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Re: Current and Anticipated Implementation Challenges Associated with the Drug Supply Chain Security Act

Dear Doctors Throckmorton, Verbois, and Jung:

Vizient, Inc. appreciates the ongoing efforts of the Food and Drug Administration (FDA) to receive stakeholder comments regarding the Drug Supply Chain Security Act (DSCSA) and we applaud the agency for issuing recent guidance[1] regarding enforcement discretion as this will

[1] *See* FDA (2023). DSCSA compliance policies establish 1-year stabilization period for implementing electronic systems, available at: https://www.fda.gov/drugs/drug-safety-and-availability/dscsa-compliance-policies-establish-1-year-stabilization-period-implementing-electronic-systems

help support ongoing patient access to medications as trading partners work towards compliance. While Vizient does not function as a trading partner, several of our provider members meet the definition of dispenser. Recognizing the importance of DSCSA implementation to our members, Vizient has worked to foster member engagement and provide educational webinars regarding DSCSA. As a result, Vizient would like to share information with FDA and provide recommendations to the agency regarding 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 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

Vizient thanks the FDA for accepting stakeholder feedback related to DSCSA and for the recent announcement indicating the agency would provide enforcement discretion until November 27, 2024, for certain DSCSA requirements. Before this announcement, Vizient conducted a member survey to better understand how members are approaching DSCSA and additional potential needs. Based on our findings, Vizient encourages the FDA to provide additional education and resources specific to the dispenser and provider communities. Additionally, we suggest FDA clarify that payer-mandated white bagging policies pose a supply chain security risk and recommend the agency share information that discourages payers and their pharmacy benefit managers (PBMs) from imposing such requirements.

Member Readiness Survey

Vizient appreciates the efforts of FDA to implement DSCSA as envisioned under law and the recent guidances which provide information related to the agency's use of enforcement discretion. While Vizient is not addressing whether a one-year delay will be sufficient time for trading partner compliance, we believe sharing additional readiness information with the agency may be of interest. With more than 250 provider respondents to a recent survey, Vizient learned that only 20% of participants reported that they are currently receiving the Transaction Information (TI) and Transaction Statement (TS) electronically from all trading partners, and 60% reported that they are receiving paper TI and TS for special order items. In addition, only 4% of survey participants reported that they were ready at the time of the survey to meet the November 2023 DSCSA requirements, including those requirements for which FDA recently granted enforcement discretion. We encourage the agency to consider this information as it considers opportunities to improve readiness.

In addition, we recommend FDA provide increased education and resources to dispensers, including hospital pharmacies, who may be challenged in interpreting and meeting the law's various requirements and exemptions. Based on Vizient's survey data, only 40% of our survey participants indicated that they felt that they had a good understanding of the requirements that were to go into effect November 27, 2023, but nearly 60% indicated that they felt they had an average, not so good, or poor level of understanding of those 2023 requirements. Given this

range of understanding of DSCSA requirements, Vizient suggests the agency provide resources, particularly office hours-like sessions, for dispensers to help address their questions, become more familiar with the law and improve their compliance efforts.

Payer-Mandated White Bagging

DSCSA Challenges for Dispensers Associated with Payer-Mandated White Bagging
As FDA is likely aware, various payers and their PBMs have imposed coverage requirements which often require physician-administered drugs to be sent from a PBM-affiliated specialty pharmacy as, effectively, a partially "dispensed" medication (i.e., the medication requires further modifications and administration but has been billed by the specialty pharmacy). For purposes of this discussion, we refer to this practice as payer-mandated white bagging. When DSCSA was signed into law, these types of payer requirements were not as prevalent, which may be due in part to the growth of high-cost medications (primarily specialty medications) that require physician administration. Thus, when DSCSA was signed into law, payer-mandated white bagging was not as common a practice. As a result, more clarity regarding these transactions in the context of DSCSA is needed to protect the safety and integrity of the supply chain.

Often, white bagged medications are sent by a specialty pharmacy without the request or awareness of the receiving pharmacy (e.g., health system pharmacy), even if the receiving pharmacy has stock readily available to fill the prescription. Further, white bagged medications are generally not sent with tracing information and without a clear reason as to why. For example, the dispenser may not know if the sending specialty pharmacy views these medications as "dispensed" that need to be redispensed[2] or whether tracing information is not sent because the specialty pharmacy believes the "specific patient need"[3] exception applies or if there is some other potential exemption or exception being used.[4] Further, the specialty pharmacy may have been granted a waiver, exception or exemption, but as outlined under guidance, it is unclear as to whether the receiving pharmacy would be considered a "trading partner" for purposes of receiving information about such waivers, exceptions or exemptions.[5] Vizient believes some of these challenges, which effectively undermine DSCSA, can be addressed if FDA provided additional clarity regarding payer mandated white bagging in the in the context of DSCSA.

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[2] *See* Pharmaceutical Care Management Association, Explaining the role of specialty pharmacies for physician-administered drugs: White bagging redispensing, https://www.pcmanet.org/wp-content/uploads/2021/11/Talking-Points-PCMA-Explaining-White-Bagging-Redispensing-2021.pdf, stating, "The provider receives the shipped package without delay following delivery because the specialty pharmacy requires the prescription be signed for by the provider or a designate at time of delivery to ensure chain of custody (in line with federal Drug Supply Chain Security Act (DSCSA) requirements)." No other mention of DSCSA compliance steps are noted in this document.

[3] *See* FDA (2022). Draft Guidance: Identifying Trading Partners Under the Drug Supply Chain Security Act, available at: https://www.fda.gov/media/159621/download, stating, "However, dispensers are not required to provide the product tracing information prior to, or at the time of, a transaction if the product is dispensed to a patient or if it is a sale by a dispenser to another dispenser to fulfill a "specific patient need.". This portion of the draft guidance does not add address circumstances where the product is not directly dispensed to a patient, but instead, sent to another pharmacy or provider to be prepared for subsequent administration.

[4] *See* National Association of Boards of Pharmacy (2021). How Board of Pharmacy Are Addressing White and Brown Bagging, available at: https://nabp.pharmacy/wp-content/uploads/2022/07/ASHP-August-2021-Webinar-Presentation-Handout.pdf

[5] Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act, (2023), available at: https://www.fda.gov/media/113342/download, *stating* "Additionally, to help ensure that trading partners in the supply chain are aware of a granted waiver, exception, or exemption, the recipient should notify its trading partners of such a waiver, exception, or exemption".

Also, compliance ambiguity can arise for dispensers receiving patient-specific products at the health system pharmacy that are not used by the patient for a range of reasons, such as dosage issues or the medication is no longer needed. If a product is not needed, then the medication is to be disposed. Further, in the event of a recall of a “dispensed" but not administered drug, the receiving pharmacy would have limited ability to prevent potentially unsafe product being administered to a patient because the pharmacy would not be able to accurately identify the at-risk product. As a result, it appears that PBMs have disregarded the purpose of DSCSA by intentionally shifting a significant volume of specialty medications outside the protections of the law by adding a step in the supply chain via payer-mandated white bagging policies and deeming these products “dispensed”.

Further, payer-mandated white bagging policies are often for high-cost medications, which FDA has recognized as being at a significantly increased risk of having suspect product enter the pharmaceutical distribution supply chain (e.g., product that has a high price in the United States; product that has been previously or is currently being counterfeited or diverted (e.g., HIV, antipsychotic, or cancer drugs)).[6] In addition, white bagging significantly limits the ability of the receiving pharmacy to evaluate the appearance of the product (e.g., packaging, labeling) to determine if it is suspect or illegitimate and providers effectively have no choice regarding the trading partner and product source – all topics which FDA encourages trading partners to consider when verifying products.[7] Yet, these payer-mandated transactions largely occur outside the auspice of the closed drug distribution system that DSCSA would establish. Vizient is concerned that the proliferation of payer-mandated white bagging creates a significant gap in the drug supply chain, but believes that this can be improved upon, should the agency make several clarifications regarding these transactions.

Opportunities for FDA to Strengthen Supply Chain Security
Generally, Vizient encourages FDA to take steps to rapidly decrease the frequency with which payer-mandated white bagging takes place, provide clarity regarding payer-mandated white bagging in the context of DSCSA and potentially support legislative changes where needed to address this gap in the supply chain.

Vizient encourages FDA to clarify that payer-mandated white bagging is a risk to supply chain safety and to discourage payers from establishing such policies. Vizient encourages FDA to work with dispensers, including licensed health care practitioners authorized to prescribe or administer medication under State law and hospital pharmacies, to develop guidance regarding best practices for circumstances where white bagging may be appropriate and specifically address specialty pharmacy practices. This guidance should aim to minimize provider and health system pharmacy burden and we welcome the opportunity to provide additional input should the agency pursue this course of action.

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[6] FDA (2021). Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification, available at: https://www.fda.gov/media/88790/download
[7] FDA (2023). Verification Obligations Under the Drug Supply Chain Security Act, available at: https://www.fda.gov/media/111468/download#:~:text=SUSPECT%20PRODUCT%E2%80%94The%20term%20%E2%80%9Csuspect,to%20humans%3B%20(C)%20is

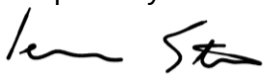
Vizient also suggests FDA consider whether payers, PBMs and their affiliated specialty pharmacies need additional licensure (e.g., wholesale distributor, third-party logistics provider) for DSCSA purposes. As noted above, white bagged medications may not align with the patient's needs (e.g., due to changes in a patient's treatment plan or dosage errors), so the patient may never actually obtain "dispensed" white bagged medications. Moreover, specialty pharmacies indirectly provide these medications to other unaffiliated dispensers for a large volume of patients, raising questions regarding whether these entities should be considered wholesale distributors. Clarity regarding registration requirements is also critical to dispensers who must deal with authorized and trusted trading partners.

Finally, we encourage FDA to work with dispenser stakeholders to provide clarity on when a medication may be considered dispensed to a patient. In addition, we encourage the FDA to work with dispensers to determine whether changes to tracing information and related exchange requirements can be modified to improve coordination and help receiving dispensers ensure the product is safe for administration without imposing undue burden.

Conclusion

Vizient applauds FDA's efforts to implement DSCSA and accept stakeholder input. Regarding both our survey and white bagging request, we welcome the opportunity to further discuss these topics with the agency. In closing, on behalf of Vizient, I would like to thank FDA for providing the opportunity to share information and recommendations. Please feel free to me 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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