PREMIER TRANSFORMING HEALTHCARE TOGETHER®

August 28, 2023

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: Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry [Docket Number FDA-2023-D-0939]

Dear Dr. Califf:

Premier Inc. appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on draft guidance entitled "*Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry [Docket Number FDA-2023-D-0939]*." FDA is soliciting public comment on FDA's interpretation of, and policies concerning, the statutory prohibition on wholesaling for certain compounded drugs. The FDA also seeks public comment on examples pertaining to how FDA intends to apply the statutory wholesaling provision.

In our comments, Premier urges the FDA to clarify several key terms to help ensure that 503B outsourcing facilities are able to safely maximize their ability to assist the healthcare ecosystem during drug shortages.

I. Background on Premier Inc.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,350 U.S. hospitals and health systems and 300,000 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 Premier's 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 hospitals access to more than 150 drugs that are or have been recently designated as shortage drugs.

To help temporarily combat drug shortages while a longer-term strategy is being developed, Premier maintains a network of 503B outsourcing facilities to compound products using current good manufacturing practices (cGMP). Given Premier's commitment to quality and safety, Premier personally audits every 503B outsourcing facility it contracts with using an assessment tool that goes above and beyond FDA and State Board of Pharmacy requirements.

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In addition, Premier has created a health system-led 503B Advisory Group for insights on outsourcing needs and supplier challenges to support managing supply disruptions, including insource compounding guidance and available alternatives on the market. Premier also engages with the FDA and sits on the FDA Compounding Center of Excellence workgroup where it helps federal partners understand the impact of 503B regulatory decisions on drug shortages and patient care.

II. Clarifying the Definition of "Resale" vs "Dispensing"

In the draft guidance, the FDA notes that the term "dispense" is distinct and different from the term "resale." However, section 503B of the Food Drug and Cosmetic Act requires that all compounded products be labeled with information prohibiting resale, including requiring the phrasing "not for resale" on all product labels. Premier is concerned that some entities, such as State Boards of Pharmacy and other regulatory agencies, may misinterpret a product labeled as "not for resale" to indicate that it cannot be dispensed. To avoid confusion, ***Premier urges the FDA to clarify that products labeled "not for resale" can be dispensed pursuant to a patient-specific prescription.***

III. Clarifying the Definition of "Intracompany Transfer"

In the draft guidance, the FDA notes that it "*generally does not intend to apply this provision to a compounded drug solely because it was moved as part of an intracompany transfer during shipment to an outsourcing facility's customer*." However, the draft guidance does not define "intracompany transfer" which can lead to further confusion regarding what does and does not constitute an appropriate transfer. Therefore, ***Premier urges the FDA to define "intracompany transfer" and adopt the National Association of Boards of Pharmacy (NABP) model pharmacy act definition of "meaning any transfer between a division, subsidiary, parent, and/or affiliated or related company under the common ownership and control of a corporate entity."*** [1]

IV. Clarifying the Prohibition on "Marketing Firm"

In the draft guidance, the FDA notes that it believes a third party, such as a marketing firm, who provides administrative support to a 503B outsourcing facility, would be subject to the wholesaler prohibition even though the third party does not take possession of the compounded product. ***Premier disagrees with the FDA's interpretation of the wholesaler prohibition as it relates to marketing firms and urges the FDA to reverse its position***.

503B outsourcing facilities, like any manufacturer or pharmacy, may market and advertise their services and products on websites or other forms of media as recognized by the *US Supreme Court in Thompson v. Western States Medical Center*.[2] Furthermore, a 503B outsourcing facility should be able to leverage a third party to assist with administrative functions such as placing orders, billing, etc. – these functions are intended to be administrative only and are no different than if an organization leveraged a behind-the-scenes third party software application on their website to assist with these functions. Given that these third parties do not take title to the product and do not receive fees akin to wholesale distributors, they should not be considered prohibited under the wholesaler prohibition.

V. Conclusion

In closing, Premier appreciates the opportunity to submit comments on the draft guidance "*Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry*."

[1] The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (August 2022). Available at https://nabp.pharmacy/members/board-resources/model-pharmacy-act-rules/.
[2] Thompson v. Western States Medical Center, 535 U.S. 357 (2002).

Premier looks forward to continuing to work with the FDA to finalize guidance and other policies to help prevent drug 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,

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Premier Inc.