PREMIER TRANSFORMING HEALTHCARE TOGETHER®

August 31, 2022

Robert M. Califf M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Submitted electronically via www.regulations.gov

Re: Solicitation for Public Comments on Risk Management Plans to Mitigate the Potential for Drug Shortages Draft Guidance [Docket Number FDA–2022–D–0277]

Dear Dr. Califf:

The Premier healthcare alliance ("Premier") appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on the solicitation for comments on draft guidance entitled, "Risk Management Plans to Mitigate the Potential for Drug Shortages *[Docket Number FDA–2022–D–0277]*." FDA is soliciting public comment on how stakeholders can develop, maintain, and implement, as appropriate, risk management plans (RMPs) to proactively assist in the prevention of drug and biological product shortages.

As a leader in addressing drug shortages for almost twenty years, Premier is pleased to see FDA move forward with implementing provisions from the Coronavirus Aid, Relief, and Economic Security (CARES) Act that Premier played a significant role in passing in March 2020. Premier's comments on the draft guidance focus on three major areas:

1. The list of "other stakeholders" who can access RMPs should be expanded to include group purchasing organizations (GPOs) given the significant role GPOs play in contracting and supply chain resiliency;
2. The list of drugs recommended to have a RMP should be streamlined to all drugs on the FDA List of Essential Medicines, Medical Countermeasures, and Critical Inputs; and
3. The requirements associated with development of a RMP should not create undue burden on manufacturers resulting in increased costs of the drugs that are then passed on to providers.

I. Background on Premier and Our Leadership in Addressing Drug Shortages

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and 250,000 Continuum of Care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. A 2006 Malcolm Baldrige National Quality Award recipient, Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with providers to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. A key component of our alliance is our Integrated Pharmacy Program, which combines

essential clinical data with purchasing power to deliver reduced costs, improved quality, safety and resiliency, and increased knowledge-sharing among healthcare professionals.

Premier has been a leader in addressing drug shortages for more than twenty years and is committed to eliminating drug shortages from both a policy perspective via legislative and regulatory action as well as pursuing market-based solutions. Premier's ProvideGx program identifies safe, high-quality supply sources for drugs that are or may be at risk of being added to the national drug shortage list. Guided by health systems with more than 1,600 hospitals across the nation, Premier's ProvideGx program creates long-term committed buying contracts that provide participating manufacturers with the surety needed to increase production. Premier's programs, including ProvideGx, currently provide members access to more than 150 drugs that are or have been recently designated as shortage drugs.

Since 2020, Premier's drug shortage programs have:

- Successfully resolved 14 drug shortages, resulting in their official delisting from the FDA shortage list.
- Ensured uninterrupted supply of many shortage drugs despite demand spikes of more than 150 percent during the pandemic.
- Continued to bring resiliency to the market by incenting the domestic manufacture of vital drugs through our investments in VGYAAN and Exela Pharma Sciences, which combined are working to bring new, domestic sources of 20 different shortage drugs and counting.

A key component to Premier's success in mitigating drug shortages is the stringent contracting and vetting process manufacturers who wish to work with Premier must undergo. This includes sharing information regarding the location of their finished dose manufacturing and active pharmaceutical ingredient (API) source. In addition, all manufacturers participating in Premier programs are vetted to enable more geographically diverse production capability, adequate safety stocks and surge capabilities to meet sudden spikes in demand. Finally, manufacturers are asked to share their redundancy and contingency plans to ensure ongoing supply of product and mitigate risk. Premier maintains this level of information for almost 6,000 unique National Drug Codes (NDCs) and leverages the information to assign a supply chain resiliency risk score to each product. That score is then utilized by Premier and its member-led sourcing committees to make contracting decisions that are in the best interest of patient care and supply chain resiliency.

Our ongoing commitment to addressing drug shortages also includes diligent advocacy efforts over the years including serving as the lead proponent of the Mitigating Emergency Drug Shortages (MEDS) Act which was incorporated and signed into law as part of the Coronavirus Aid, Relief, and Economic Security (CARES) Act in March 2020. Premier's efforts resulted in the addition of section 506C(j) to the Federal Food, Drug, and Cosmetic Act which requires certain manufacturers to develop, maintain, and implement, as appropriate, a "redundancy risk management plan that identifies and evaluates risks to the supply of the drug, as applicable, for each establishment in which such drug or active pharmaceutical ingredient of such drug is manufactured." Premier is pleased to see the FDA move forward with implementing these provisions with release of this draft guidance.

Premier will continue to innovate and collaborate across diverse stakeholders to address ongoing drug shortages.

II. Stakeholders in the Manufacturing Supply Chain

The draft guidance categorizes stakeholders in the drug supply chain as primary stakeholders, secondary stakeholders and other stakeholders. As drafted, the guidance defines other stakeholders as "not primary or secondary stakeholders, such as inactive ingredient manufacturers, packagers and distributors." The guidance further notes that primary stakeholders should share RMPs with other stakeholders recognizing that other stakeholders may otherwise not have access to this information but do play an important role in the supply chain. The sharing of this information is intended "…to incorporate the broad strategies of the primary stakeholder's RMP into their own plans and also contextualize the risks identified in the primary stakeholder's RMP, specifically for the manufacturing facility. Sharing the primary stakeholder's RMPs with secondary and other stakeholders may also further refine the mitigation and avoidance strategies specific to the individual drug, or its unique manufacturing process."

Premier appreciates FDA's recognition that other stakeholders can benefit from the receipt of this information and augment risk mitigation strategies for drug shortages. ***Given the significant role GPOs play in contracting and supply chain resiliency, Premier urges the FDA to broaden the definition of "other stakeholder" to include GPOs.*** Clearly defining GPOs as an other stakeholder is critical to augmenting the robust vetting and contracting processes GPOs already undertake. Additional visibility and transparency into RMPs will only help GPOs further their work in risk scoring and supporting the creation of resilient supply chains to mitigate drug shortages.

III. Products for Which RMPs Are Recommended

In addition to the categories required to have a RMP by the CARES Act, the draft guidance enumerates several product categories that FDA recommends have a RMP due to concerns that a supply disruption of these products would have a detrimental impact to patient care. Suggested categories include drug products that lack appropriate alternatives, medical countermeasures and products with a sole API source. While well intended, Premier is concerned that information of this nature is not readily available and would place undue burden on manufacturers. For example, FDA notes that API establishments are named in an approved FDA application. However, to our knowledge, the FDA does not publish a list of products with a sole API source. Therefore, manufacturers would have to sift through a multitude of applications and make a self-determination as to whether all competing manufacturers of a product use a single API source. Furthermore, FDA currently does not require manufacturers to report the volume of product that comes from each listed API source. For example, a manufacturer may have three API sources listed in their application but in reality have 100% of their API come from a single source. Absent this level of detail, it would not be possible for a manufacturer to determine the sole source risk.

To mitigate this burden and confusion, ***Premier urges FDA to recommend that all products listed on the FDA List of Essential Medicines, Medical Countermeasures, and Critical Inputs maintain a RMP***. Created in 2020, the list was intended to ensure the American public is protected against outbreaks of emerging infectious diseases as well as chemical, biological, radiological, and nuclear threats. The list was also intended to ensure sufficient and reliable, long-term domestic production of these products, and to minimize potential shortages by reducing dependence on foreign manufacturers of these products. Premier believes this list should serve as the sole recommendation for additional products that should have a RMP given the importance of the list. However, as Premier as previously articulated, the FDA should work with the private sector to regularly update the list to ensure it remains dynamic, accounts for new therapies, and incorporates special patient populations such as pediatrics.

IV. RMP Framework and Development Strategy

While Premier appreciates FDA's robust framework and development strategy for RMPs, Premier is concerned, however, that the outlined requirements may place undue burden on manufacturers and result in price increases. In many cases, the products subject to a RMP are older, generic injectable medications that have a relatively low purchase price. Placing additional regulatory burden on these manufacturers for such low-revenue products will likely increase their need to hire additional staff and then pass on those costs to providers. The challenge, of course, is that providers are facing immense financial pressures and are unable to absorb price increases. Premier is also concerned that the intense regulatory burden may deter new market entrants for these products.

Therefore, ***Premier recommends that FDA carefully reconsider the RMP framework to minimize regulatory burden on manufacturers***. For example, the FDA could consider a pilot phase with more flexibility around the format of RMPs and the type of information that must be incorporated, including permitting manufacturers to leverage existing RMPs or those that meet European requirements from a harmonization perspective. The FDA could then study the impact of ensuring organizations have a RMP, regardless of format, on mitigating drug shortages and make determinations as to whether a standardized format or additional rigidity is required moving forward.

V. Conclusion

In closing, Premier appreciates the opportunity to submit comments on the draft guidance "*Risk Management Plans to Mitigate the Potential for Drug Shortages*." Premier looks forward to continuing to work with the FDA to finalize guidance and other policies to help prevent drug and biological shortages.

If you have any questions regarding our comments or need more information, please feel free to contact me at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

Soumi Saha, PharmD, JD
Senior Vice President, Government Affairs
Premier Inc.