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Thomas J. Engels
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MC 20852

Re: 340B Program Notice: Application Process for the 340B Rebate Model Pilot Program (HHS Docket No. HRSA-2025-14619)

Dear Administrator Engels,

Vizient, Inc. appreciates the opportunity to provide feedback to the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA)[1] notice and request for comments (RFC) regarding the application process for the 340B Rebate Model Pilot Program (hereinafter "Pilot Program"). Vizient appreciates the efforts of HRSA to address issues critical to covered entities (CEs), including data security, handling of patient identifying information and CE-reported elements. However, Vizient is concerned that the Pilot Program, particularly if expanded, will create significant challenges for CEs. While we oppose providing access to 340B pricing retrospectively via a rebate, we also offer comments to HRSA that aim to minimize disruptions to CEs related to the Pilot Program, especially given the rapid implementation timeline. Further, should the Pilot Program advance for calendar year 2026, we recommend that HRSA carefully consider and evaluate the need to expand the pilot program.

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 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. Vizient provides expertise, analytics, consulting services and a contract portfolio that represents $140 billion in annual customer purchasing volume to improve patient outcomes and lower costs.

Comments

In our comments we respond to various policies provided in the RFC and 340B Rebate Model Pilot Program Frequently Asked Questions (FAQs)[2], and reiterate our concerns with manufacturers shifting away from prospective access to 340B pricing to retrospective access. Since the RFC announces the availability of an immediately effective Pilot Program, with an effective date of January 1, 2026 for approved models, we recommend that HRSA promptly

[1] The OPA administers the 340B Drug Pricing Program.
[2] https://www.hrsa.gov/opa/340b-model-pilot-program

consider modifications to the Pilot Program to minimize burdens on CEs and the patients they serve.

Are there any additional flexibilities to maximize efficiency and efficacy for participating manufacturers that should be considered in the pilot design?

In the RFC, HRSA already provides significant flexibilities to manufacturers, allowing them to design each element of the rebate model program criteria (e.g., IT platform selection, notice, technical assistance/ customer service component, data security and protection). As a result, there may be significant variation in each manufacturer's plans which adds operational burden to CEs as they must navigate multiple plans. Further, variation in manufacturer pilot design may hinder consistent evaluation of the Pilot Program's effectiveness. As such, Vizient strongly discourages providing additional flexibilities to manufacturers. Rather, we believe additional limitations on manufacturers are needed.

Are there any additional safeguards to mitigate adverse, unintended impacts for covered entities that should be considered in the pilot design?

Safeguards Related to Manufacturers

The RFC provides certain safeguards to CEs, such as assurances that IT platform data is secure and protected, and collection of data elements is limited to those items specified in the RFC. Vizient appreciates the recognition of the need to ensure data security and protections are in place for CEs. This safeguard should be strengthened, however, to limit how manufactures and IT platforms can potentially use submitted data such that use is confined to the Pilot Program. Another safeguard HRSA should consider is to promptly end a manufacturers' ability to participate in the Pilot Program should data security and use issues occur.

In the Notice, manufacturers would have the option to specify in their plans whether rebates will be paid the package or unit level. Yet, manufacturers are also required to pay rebates within 10 calendar days of data submission by CEs. It is unclear from the RFC how rebates would be paid at the package level within 10 days if the data submitted is for less than a package. In addition, permitting manufacturers to reimburse at the package level may cause significant challenges for small and rural providers who furnish a lower volume of impacted medications. Such providers would be under significant financial strain as it is unclear whether they would receive a rebate in a timely fashion (i.e., 10 days after data submission) as the data submitted may not reflect enough medication was dispensed for a package size rebate. Further, providing the option for variable rebate payment adds unnecessary variation to the program and administrative burden for CEs. HRSA could prevent such issues by not providing an option for manufacturers to specify package level reimbursement.

In addition, more safeguards are needed to prevent manufacturers from advancing plans that can disrupt patient care and operations for CEs. For example, through a rebate approach for 340B, CEs will need to purchase products at higher upfront prices (e.g., Wholesale Acquisition Cost) while waiting for rebates. Additional funds will be needed by CEs to support these higher upfront prices and CEs may not be able to afford such purchases. As a result, patient access to needed medications could be compromised. Further, CEs will have the added burden of needing to review any rebates provided by manufacturers to ensure accuracy and to devote additional resources should disputes emerge. As such, for purposes of pilot design, Vizient suggests that additional protections (e.g., additional data protections, funding to support

additional personnel, expenses associated with third-party administrator fees) for CEs be included to address these financial and operational challenges.

Safeguards to Prevent Broad Disruption

HRSA should also consider narrowing the scope of products or volume of rebates that a manufacturer is permitted to provide such that most purchases remain prospective. Additionally, HRSA should consider limiting the Pilot Program to certain states, such as those states whose laws, Medicaid regulations or guidance, would not need to be modified or reinterpreted to adapt to the Pilot Program. Further, HRSA could make CE participation in the Pilot Program voluntary.

Vizient notes that additional protections and resources may be needed for CEs in advance of and during the Pilot Program. CEs will likely need to use additional resources, including hiring additional staff, to implement the program even though only 10 drugs would be included initially. As such, Vizient suggests that HRSA consider strategies to provide additional support to CEs to address this additional burden.

Safeguards to Prevent Confusion or Conflicting Policy

As HRSA is aware, certain states have requirements related Medicaid billing for medications at actual acquisition cost. Under the Pilot Program, covered entities' invoice prices would reflect a standard acquisition cost (i.e., wholesale acquisition cost (WAC)), and the covered entity would receive a rebate. As recently indicated in HRSA's Pilot Program FAQ[3], "While the upfront purchase will occur at WAC, the cost of a 340B eligible purchase is expected to be the 340B ceiling price, once the rebate is paid… Covered entities should work with state Medicaid agencies to determine best practices for billing." CEs may have challenges in determining how to be compliant with various state laws under this Pilot Program, particularly since CEs cannot seamlessly download large volumes of ceiling price information from the Office of Pharmacy Affairs Information System (OPAIS) Pricing Component. Should state Medicaid programs need additional information, Vizient encourage HRSA to make OPAIS Pricing Component information available to CEs in a more user-friendly format. Further, Vizient is concerned that state Medicaid agencies and the Centers for Medicare and Medicaid Services (CMS) will need to release additional information to help CEs adapt to the Pilot Program and that they may not have enough time to consider needed changes and provide notice to CEs of those changes before the Pilot Program goes into effect.

In addition, despite the Pilot Program helping facilitate access to appropriate pricing (i.e., Maximum Fair Price, 340B Price), it appears that CMS has not released information in response to the Pilot Program. For example, clarification from CMS regarding "actual acquisition cost" interpretation may be needed to help ensure accurate reporting of drug acquisition costs given the newness of the Pilot Program. Vizient recommends that HRSA work with CEs and CMS to identify and provide clarifications to existing policies and regulations in the context of the Pilot Program.

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[3] https://www.hrsa.gov/opa/340b-model-pilot-program stating, "While the upfront purchase will occur at WAC, the cost of a 340B eligible purchase is expected to be the 340B ceiling price, once the rebate is paid. It should be noted that covered entities have access to view the 340B ceiling prices through the Office of Pharmacy Affairs Information System (OPAIS) Pricing Component. Covered entities should work with state Medicaid agencies to determine best practices for billing."

Are there any additional data or reporting elements that should be required to improve implementation and evaluation of the pilot?

CE Claim-related Data Elements

In the RFC, HRSA indicates that manufacturer plans should limit data element requests to only readily available pharmacy claim fields.[4] Since many different site of care types may dispense the 10 products on the Medicare Drug Price Negotiation Program list,[5] Vizient is concerned that the specific data elements may be particularly challenging for other sites of care to report given variation in billing forms, potentially resulting in excessive denials from manufacturers, delays in claims submission or additional fees on the covered entity to try to modify systems or engage in disputes to access rebates. As a result, Vizient recommends that HRSA consider these additional challenges (e.g., changes to billing practices, additional reporting requirements, denials, disputes etc.) for covered entities as it considers the financial burden of the Pilot Program.

Should CEs be unable to meet these administrative demands based on their current operations, including if their current billing forms do not support any of the data elements listed, then HRSA should allow them to opt out of the Pilot Program, at least initially. Since HRSA may expand the Pilot Program, we believe that updating the data elements could be done in future years, rather than requiring CEs to begin reporting specific data elements (e.g., Rx Bank Identification Number (BIN) or Rx Processor Control Number (PCN)) solely for purposes of this Pilot Program. As such, HRSA should work with manufacturers to clarify that only those CEs submitting a pharmacy claim, as opposed to a medical claim, could be impacted by the Pilot Program.

Also, the RFC indicates that CEs are "afforded opportunities to raise concerns with the Office of Pharmacy Affairs..." and the FAQ provides an email address for CEs to raise concerns while noting that manufacturer participation in the Pilot Program may be revoked if rebate reimbursement issues are not resolved in a timely fashion.[6] Vizient strongly recommends that HRSA provide additional information regarding CE expectations after reporting issues to HRSA and a mechanism for CEs to track the status of a concern. Aggregated information regarding CE complaints could also be made available to enhance transparency. Vizient also encourages

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[4] In the RFC, HRSA indicates that "All data requested as part of the Plan should be limited to only the following readily available pharmacy claim fields:
a. Date of Service
b. Date Prescribed
c. RX number
d. Fill Number
e. 11 Digit National Drug Code (NDC)
f. Quantity Dispensed
g. Prescriber ID
h. Service Provider ID
i. 340B ID
j. Rx Bank Identification Number (BIN)
k. Rx Processor Control Number (PCN)"

[5] https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices

[6] https://www.hrsa.gov/opa/340b-model-pilot-program

HRSA to proactively communicate with CEs to identify issues with manufacturers and to provide technical assistance to CEs and contract pharmacies.

Manufacturer Data Sharing

While the RFC requires manufacturers to submit plans for approval, it is unclear how approval status and plan content will be shared with CEs and other stakeholders. The recent FAQs from HRSA indicate that OPA will provide a summary of all approved rebate model plans on its website and reiterates that manufacturers must communicate plan details to CEs 60 days before implementation. While this clarification is helpful, Vizient believes additional information sharing is needed to support transparency and implementation given that summary information may be inadequate and that manufacturers have significant latitude in their communications with CEs. Vizient encourages HRSA to increase transparency by requiring manufacturers to share complete rebate model plans and to post these plans on OPA's website. HRSA could also provide notice when a manufacturer's rebate model plan is denied for the Pilot Program.

Also, the RFC indicates manufacturer plans should "ensure that 340B rebates are not denied based on compliance concerns with diversion or Medicaid duplicate discounts…". Vizient appreciates the limited opportunities that exist for manufacturers to deny 340B rebates. To ensure manufacturers adhere to this requirement, Vizient suggests that manufacturers regularly share data regarding denials and the reasons for those denials. This reported information should be validated by HRSA with input from CEs, where appropriate, to confirm accuracy of manufacturers' data.

Evaluation

Lastly, regarding evaluation of the pilot program, the Notice indicates that assessment of the Pilot Program will include "OPA's evaluation of data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback." As drafted, this evaluation appears to primarily rely on manufacturer data which may be biased or not reflect CE experiences. While CE and other stakeholder feedback would also be considered, Vizient is concerned that the qualitative and informal nature of this evaluation approach may not fully represent the effectiveness of the Pilot Program. While Vizient is extremely sensitive to additional survey and administrative burdens that could be associated with providing quantitative data and other qualitative data, we believe OPA should work more closely with CEs to identify a more robust approach to evaluate the Pilot Program.

Are there any potential implementation issues not yet sufficiently accounted for in the pilot design (e.g., logistical or administrative burdens)?

HRSA Enforcement Approach

Vizient appreciates that the RFC indicates that CEs may raise concerns with HRSA if there are issues with rebate delays and denials, or any other administrative or logistical issues emerging through implementation of the rebate model. In the FAQ, HRSA indicates that "A manufacturer that is unable to timely resolve rebate reimbursement issues may have its participation in the pilot program revoked." We encourage HRSA to clarify that it may terminate the Pilot Program or a manufacturer's participation in the Pilot Program based on a range of issues, including manufacturers not resolving rebate reimbursement issues in a timely manner. Further, HRSA could provide strict limitations on the ability of a manufacturer to participate in future iterations of

the Pilot Program, should it be expanded to include other products, if manufacturer's actions lead to recurring challenges for CEs.

Coordination with the Centers for Medicare and Medicaid Services

While the scope of products impacted by the Pilot Program are only those products that will be negotiated through the Medicare Drug Price Negotiation Program (MDPNP) for initial price applicability year (IPAY) 2026 which is for Part D drugs only, the Pilot Program would apply regardless of payer and potentially to all CE types. For those CEs that are impacted by IPAY 2026, they are already working to attempt to prepare for the start of the calendar year 2026, and the inclusion of additional payer types adds increased burden and complication. In addition, for other CEs, the Pilot Program needlessly imposes their participation given there would be no data test for whether the Pilot Program could help support implementation of the MDPNP since those CEs are not directly impacted by IPAY 2026. Vizient is concerned that the broad scope of the Pilot Program, considering both payers and CEs, unexpectantly and unnecessarily creates excessive additional burdens for CEs that were intentionally not included in MDPNP IPAY 2026 policy.

Also, the RFC does not detail how components of the Pilot Program are meant to work alongside the MDPNP's Maximum Fair Price (MFP) or whether additional review was undertaken to ensure the Pilot Program and MDPNP are not disruptive to one another. For example, under the Pilot Program, plans "should ensure that all rebates are paid to the covered entity (or denied, with documentation in support) within 10 calendar days of data submission" and plans "should ensure that 340B rebates are not denied based on compliance concerns … and should provide for rationale and specific documentation for reasons claims are denied (*e.g.,* deduplication for MFP or 340B rebate provided to another covered entity on the same claim)." Vizient appreciates that HRSA recognizes the need for prompt payment of rebates and that manufacturers should not be able to deny claims without documentation. However, we are concerned that circumstances may arise where manufacturers inappropriately deny 340B rebates because a claim may be eligible for MFP or where MFP is provided and the 340B rebate not appropriately provided. Further, Vizient is concerned that CEs may also face operational challenges in trying to distinguish when MFP or 340B pricing should have been provided so may be unaware when an error occurs. Vizient encourages HRSA to work closely with CEs and the Centers for Medicare and Medicaid Services (CMS) to proactively avoid scenarios where CEs are denied the appropriate rebate due to the interplay of both rebate models. Also, Vizient suggests the HRSA consider whether a shorter payment window would be possible as CEs to minimize the duration of financial strain.

In addition, Vizient reiterates our above recommendation that additional guidance be provided from CMS related to actual acquisition cost, as noted above.

Additional Financial Burden on CEs

The Pilot Program does account for the additional cost and administrative challenges that CEs will need to incur. As provided, CEs will spend significant costs upfront to acquire medications at WAC, rather than the lower, 340B price. Then, CEs will have to wait until a patient needs a medication, the claim is submitted and data elements submitted to receive a rebate which will take time, particularly for medications that are not frequently or consistently used. Further, the CE would need to use additional resources to track claims to ensure rebates are provided and potentially reconsider which medications it can afford to hold in inventory, which could have downstream consequences on patient access. This combination of factors results in an

extremely large financial demand being placed on hospitals who already operate on narrow margins.[7] Vizient is concerned that the pilot design has not adequately considered these financial limitations, including whether CEs will be able to afford retrospective rebates or whether resources are available for CEs to adapt (e.g., hiring additional staff). As such, Vizient strongly recommends that HRSA perform a detailed economic impact analysis to ensure that CEs will not be adversely impacted, particularly small and rural CEs.

Vizient thanks HRSA for issuing the RFC as it provides an opportunity for stakeholder input. We also appreciate the protections provided to CEs but believe additional limitations on manufacturers are warranted. Thank you for your consideration. Please do not hesitate to contact me at (202) 354-2607 or shoshana.krilow@vizientinc.com if you have any questions or if we can be of assistance.

Sincerely,

Shoshana Krilow
Senior Vice President, Public Policy & Government Relations

[7] https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-may-2025-data