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

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

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Seshamani:

Vizient, Inc. appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services (CMS) Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (hereinafter the "Draft Guidance").[1] Also, Vizient thanks CMS for hosting listening sessions regarding the Draft Guidance to better understand stakeholder perspectives regarding implementation of the drug price negotiation provisions of the Inflation Reduction Act (IRA). While Vizient is not commenting on all questions posed in the Draft Guidance, Vizient urges CMS to better ensure that implementation of the IRA will not have unintended consequences for providers and that significant effort is made to ensure access to the MFP is provided prospectively. Further, Vizient recommends that CMS work closely with providers, particularly hospitals and health systems, to ensure implementation of the IRA's drug negotiation provisions do not cause harm, disruption, and administrative burden on providers.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics and consulting services, as well as a contract portfolio that represents $140 billion in annual purchasing volume. Solutions and services from Vizient improve the delivery of high-value care by aligning cost, quality and market performance. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

[1] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Recommendations

Vizient appreciates the willingness of CMS to consider stakeholder feedback regarding the Draft Guidance which provided additional information regarding manufacturer effectuation of the Maximum Fair Price (MFP) in calendar years 2026 and 2027. While Vizient thanks CMS for clarifying that for 2026 and 2027, the agency "does not expect manufacturers to provide access to the MFP of a selected drug to hospitals, physicians, and other providers of services and suppliers with respect to a drug furnished or administered to MFP-eligible individuals enrolled under Part B, including an individual who is enrolled in an MA plan"[2], we do have concerns that the Draft Guidance could negatively impact hospitals and other providers, especially if such policies continued for future years or if there is disruption to the 340B Program.

40.4 Providing Access to the MFP in 2026 and 2027

Voluntary Facilitation of the Retrospective Payments

In the Draft Guidance, CMS is soliciting comment on two distinct payment facilitation options which would be optional for dispensing entities and involve a Medicare Transaction Facilitator (MTF). The first option would involve the MTF collecting banking information from participating dispensing entities and providing that information to Primary Manufacturers electing to receive such information for the Primary Manufacturer to provide payment to those accounts. The second option would involve the MTF receiving aggregated refund amounts from participating Primary Manufacturers and passing through the refunds to participating dispensing entities.

Should CMS continue to develop a retrospective model despite our continued and prior concerns, we believe that the second option would be less harmful than the first option, and we provide additional considerations for the agency. In addition, Vizient notes our strong opposition to the first option as we are extremely concerned that it could lead to unintended consequences for providers, particularly as it is unclear whether manufacturers would find alternative uses for any data obtained to the detriment of providers, and there would be even less transparency and oversight to manufacturer practices, while also adding complexity for providers.

Vizient believes that second option is preferable since it would help minimize burden on dispensing entities as they would need to ensure only one entity, the MTF, has accurate banking information and the dispensing entity would need to track fewer transactions. Further, option two would limit variability in how Primary Manufacturers could provide payment to accounts. Also, Vizient believes option two provides greater transparency and assurance that dispensing entities would be reimbursed as CMS, through the MTF, could more easily consider this information when evaluating compliance.

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[2] https://www.cms.gov/files/document/medicare-drug-price-negotiation-draft-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf

Also, in the Draft Guidance, CMS provides that if a dispensing entity chooses to utilize the MTF payment facilitation functionality and later decides to no longer utilize it or modifies the selection of drugs for which it will use the MTF payment facilitation, the dispensing entity must notify CMS of this decision at least 90 calendar days prior to the effective date of the change. Given the MTF payment facilitation functionality has yet to be tested, implementation challenges could emerge that result in excessive payment delays to dispensing entities. As CMS is aware, providers often operate on extremely narrow margins, thus delays in payment can be highly disruptive to operations. Vizient is concerned that the 90 calendar day notice period could result in significant financial challenges for providers, especially if issues emerge with the MTF, such as a cybersecurity incident, that delay payment. Providers would effectively be forced to endure such challenges for an excessively long period of time. **Vizient urges CMS to consider opportunities to shorten the notice requirements for dispensing entities if they decide to no longer utilize the MTF payment functionality.**

In addition, in the Draft Guidance, CMS is soliciting comments on other potential considerations for facilitation services that may be provided through the MTF for dispensing entities. **To help minimize burden associated with identifying 340B claims, Vizient recommends that CMS ensure 340B third party administrators (TPAs) acting on behalf of covered entities can integrate with the MTF to identify 340B-eligible claims.** The automated process supported by the TPAs addresses the inherent risk and burden of the manual process for claim indicators. TPAs can identify 340B-eligible claims within 24 hours of prescription processing for inclusion in the Prescription Drug Event (PDE) submission to the Drug Data Processing System (DDPS) and supporting the 14-day prompt-MFP payment window. **Vizient believes including TPA functionality with the MTF process to effectuate the MFP price will be the least disruptive to the current prescription dispensing and support integrity for the IRA and 340B programs.**

<u>30-day Window for Plans to Submit Prescription Drug Event Records</u>

In the Draft Guidance, CMS indicates it is evaluating whether the current 30-day window for plans to submit PDE records should be shortened to seven days to ensure dispensing entities receive timely payment of MTF refunds. As CMS considers shortening the 30-day window to a 7-day window, Vizient suggests that the agency also consider policy for when unclaimed prescriptions must be returned to stock, which is often 14 days from the fill date and can result in an adjudicated claim being reversed. Vizient thanks the agency for considering opportunities to better ensure dispensing entities receive timely payment.

Also, in the Draft Guidance, CMS notes that it is evaluating options for the process, timing, and frequency by which files containing claims-level data elements will be transmitted from the MTF to Primary Manufacturers. As providers operate on slim margins and cannot afford to wait to be made whole on medications that are eligible for MFP pricing, including for several weeks or months, **Vizient urges CMS to transmit data from the MTF to Primary Manufacturers on a daily basis to prevent delays in processing.**

Further, additional attention should be paid to ensure the MTF promptly reviews data received. As provided in the Draft Guidance, delays on the part of the MTF will also delay the start of the

14-day prompt payment window, ultimately delaying when a dispensing entity would be made whole, among other potential concerns. **Vizient recommends that CMS require the MTF to promptly review received data, in addition to sending data to the MTF daily.**

Payment Elements

In the Draft Guidance, CMS provides that Primary Manufacturers, inclusive of any of the Primary Manufacturer's contracted parties, will be required to include in the report with payment-related data the corresponding data elements previously transmitted by the MTF in addition to the payment elements listed in Table 3 of the Draft Guidance for all claims that are transmitted by the MTF to the Primary Manufacturer regardless of whether a refund was paid. Also, these payment elements would be submitted to the MTF with the corresponding information from the MTF claim-level data elements file. Notably, in Table 3, CMS indicates that leaving certain payment elements blank will also have a meaning (e.g., If "MFP Refund Transaction Date", "Confirmation of MFP Refund to Dispensing Entity", and "Amount of Payment Sent as the MFP Refund" is left blank then that would mean the claim was prospectively purchased or a refund was not sent). Vizient discourages CMS from permitting any fields from being left blank, particularly where different inferences could be drawn if a field is left blank as this could create unnecessary confusion. In addition, it is unclear how CMS would interpret circumstances where only one field is left blank. **Vizient suggests that CMS refrain from allowing fields to be left blank to promote greater clarity and consistency.**

Electronic Remittance

In the Draft Guidance, CMS welcomes comment on the concept of the MTF creating and sending an electronic remittance advice to dispensing entities to reconcile the payment provided by the Primary Manufacturer's retrospective refund payments. Vizient provider members have expressed concerns regarding the administrative burdens that could emerge as a result of the Drug Price Negotiation Program, including efforts to ensure refunds have been appropriately provided. Vizient believes that having the MTF create and send electronic remittances in advance to dispensing entities may help minimize administrative burden. Vizient suggests that electronic remittance advice be provided at the same time payment is provided to the dispensing entity.

Additionally, CMS welcomes feedback on other methods for electronic remittance advice, including Primary Manufacturer electronic remittance advices, and specific data elements for such electronic remittance advices to ensure that accounts receivables can be closed for dispensing entities. Vizient suggests that such information should be standardized and compatible with current systems and processes providers, such as hospitals, utilize for similar processes. Vizient would have concerns if each Primary Manufacturer followed different approaches for electronic remittance as this would increase burden. As noted above, utilizing the MTF for this process may help minimize administrative burden on the part of providers.

Also, regarding claim adjustments and reversals, CMS invites comments on whether CMS should recognize a certain timeframe for paying or collecting claim adjustments, whether these should be considered as offsets to future claims to a dispensing entity that was overpaid, and

any additional approaches commenters may wish to see from the MTF data functionality for addressing claim adjustments. Vizient supports the use of the MTF for claims adjustments and reversals as this could avoid scenarios where manufacturers try to claw back or withhold funds from providers. Vizient anticipates that we would have additional comments regarding the role of the MTF should additional information about the MTF be made available, including real-world testing of different processes. **We encourage CMS to work with providers and share information about the MTF, and any related testing or pilots, before finalizing the scope of roles the MTF will perform.**

Nonduplication with 340B Ceiling Price

In the Draft Guidance, although CMS recognizes the various functions of TPAs in the context of the 340B Program, the agency does not provide guidance to enable the integration of TPAs with the MTF to identify 340B-eligible claims. Rather, CMS only "strongly encourages manufacturers to work with dispensing entities, covered entities and their 340B TPAs, and other prescription drug supply chain stakeholders (e.g., wholesalers) to facilitate access to the lower of the MFP and the 340B ceiling price".[3] Vizient members, many of which are 340B covered entities, recognize the need for nonduplication of a covered entity's access to both the 340B ceiling price or MFP for a given claim. TPA software programs (e.g., stand-alone split billing systems or functionality within pharmacy dispensing systems) are currently integral in the 340B program to identify 340B-eligible claims vs. non-340B-eligible claims. Their performance has been proven to support program compliance by 340B covered entity internal audits as well as Health Resources & Services Administration (HRSA) audits for 340B program integrity. **Vizient urges CMS to enable the integration of covered entities' TPAs with the MTF to identify 340B-eligible claims irrespective of the use of claim indicators**.

As noted in the Draft Guidance, CMS would allow the Primary Manufacturer to calculate the difference between MFP and 340B price to support the nonduplication efforts. Vizient is concerned this approach introduces another complex process and burden for 340B covered entities, particularly when each primary manufacturer can establish their own process.
In the Draft Guidance, CMS outlines a retrospective refund model to effectuate access to the MFP, however, by enabling this method of accessing 340B discounts, CMS may be unintentionally altering how the 340B discount is provided to covered entities that goes beyond MFP drugs and therefore beyond CMS's authority. **Vizient urges CMS to avoid final guidance that enables a retrospective payment of the 340B discount.** In other words, CMS should clarify that a manufacturer would not be permitted to utilize information obtained through the MTF or as otherwise required to comply with the Drug Price Negotiation Program for other purposes, including providing access to 340B pricing. Further, CMS should emphasize to manufacturers that the statutory requirement to provide access to the MFP to 340B covered entities in a nonduplicated amount to the 340B ceiling price does not mean that manufacturers can delay providing access to 340B pricing.

[3] Draft Guidance at pg. 50

Also, the Draft Guidance's 340B refund model does not include detail regarding transparency and oversight in how the 340B refund is returned to the covered entities in the same way that this is created for the MFP refund with the MTF. Without this transparency or oversight, this model could result in manufacturers conditioning 340B sales or discriminating 340B access. This would result in additional labor, time, and costs, which could strain safety net providers even further.

Furthermore, there is no time-limit specified in the Draft Guidance that requires prompt payment by the primary manufacturer. This lack of a time-limit and the varied methods for implementing 340B refund models may lead to increased Administrative Dispute Resolution (ADR) suits and loss of transparency for HRSA.

It is important to consider these potential challenges and burdens that may arise from implementing the Draft Guidance. Safety net providers rely on the 340B program to support their services to underserved populations. Vizient urges CMS to include and financially support HRSA's Office of Pharmacy Affairs in meeting the statutory requirement for Nonduplication with 340B Ceiling Price and MFP so that both drug pricing programs can meet their congressional intent. Also, Vizient recommends that CMS work more closely with covered entities to identify alternative policies that would not harm covered entities or cause disruption.

90.2 Monitoring of Access to the MFP in 2026 and 2027

<u>340B Program</u>

As noted in the Draft Guidance, CMS is exploring the scope of disputes and complaints that the agency may remediate in the context of an otherwise private transaction between the Primary Manufacturer and dispensing entity. Regarding disputes related to the 340B Program, Vizient believes the HRSA 340B ADR process is appropriate to use when the 340B price is not made available by the Primary Manufacturer. To help streamline these cases, providers and HRSA would need access to the documentation indicating that the Primary Manufacturer did or did not provide the MFP refund in the case of a 340B-eligible drug. As such, Vizient encourages CMS to finalize policy that sets a clear expectation that Primary Manufacturers must demonstrate their justification of nonpayment of MFP because the claim was 340B eligible when the 340B price is less than MFP. The requirement for the Primary Manufacturers to justify their rationale for the nonpayment promotes transparency and accountability for CMS and dispensers.

Given the potential increase in the number of 340B disputes as a consequence of the negotiation program, Vizient believes that HRSA will require financial support, such as support from CMS, to effectively handle these disputes. Also, Vizient anticipated that such collaboration can help ensure that covered entities have a clear and efficient pathway to either obtain the 340B price or receive an MFP refund when appropriate.

Vizient believes it is important for CMS to work with HRSA to establish clear processes for dispute resolution, ensuring that dispensers receive the appropriate drug price and promoting transparency and accountability in both the 340B Program and Medicare Drug Price

Negotiation Program. Also, given dispensers eligible for 340B will likely have multiple dispute resolution processes to obtain either the 340B price or MFP, a clear framework is needed to prevent redundancy and confusion.

Reports of Complaints and Disputes

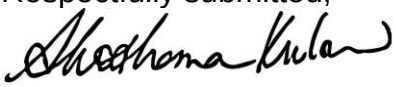
Should a dispute emerge that is not related to the 340B program, Vizient urges CMS to ensure that such a process is accessible to dispensing entities without unnecessary burden. We encourage the agency to learn from other dispute resolution processes involving providers. For example, as seen in the context of surprise billing, an extremely large volume of disputes has been brought, resulting in a backlog and several of the disputes may be missing elements to advance the resolution process. Vizient cautions CMS from providing a dispute resolution process that is too complex and burdensome for providers as they effectively face financial risk with each transaction involving a product selected for negotiation and when filing a dispute (e.g., delays in payment, financial and administrative burdens associated with collecting data to file a claim, potential fees associated with filing a claims). Therefore, Vizient urges CMS to work closely with providers to streamline any dispute process and to utilize the MTF where appropriate to proactively address circumstances where manufacturers are slow to provide refunds.

Also, Vizient suggests that CMS provide opportunities for providers to issues complaints and disputes. Such information could be used to inform enforcement activity, in addition to helping support the prompt resolution of disputes. For example, should a complaint be issued regarding a new issue impacting the program, CMS could proactively share steps that manufacturers could take to promptly resolve such issues.

Conclusion

Vizient thanks CMS for the opportunity to share feedback in response to the Draft Guidance. Vizient emphasizes the importance of minimizing provider burden, including avoiding disruptions to current purchasing and reimbursement practices. 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 us the opportunity to comment on the 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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