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Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Administrator Oz,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) draft guidance for the third cycle of the Medicare Drug Price Negotiation Program (MDPNP), the first cycle of renegotiation, and the Primary Manufacturer effectuation of the Maximum Fair Price (MFP) for 2026, 2027 and 2028 for the implementation of the Inflation Reduction Act (IRA) (hereinafter "draft guidance"). Consistent with prior comments, Vizient is concerned that various elements of the MDPNP, particularly the retrospective refund, will be disruptive to providers and the patients they serve.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents $140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

Recommendations

Vizient is responding to elements of the Draft Guidance which would pose challenges to providers. We continue to urge CMS to better address provider concerns, particularly related to additional financial strain and administrative burdens associated with variable Primary Manufacturer effectuation plans (e.g., retrospective rebate models) and challenges with the complaint and dispute resolution processes. Vizient offers suggestions for the agency's consideration, including that the agency work closely with providers to better ensure the MDPNP does not cause harm and disrupt care.

Section 40 – Requirements for Manufacturers of Selected Drugs

40.4 Providing Access to the MFP in 2026, 2027, and 2028

In the Draft Guidance, CMS indicates that it is not yet including detailed policy on providing access to the MFP for selected drugs payable under Part B. However, CMS also notes that the agency aims to align the Part B policies and operations for providing access to the MFP with

those for Part D. Vizient appreciates that CMS identifies different topics related to Part B in the Draft Guidance for feedback (e.g., how effectuation of the MFP refund payments for drugs payable under Part B may differ from what is outlined for Part D) and agrees that additional information is needed before CMS provides detailed policy on access to the MFP under Part B. Vizient recommends that CMS, in developing Part D policies, simultaneously consider the feasibility of alignment with Part B by engaging directly with providers. Further, we encourage CMS to clarify the circumstances, particularly in the context of effectuating access to the MFP, in which it currently anticipates Part B policy and operations will differ from Part D.

Also, in the Draft Guidance, CMS seeks feedback regarding different functions of the Medicare Transaction Facilitator (MTF) and whether these functions can be replaced by private solutions. As CMS is aware, the MDPNP has yet to be implemented and IPAY 2028 will pose new challenges as more types of providers and products will be included in the program. While Vizient appreciates the agency's interest in gaining feedback, we are concerned that these decisions will be made prematurely and without provider input. As such, Vizient cautions CMS from narrowing the role of the MTF.

Vizient appreciates that CMS will provide effectuation plans to dispensing entities via the MTF and to other stakeholders upon request, as this will add significant transparency. We urge CMS to keep this flexibility as the Draft Guidance is finalized. Vizient also urges CMS to provide additional transparency by sharing information about access to the MFP. For example, reporting aggregated information stratified by product regarding the volume of MFP denials, reasons for denial, frequency with which the prompt pay requirements were not met and expenses associated with denials would help add to this transparency. Vizient also encourages CMS to work with providers to define and identify other data elements related to the complaint and dispute process.

40.4.1 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount

In the Draft Guidance, CMS indicates that regardless of whether the MFP is passed through the MTF Payment Module (PM) or payment is made outside of the PM, neither Primary Manufacturers nor their third-party vendors shall charge dispensing entities any transaction or other fees for the pass-through of the MFP refund to the dispensing entity. As CMS is aware, providers are already under significant financial strain and imposing greater upfront costs on providers while they wait for refunds exacerbates these strains. Although Vizient appreciates the agency's clarification to prevent additional fees, Vizient continues to urge CMS to ensure prospective access to the MFP to support providers, rather than a retrospective refund. Alternatively, if retrospective refunds are permitted, CMS should strengthen prompt payment requirements so that the MFP is effectuated as soon as possible by the Primary Manufacturer, including when the Primary Manufacturer or their third-party vendor lacks certainty about the appropriateness of MFP pricing.

Regarding the potential pass-through of fees, Vizient believes additional clarifications and protections would be helpful for providers. For example, CMS could provide information about how it intends to monitor whether additional fees are passed through to providers or how CMS plans to identify such fees. CMS could also make clear that Primary Manufacturers cannot limit access to medications by requiring providers to contract with third parties, particularly those who charge fees to providers or require additional information from providers. Vizient encourages CMS to regularly collaborate with providers to respond to these and other questions, as they emerge.

In addition, CMS may not be aware that providers can face other types of burdens should payment be provided outside of the PM, even if additional fees are prohibited. For example, third-party solutions that are not interoperable with existing systems or require use of new portals shift burden onto providers and should be avoided. Vizient encourages CMS to ensure that Primary Manufacturers and their third-party vendors do not create additional burden or fragmentation from the provider perspective.

Lastly, the Draft Guidance does not detail providers' recourse opportunities or the scope of the agency's oversight in the context of Primary Manufacturers' third-party vendors. Should Primary Manufacturers' arrangements with third parties be the source of disruption for providers (e.g., withholding of the MFP, inaccurate payments), CMS should provide policy to ensure such issues are promptly resolved and that dispensers are not burdened in having to communicate with multiple vendors or through different platforms, which adds burden. Should recurring issues emerge with certain vendors or practices, Vizient suggests CMS consider how these issues can be most promptly resolved and prevented, including by adding transparency regarding problematic practices.

40.4.2 Medicare Transaction Facilitator Data Facilitation

CMS requests comments on what role, if any, the MTF and/or Primary Manufacturers could play in notifying dispensing entities of claims that are not resolved within the timeframes noted in the Draft Guidance. Vizient believes it is critical that dispensing entities are immediately notified if a claim is not resolved and should receive clear status updates regarding claim resolution. Such communications should be clear and opportunities for standardization should be explored. In addition, to add transparency, providers should have easy access to the documentation and other resources Primary Manufacturers use when determining a claim's eligibility for a refund.

40.4.5 Nonduplication with 340B Ceiling Price

In the Draft Guidance, CMS indicates that a Primary Manufacturer may not provide access to the MFP if the claim is 340B-eligible and the MFP is greater than the 340B ceiling price. Also, CMS clarifies in the Draft Guidance that the Primary Manufacturer would be required to provide documentation demonstrating the claim was 340B-eligible and the 340B ceiling price was lower than the MFP request from CMS. Based on this information, providers may not have access to the documentation the Primary Manufacturer provides to CMS, but such documentation may be useful to providers should potential complaints or disputes emerge. Vizient suggests CMS require Primary Manufacturers to share this information with providers.

In addition, Vizient believes the Draft Guidance provides excessive latitude for Primary Manufacturers with respect to ensuring there is nonduplication with the 340B ceiling price, while also allowing Primary Manufacturers to defer refunds based on these concerns. Should retrospective refunds be permitted in the 340B program and the MDPNP, Vizient is concerned that providers will be in a position where a Primary Manufacturer does not provide either the 340B price or MFP. In these circumstances, provider access to appropriate pricing could hinge on burdensome complaint and dispute resolution processes and refund payments to providers would be excessively delayed, if paid at all. Vizient urges CMS to provide additional oversight of Primary Manufacturer decisions and financial support to providers as complaints and disputes are being resolved. Further, Vizient recommends modifying the Draft Guidance such that the Primary Manufacturer would be required to provide documentation demonstrating the claim was identified as 340B-eligible and the 340B ceiling price was lower than the MFP. In addition, as noted in more detail below regarding the complaint and dispute resolution processes, to prevent excessive financial harm to providers (i.e., non-payment or excessive delays of refunds), we recommend that the MFP refunds be given to the provider promptly, unless the Primary

Manufacturer is certain payment is improper (e.g., Primary Manufacturer is certain the 340B ceiling price was provided). Finally, we recommend CMS provide clear guidance for the MFP/340B complaint and dispute processes that can be handled at the claim level.

80. MFP-Eligible Individuals in 2026, 2027, and 2028

In the Draft Guidance, CMS indicates that beginning in 2028 for drugs selected or renegotiated for initial price applicability in year 2028, MFP-eligible individuals will include those enrolled under Part B, including those enrolled in a Medicare Advantage (MA) plan under Part C. While Vizient appreciates that CMS seeks feedback regarding the implications of including MA beneficiaries in the MDPNP, Vizient is concerned that broadening the scope of MFP-eligible individuals could add significant, unnecessary complications during a period where providers will also have to adjust to the MDPNP. Additionally, should MA plans align reimbursement rates with those provided under the MDPNP, Vizient believes it is imperative that providers have access to the MFP to avoid being significantly under-reimbursed.

Vizient is also concerned that other payers may aim to align reimbursement rates to providers with those provided under MDPNP, but provider access to the MFP will not be required in these circumstances. Should this occur, providers may incur significant financial losses due to inadequate reimbursement and related operational issues. While beyond the scope of the MDPNP, Vizient recommends CMS more broadly provide policy to prevent other types of payers from reducing provider reimbursement to align with rates resulting from the MDPNP, since providers will likely not have access to MFP for those products outside of the MDPNP and the related infrastructure (e.g., CMS oversight, MTF PM and DM) to support the program.

Lastly, Vizient reiterates our concerns that Primary Manufacturers may excessively withhold payments by improperly identifying non-MFP-eligible individuals. As a result, providers could face excessive delays for refunds, assuming they are able to utilize the complaint and dispute resolution processes. Vizient recommends that access to the MFP, including refunds, be given promptly to providers, unless the Primary Manufacturer is certain an individual is not MFP-eligible.

90.2.2. Centralized Intake System for Complaints and Disputes Related to MFP Availability and MTF Functionality

In the Draft Guidance, CMS details the complaint and dispute process, which will have two "tracks". The first track is a dispute functionality within the MTF regarding a technical aspect of the MTF process[1] and the second track is a complaint process that will include any issues that do not qualify as disputes (e.g., MFP not being made available; concerns regarding credit/debit ledger system). As CMS is aware, hospitals have limited resources and face challenges in devoting resources to raising and resolving complaints and disputes, especially given the resources spent on learning and implementing variable effectuation plans, and monitoring refund payments. Providers will likely be in an untenable position of having to decide whether to devote even more resources to dispute and complaint processes with uncertain outcomes. To prevent harm to providers, Vizient urges CMS to ensure that the MFP is prospectively provided to reduce burden and simplify the MDPNP. Again, should retrospective payment be permitted, refunds should be provided unless the Primary Manufacturer is certain that doing so is

[1] As provided in the Draft Guidance, "Under the Negotiation Program, CMS considers a dispute to be a specific, identifiable challenge to a technical aspect of the MTF system and process (e.g., claims included as potentially requiring an MFP refund)."

inappropriate and shares information demonstrating their position, as this heightened level of certainty may also limit the frequency of track 2 complaints. Vizient also recommends CMS provide additional technical assistance to providers throughout the complaint and dispute processes.

Lastly, Vizient strongly encourages CMS to share information regarding the complaint and dispute processes to add transparency. For example, information regarding complaint and dispute volumes, types of disputes, dispute duration and dispute outcomes (e.g., was the dispute rectified in favor of the provider) on an aggregated basis stratified by product will help increase transparency and inform future policies. Vizient encourages CMS to work with providers to define and identify other data elements to share related to the complaint and dispute processes.

Conclusion

Vizient appreciates CMS's efforts to gain additional feedback regarding the MDPNP. Vizient provides solutions and services that improve the delivery of high-value care for more than 65% of the nation's healthcare providers. In closing, on behalf of Vizient, I would like to thank CMS for providing the opportunity to respond to this 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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