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September 18, 2026

Submitted electronically via: IRARebateandNegotiation@cms.hhs.gov

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program Draft Guidance: Manufacturer Effectuation of the Maximum Fair Price in 2028

Dear Administrator Oz,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Draft Guidance on Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2028 under the Medicare Drug Price Negotiation Program (MDPNP) (hereinafter, "Draft Guidance"). The Draft Guidance is particularly important for providers because it establishes new processes for effectuating the MFP for selected drugs payable under Medicare Part B beginning in 2028. Consistent with our prior comments, Vizient remains concerned that retrospective refund models, variable manufacturer processes, and new data and enrollment requirements will create provider burden which may ultimately disrupt patient access to selected drugs.

Background

Vizient® enables healthcare providers to deliver better, more affordable care by improving financial sustainability, enhancing system performance, and accelerating strategic growth. More than two-thirds of the nation's acute care providers and more than one-third of ambulatory providers rely on Vizient solutions and services. By combining the nation's most influential healthcare leader networks with industry-leading data and analytics, comprehensive solutions, and advisory services through Kaufman Hall, Vizient helps providers achieve financial, clinical, and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at vizient.com.

Recommendations

Vizient appreciates the agency's efforts to provide detailed processes and requirements related to manufacturer effectuation of the MFP in 2028 with respect to selected drugs payable under Part B and/or covered under Part D. As part of this effort, the Draft Guidance describes procedures that may be applicable to drug manufacturers, Medicare Part D plan sponsors (both Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug (MA-PD) Plans),

Medicare Advantage organizations, pharmacies, mail order services, and other dispensing entities that dispense drugs covered under Medicare Part D (hereinafter "dispensing entities"), in addition to hospitals, physicians, and other providers of services and suppliers that furnish or administer drugs payable under Medicare Part B (hereinafter "Part B providers"). In our comments, Vizient specifically offers feedback on the impact of the Draft Guidance on Part B providers.

40.4 Providing Access to the MFP in 2028

In the Draft Guidance, CMS provides that a Primary Manufacturer must provide access to the MFP in one of two ways: (1) prospectively ensuring that the price paid by the dispensing entity and/or Part B provider when acquiring the drug is no greater than the MFP; or (2) retrospectively providing reimbursement for the difference between the dispensing entity and/or Part B provider's acquisition cost and the MFP. Should a retrospective reimbursement approach be finalized, Part B providers will face significant disruptions due to increased administrative burden, higher upfront costs, lagging refunds, and disputes with manufacturers. While such burdens and challenges have already been imposed on dispensing entities for Initial Price Applicability Years (IPAYs) 2026 and 2027, it is expected that similar issues will emerge for Part B providers.[1] Hospitals are already operating under narrow financial margins, as highlighted in a recent Hospital Flash Report from Kaufman Hall, and permitting retrospective access to the MFP unnecessarily exacerbates these challenges. Vizient urges CMS to require that Primary Manufacturers provide prospective access to the MFP.

Should CMS finalize allowing retrospective reimbursement, additional protections should be in place for Part B providers. For example, CMS could strengthen Primary Manufacturer requirements related to cash-flow mitigation arrangements to ensure they are broadly available and easily accessible with minimal burden on Part B providers. In addition, CMS could work with dispensing entities to identify circumstances where timely payments are not provided and consider solutions to avoid recurrence of these issues for all providers.

40.4.1.2 Retrospective Refund Amount to Effectuate the MFP and the Standardized Default Refund Amount for Drug Payable Under Part B

In the Draft Guidance, CMS describes a unique challenge in calculating the appropriate standard default refund amount (SDRA) for selected drugs payable under Part B because these products are billed with a Healthcare Common Procedure Coding System (HCPCS) code, which can include multiple National Drug Codes (NDCs). As the agency is aware, each NDC could have a different average sales price (ASP) and wholesale acquisition cost (WAC), making both the HCPCS code and resulting SDRA less accurate. As noted in Table 3 of the Draft Guidance (pg. 19), CMS seeks feedback on options to calculate the SDRA for selected drugs payable under Part B. Prospective access to the MFP would alleviate the need for a SDRA and much of

[1] https://www.vizient.com/insights/podcasts/verified-rx/inside-the-medicare-transaction-facilitator-early-wins-and-growing-pains

the administrative and cost burdens associated with a retrospective model primarily because prospective pricing prevents distorting access to the MFP, which occurs under a retrospective model where approximation approaches to determine the refund amount are needed. While Vizient appreciates the agency's interest in gaining stakeholder feedback regarding the SDRA, we encourage CMS to reconsider whether the benefits of allowing a retrospective refund are outweighed by the complexity, inaccuracies, and burdens associated with such a model.

While Vizient recommends the agency utilize prospective pricing, we acknowledge that CMS is considering whether to use WAC or ASP as a pricing metric should a retrospective model advance. Since ASP is an average price, some Part B providers may be paying more than ASP. If CMS selected this for the SDRA, some providers would be inadequately reimbursed. To avoid under-reimbursement challenges for providers, Vizient suggests CMS refrain from utilizing ASP for the SDRA.

Should CMS use WAC for the SDRA despite our concerns about the retrospective model, Vizient notes that this may increase cash flow concerns for providers who purchase at WAC, rather than a contracted or discounted price. Vizient has raised cash flow concerns to both CMS and the Health Resources and Services Administration in the context of the MDPNP and the 340B Rebate Model Pilot Program, which would replace the upfront 340B price with WAC.[2,3] While, in the Draft Guidance, CMS notes some approaches that manufacturers could utilize to support providers anticipating a material cash flow concern, it is unclear which, if any, of these measures Primary Manufacturers will use for Part B providers and the effectiveness of each approach. Further, additional analysis regarding dispensing entities' experiences with these support options could help stakeholders evaluate whether additional guardrails may be needed to ensure these serve their intended purpose. Vizient encourages CMS to provide additional oversight related to these Primary Manufacturer supports for entities anticipating a material cash flow concern, including if the agency anticipates Part B providers will have higher upfront prices.

Lastly, in the Draft Guidance, CMS indicates that the Primary Manufacturer must include whether it will use "the dispensing entity's and/or Part B provider's actual acquisition cost or a reasonable proxy for such a cost, such as the standardized pricing metric used in the calculation of the SDRA, to provide retrospective refunds to a dispensing entity and/or Part B provider." While CMS seeks comment on various approaches the agency is considering for the SDRA, it is unclear what degree of discretion a Primary Manufacturer has in establishing a reasonable proxy of the provider's actual acquisition cost. Vizient encourages CMS to ease provider burden and alleviate confusion by limiting potential variability among Primary Manufacturers' plans to make MFP available. Similarly, CMS should ensure that to make MFP available, manufacturer plans utilize providers' existing purchasing approaches and do not limit provider purchasing options.

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[2] https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/977db951625d4e0c8e0ec48c6b426342
[3] https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/d533fd0e5cb1495995e9d39a21ec9053

Conclusion

Vizient thanks CMS for the opportunity to comment on the Draft Guidance. Vizient's 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 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 issues.

Respectfully submitted,

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