

March 31, 2023

Submitted via email to: IRAREbateandNegotiation@cms.hhs.gov

Dr. Meena Seshamani, M.D., PhD.
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Part D and Part B Inflation Rebate Comments

Dear Dr. Seshamani:

Vizient, Inc. appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) Medicare Part B Inflation Rebate Program Guidance¹ and Medicare Part D Inflation Rebate Program Initial Guidance². Also, Vizient thanks CMS for releasing additional resources to help stakeholders better understand the agency's Inflation Reduction Act (IRA) implementation efforts and plans. While Vizient is not commenting on all questions posed in each guidance, we are providing comments applicable to both guidances as related to the 340B Drug Discount Program.

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 appreciates the willingness of CMS to consider stakeholder feedback regarding Medicare inflation rebate guidances issued on February 9, 2023. As provided in the IRA, CMS must exclude 340B units from Part B and Part D inflation rebate requests. In the February 2023 guidances, CMS proposes a policy to use claim modifiers (SCC20 for Part D; JG/TB for Part B) as a mechanism to identify the 340B units to exclude. Vizient is concerned that such

¹ <https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf>

² <https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf>

policy would unnecessarily increase administrative burden on healthcare providers and recommends CMS revise its guidances so that claims do not need to include a modifier.

Part B Claims

Regarding Part B claims, CMS would require the use of the “JG” or “TB” modifiers on Part B claims. As noted in Vizient’s CY 2023 Outpatient Prospective Payment System (OPPS) Proposed Rule [comments](#) regarding use of these modifiers, we continue to believe this proposal is unnecessary and imposes additional burden. Vizient also notes that since the policy in the guidance would impact all 340B covered entities we are concerned that additional education and time will be needed for implementation, and such policy is associated with long-term significant administrative burden. To help reduce administrative burden, Vizient suggests CMS exclude all units of separately payable Part B drugs billed by 340B participating providers instead of requiring modifiers.

Part D Claims

As noted above, Vizient’s concerns related to the Part B guidance are also applicable to the Part D guidance. In the Part D guidance, CMS would require a pharmacy to use the “20” submission clarification code to indicate use of the 340B drug at the time of adjudication or dispensing of the claim. Vizient is concerned this policy cannot be practically implemented due to challenges in identifying 340B prescriptions at the point of sale. As CMS may be aware, pharmacies often use a replenishment model whereby the 340B eligibility of the patient and prescription is determined retrospectively. As a result, covered entities would need to review every claim submitted and reverse and resubmit to add the modifier on every Medicare 340B Part D claim; Vizient questions whether this is even operationally possible. At most, CMS could potentially work with covered entities to consider alternatives to obtain the needed information through less burdensome and disruptive means, such as a clearinghouse model.

Provider Input

Vizient understands that the IRA included several ambitious deadlines which CMS has worked to adhere. We appreciate the agency’s efforts promptly share information with stakeholders and seek comment. As the agency continues to release guidance and resources regarding IRA implementation, we suggest the agency consider summarizing resources to better clarify the potential impact to providers. For example, the Part D guidance is directed to “Pharmaceutical Manufacturers of Part D Rebatable Drugs and Other Interested Parties”. Upon review of the guidance, it is unclear whether providers are included as an “other interested party”. Given providers are heavily focused on the unwinding of the COVID-19 public health emergency, we encourage CMS to provide more provider-specific resources regarding IRA implementation. Doing so will help encourage early provider input which will be critical to smooth implementation of the IRA.

Conclusion

Vizient thanks CMS for the opportunity to share feedback in response to the guidances. Vizient emphasizes the importance of minimizing provider burden and proactively engaging providers regarding IRA implementation plans to gain their feedback and perspectives. As noted throughout Vizient’s comments, we appreciate the agency’s efforts to adhere to Congress’s

deadlines and efforts by the agency to make information available regarding implementation plans.

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 the CMS for providing us the opportunity to comment on the guidances. 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 issues.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shoshana Krilow", with a stylized flourish at the end.

Shoshana Krilow

Senior Vice President of Public Policy and Government Relations
Vizient, Inc.