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

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Importation of Prescription Drugs; Notice of Proposed Rulemaking (Docket No. FDA-2019-N-5711)

Dear Commissioner Hahn,

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration (FDA) notice of proposed rulemaking, "Importation of Prescription Drugs" (hereinafter, "Proposed Rule") as the proposed policies impact our members and the patients they serve.

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

Like FDA, supply chain security and access to safe and effective medications are of paramount importance to Vizient and our members. The Proposed Rule provides a framework to guide states, pharmacists and wholesale distributors in developing a Section 804 Importation Plan (SIP) Proposal for FDA review and approval and indicates several pre- and post-importation requirements. While we are not commenting on all of the questions FDA raises in the Proposed Rule, we do recommend both FDA and the Secretary of the Department of Health and Human Services (HHS) err heavily on the side of supply chain security and integrity when considering aspects of the Proposed Rule, including extensive responsibilities of SIP Sponsors, that could be strengthened to ensure patient safety.

Secretary's Certification to Congress

The Proposed Rule indicates that, upon its potential finalization, the Secretary will certify to Congress that drug importation would "pose no additional risk to the public's health and safety" and would "result in a significant reduction in the cost of covered products to the American consumer".[1] Vizient is concerned the proposed certification timeline is unclear and may be premature for several reasons. The Proposed Rule indicates HHS may engage in additional, future rulemaking to address uncertainty pertaining to Medicaid rebates[2] which would likely impact the determination around cost savings. In addition, FDA's Preliminary Regulatory Impact Analysis indicates FDA is "unable to estimate the cost savings from this proposed rule" since the agency lacks information needed to determine cost savings. Given the Secretary must certify drug importation would result in a significant reduction in cost, it is unclear how the Secretary could provide this certification based on the current information gaps and expected, related future rulemaking. Vizient encourages FDA to elaborate on this issue. Also, the Proposed Rule does not detail whether the Secretary would need a SIP Plan at the time certification is made. Should certification be made without a SIP Plan, Vizient suggests FDA clarify how the cost-savings element of the certification requirement can be satisfied.

Regarding the Secretary's certification that there would be no additional risks to the public's health and safety, the Proposed Rule may not provide adequate assurances as currently drafted. The Proposed Rule places significant pre-market and post-market requirements on a SIP Sponsor(s) and their written plans to address issues such as recalls and compliance oversight. While Vizient appreciates FDA's efforts to ensure SIP Sponsors consider how to address these issues, we are concerned written plans alone may not be enough to prevent future risks to public health and safety. Vizient recommends FDA also evaluate whether a SIP Sponsor has the ability and resources to execute the written plans.

Alternative Drug Pricing Solutions

Vizient lauds FDA's work to address drug pricing by identifying opportunities to increase competition, thereby decreasing medication costs. FDA indicates that the proposed importation plans are being offered as means to lower costs for American consumers. However, importation proposals may detract from FDA's overall, limited resources which could be spent on other mechanisms to enhance competition. Vizient encourages the agency to work with HHS to consider the most effective use of the agency's resources. To the extent possible, Vizient encourages FDA to provide information regarding how the Proposed Rule will alter FDA's staffing and resource allocation to help stakeholders better understand how the agency's operations may be impacted by the Proposed Rule.

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[1] 84 Fed. Reg. 70798 at 70801 *stating*, "Section 804(l)(1) of the FD&C Act provides that section 804 shall become effective only if the Secretary certifies to the Congress that the implementation of this section will pose no additional risk to the public's health and safety, and result in a significant reduction in the cost of covered products to the American consumer. The Secretary would make this certification to Congress upon issuance of a final rule based on this proposal."

[2] 84 Fed. Reg. 70798 at 70801

Post-Importation Requirements

Vizient recognizes FDA's efforts to ensure safeguards are in place to protect patients and public health post-importation. In the Proposed Rule, FDA indicates that a SIP Sponsor or Importer would be responsible for numerous post-importation requirements, such as effectuating recalls and adverse event reporting, which will require resources from the SIP Sponsor, Co-Sponsor and Importer, among others.[3] From the Proposed Rule, it is unclear how FDA would attempt to ensure these post-importation requirements can and will be satisfied.

Additionally, the Proposed Rule places a significant emphasis on these entities and their written policies and procedures, without proposing specific requirements. For example, the Proposed Rule requires that the SIP Sponsor effectuate a recall in accordance with its written recall plan. Vizient is concerned this proposal does not align with current expectations related to recalls, including the agency's recent draft guidance on initiating recalls which outlines preparation activities (e.g., personnel training, adequate product coding created for each lot, batch or unit, distribution record maintenance and investigation).[4] As FDA is aware, a recall has significant implications not only on patient access, but also on the hospitals and other providers who must identify alternative treatment solutions. A tremendous amount of coordination and communication of accurate information is required to prevent patient harm. Unfortunately, by requiring only written plans and placing significant responsibility on potentially ill-prepared entities, the Proposed Rule provides minimal protections to ensure recalls will be effectively and efficiently administered and other post-importation requirements satisfied. Vizient suggests FDA align post-importation requirements for SIP Sponsor's and co-Sponsors' with related FDA rulemaking and guidances, such as the draft guidance referenced above.

In addition, Vizient seeks clarity regarding the recall process in the Proposed Rule. As recalls are being investigated for FDA-approved products, communications with entities such as FDA and stakeholders may occur before an official recall is announced. Given Health Canada would no longer have jurisdiction over these imported products and has different recall systems than FDA, it is unclear whether and how FDA, SIP Sponsors, Importers, and Health Canada would work together before, during, and after a recall, if at all.

Temporary Importation

Vizient appreciates FDA's efforts to improve patient access to medication, including when there is a shortage, but has concerns that the Proposed Rule does not consider potential international effects, such as the Canadian government's response. The Regulatory Impact Analysis provided by HHS states that the Canadian government may respond by banning wholesale

[3] 84 Fed. Reg. 70798 at 70822
[4] Food and Drug Administration, (April 2019). Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C Draft Guidance, available at: https://www.fda.gov/media/123664/download, last accessed, March 3, 2020.

prescription drug exports.[5] Vizient is concerned the Proposed Rule may have unintended consequences that ultimately limit access to medications when they are in shortage. As FDA is aware, the agency occasionally exercises enforcement discretion to allow importation of foreign drugs in cases where there is a shortage of a critical, approved US drug, and the shortage cannot be resolved by manufacturers of the approved US drug in the immediate future.[6,7] While Vizient recognizes FDA cannot predict the Canadian government's response to an importation rule being finalized, we recommend FDA collaborate with Canadian authorities to prevent unintended consequences.

Quality

Vizient appreciates FDA's ongoing commitment to monitor the quality of FDA-approved drugs legally marketed in the United States. FDA's Report on the State of Pharmaceutical Quality elucidates on quality by stating, "a quality drug is consistently safe and effective, free of contamination and defects."[8] Vizient and our members emphasize how critically important medication quality is to patients and the US supply chain. Vizient urges FDA to carefully consider and clarify how the framework in the Proposed Rule, which effectively delegates many of FDA's roles to state and private stakeholders and foreign entities, can be implemented to assure medication quality.

Conclusion

Vizient welcomes FDA's extensive discussion of options and its emphasis on requesting comments, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. Again, Vizient stresses the importance of supply chain security and medication safety to our company and members.

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many are specialized, including academic medical centers and pediatric facilities. Individually, our members are integral partners in their local communities, and many are ranked among the nation's top health care providers. In closing, on behalf of Vizient, I would like to thank CMS for providing us the opportunity to comment on this important proposed rule.

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[5] Department of Health and Human Services, Importation of Prescription Drugs Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, Docket No. FDA-2019-N-5711, available at: https://www.fda.gov/media/133553/download, last accessed February 28, 2020.
[6] *See* Food and Drug Administration, Frequently Asked Questions Temporary Importation of Lipodox, available at: https://www.fda.gov/media/83117/download, last accessed February 11, 2020.
[7] *See also,* Government Accountability Office, Drug Shortages Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability, available at: https://www.gao.gov/assets/670/660785.pdf, last accessed: February 11, 2020.
[8] Food and Drug Administration (2020). Report on the State of Pharmaceutical Quality, available at: https://www.fda.gov/media/125001/download, last accessed: February 28. 2020.

Please feel free to contact me, or Jenna Stern at (202) 354-2673 or jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,

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