799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Dr. Janet Woodcock
Acting Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

Re: Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Revised Draft Guidance for Industry; Availability (Docket No. FDA-2016-D-0271)

Dear Dr. Woodcock:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA) revised draft guidance entitled "Hospital and Health System Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act" ("revised draft guidance"). Vizient applauds FDA for including stakeholder feedback in the revised draft guidance and encourages the agency to consider additional modifications to the revised draft guidance.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we provide various proposals for FDA to consider as it works to finalize the revised draft guidance which will describe how FDA intends to apply certain provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to human drug products compounded by State-licensed pharmacies that are not outsourcing facilities and are distributed for use within a hospital or health system. Notably, compounded products, including those compounded by hospitals and health systems, are often needed due to the lack of commercial availability of these products. Therefore, the ability to compound medications helps fill treatment gaps and maintain access to medications. Vizient applauds FDA's decision to remove the one-mile

radius geographic limitation for distributing compounded drugs to healthcare facilities[1] that was in prior iterations of the revised draft guidance and encourages the agency to consider other policies that streamline compliance and ensure safety. Also, Vizient thanks FDA for hosting a webinar on November 17, 2021, regarding the revised draft guidance.

Circumstances in which FDA Generally Does Not Intend to Take Action with Respect to the Prescription Requirement

In the revised draft guidance, the agency outlines circumstances when it generally does not intend to take action regarding the requirement that compounding take place only if there is a valid prescription order for an identified patient. FDA states that it generally does not intend to take action if a hospital or health system compounds and distributes a compounded drug product without meeting the prescription requirement if the practice is strictly limited and controlled, and three specific circumstances are met. One of those three circumstances is that the compounded drugs are used or discarded within 24 hours of transfer out of the pharmacy. While the revised draft guidance does not clarify why 24 hours was selected, per a recent webinar held by FDA, we understand the agency provided this timeline to mitigate possible health risks of having compounded drugs sitting on the shelf for an extended period of time.

Vizient's members are significantly concerned with the 24-hour requirement as it will unnecessarily strain resources and increase waste. For example, regarding labor, members noted that the 24-hour requirement would require health systems to provide multiple deliveries to every area of the organization rather than optimizing automated medication dispensing cabinets. Additionally, since hospitals already adhere to USP <797> beyond-use-dating (BUD), imposing a different 24-hour rule for some products will create confusion and additional workload to manage different workflows for different products. Also, given that USP BUD guidelines are quite stringent for 503A pharmacies, Vizient notes these requirements already mitigate health risks. In addition, Vizient members anticipate the 24-hour rule will increase waste of scarce resources (e.g., injectable generic medications and syringes) by requiring those unused medications to be prematurely discarded from refrigerated automated medication dispensing cabinets. Given these concerns, Vizient urges FDA to remove the 24-hour requirement from the revised draft guidance and replace it with USP <797> BUD requirements. Should the agency feel that additional controls are needed, we encourage the agency to consult with hospitals and health systems to identify alternative options.

Use of 503B Compounding Pharmacies

Vizient appreciates FDA's efforts to address the compounding needs of hospitals and health systems. While the revised draft guidance does not apply to human drug products compounded by outsourcing facilities, the policies provided in the revised draft guidance seem to encourage the use of outsourcing facilities in certain circumstances. For example, in the revised draft guidance FDA states, "We encourage hospitals and health systems to look to outsourcing facilities, or to register their pharmacies as outsourcing facilities, when they wish to obtain non-patient specific compounded drug products." Vizient members may be reluctant to use outsourcing for the reasons outlined below.

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[1] *See* Food and Drug Administration, *FDA Revises Hospital and Health System Compounding Guidance to Help Preserve Patient Access to Compounded Drugs* (October 6, 2021), available at: https://www.fda.gov/news-events/press-announcements/fda-revises-hospital-and-health-system-compounding-guidance-help-preserve-patient-access-compounded, last accessed: November 28, 2021. (The one-mile radius geographic limitation is FDA's prior intention "not to take action if a hospital or health system pharmacy distributes compounded drugs to healthcare facilities within a one-mile radius, that are owned and controlled by the same entity that owns and controls the pharmacy.")

Quality
Based on member searches and experiences with the FDA website, there is inadequate information regarding the quality of an outsourcing facility. While FDA provides a helpful list of Registered Outsourcing Facilities on their website, there is no published information regarding resolution of findings if there is a deficiency or information more broadly available on overall quality of products compounded by outsourcing facilities. Vizient encourages FDA to enhance its website by sharing additional information with stakeholders regarding resolutions or quality.

Shortages
Hospitals may lose their entire inventory of compounded products in the event of a recall from an outsourcing facility (more than 100 recalls to date). For example, hospitals may not be able to purchase sufficient product to compound for immediate use due to limited vial availability at wholesalers or they may not be provided an allocation to purchase short-supply vials if they have been relying on an outsourcing facility.

Lack of Commercial Products
FDA has yet to approve ready-to-use products required in hospitals resulting in non-patient specific compounding to meet emergent patient care needs. Vizient encourages FDA to identify strategies to encourage manufacturers to seek approval for commonly compounded, ready-to-use products.

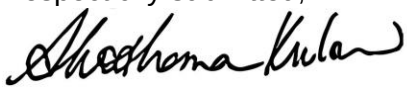
Costs
Vizient notes that, according to our members, most health systems do not have the resources to register a stand-alone facility for outsourcing needs. Compounded products purchased from an outsourcing facility may be more costly without quality guarantees. As a result, use of 503B facilities or alternative approaches can be financially challenging and pose quality concerns. Thus, to the extent practicable, Vizient encourages FDA to work with hospitals and health systems to better identify opportunities to better ensure access to quality, compounded medications at a reasonable cost.

Safety
To better support safety, Vizient encourages FDA to share information about the quality of outsourcing facilities or provide hospitals a means to confirm information shared by outsourcing facilities with FDA.

Conclusion

Vizient welcomes FDA's revised draft guidance and opportunity for comments as it provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. On behalf of Vizient, I would like to thank FDA for providing us the opportunity to comment on the implications of the revised draft guidance. Please feel free to contact me at (202) 354-2600 or Jenna Stern, Sr. Director of Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,



Shoshana Krilow
Sr. Vice President of Public Policy and Government Relations
Vizient, Inc.