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Center for Drug Evaluation and Research Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Identifying Trading Partners Under the Drug Supply Chain Security Act (Docket No. FDA-2017-D-1956)

Dear Dr. Jung:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) revised draft guidance, "Identifying Trading Partners under the Drug Supply Chain Security Act (hereinafter "Revised Draft Guidance"). Vizient applauds the FDA for taking steps to assist the industry, particularly dispensers, in understanding how to categorize the entities in the drug supply chain in accordance with the Drug Supply Chain Security Act (DSCSA).

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 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 $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In our comments, we respond to FDA's Revised Draft Guidance and offer suggestions for FDA's consideration as certain sections may benefit from further clarification. Vizient works closely with pharmacy leaders, particularly those in hospitals and health systems. As such, our comments reflect information based on our communications with members and where we believe additional clarity would be helpful.

Licensure

In the Revised Draft Guidance, FDA indicates that is will generally consider a third-party logistics provider (3PL) to be fully licensed for DSCSA purposes, unless FDA determines that the 3PL is not utilizing good product handling and distribution practices and publishes notice thereof. FDA further provides that such notice would be posted on FDA's DSCSA webpage. Vizient is concerned that it may be too burdensome to check the DSCSA webpage each time a 3PL is involved in a transaction covered by DSCSA, particularly for dispensers. Vizient suggests FDA consider additional communication mechanisms to more effectively

communicate 3PL licensure revocation to help ensure only authorized trading partners are engaging in transactions.

Manufacturers as Trading Partners Under DSCSA: NDA-, BLA-, or ANDA-Holder, or Co-Licensed Partner of a Manufacturer

In the Revised Draft Guidance, FDA notes that there has been confusion regarding which manufacturer should register under section 510 of the Food, Drug and Cosmetic (FDC) Act to be considered an authorized trading partner. Regarding NDA-, BLA-, or ANDA-Holders, or Co-Licensed Partners of a Manufacturer, FDA indicated that such an entity would be an authorized trading partner without being registered under section 510 so long as such entities are compliant with obligations under section 510 of the FD&C Act, if applicable. Vizient notes that it would be challenging for a dispenser to determine such compliance and so, would be similarly challenged to determine if these entities are authorized trading partners. Vizient encourages FDA to consider an alternative policy approach regarding the authorized trading partner requirement in this context such that the burden to evaluate compliance would not rest on dispensers.

Dispensers as Trading Partners Under the DSCSA

Vizient appreciates FDA's clarification in the Revised Draft Guidance regarding warehouses and distribution centers. As provided in DSCSA, the definition of dispenser includes the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor. In addition, the Revised Draft Guidance indicates that such warehouse and distribution centers are no longer considered wholesale drug distributors, unless such facilities are also engaged in wholesale distribution activities. Vizient appreciates FDA's clarification as warehouses and distribution centers are critical to hospitals and health systems because, among other benefits, they improve efficiency, support streamlined access to medications, improve purchasing decisions and reduce workload. Vizient encourages FDA to retain this clarification as the Revised Draft Guidance is finalized.

Specific Patient Need

Lastly, in the Revised Draft Guidance, FDA aims to clarify that a specific patient need transaction would not require that the transferring dispenser provide product tracing information. However, FDA does indicate that other DSCSA dispenser requirements may need to be met. Vizient appreciates FDA's clarification, especially as it makes clear that a dispenser would not need to register as a wholesale distributor to provide medications for a specific patient need. However, Vizient believes that additional clarity is needed as hospitals and health systems may continue to decline to engage in specific patient need transactions given such uncertainty for the pharmacy providing such medication. Vizient suggests FDA further clarify other dispenser requirements that would need to be met and to provide examples of specific patient need transactions in the context of DSCSA's various requirements. For example, it is unclear what information a pharmacy would need to retain to prove the transaction was for a "specific patient need". Vizient encourages FDA to clarify such information without imposing unnecessary burden on dispensers (e.g., sending dispenser could document a specific patient need without validating the prescription or taking other steps to verify the requesting pharmacy's need).

Also, prior to DSCSA, specific patient need transactions would often involve the product being replaced by the pharmacy who initially requested the product. These "borrow and loan" types of transactions were one way the sending pharmacy was made whole after sharing product. Vizient encourages FDA to clarify how sending pharmacies may be made whole after specific

patient need transactions. Vizient believes that a lack of clarity regarding this issue may continue to have a chilling effect on the frequency of specific patient need transactions and, ultimately, negatively impact patient care and access to needed medications.

Conclusion

Vizient appreciates FDA's efforts to release the Revised Draft Guidance and provide an opportunity for stakeholder input. Vizient has engaged in numerous efforts to support access to medications. In closing, on behalf of Vizient, I would like to thank FDA for providing the opportunity to respond to this Revised Draft Guidance. 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,

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Vizient, Inc.