategic advisor to their members. To assist providers in managing the complex system of purchasing, many GPOs offer e-commerce solutions. These platforms help providers streamline purchasing and reduce administrative overhead by using a web-based product ordering system. Additionally, some GPOs assist providers in reducing medical errors by helping to standardize product use in hospitals and to educate clinicians on best practices.¹⁹ GPOs often offer benchmarking data services for staffing, inventory controls and other programs by working directly with their provider members to identify opportunities for cost savings and to identify processes for measuring outcomes. In turn, this helps hospitals improve patient capacity and health outcomes. Other services GPOs offer include continuing medical education, materials management outsourcing, and market research.

¹⁹Healthcare Supply Chain Association. *A Primer on Group Purchasing Organizations*, http://www.supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf (accessed November 2, 2011).

GPOs Role in Alleviating Drug Shortage Issues for Provider Members

The GPOs sit at the critical nexus in the drug supply chain—a position that allows them to objectively partner with and seamlessly integrate all of the affected parties to limit the impact of a shortage of vital medications for patients. This role is particularly important at this critical time when GPOs can help ameliorate the impact of the drug shortage crisis.

GPOs track data on drug shortages to stay current and alert their members of any potential for drug supply disruptions. For example, since 2001, one GPO²⁰ has funded the drug shortage tracking database of the Drug Information Service (DIS) at the University of Utah, one of the most comprehensive drug shortage tracking databases in the country. The DIS researches and investigates drug shortages and shares their findings with the American Society of Health-System Pharmacists (ASHP), which in turn publishes drug shortage alerts on its website for all health care providers to view.

Further, GPOs are involved in tracking drug shortage developments by communicating with manufacturers and distributors to foreshadow any problems with the drug supply. GPOs recognize that while they face competition from wholesalers in terms of drug pricing contracts, their mutual relationship and collaboration are critical in light of the drug shortage problem. The contracting strategies implemented by some GPOs help strengthen communication on shortages with manufacturers. For instance, the contract may be crafted to require prompt GPO notification of supply problems and , as previously noted, may include strong “failure to supply” clauses.

GPOs help their members lessen the exposure to drug shortages by sourcing and selecting the most reliable manufacturers (and, at times, awarding alternate manufacturers) when awarding contracts. The manufacturer’s reliability is evaluated based on their past performance on drug supply. This is especially important for hospitals with single-source contracts where all of the specific drug supply is purchased from one manufacturer. In those instances, even a small disruption in supply can have an adverse impact on the hospital’s ability to provide patients with necessary drugs.

Finally, hospitals benefit tremendously from GPOs’ analytical capabilities that include utilization reports by drug category and generic substitution opportunity analysis. These reporting tools can help hospitals prepare for and address drug shortages once they occur.

²⁰ Novation

Identifying Solutions to the Drug Shortage Dilemma

Multiple stakeholders within the healthcare policy community are working to find solutions to the drug shortage dilemma. President Obama issued an Executive Order on October 31, 2011 that directs the FDA and the Department of Justice to take specific steps to mitigate the current drug shortages, prevent future shortages, and protect patients from price gouging.²¹ Members of the U.S. Senate have formed a bi-partisan working group to address the current problem. The group called for a Senate Health Education Labor Pensions (HELP) Committee hearing and for a briefing from HHS. In 2011, two members of the bi-partisan working group introduced legislation that would require prescription drug manufacturers to give early notification to the FDA of any incident likely to result in interruptions in supply or product discontinuations.²² A similar measure has been proposed in the U.S. House of Representatives.²³ Additionally, an ongoing investigation on prescription drug price gouging is being conducted by the House Committee on Oversight and Government Reform.²⁴

The FDA is working to improve its internal processes to increase its effectiveness in preventing and mitigating drug shortages. The agency has recently conducted a review of its medical product shortage activities and developed an action plan that includes hiring additional staff.²⁵ This FDA working group has also issued a statement reminding manufacturers of their responsibilities under current regulation to notify FDA in advance of the potential for a shortage.

The GPO industry supports the recent regulatory and legislative activities aimed at solving the drug shortage issue. HSCA is currently working with the FDA, the White House and congressional members to identify multifaceted solutions to the drug shortage problem. HSCA also applauds the Generic Pharmaceutical Association (GPhA) for their recently proposed innovative and constructive private sector solution through the Accelerated Recovery Initiative (ARI).²⁶ ARI brings all health care supply chain stakeholders together through a third-party entity. This independent entity will gather current and future product supply information; use the information to identify existing and potential supply gaps, focusing on products with an expected shortage time of longer than 90 days; and involve a high-level "SWAT" team within the FDA to quickly respond to shortages. The HSCA looks forward to working with GPhA on this interesting proposal.

²¹ Executive Order - Reducing Prescription Drug Shortages, <http://m.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages>

²² S. 296: The Preserving Access to Life-Saving Medications Act, <http://www.gpo.gov/fdsys/pkg/BILLS-112s296is/pdf/BILLS-112s296is.pdf>

²³ H.R. 2245: Preserving Access to Life-Saving Medications Act of 2011, <http://www.govtrack.us/congress/bill.xpd?bill=h112-2245&tab=summary>

²⁴ http://democrats.oversight.house.gov/index.php?option=com_content&view=article&id=5445&Itemid=107

²⁵ A Review of FDA's Approach to Medical Product Shortages, FDA, October 31, 2011
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM277755.pdf>

²⁶ <http://www.supplychainassociation.org/news/79430/HSCA-Commends-Generic-Pharma-Association-for-Innovative-Proposed-Solution-to-Critical-Drug-Shortages.htm>

GPOs are Committed to Mitigating Drug Shortages

As an industry, HSCA's members are committed to mitigating this public health crisis. Collectively, we have identified several areas where GPOs can play an important role in helping to mitigate the patient access issues inherent in the drug shortage crisis.

- 1) The GPO industry is committed to working with manufacturers to ensure appropriate supply of products and encourage distributors to provide a pedigree of products to providers.
- 2) The GPO industry is committed to working with our supplier partners to communicate product demands from our provider members. By communicating this information to manufacturers in a timely fashion, manufacturers should have more advance notice about demand to assist in planning for production capacity.
- 3) The GPO industry is committed to alerting our members of potential access issues. Modes of communication include webinars, conferences, newsletters and electronic alerts as issues warrant.

In addition to our market-based efforts, we call on all relevant stakeholders to support our charge to address the drug shortage crisis. HSCA members are committed to partnering with all members of the distribution chain to find proactive, novel, and flexible means to ensure patients receive their critical medications. Finding solutions to the interconnected issues at play to prevent drug shortages will require coordination from all levels of the supply chain including FDA, manufacturers, and health care providers. HSCA has identified specific recommendations that aim to mitigate drug shortages by improving the FDA's approval processes; adopting early notification systems and public communication; and, implementing market and operational efficiencies.

Responsible Party	Recommendation
Improving the FDA Approval Processes	
Federal Government	<p>Require collaboration between FDA, DEA and the Attorney General to increase manufacturing production quotas during drug shortages. Regulations involving manufacturing quotas of controlled substances limit the ability of the FDA and manufacturers to address drug shortages in an expedited manner. Require collaboration between the Drug Enforcement Agency and the Attorney General to establish a process that would streamline manufacturing production quotas in response to drug shortages of controlled substances. The multiple government departments responsible for controlled substances should be required to regularly communicate on how their actions may affect the supply of medically necessary drugs.</p>
Federal Government	<p>Maintain the appropriate resources necessary to ensure timely responses to market entry and production issues: On October 31, 2011, an Executive Order was signed increasing the number of full-time employees at the FDA from 4 to 11 in the Drug Shortage Program. An additional 25 people deployed from other departments now work on shortages at any given time.</p>
Federal Government	<p>Institute an accelerated approval process for new sources of supply or manufacturing for items listed as being in short supply: Implement an abbreviated approval process to speed up production of therapeutic equivalent products that are in short supply.</p>
Adopting Early Notification System and Public Communication	
Manufacturers	<p>Provide GPOs with early, advanced warning: Manufacturer notification to GPOs can assist the GPO and member facilities in the preparation of a drug shortage. With early warning, alternative policies, procedures, and/or order sets and physician education can occur, helping facilities better prepare to withstand a drug shortage. Early warnings will allow the GPO to assist members by providing guidance documents to membership regarding the length and severity of the shortage, and provide membership with alternative therapies or other mitigation strategies.</p>
Federal Government	<p>Enact proposed legislation to mandate early warning of drug discontinuation or shortages: Congress is currently reviewing the H.R. 2245 bill, "The Preserving Access to Life-Saving Medications Act," which expands FDA's authority so that the agency has the tools to help minimize the impact of drug shortages on patient care. Organized support in the form of lobbying and letter writing will help with bill passage. Reinforcement of ASHP's effort should be made, and all pharmacies should be encouraged to use the ASHP's online advocacy tools to contact representatives.</p>
Federal Government	<p>Strengthen current FDA six-month rule: Current FDA rules recommend a six month advance notification when the manufacturer plans to discontinue a critical drug. FDA's lack of regulatory authority to notify the public of drug shortages in advance leaves many providers and patients ill-informed of supply problems. Require manufacturers to provide the FDA and the Drug Enforcement Agency notification either: (1) six months prior to a discontinuation or interruption in the manufacture of a medically necessary drug or, (2) as soon as practicable after the manufacturer becomes aware of the discontinuance or interruption that may result in reduction in the total supply of the drug manufactured by the individual manufacturer, as compared to historic demand. This recommendation should be a requirement with strict monetary penalties for companies who do not give notification prior to discontinuing the medication. Current rules are not enforced, nor linked to repercussions.</p>

Responsible Party	Recommendation
All stakeholders	<p>Develop a broader definition of how FDA defines medically necessary drugs: FDA, ASHP, and other physician organizations should develop a single critical drug list. Currently many drug therapies that are in shortage are not determined by the FDA to be medically necessary. This list would determine which medications are considered critical for healthcare facilities. The drug list would consist of drugs that have limited alternatives, use in surgery or catheter labs, or treat life-threatening conditions (oncology, myocardial infarction, etc).</p>
Federal Government	<p>Improve FDA website to enhance communication: Improve the FDA CDER drug shortage website, make updates clear; highlight new material; make notifications downloadable or printable; make website alphabetically linked; provide alternative drug guidance and dosing assistance associated with drugs in short supply; provide better estimations of shortage resolution so facilities can develop their contingency strategies</p>
Federal Government	<p>Require immediate allocation of these products by the manufacturer and their authorized distributors to minimize speculative purchasing and hoarding: Require manufacturers to immediately allocate remaining products in supply and work with authorized distributors to ensure products are properly allocated and available to hospitals at reasonable prices and most importantly the integrity of products is maintained.</p>
Implementing Market and Operational Efficiencies	
Federal Government	<p>Improve FDA regulatory violation process: Various inefficiencies in the FDA regulatory review process for current good manufacturing practices (cGMP) have been exposed during this drug shortage crisis. The prolonged turnaround time in re-reviewing a site, extended delays in releasing improved products and confusing or missing guidance to assist manufacturers in returning to regular production have been identified. The FDA must standardize turnaround times, improve and standardize reviews and frequency of FDA reviews to identify problems prior to shutting down facilities.</p>