PREMIER TRANSFORMING HEALTHCARE TOGETHER®

December 6, 2021

Janet Woodcock, MD
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: [Docket No. FDA-2016-D-0271-0081] - Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry

Submitted electronically to: www.regulations.gov

Dear Dr. Woodcock,

Premier appreciates the opportunity to submit comments on the draft guidance for industry titled "*Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act*" that was published in the *Federal Register* on October 7, 2021. The draft guidance describes how the Food and Drug Administration (FDA) intends to apply certain provisions of section 503A of the Federal Food, Drug & Cosmetic Act to drug products that are compounded by state-licensed pharmacies for distribution within a hospital or health system. In general, Premier greatly appreciates removal of the one-mile radius rule, an issue with which hospitals have historically raised concern. However, we remain concerned about provisions of the draft guidance that conflict with United States Pharmacopeia (USP) provisions and may lead to increased waste, shortages, and costs.

I. Background on Premier Inc.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and approximately 225,000 other providers and organizations 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 members 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 and safety, and increased knowledge-sharing with other 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, including propofol; metoprolol; cysteine hydrochloride; sodium bicarbonate; diphenhydramine; hydromorphone; lidocaine; morphine; thiamine; phytonadione injection; amiodarone; sterile water; ibutilide

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fumarate; vincristine sulfate; and emergency, pre-filled syringes of calcium chloride, epinephrine, sodium bicarbonate, atropine sulfate, dextrose and lidocaine. All manufacturers participating in the program are vetted to enable more geographically diverse production capability, adequate safety stocks and surge capabilities to meet sudden spikes in demand.

II. Reconsideration of the of the "One-Mile Radius" Provision

On April 6, 2021, FDA issued several clarifications related to compounding and stated that the "one-mile radius" provision, remained in draft format and that the FDA intended to revise the policy prior to finalizing. Waiver of the "one-mile radius" provision during the pandemic response was critical as it permitted hospitals to consolidate pharmacy services to a single hub, thereby helping to preserve personal protective equipment (PPE), maximize the use of available pharmacy staff, ensure critical compounded medications for available for patient care, and mitigate drug shortages at the local level.

Premier has long advocated that the "one-mile radius" provision places a geographical limitation on non-patient specific compounding that is arbitrary and can have negative consequences on access to compounded medications, such as encouraging compounding at the patient bedside which can lead to increased rates of medication errors. In lieu of an arbitrary geographical standard, Premier has urged the FDA to adopt a time-based standard, specifically USP chapters <797> and <800>, that is rooted in scientific evidence for sterility and stability of the compounded product.

Premier applauds the FDA for revoking the "one-mile radius" provision and urges the FDA to move forward with finalizing this provision in final guidance.

III. Timeline for Discarding of Medications Upon Transfer Out of the Pharmacy

FDA's draft guidance notes that compounded drugs should be used or discarded within 24 hours of transfer out of the pharmacy. Furthermore, the guidance notes that 24 hours was selected as the window as the Agency believes drugs compounded under 503A should be used for emergencies and products needed for longer duration should be obtained from 503B outsourcing facilities.

Premier is concerned that the 24-hour timeframe noted by the FDA can be arbitrary and may conflict with USP standards, as well as FDA-approved manufacturer labeling, resulting in unnecessary waste and increased costs. In addition, this requirement would further strain workforce shortages that are pervasive in healthcare as it would be labor intensive and require the compounding and re-compounding of products to comply with the arbitrary 24-hour timeframe. Furthermore, Premier is concerned that the introduction of a third standard will further cause confusion as pharmacists grapple with determining if a compounded product's expiration date should be accounted for using the FDA standard, the USP standard, or the manufacturer label standard.

Furthermore, many hospitals and health systems have invested significantly in centralized compounding, including robotics, to improve efficiencies, reduce errors, minimize contamination, and comply with USP standards. Sufficient time for delivery from the centralized location to the site of care must be accounted for and the arbitrary 24-hour timeframe would severely limit the use of a product upon arrival at the site of care further contributing to waste.

In lieu of introducing a new arbitrary standard, Premier urges the FDA to defer to time-based standards, specifically USP or the FDA-approved manufacturer labeling, that are rooted in scientific evidence for sterility and stability of the compounded product.

IV. Enforcement Discretion

The FDA notes that enforcement decisions will be on a case-by-case basis, and that the Agency recognizes they they are unable to "take enforcement action against every violation, and that it needs to make the best use of limited Agency resources." Therefore, the FDA speaks to the need for state Boards of Pharmacy or other local governing bodies to enforce the guidance. Premier is concerned that local enforcement of federal policy may lead to various interpretations of the guidance resulting in varying compliance and enforcement rubrics. Inconsistency in enforcement standards creates operational challenges for hospitals and health systems that operate across multiple jurisdictions and therefore may be subject to several interpretations of the same guidance document.

To create consistency in enforcement of the guidance at the local level, Premier urges the FDA to issue guidance and training to state Boards of Pharmacy and other local governing bodies clearly articulating the standards to enforce. Guidance and training should include examples of enforcement scenarios and an opportunity for local enforcement authorities to seek feedback from the FDA prior to issuing citations.

V. Obtainment of Provider Statement

The FDA notes that a pharmacy must obtain a statement from the prescriber specifying the need for the compounded product in addition to other details prior to fulfilling the order. Requiring a statement of this nature prior to preparing or dispensing the product can result in unnecessary delays in patient care, especially overnight or in staffing shortage situations. An alternate option should be made available in these situations elevating the role of the pharmacist to act in the best interest of patient care.

Premier recommends that in situations where receipt of the prescriber statement may delay patient care, delegating authority be provided to the pharmacist. Such authority and documentation requirements should be detailed in a policy and procedure approved by the P&T Committee.

VI. Discrepancies Between FDA and USP Definition of Compounding

Premier continues to remain concerned about the discrepancy in the definition of compounding utilized by FDA and USP. For example, FDA considers the transfer of medication from one container to another without making any changes, such as drawing up syringes from a larger container, as repackaging. In contrast, that practice is considered compounding under USP <797>. Variances in definitions and requirements creates confusion for pharmacists regarding compliance standards and beyond-use-dating.

Premier urges the FDA to work with USP to ensure consistency in definitions, standards, and requirements for compounding to minimize confusion at the patient-care level.

VII. Conclusion

In closing, Premier appreciates the opportunity to submit comments on the draft guidance "*Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act*." Premier looks forward to working with the FDA to ensure compounded drug products can be made available for patient care in a safe and timely manner.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, PharmD, JD, Vice President of Advocacy, at soumi_saha@premierinc.com or 732-266-5472.

Sincerely,

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