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Submitted electronically via: www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Agency Information Collection Activities: Proposed Collection; Comment Request (Docket No.: CMS-2024-0323; Form CMS-10912; OMB Control Number: 0938-New)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Information Collection Request ("ICR"), which includes several forms[1], as implementation of the Medicare Drug Price Negotiation Program ("MDPNP") has a significant impact on our healthcare provider members and the patients they serve. Vizient continues to express concerns about implementation of the MDPNP from the provider perspective, particularly given the administrative burden, financial challenges and anticipated lack of transparency from manufacturers, as described in prior comments.

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 forms included in the appendix of the ICR that may pose challenges to providers. We continue to urge CMS to better address concerns providers have raised related to the MDPNP, particularly related to additional financial strain and administrative burden given the significant variation that may exist within effectuation plans, including harmful retrospective rebate models, and challenges associated with a dispute resolution process. Vizient offers suggestions for the agency's consideration regarding several forms included in the ICR, including certain questions, and we urge the agency to work more

[1] The ICR includes the following forms: Drug Price Negotiation Program MTF DM Dispensing Entity and Third-Party Support Enrollment Form (Appendix A); Drug Price Negotiation Program MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form (Appendix B); Drug Price Negotiation Program MTF DM Primary Manufacturer Payment Elements Form (Appendix C); and Drug Price Negotiation Program Complaint and Dispute Intake Form (Appendix D).

closely with providers to better ensure the MDPNP does not cause them harm and, indirectly, harm the patients they serve.

Comments regarding Appendix B: Drug Price Negotiation Program Medicare Transaction Facilitator (MTF) Data Module (DM) Primary Manufacturer MFP Effectuation Plan Form

According to the ICR, the MDPNP MTF DM Primary Manufacturer Maximum Fair Price (MFP) Effectuation Plan Form is designed to collect the necessary information from Primary Manufacturers related to the MFP Effectuation Plan. As currently drafted, there are no questions about steps manufacturers have taken to inform their effectuation plans to ensure they are reasonable to providers, no clear CMS approval process and it is unclear how incomplete or blank answers in the response section of the form would be treated. As a result, Vizient is concerned that this form may be too lenient, risking that this form would effectively be viewed as optional for manufacturers, and that the form does not provide adequate insight to the effectuation process. Vizient urges CMS to consider opportunities to enhance this form to better ensure that manufacturers are transparent, have tested and vetted detailed effectuation plans with providers and the forms are completed. Further, CMS should clarify its review and approval process for this form, particularly if coordination with other stakeholders or government agencies is needed to validate any information, to support smoother implementation.

Regarding Question 4, CMS asks the Primary Manufacturer to include their process for nonduplication of claims that are 340B eligible and not subject to MFP availability, and requests that certain additional information be included. As noted above, we are concerned that there may be too much flexibility in how these forms are completed by manufacturers and that CMS review and oversight is unclear. Further, Vizient notes that the form does not request that the Primary Manufacturer demonstrate how 340B program requirements would be followed under the effectuation plan, a point which was included in the Final Guidance.[2] We suggest the form be modified to ask this information of manufacturers, and that a more stringent review be provided by CMS, which would help ensure the form is more thoughtfully completed.

In Question 6, manufacturers are to choose one of four methods to calculate MFP refunds, but there is limited additional information asking how manufacturers will ensure transparency throughout the refund process. As CMS is aware, reconciling payments between pharmacies and pharmacy benefit managers (PBMs) has been a longstanding challenge which the agency should avoid duplicating through the MDPNP. Transparency is lacking in multiple ways, including that there is no indication on the forms whether providers (or what proportion of providers) were consulted regarding alternative refund amounts as considered in the Final Guidance[3] or how providers can seamlessly access and validate information manufacturers rely upon when providing MFP refunds. Also, in the form, there is no acknowledgement of whether a manufacturer has communicated with a provider to determine that an alternative amount is appropriate. While Vizient does not believe specific agreements between providers and manufacturers need to be disclosed for this purpose, we encourage CMS to add fields to

[2] In the Final Guidance (pg. 55), CMS provides, "CMS also notes that nothing in this guidance modifies a manufacturer's statutory obligations under section 340B(a)(1) of the PHS Act, including the obligation to provide the 340B ceiling price to eligible entities. Nothing in this guidance alters a manufacturer's liability under section 340B of the PHS Act for an overcharge violation and sanctions for failure to provide the 340B ceiling price to eligible entities pursuant to section 340B(d)(1)(B)(vi) of the PHS Act and 42 C.F.R. § 10.11."

[3] In the Final Guidance (pg. 69), CMS notes that "CMS encourages Primary Manufacturers and dispensing entities to work together to establish an MFP refund amount using the SDRA or the dispensing entity's actual acquisition cost or an adjusted standardized pricing metric that ensures the MFP has been made available prior to the issuance of MFP refund payments between the interested parties."

enhance transparency, such as asking whether manufacturers have reached agreements with providers for alternative amounts or whether they plan on imposing alternative amounts unilaterally. Should the latter be permitted, which Vizient opposes, Vizient suggests that CMS consider more closely monitoring these manufacturers' behaviors to ensure providers are not harmed, as the dispute resolution process may pose a host of challenges to providers, particularly in these circumstances.

In Question 7, CMS notes that Primary Manufacturers should "Include a description of the documentation the manufacturer intends to retain to support any MFP refund calculations that do not use the Standard Default Refund Amount." Vizient is concerned that manufacturers may use this as an opportunity to request additional information be reported from providers, which would be burdensome for providers. While, at the same time, the manufacturer would not have to disclose or justify the specific need for the data. Vizient suggests that CMS clarify in the question that manufacturers may not request additional documentation from providers.

Regarding Questions 9-13, CMS requests information regarding alternative purchasing arrangements and notes that CMS may request copies of these contracts. Contracts may take a range of forms, such as having multiple products or purchasing circumstances considered and including other terms and conditions, such as confidentiality requirements, posing challenges for disclosure. Vizient encourages CMS to consider more targeted and flexible approaches to requesting information regarding alternative purchasing agreements given such agreements may not solely include products negotiated under the MDPNP.

Lastly, regarding Question 22, which relates to manufacturers assisting entities (e.g., pharmacies) with material cashflow concerns, CMS permits manufacturers to include additional qualifying criteria. Vizient suggests that CMS revise this section to remove 22c to clarify that manufacturers do not have discretion to determine whether a material cashflow concern exists. A determination of whether a material cashflow concern exists should be based on the entity's determination, not a manufacturer's decision.

Comments regarding Appendix D: Drug Price Negotiation Program Complaint and Dispute Intake Form

Vizient appreciates the establishment of a complaint and dispute process but recommends enhancements to make it more accessible and feasible for providers, who often have fewer resources than manufacturers. For example, more detailed guidance regarding the distinction between a complaint and dispute would be helpful, particularly as diverse scenarios arise. In addition, Vizient suggests that CMS give providers more flexibility regarding supporting documentation needs, as the examples noted on the form may be excessively burdensome to obtain and there could be a range of challenges in sharing certain information (e.g., confidential information, information containing patient information, sensitive information).

Further, Vizient notes that it is unclear how CMS will use or share this information once submitted. As a result, Vizient suggests that CMS provide significant deference to providers' detailed description of issues and for providers, not require additional supporting documentation. As a less burdensome alternative for providers, CMS could accept an attestation regarding the accuracy of the information shared rather than requiring supporting documentation to be uploaded in the initial complaint or dispute process.

Conclusion

Vizient thanks CMS for considering feedback related to the ICR and we continue to encourage the agency to consider provider perspectives as it works to implement the MDPNP.

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 the opportunity to comment on the ICR. 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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