799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

April 14, 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 Drug Price Negotiation Program Guidance

Dear Dr. Seshamani:

Vizient, Inc. appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services (CMS) Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (hereinafter the "Guidance").[1] Also, Vizient thanks CMS for releasing additional resources to help stakeholders better understand the agency's Inflation Reduction Act (IRA) implementation efforts and plans. The Guidance is for implementation of the Negotiation Program for initial price applicability year 2026. While Vizient is not commenting on all questions posed in the guidance, Vizient emphasizes the importance of considering healthcare providers' perspectives as certain policies contemplated in the guidance may impact patient care.

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 drug price negotiation guidance issued on March 15, 2023. As noted in the Guidance, the IRA established the Medicare Drug Negotiation Program (hereinafter the

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

"Negotiation Program") to negotiate Maximum Fair Prices[2] (MFPs) for certain high expenditure, single source drugs and biological products. Vizient's comments encourage CMS to clarify aspects of the Guidance and offers recommendations to improve transparency of the negotiation process.

Identification of Selected Drugs for Initial Price Applicability Year 2026

Identifying Potential Qualifying Single Source Drugs

In the Guidance, CMS indicates that the agency will identify single source drugs by using a process that applies to drug products and a separate process that applies to biological products. For biological products, CMS provides that "all dosage forms and strengths of the biological products with the same active ingredient and the same holder of the Biologics License Application (BLA), inclusive of products that are marketing pursuant to different BLAs." As CMS is likely aware, biological products may have presentations in which there may be the same active ingredient/moiety but variation in administration, inactive ingredients or additional active ingredient/moiety (e.g., such as when a "biobetter" is developed[3]). Vizient encourages CMS to work with stakeholders to identify an evaluation process to determine when it would be appropriate group certain biological products together.

Delay in the Selection and Negotiation of Certain Biologics with High Likelihood of Biosimilar Market Entry

As noted in the Guidance, the Secretary may delay a biological from being selected for negotiation if certain circumstances are met, including if the Secretary determines there is a high likelihood that a biosimilar will be both FDA approved and marketed before September 1, 2025. Such a delay could occur if a Biosimilar Manufacturer's Initial Delay Request[4] is granted.

In the Guidance, CMS details that an Initial Delay Request must clearly demonstrate that patents related to the reference drug are unlikely to prevent the biosimilar from being marketed before September 1, 2025. CMS provides that it will consider this requirement met if "one or more court decisions establish the invalidity, unenforceability, or non-infringement of any potentially applicable non-expired patent relating to the Reference Drug that the patent holder asserted was applicable to the Biosimilar."[5] Vizient notes that there are often remaining, active patents for the reference product related to indications and that biosimilars will frequently enter the market with fewer indications than the reference product. As a result, market entry tends to

---

[2] As provided in the Guidance, "In accordance with section 1191(c)(3) of the Social Security Act, ("the Act"), maximum fair price means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c) of the Act) with respect to such period, the price negotiated pursuant to section 1194 of the Act, and updated pursuant to section 1195(b) of the Act, as applicable, for such drug and year."

[3] *See* Sharma A, Kumar N, Kuppermann BD, Bandello F, Loewenstein A. Biologics, biosilimars, and biobetters: different terms or different drugs? Eye (Lond). 2019 Jul;33(7):1032-1034. doi: 10.1038/s41433-019-0391-5. Epub 2019 Mar 7. PMID: 30846867; PMCID: PMC6707288, referring the term "biobetter" but noting that it has been widely used but is still not a defined term.

[4] CMS will remove from the ranked list of 50 negotiation-eligible drugs as described in the Guidance any negotiation-eligible drug for which the inclusion on the selected drug list is delayed in accordance with the IRA. The IRA contemplates two potential requests under the Biosimilar Delay: (1) a request to delay the inclusion of a Reference Drug by one initial price applicability year ("Initial Delay Request"), as stated in the IRA; and (2) a request to delay the inclusion of a Reference Drug for which an Initial Delay Request has been granted for a second initial price applicability year ("Additional Delay Request") as stated in the IRA.

[5] Guidance, pg. 19

depend on whether there are substantive, non-expired patents. Vizient encourages CMS to clarify the Initial Delay Request policy in circumstances where a biosimilar may be marketed with fewer than all of the indications from the reference product.

Another circumstance that could be demonstrated in the Initial Delay Request related to whether the patent-related issues may prevent the biosimilar from being marketed is "the Biosimilar Manufacturer has a signed legal agreement with the Reference Manufacturer that permits the Biosimilar Manufacturer to market the Biosimilar in one or more dosage form(s), strength(s), and indication(s) before September 1, 2025, without imposing improper constraints on the Biosimilar Manufacturer." Vizient appreciates the agency's inclusion of this policy as it may encourage Reference Product manufacturers to make agreements with biosimilar manufacturers to support competition before the product would be potentially eligible for negotiation. Vizient encourages CMS to clarify "without imposing improper constraints on the Biosimilar Manufacturer", as it is unclear how CMS will interpret this provision as different agreements develop, such as those that include licensing agreements.

Similarly, CMS indicates that it will consider active litigation to be determinative that there is not clear and convincing evidence that the biosimilar will be marketed before September 1, 2025. Vizient asks that CMS clarify whether the scope of the litigation will be considered, particularly where the biosimilar could be approved and marketed with a limited set of indications, even if there is ongoing active litigation.

Another requirement for the Initial Delay Request is that it must clearly demonstrate that the Biosimilar Manufacturer will be operationally ready to market the biosimilar before September 1, 2025. To assess this requirement, in part, CMS will consider "a manufacturing schedule consistent with the public-facing statements and any revenue expectations." In addition, CMS includes in the process to submit an Initial Delay Request, that the biosimilar manufacturer include the manufacturing schedule for the biosimilar as submitted to the FDA during its review of the licensure application, to the extent available. Vizient encourages CMS to also consider collaborating with the Food and Drug Administration (FDA), to identify key milestones that would indicate the likelihood of approval and marketing and whether information could be more readily shared between FDA and CMS, especially if CMS would like to confirm aspects of the submission or if the agency has additional questions for FDA. Also, as FDA policy may evolve, we recommend CMS evaluate such policies for their impact on the negotiation process, including Initial Delay Requests.

Negotiation Factors

In the Guidance, CMS provides additional details regarding the sources CMS intends to use regarding therapeutic alternatives to a selected drug which would be relevant during the negotiation process.[6] As provided in the Guidance, academic experts, clinicians and interested

[6] As noted in the Guidance, "section 1194(e)(2) of the Act directs CMS to consider evidence about alternative treatments to the selected drug, as available, including:

parties may submit information on selected drugs and their therapeutic alternatives. While CMS notes that all such information related to drugs selected for initial price applicability year must be submitted to CMS by October 2, 2023, it is unclear how such information should be submitted, in what format and whether CMS will proactively identify data needs for interested parties' input. In addition, it is unclear whether CMS envisions a similar process for future price applicability years and whether such processes will be similar for Part B and Part D drugs.

Also, CMS indicates that it may consult outside subject matter and clinical experts on topics related to alternative treatments to the selected drug. Vizient actively provides data-driven insights to help healthcare providers achieve cost efficiencies, performance gains, and clinical improvements. For example, Vizient's list of essential medications for high-quality patient care is developed by Vizient pharmacy experts to identify medications where, if not available, would prove the greatest threat to a hospital's ability to provide immediate and high-quality patient care. The list also connects pharmacy leaders to mitigation strategies, which are ready-to-use documents with pertinent clinical and operational strategies to address shortages at the institutional level. Given Vizient's role in supporting members and pharmaceutical expertise, we would welcome any request from CMS to consult with our subject matter and clinical experts.

Lastly, as detailed in Appendix C of the Guidance, CMS indicates that 340B pricing data would be collected for use in the Negotiation Program. Vizient discourages CMS from using 340B pricing data for purposes of the Negotiation Program as doing so may have unintended consequences for the 340B Program. For example, Vizient is concerned that using 340B pricing to help set the MFP, which would be published, could result in commercial payers using this information to set discriminatory reimbursement for 340B covered entities based on that pricing. As a result, safety net providers would be limited in their ability to serve their communities. Also, Vizient notes that 340B prices are excluded from a manufacturer's non-federal average manufacturer price (non-FAMP) calculations. We encourage the agency to consider this information as it decides the appropriateness of collecting this information for negotiation purposes. While Vizient appreciates that CMS has provided some language in the Guidance to help ensure ongoing access to 340B pricing, we recommend CMS remove 340B pricing from the negotiation factors to help minimize disruption to safety net providers.

Establishment of a Single Proposed MFP for Negotiation Purposes

CMS indicates that, for the purposes of determining a single price included in an initial offer, the agency intends to base the single price on the cost of the selected drug per 30-day

1. The extent to which the selected drug represents a therapeutic advance compared to existing therapeutic alternatives for the selected drug and the costs of such existing therapeutic alternatives;
2. FDA-approved prescribing information for the selected drug and its therapeutic alternatives;
3. Comparative effectiveness of the selected drug and its therapeutic alternatives, including the effects of the selected drug and its therapeutic alternatives on specific populations (including individuals with disabilities, the elderly, the terminally ill, children, and other patient populations, herein referred to as "specific populations"); and
4. The extent to which the selected drug and the therapeutic alternatives to the drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy."

equivalent supply[7], weighted across dosage forms and strengths, as applicable. Vizient suggests CMS consider price per 30-day treatment for oral medications and price per-dose for injectable medications. For injectable medications, this option may enable better comparisons between products that are listed as therapeutic alternatives.

In addition, Vizient encourages CMS to share information publicly regarding its application of this methodology, including its approach to identify a single price for use at each step in the negotiation process. While CMS notes that the Guidance is applicable to Part D drugs, such information may help inform stakeholder comments on future iterations of the Guidance and for Part B drugs. For example, additional information regarding circumstances where the single price was more challenging to calculate due to more complex dosing intervals would be helpful to share with stakeholders.

Also, as related to the methodology for developing an initial offer, CMS indicates that to evaluate the clinical benefit conferred by the selected drug compared to its therapeutic alternative(s), CMS aims to broadly evaluate the body of clinical evidence, including data received from the public and through consults with clinical and academic experts. As noted above, Vizient possesses a unique perspective, including data and analytics capabilities that would likely be relevant to the agency as it adjusts the starting point for the negotiation based on the clinical benefit. Vizient reiterates our willingness to serve as resource to CMS.

Per the IRA, CMS is to consider a range of factors when developing an initial offer, including manufacturer-specific data and evidence about therapeutic alternatives. In the Guidance, CMS also notes that in determining the initial offer, it will consider various aspects of a selected drug's clinical benefit drug compared to therapeutic alternatives. While not exhaustive, the agency indicates it will consider factors related to clinical benefit, safety and patient experience. Vizient encourages CMS to also consider resiliency and supply assurance when evaluating such products. While a more frequent concern with multisource medications, the market has had to withstand interruptions of sole source, branded pharmaceuticals, including biologic products.

Monitoring Access to the MFP

As provided in the IRA, the Primary Manufacturer[8] is to provide access to the MFP to MFP-

[7] CMS clarifies the cost of the selected drug would be per 30-day equivalent supply rather than per unit (e.g., tablet, capsule, injection)

[8] As provided in the Guidance, "In section 1191(c)(1) of the Act, the Negotiation Program statute adopts the definition of "manufacturer" established in section 1847A(c)(6)(A) of the Act. Section 1193(a)(1) of the Act establishes that CMS will negotiate an MFP with "the manufacturer" of the selected drug. To the extent that more than one entity meets the statutory definition of manufacturer for a selected drug for purposes of initial price applicability year 2026, CMS intends to designate the entity that holds the NDA(s)/BLA(s) for the selected drug to be "the manufacturer" of the selected drug (hereinafter "Primary Manufacturer"). Likewise, for initial price applicability year 2026, CMS intends to refer to any other entity that meets the statutory definition of manufacturer for a drug product included in the selected drug and that either (1) is listed as a manufacturer in an NDA or BLA for the selected drug or (2) markets the selected drug pursuant to an agreement with the Primary Manufacturer as a "Secondary Manufacturer." Secondary Manufacturers would include any manufacturer of any authorized generics and any repacker or relabeler of the selected drug that meet these criteria."

eligible individuals[9] at the pharmacy, mail order service or other dispenser at the point of sale, and to the pharmacy, mail order service, or other dispenser with respect to such MFP-eligible individuals who are dispensed the selected drug. Also, CMS "reiterates that the requirement to provide access to the MFP applies to all sales of the selected drug to MFP-eligible individuals and to pharmacies, mail order services, and other dispensers that are providing a selected drug to an MFP-eligible individual".[10] Vizient appreciates the agency's clarification as it may help prevent access challenges for providers. We encourage CMS to gain additional input from providers to determine whether other aspects of the Guidance should be clarified.

In the Guidance, regarding operationalizing access to the MFP, CMS also notes "there is widespread use of chargeback payments and rebate mechanisms among the pharmaceutical stakeholders in the private sector, which allows for entities to receive rebates or discounts on their purchases after those purchases are made, based on the specific population to whom the drug or biological is dispensed."[11] Vizient is concerned that circumstances where the dispenser would have to submit for a rebate would add administrative burden, especially as additional review may be needed to identify when a rebate request would need to be submitted. Also, Vizient emphasizes the financial challenges that dispensers would endure due to higher inventory costs upfront and, adding to this, creating cash flow issues while waiting for both reimbursement and the manufacturer to make them whole. These financial challenges would be exacerbated as MFP reimbursement would also be lower. We encourage CMS to work with dispensers to identify options that would be less burdensome from both an administrative and financial perspective. Our comments would also apply should the agency consider a similar approach for Part B. We urge the agency to work closely with healthcare providers in refining this policy.

Similarly, we request the agency to work with providers in identifying their implementation needs and a process to report circumstances in which MFP pricing is not made accessible, including delays or burdensome processes to obtain such pricing. As noted, barriers to obtain such pricing could result in pharmacies and other dispensers taking financial losses that would likely be untenable and potentially jeopardize patient access to care. We urge CMS to carefully consider these concerns and regularly work with providers on solutions before and after implementation for both Part B and Part D. Further, we encourage CMS to develop policies to help ensure manufacturers provide prompt payment to providers and do not unnecessarily delay payments, including by imposing additional demands on providers.

---

[9] As provided in the Guidance, "In accordance with section 1191(c)(2) of the Act, the term "maximum fair price eligible individual" means, with respect to a selected drug, the following: in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under Medicare Part D or an MA–PD plan under Medicare Part C (including enrollees in Employer Group Waiver Plans (EGWPs)) if coverage is provided under such plan for such selected drug; and/or in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under Medicare Part B, including an individual who is enrolled in an MA plan under Medicare Part C, if payment may be made under Part B for such selected drug."

[10] Guidance, p. 60

[11] Guidance, p. 65

Monitoring for Bona Fide Marketing of Generic or Biosimilar Product

As provided in the IRA, a selected drug will no longer be subject to the negotiation process if certain circumstances are met, including a determination that a generic or biosimilar has been marketed as evidenced by prescription drug event (PDE) data.[12] CMS intends to monitor whether "robust and meaningful" competition exists in the market once a selected drug is no longer a selected drug. While CMS seeks comment on the most effective ways to monitor whether robust and meaningful competition exists in the market, Vizient encourages the agency to first clarify what is meant by "robust and meaningful" competition.

Also, CMS provides examples of monitoring including whether the generic drug or biosimilar biological product is regularly and consistently available for purchase through the pharmaceutical supply chain, and whether it is available for purchase by community retail pharmacies in sufficient quantities from their wholesale suppliers. Vizient believes other data, such as national market share, presence at distributors, on group purchasing organization (GPO) contracts, and included in payer formularies could be among the several factors CMS considers to help inform whether "robust and meaningful" competition exists, depending on the context (e.g., Part B or D drugs) and product. Vizient also encourages CMS to gain insights from stakeholders as it evaluates whether "robust and meaningful" competition exists.

Research and Development Costs

In the Guidance, CMS outlines its interpretation of the primacy manufacturer's research and development costs which are to be collected and used in the Negotiation Program. Vizient believes publicly sharing research and development costs, including recoupment of such costs, could help improve transparency. To the extent possible we encourage CMS to make this information publicly available. Should such availability not be possible, we suggest the agency consider making this information available in an aggregated view as this would also help improve transparency and understanding of true research and development expenditures.

Provider Input

Vizient understands that the IRA included several ambitious deadlines to which CMS has worked to adhere. We appreciate the agency's efforts at promptly sharing information with stakeholders and seeking 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 and consistently seek their input. In addition, while the Guidance focuses on Part D drugs, we encourage the agency to clarify aspects of the Guidance that may also be applicable to Part B so that stakeholders may

[12] The two circumstances are, "(1) the FDA has approved a generic drug under section 505(j) of the FD&C Act that identifies as its reference listed drug a product that is included in the selected drug, or the FDA has licensed a biosimilar biological product under section 351(k) of the PHS Act that identifies as its reference product a product that is included in the selected drug; and, (2) the generic drug or biosimilar biological product, as applicable, is marketed pursuant to such approval or licensure."

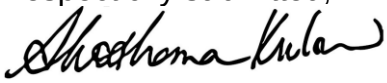
respond before the Part D policies are implemented and would potentially be more challenging to modify for Part B.

Conclusion

Vizient thanks CMS for the opportunity to share feedback in response to the Guidance. Vizient emphasizes the importance of minimizing provider burden and proactively engaging providers regarding IRA implementation plans to gain their feedback and perspectives.

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 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 issues.

Respectfully submitted,



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