

Drug shortages 2014:
A Premier healthcare alliance update

February 2014 | Premier, Inc.

Executive summary

The U.S. continues to face drug shortages that challenge care providers to properly treat patients without incurring excessive extra costs. In February of 2014, the Food and Drug Administration (FDA) reported¹ that the number of new drug shortages from January to September 30, 2013 was at 38 – a significant decrease compared to the 117 new shortages during calendar year 2012. However, longer-standing, ongoing drug shortages remain at more than 300 drugs.

No one cause explains drug shortages. Contributing trends include quality of active pharmaceutical ingredients, drug recalls, industry consolidation, quality control issues at manufacturing plants, lack of manufacturing line capacity and just-in-time inventories. Regulatory and financial pressures further compound the problem.

Drug shortages have been associated with delays or cancellations of necessary medical procedures; added risk of patient care errors and adverse events; and increased costs for providers through the substitution of more expensive therapeutic alternatives.

To obtain more information about the magnitude of current drug shortages and the experiences of hospitals in dealing with them, Premier, Inc. recently surveyed its member pharmacy experts. This survey updates research conducted at the height of the drug shortage crisis in 2010 and published in 2011, which served as one of the first to document the seriousness of the drug shortage problem. According to survey respondents, in the last six months:

Drugs in shortage - The most common shortage drugs include:

- Electrolytes, IV fluids and parenteral nutrition solutions, which provide patients unable to take oral fluids or food with needed hydration and nutrition intravenously.
- Cardiovascular agents used to treat heart disease and other cardiac conditions (Ex: nitroglycerin IV solution), and surgical agents used for surgery preparation/anesthesia and sedation (Ex: propofol).

Patient safety impact

- Drug shortages continue to present a patient safety risk, similar to 2010.
- But the prevalence of shortages and the degree to which they affect patient care is decreasing. Twice as many respondents did not experience a shortage that could delay/cancel care, compared to 2010.

Financial impact

- Similar to the 2010 survey, shortages continue to add unnecessary expense for hospitals. Almost every respondent needed to purchase more expensive generic alternatives or more expensive products from a direct manufacturer source. Hospitals also continued to add staff to deal with shortages. This is in addition to staff added when the shortage was at its height.
- U.S. hospitals incurred an annual average of \$229.7 million in additional costs between 2011 and 2013, as they were forced to purchase more expensive generic substitutes for shortage drugs. The financial impact is likely much higher since research excludes drugs purchased from off-contract distributors or with therapeutic alternatives, as well as indirect costs such as added labor.

Results suggest providers have become more acclimated and capable of handling supply chain disruptions, implementing more effective programs to cope with long-term, ongoing shortages. However, providers continue to face challenges in managing severe supply chain “spikes” in demand, which can create shortage situations of an undetermined timeframe.

Results also show group purchasing organizations (GPOs), as agents of hospitals, are part of the solution to the drug shortage problem, working to create a competitive marketplace and ensure a continuous supply.

¹ First Annual Report on Drug Shortages for Calendar Year 2013. Margaret A. Hamburg, M.D. February 5, 2014. <http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM384892.pdf>.

Premier is committed to solving drug shortages for American patients. The alliance continues to create heightened awareness of and education around the issue, working with providers, policy makers and generic manufacturers to provide safe alternatives and distribution.

February 2014 Drug Shortage Survey

Methodology

In 2010, Premier conducted an [electronic survey](#) over a six month period (July - December 2010) of 330 pharmacy experts representing Premier alliance member hospitals (urban/rural, small/mid-sized/large) to obtain information about their experiences with drug shortages. Findings were published in a March 2011 white paper².

A similar survey was conducted over a five week period in December 2013 – January 2014. Responses were collected from 124 pharmacy experts (margin of error +/- 5.3 percent to 8.8 percent). The majority of respondents were pharmacists. Approximately 61 percent were from midsized hospitals (200 to 500 beds) and large hospitals (500 beds+) and 39 percent from small hospitals (less than 200 beds), with 69 percent from non-rural areas.

Survey results

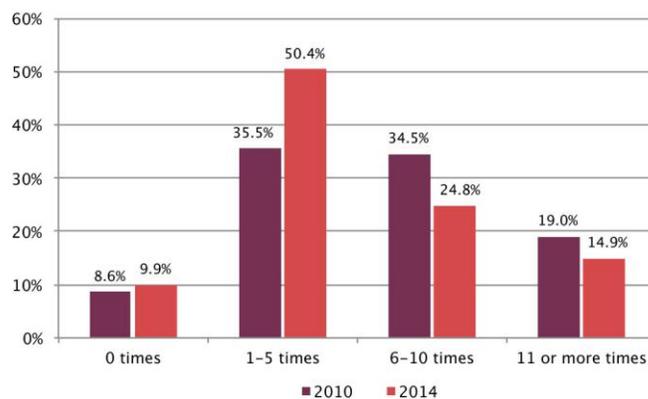
Quality/safety impact

Drug shortages may result in a delay or cancellation of necessary medical procedures, as well as increased time and expense in protecting against errors or adverse events because of the substitution of alternative medications. This is particularly an issue if prescribers are not as familiar with alternative dosing and potential interactions with other drugs.

Survey results suggest drug shortages continue to present a patient safety risk, with 90 percent of respondents experiencing at least one shortage in the last six months that may have caused a medication safety issue or error in patient care, compared to 91.4 percent in 2010 (Figure 1a).

But the prevalence of shortages that affect patient care looks to be decreasing. Compared to 2010, the percentage of respondents enduring fewer shortages (one-to-five) over the last six months increased by 30 percent (50.4 percent vs. 35.5 percent in 2010), while the percentage experiencing six or more occurrences decreased 26 percent (39.7 percent vs. 53.5 percent in 2010).

Figure 1a. Amount of drug shortages that may have caused a potential medication safety issue or error in patient care over the last six months

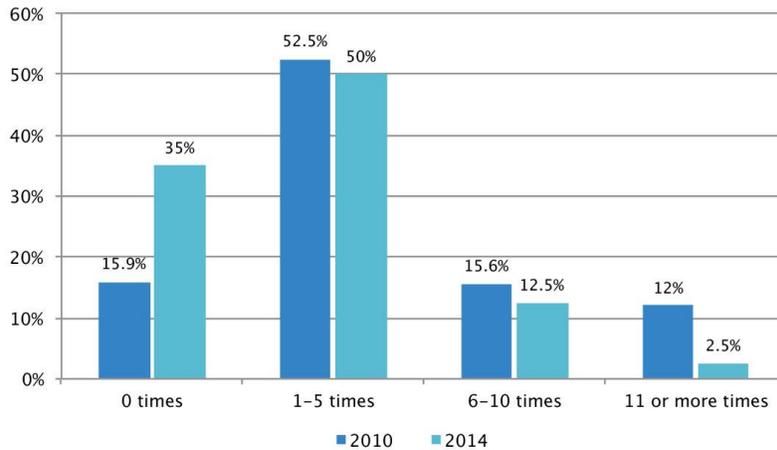


*2014 Premier Drug Shortage Survey

² Navigating Drug Shortages in American Healthcare: A Premier healthcare alliance analysis. C. Cherici, MBA, RPh; J. Frazier, PharmD; M. Feldman, MS, RPh; B. Gordon, PharmD; C. Petrykiw, PharmD CDE; W. Russell, PharmD, FASHP; J. Souza, RPh. March 2011. www.premierinc.com/about/news/11-mar/drug-shortage-white-paper-3-28-11.pdf

In addition, fewer respondents experienced drug shortages in the last six months that delayed or canceled patient care (Figure 1b). According to respondents, 35 percent did not experience a shortage that could have delayed or cancelled care, a two-fold improvement compared to 2010 (15.9 percent). And the percentage of respondents enduring six or more occurrences decreased 45.7 percent compared to 2010 (15 percent vs. 27.6 percent).

Figure 1b. Amount of drug shortages that resulted in a delay or cancellation of a patient care intervention over the last six months

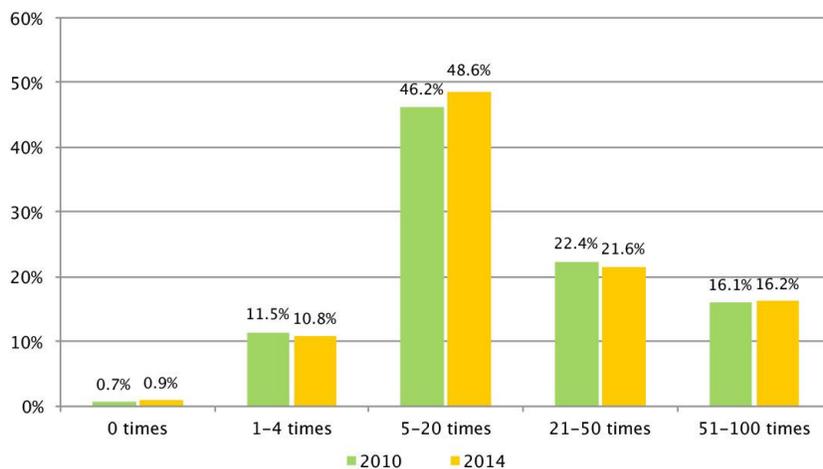


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Financial impact

Survey results suggest shortages continue to result in the incurrence of unnecessary costs to properly care for patients. Over the last six months, more than 99 percent of respondents said a shortage led to the purchase of a more expensive generic alternative, equivalent to results from 2010 (Figure 2a.).

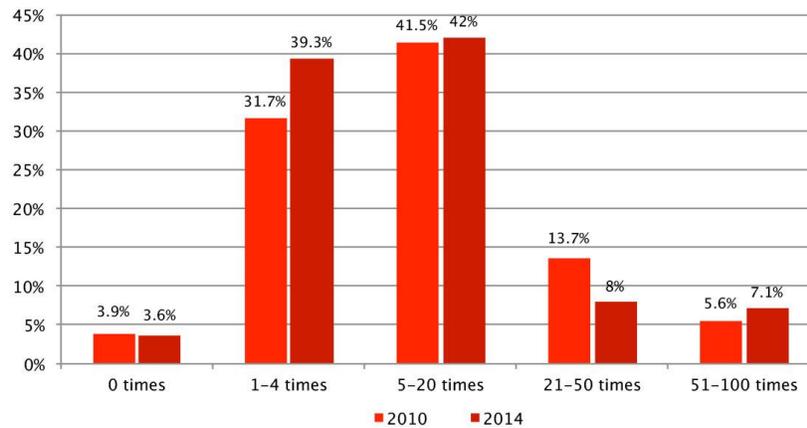
Figure 2a. Amount of drug shortages that required the purchase of a more expensive generic alternative over the last six months



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Also, 96.4 percent of respondents had to purchase a more expensive therapeutic alternative over the last six months due to a shortage, equivalent to results from 2010 (Figure 2b.).

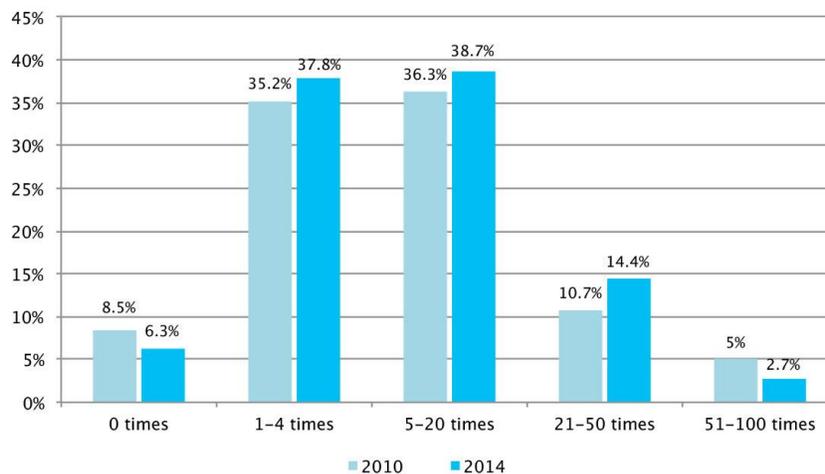
Figure 2b. Amount of drug shortages that required the purchase of a more expensive therapeutic alternative, over the last six months



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And 93.7 percent of respondents said a shortage required the purchase of a more expensive product from a direct manufacturer source over the last six months, compared to 91.5 percent in 2010 (Figure 2c.).

Figure 2c. Amount of drug shortages that required the purchase of a more expensive product from a direct manufacturer source, over the last six months



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Overall, the most often cited shorted drugs affecting patient safety and cost were:

- Electrolytes, IV fluids and parenteral nutrition solutions, which provide patients unable to take oral fluids or food with needed hydration and nutrition intravenously.
- Cardiovascular agents used to treat heart disease and other cardiac conditions (Ex: nitroglycerin IV solution), and surgical agents used for surgery preparation/anesthesia and sedation (Ex: propofol).

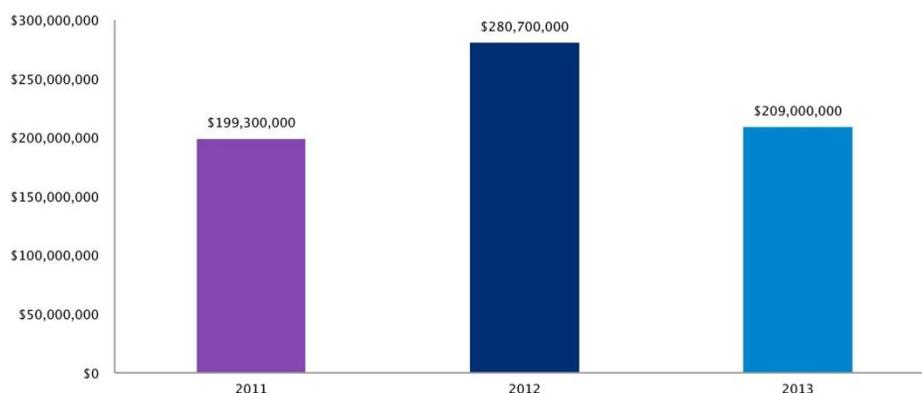
Analysis of added costs

Premier's ability to analyze the pharmaceutical supply chain data of its members enables it to provide details on the financial impact of drug shortages. Based on Premier's current membership of hospitals

and other non-acute care sites using Premier's Purchasing Partners services, the annualized financial impact of purchasing more expensive generic alternatives added an approximate average expense of \$56 million in 2011, \$77 million in 2012 and \$61 million in 2013.

From a national standpoint, the analysis* suggests that all U.S. hospitals spent approximately an additional \$199.3 million in 2011, \$280.7 million in 2012 and \$209 million in 2013 through the purchase of more expensive generic substitutes (Figure 3.). The total economic impact is likely much higher since the financial analysis excludes drugs purchased from off-contract distributors, or those with therapeutic alternatives. The research also does not include indirect costs such as added labor needed to manage shortages and secure alternative supplies.

Figure 3. Additional hospital spending on generic substitutes



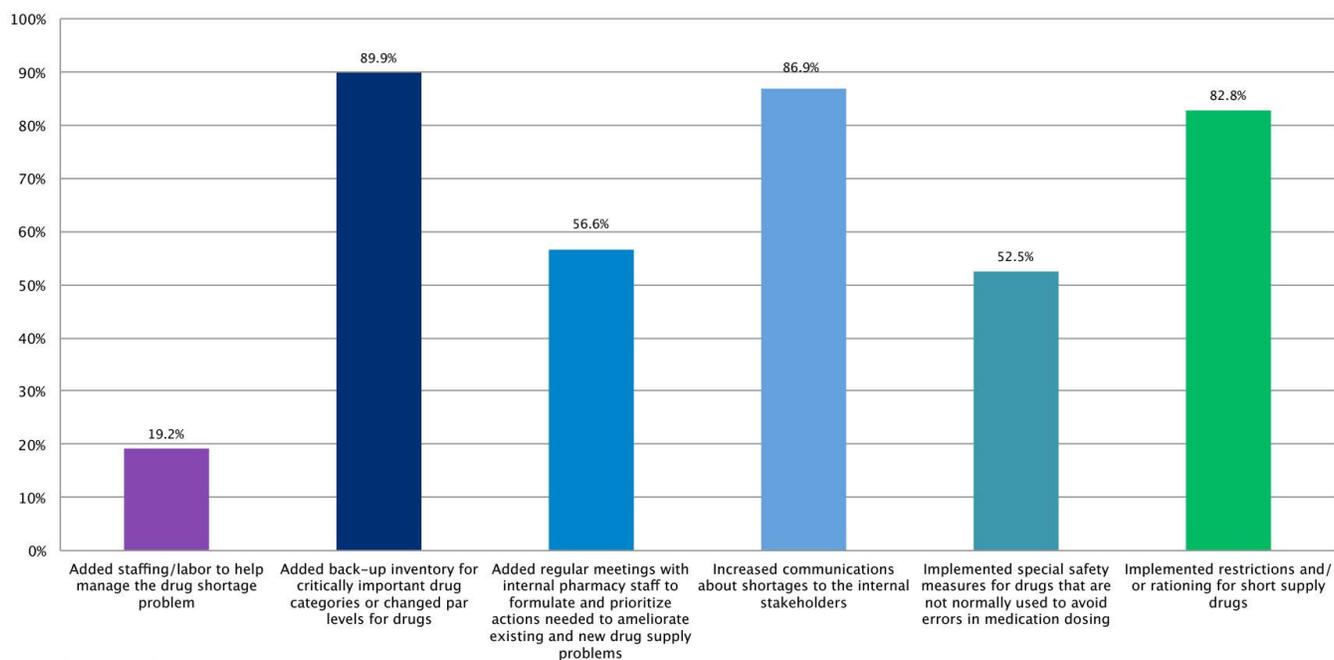
*Purchasing data supplied by Premier, Inc. to estimate additional replacement cost of on-contract back-ordered drugs versus available generic equivalent drugs. Price differential was determined by subtracting the actual cost of the generic equivalent from the actual cost of the back-ordered drug and multiplying this by the volume purchased for the hospital sample. Projected additional replacement cost was determined by dividing the total volume cost by the number of staffed beds for the hospitals in the sample and multiplying this rate by the number of staffed beds reported for US hospitals by the American Hospital Association (due to unavailability of data, staffed beds from 2012 was used for 2013). Additional replacement cost only applies to the cost differential for the hospital (lost revenue) and does not take into consideration the cost of hospital and pharmacy operations or the labor required for administration of the medication, or the cost of drugs purchased from off-contract distributors or directly from the manufacturer. The projections should thus be considered conservative.

Drug shortage strategies

Care providers have become more skilled and capable of handling supply chain disruptions, implementing more effective programs to cope with ongoing, long-term shortages. According to survey results (Figure 4a.):

- 89.9 percent added back-up inventory or adjusted par levels for critically important drug categories.
- 86.9 percent increased communications about shortages to the internal stakeholders.
- 82.8 percent implemented restrictions and/or rationing for short supply drugs.
- 56.6 percent added regular meetings with internal pharmacy staff to formulate and prioritize actions needed to ameliorate existing and new drug supply problems.
- 52.5 percent implemented special safety measures for drugs that are not normally used to avoid errors in medication dosing.
- 19.2 percent said they had to add additional staff.

Figure 4a. How providers are reducing the financial and quality impact of drug shortages (all that apply)



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However, providers continue to face challenges in managing severe supply chain “spikes” in demand, which can create shortage situations of an undetermined timeframe. To provide an example, after this survey was conducted, Premier received numerous reports of shortages for intravenous (IV) solutions, particularly saline solutions used to hydrate patients with a variety of conditions. According to the FDA, the shortage appears to have been triggered by increased and un-forecasted demand from hospitals using the solutions to treat patients with the flu³, as well as quality issues related to IV pumps.

Unlike many shortage events, which can be triggered by a manufacturer leaving the market or closing a production line and addressed with advance notice to the FDA and providers, this particular shortage was largely unpredictable. Because of this, the IV shortage created a “shock” to the healthcare system that hospitals were not prepared to handle. As a result, shortages caused by a demand spike remain an area of concern and a problem in need of more effective solutions across the supply chain.

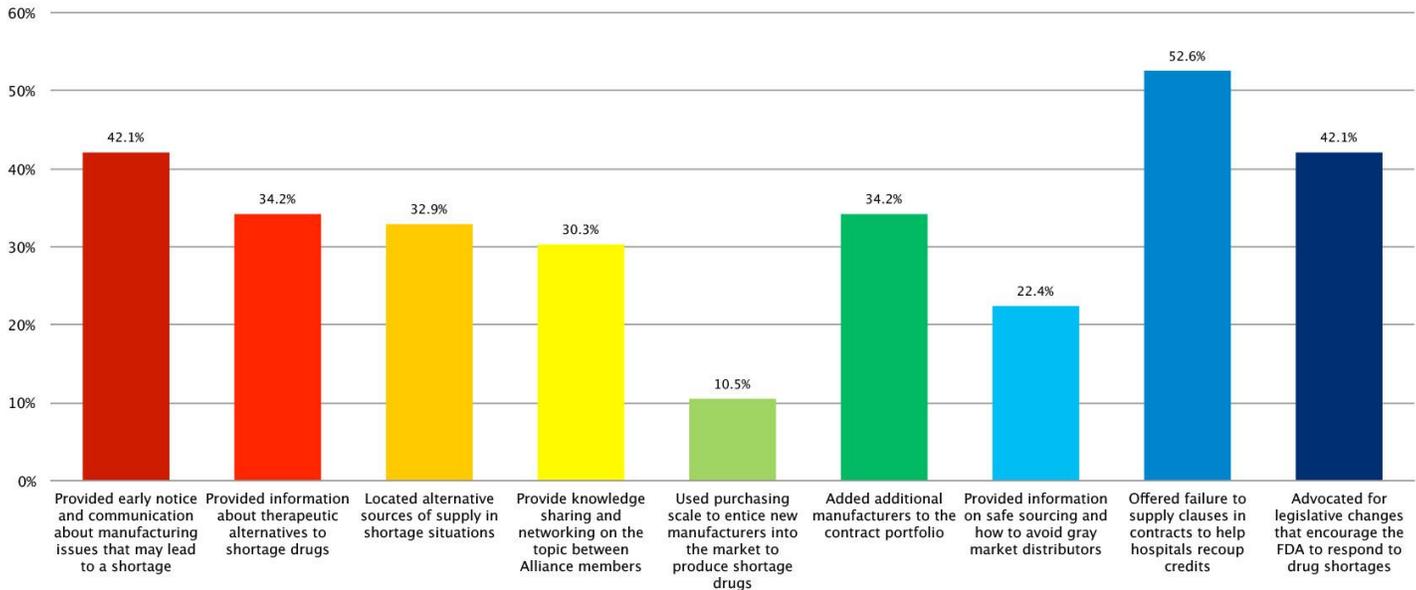
GPO's role

Members of the Premier alliance indicated that group purchasing organizations (GPOs) serve as part of the solution to the drug shortage problem. According to respondents, when asked how their GPO assisted them with managing shortages (Figure 4b):

- 52.6 percent cited failure to supply clauses in contracts to help hospitals capture monetary compensation when shortages occur and the provider has to purchase a more expensive alternate drug.
- 42.1 percent cited both advocating for legislative changes encouraging FDA to respond to drug shortages, and providing early notice/communication about manufacturing issues.
- 34.2 percent said both adding additional manufacturers to contract portfolios, and providing information about therapeutic alternatives to shortage drugs.
- 32.9 percent suggested locating alternative sources of supply in shortage situations.
- 30.3 percent cited providing knowledge sharing and networking on the topic among providers.

³ <http://www.fda.gov/drugs/drugsafety/ucm382255.htm>

Figure 4b. How GPOS are assisting providers in managing drug shortages (all that apply)



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Premier efforts

Premier is committed to providing solutions that can help solve the ongoing drug shortage problem.

The Premier alliance is continually working with providers and manufacturers through a voluntary and transparent contracting process to help prevent and mitigate the impact of drug shortages, with a focus on balancing safety with access and cost, and using market forces to encourage competition and high quality.

In addition to the programs cited by pharmacists in the survey, Premier only contracts with generic manufacturers with a strong record with FDA, thereby reducing the risk that a shortage will result due to a quality problem or unexpected recalls. Premier works with these manufacturers to provide safe alternatives, exploring private sector solutions through new agreements with a broader scope of generic drug manufacturers. This includes bringing new manufacturers into the generic injectable market, such as Heritage Pharmaceuticals Inc.⁴

Premier also:

- Contracts with multiple suppliers in each therapeutic category whenever possible to create market redundancy and reliable sources of supply.
- Provides strategies to health systems on how to stretch limited supplies.
- Works with pharmaceutical distributors to manage drugs on the shortage list through allocation programs that prevent uneven distribution across care providers.
- Offers an automated failure-to-supply program, helping hospitals easily capture millions of dollars in compensation when drug shortages occur and the provider has to purchase an alternate drug at a higher cost.

⁴ Premier healthcare alliance Reinforces Leadership Role in Reducing Drug Shortages, Creating Safer and Healthier Marketplace. Premier, Inc. August 15, 2013. <http://www.businesswire.com/news/home/20130815005792/en/Premier-healthcare-alliance-Reinforces-Leadership-Role-Reducing>

- Stresses ongoing communication through educational opportunities for:
 - Providers and clinicians, on specific drugs and therapeutic options/alternatives to drugs experiencing a shortage; contractual options if a manufacturer suddenly experiences a problem leading to shortages of a product(s) in the marketplace; possible duration of manufacturing disruption and ability to return to the market; and techniques to help stretch limited supplies.
 - Distributors, regarding specific supplies in the supply chain and allocation plans that can be shared with providers.
 - Manufacturers, regarding issues with manufacturing and demand.

Conclusion

Drug shortages can present significant risk to public health. Based on our survey findings, hospitals are using a variety of strategies to manage hundreds of persistent drug shortages. These efforts require ongoing and costly management by hospital personnel, as well as significant efforts by GPOs to help reduce and manage shortages.

While ongoing shortages remain a problem, the supply chain is also vulnerable to shortage “spikes” that significantly disrupt patient care and hospital operations. Today, hospitals are in the midst of one such “spike” related to intravenous solutions. These types of shortages remain an area of concern and a problem in need of more effective solutions across the supply chain.

Steps have been taken by lawmakers, FDA, manufacturers, hospitals and GPOs to reduce the incidence and manage drug shortages. These efforts are having a positive impact, but drug shortages continue to plague hospitals and require an ongoing urgency and commitment by all stakeholders.

About Premier, Inc.

Premier, Inc. (NASDAQ:PINC) is a leading healthcare improvement company, uniting an alliance of more than 2,900 U.S. hospitals and nearly 100,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and advisory and other services, Premier enables better care and outcomes at a lower cost. Premier, a Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, N.C., Premier is passionate about transforming American healthcare. Please visit Premier’s news and investor sites on www.premierinc.com; as well as [Twitter](#), [Facebook](#), [LinkedIn](#), [YouTube](#), [Instagram](#), [Foursquare](#) and [Premier’s blog](#) for more information about the company.