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Submitted electronically via: www.regulations.gov

The Honorable Carole Johnson
Administrator
Department of Health and Human Services
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Re: 340B Drug Pricing Program; Administrative Dispute Resolution (Docket No. 2021-0004)

Dear Administrator Johnson,

Vizient, Inc. appreciates the opportunity to comment on the Health Resources and Services Administration (HRSA) proposed rule to revise the current 340B administrative dispute resolution (ADR) process (hereinafter "Proposed Rule"). Generally, as provided in the Proposed Rule, the purpose of the ADR process is to resolve claims from covered entities when manufacturers overcharge them for covered outpatient drugs and for claims by manufacturers after their audit indicates a covered entity has violated the prohibition on diversion. There have been policy and operational challenges associated with implementing the 2020 rule which have prompted additional rulemaking.

Vizient applauds HRSA for proposing changes to the ADR process that aim to make the ADR process more accessible, administratively feasible and timely. However, we continue to emphasize the ongoing harm covered entities are enduring as manufacturers continue to halt or restrict the dispensing of 340B drugs at contract pharmacies. We appreciate the efforts of HRSA in responding to these harmful actions by manufacturers, such as HRSA's efforts to provide notice to manufacturers that their actions related to contract pharmacy limitations are in violation of the 340B statute[1] and referring manufacturers to the HHS Office of the Inspector General in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

[1] https://www.hrsa.gov/opa/program-integrity

Recommendations

In our comments, we respond to various questions and policies provided in the Proposed Rule. We thank HRSA for the opportunity to share recommendations related to a new ADR process. We emphasize the importance of ensuring that future regulations provide an ADR process that is accessible and administratively feasible for covered entities.

Panel Composition

HRSA proposes that the 340B ADR Panel would be comprised of Office of Pharmacy Affairs (OPA) staff. Also, each 340B ADR Panel member is to be screened prior to reviewing a claim to help ensure there are no conflicts of interest prior to reviewing a specific claim. In addition, HRSA proposes that the dedicated OPA staff members will have specific ADR duties as part of their job functions and that staff with these job functions will also be screened prior to being assigned to a 340B ADR Panel. Vizient appreciates efforts to prevent conflicts of interest and utilization of OPA staff given their expertise in the 340B Program.

Also, HRSA proposes that the 340B Panel may consult with, as appropriate or necessary, other staff within OPA, other HHS offices, other Federal agencies, or with outside parties to the extent additional information is needed. Vizient appreciates the need to consider multiple perspectives, especially as the future, unique aspects of disputes undergoing the ADR process remain to be seen. However, to the extent possible, Vizient encourages HRSA to also consider opportunities to screen such individuals for conflicts of interest, particularly conflicts of interest with manufacturers.

Claims

In the Proposed Rule, HRSA strongly encourages manufacturers and covered entities to work in good faith to resolve disputes before claims are initiated. In the Proposed Rule, HRSA seeks comment on whether a threshold for attempts at communication should be established. Vizient discourages HRSA from setting a threshold for attempts or rigid communication requirements as a requirement for a covered entity's claim to be accepted. Vizient is concerned such a threshold could discourage immediate responses from manufacturers and result in additional burden on covered entities who are already facing staffing challenges and have limited resources. However, additional guidance from HRSA regarding outreach efforts or documentation that a covered entity can maintain to demonstrate their good faith efforts may help covered entities, while still providing flexibility to the covered entity, especially if the manufacturer is not responsive or slow to respond.

Also, Vizient notes that the expectation that manufacturers and covered entities work in good faith to resolve disputes should not be excessively burdensome, particularly for covered entities. For example, guidance could be considered to prevent manufacturers from requesting information from a covered entity that is unnecessary or excessively burdensome in the context of a good faith effort to resolve the dispute in question.

Further, to the extent HRSA is aware of manufacturers repeatedly refraining from engaging in good faith to resolve disputes or where their demands result in excessive administrative burden for covered entities, we encourage that information be shared with the 340B ADR

Panel and HRSA to potentially inform decisions, enforcement action or policy, more broadly.

To make the process more accessible, HRSA also proposes to remove the $25,000 minimum threshold for claims. Vizient is supportive of this proposal, as it will allow more covered entities' claims to be considered through the ADR process. Similarly, Vizient appreciates proposed changes to make the ADR process more broadly accessible by, for example, proposing to no longer rely on the Federal Rule of Evidence and Civil Procedure which created numerous additional challenges for covered entities to navigate, including increased costs.

Extensions

Regarding deadlines and procedures for filing a claim, in the Proposed Rule, HRSA indicates, "If the initiating party does not respond to a request for additional information within the specified time frame or request and receive an extension, the claim will not move forward to the 340B ADR Panel for review." Vizient appreciates that HRSA has provided a process that enables OPA to conduct an initial review of the claims and to allow the initiating party to respond to HRSA's request for additional information regarding the claim. To improve upon the extension process outlined, Vizient encourages HRSA to instead allow that covered entities' requests for an extension be presumed to be granted rather than also requiring that the extension be granted within the specified timeline. As proposed, it is unclear how much time would be needed to evaluate requests for extensions or how long it would take for such requests to be granted. To address this concern, Vizient encourages HRSA to provide additional flexibility regarding such extensions when a covered entity is filing a claim.

340B ADR Panel Decision Process

In the Proposed Rule, HRSA indicates when the 340B ADR Panel will conduct an initial review of the claim. Also, the 340B ADR Panel will "determine if the specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending Federal court. If this determination is made, the 340B ADR Panel will suspend review of the claim until such time the issue is no longer pending in Federal court."[2] Vizient notes our concern that the proposed policy of suspending a claim may cause excessive delays which would harm covered entities as cases could last for several years until a decision is made. In addition, it is unclear how the 340B ADR Panel will proceed if a new case is brought before a Federal court while the claim is pending, or how the decision about a claim being the same or similar to an issue that is pending in Federal court will be made. Vizient encourages HRSA to clarify these points before finalizing this policy.

In addition, while the Proposed Rule indicates that the 340B ADR Panel will review claims or issues pending in Federal court, it is unclear as to whether HRSA's expectation is that the ADR process would always be utilized before matters are raised in Federal court. We encourage additional clarity regarding this point should the policy to suspend claims be finalized.

[2] https://www.federalregister.gov/d/2022-25752/p-63

Lastly, given recent instances in which a range of manufacturer-led policies (e.g., restricting or limiting the use of contract pharmacies, additional reporting requirements) has resulted in manufacturers not adhering to statutory requirements, we encourage HRSA to clarify that such issues are eligible to be reviewed by the 340B ADR Panel.

Reconsideration
HRSA proposes a reconsideration process upon demonstration that the 340B ADR Panel decision may have been inaccurate or flawed. Vizient encourages additional information or clarity be provided regarding this reconsideration process so that stakeholders can better understand the type of information that would be needed to initiate reconsideration and the interpretation of "inaccurate or flawed", as these may be subjective terms.

Decisions
As proposed, the 340B ADR Panel will prepare a decision letter based on its review and transmit the decision letter to all parties and the OPA Director. In prior rulemaking, such decisions would be made public and help inform the outcome of future decisions. Vizient encourages HRSA to clarify whether decisions under the revised process will be made available, and if so, the impact of those decisions on other claims. Sharing such information may be helpful, as it could help inform decisions by manufacturers or covered entities to adjust their practices, however, we do not believe such decisions should be precedential.

Impact
While the Proposed Rule notes that HHS does not anticipate the introduction of the ADR process to result in significant economic impacts, Vizient encourages the sharing of additional information regarding the impact of the updated ADR process, if finalized. For example, information regarding the proportion of covered entity claims that do not meet filing requirements or missed submission deadlines may be helpful to share should additional changes to the process be warranted in the future.

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. In closing, on behalf of Vizient, I would like to thank HRSA for providing us the opportunity to comment. 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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