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February 2, 2023

Submitted electronically via https://www.regulations.gov/

Dr. Robert Califf
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Drug Supply Chain Security Act Implementation and Readiness Efforts for 2023; Public Meeting; Request for Comments (Docket No. FDA-2022-N-2671)

Dear Dr. Califf:

Vizient, Inc. appreciates the Food and Drug Administration's (FDA's) efforts to communicate with stakeholders via the December 7-8, 2022 public meeting and through this request for comments (hereinafter, "RFC"). Vizient applauds the FDA for taking steps to assist the industry, particularly dispensers, in preparing for the implementation of enhanced drug distribution security requirements that will go into effect on November 27, 2023.

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 60% of the nation's acute care providers, which includes 97% 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 $130 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 respond to FDA's RFC and offer comments in response to several topics discussed during the December 2022 public meeting. As FDA may be aware, Vizient works closely with pharmacy leaders, particularly those in hospitals and health systems. As such, our comments reflect information based on our communications with these dispensers.

Role of Third-Party Services and External Stakeholders

During the December 2022 public meeting, several organizations presented their efforts related to readiness for 2023. Vizient appreciates the agency's efforts to convene stakeholders to support this type of information sharing. However, for stakeholders, such as dispensers, who were unable to attend the public meeting or those who may be less familiar with FDA's public meeting process, it can be challenging to place the function of different stakeholders' offerings and initiatives in the context of compliance, as the meetings are not recorded and limited information is provided after a meeting occurs. For example, a common question dispensers ask is how DSCSA will be enforced, particularly at the state level. During the public meeting, helpful presentations from organizations like the National Association of

Boards of Pharmacy outlined key issues from a state board of pharmacy perspective (e.g., how will regulators assess trading partner compliance with DSCSA?), however, it is unclear how FDA views these efforts or if these types of questions will be clarified by FDA.

In addition, during the public meeting, questions were rhetorically posed, such as whether "standards for tracing and verification require credentialing as currently explored". These types of questions can prompt additional questions from stakeholders, yet it is unclear where stakeholders should look for answers (e.g., state boards of pharmacy, FDA). Given the importance of state regulators in helping shape compliance, Vizient encourages FDA to provide additional feedback in response to these types of questions posed during the meetings, or general questions posed to the agency via email. Alternatively, where enforcement decisions have yet to be made, clarifying that status would also be helpful to stakeholders.

Education

Given the vast range of materials and resources being presented, Vizient encourages FDA to consider additional guidance or information regarding actionable steps and services dispensers may need. For example, the FDA DSCSA dispenser-focused page is helpful in outlining high-level requirements of the law, but examples of different compliance approaches and potential complexities are not clear (e.g., messaging standards are not referenced; clarification regarding circumstances like contract pharmacies or whitebagging are not addressed). As a result, dispensers, particularly those with limited resources or staffing constraints, may not be aware of different guidance documents or how the agency anticipates technology solutions will help ease compliance challenges. While Vizient appreciates the agency's efforts to provide significant flexibility regarding compliance, we also encourage the agency to consider enhancing the dispenser-focused DSCSA page with examples of compliance approaches, including in circumstances where dispensers rely on multiple wholesale distributors to store transaction information and potential scenarios that a dispenser may encounter where a suspect product is identified. While much of this information may be available from other stakeholders or in different guidance documents, it would be helpful to centrally provide these materials and share examples applying such resources to support education.

Also, Vizient suggests a designated FDA email for dispensers to ask the agency questions or to share their insights regarding readiness, as it may help encourage their engagement. Vizient believes these types of efforts could also help the agency reach more trading partners who can share information regarding readiness for November 2023.

November Deadlines

As FDA is aware, November 2023 is rapidly approaching. While the agency has previously provided enforcement discretion regarding different deadlines under DSCSA, our understanding is that the agency is not currently planning on providing such enforcement discretion in the future. To the extent the agency is considering providing enforcement discretion, we encourage the agency to share that information with stakeholders as early as possible. Alternatively, should the agency need additional information regarding readiness over the next several months, Vizient encourages FDA to clarify specific questions so that other stakeholders may use such information to gain input or survey certain trading partners on topics of most interest to the agency related to November 2023 compliance.

Conclusion

Vizient appreciates FDA's efforts to gain stakeholder feedback regarding DSCSA readiness, especially as November 2023 approaches. In closing, on behalf of Vizient, I would like to thank FDA for providing the opportunity to respond to this RFC. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

Shoshana Krilow
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Vizient, Inc.