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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

The Honorable Xavier Becerra
Secretary
Department of Health and Services
Humbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Avenue, NW
Washington, DC 20220

The Honorable Martin Walsh
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

The Honorable Kiran Ahuja
Director
U.S. Office of Personnel Management
1900 E Street, NW
Washington, DC 20415

Re: Office of Personnel Management; Department of the Treasury; Department of Labor; Department of Health and Human Services: Requirements Related to Surprise Billing; Part II (Docket No. TD 9955; CMS9908-IFC)

Dear Secretary Becerra, Secretary Walsh, Secretary Yellen and Director Ahuja:

Vizient, Inc. appreciates the opportunity to comment on the Office of Personnel Management (OPM), Department of the Treasury (Treasury), Department of Labor (DoL), and Department of Health and Human Services (HHS) (the Departments) interim final rule with request for comments, "Requirements Related to Surprise Billing; Part II" (hereinafter IFC). The IFC provides regulations to implement various provisions of the No Surprises Act (NSA), which was enacted as part of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260). The NSA aims to protect patients receiving group or individual health insurance coverage from surprise medical bills and outlines how patient cost-sharing must be determined, among other provisions.

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 50% of the nation's acute care providers, which includes 95% 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 $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to various issues raised in the IFC and offer our recommendations for the Departments to consider to further enhance the regulations in a

manner that continues to protect patients while minimizing negative, unintended consequences. Specifically, we urge the Departments to withdraw elements of the regulation that overweight the Qualifying Payment Amount (QPA) in the Independent Dispute Resolution (IDR) process, among other recommendations. We thank the Departments for the opportunity to share our views on the IFC and believe the following areas are important for the Departments to consider as the agencies work with stakeholders to implement the IFC.

Federal Independent Dispute Resolution for Plans, Issuers, Providers and Facilities

Certified IDR Selection
The IFC provides that if the parties do not mutually agree upon a certified IDR entity (including if there is a conflict during the selection process), then the Departments would randomly select a certified IDR entity within 6 business days after the date of initiation of the Federal IDR process. Vizient requests the Departments provide the disputing parties another chance, if requested, to mutually select a certified IDR entity should a conflict be identified before random selection occurs. Given the newness of the regulation and unfamiliarity with certified IDR entities, Vizient believes it is important that the Departments allow for flexibility where mutually agreed upon in the IDR process, including certified IDR selection.

In the IFC, the Departments seek comment on whether the random selection method should be limited only to certified IDR entities that charge a fee within the allowed range or whether additional factors should be used (e.g., whether the specific fee of the certified IDR entity should be selected or if other factors should be considered, like how often the certified IDR entity chooses the amount closest to the QPA). Should an alternative random selection method that considers other factors be used, Vizient strongly discourages the Departments from considering factors like how often the certified IDR entity chooses the amount closest to the QPA. Vizient is concerned such factors may unintentionally discourage the arbiter from meaningfully reviewing and deciding each dispute, as straying from the QPA may have negative business consequences for the arbiter who may be less likely to be selected should deviation occur. Also, Vizient is concerned the Departments are excessively and improperly relying on the QPA in the IDR process in a manner that is inconsistent with Congressional intent and the legislative text.[1,2] Vizient discourages the Departments from implementing policies that further integrate the QPA in the surprise billing regulatory framework, including as a factor to be considered for certified IDR selection.

Submission of Payment Offers and Additional Information to the Certified Entity
Following selection of the certified IDR entity and confirmation from the IDR entity that the federal IDR process applies, the parties must submit payment offers. As noted in the IFC, the offer must be expressed as both a dollar amount and the corresponding percentage of the QPA represented by that dollar amount. As noted above, Vizient is concerned that the Departments are excessively weighting and structuring the IDR decision process around the QPA. Regarding offer submissions, Vizient is concerned that requiring providers to submit the corresponding percentage of the QPA represented by the offered dollar amount effectively provides yet another way that the QPA is overly and unnecessarily emphasized during the IDR process. In addition, as submissions may be batched, it may be even more time intensive to submit offers as a portion of the QPA, particularly given uncertainty regarding processes

[1] https://wenstrup.house.gov/uploadedfiles/2021.11.05_no_surprises_act_letter.pdf
[2] Public Health Services Act (PHSA) § 2799A–1(c)(5)(A).

related to batching, as exemplified by the Departments' various requests for additional information. As such, Vizient suggests the Departments remove the requirement to submit the offer as a corresponding percentage of the QPA to better address stakeholder concerns regarding the weighting of the QPA in the IDR process and to ease provider burden.

Also, the IFC indicates that parties may submit any information related to the offer (except for information related to usual and customary charges, billed amount and public payor rates which the certified IDR entity may not consider) but does not provide guidance regarding how the IDR entity must consider this additional information. Absent clear and consistent directions regarding submission of such information, hospitals may expend significant resources compiling and developing information relevant to the dispute with no assurance that such information will be fairly and appropriately weighted and reviewed by the certified IDR entity. Vizient encourages the Departments to make clear in directions to certified IDR entities that they must carefully review additional information submitted by hospitals and other providers related to the offer. Vizient urges the Departments to work with hospitals and other providers in developing and refining guidance to certified IDR entities to ensure provider submitted information is appropriately reviewed.

Payment Determination Made by the Certified IDR Entity

According to the IFC, the certified IDR entity must select one of the offers submitted by the plan or issuers or the provider or facility to be the out-of-network rate within 30 business days of the selection of the certified IDR entity. In selecting the offer, the certified IDR entity must presume that the QPA is an appropriate payment amount and select the offer closest to the QPA, assuming other factors[3] are not considered by the arbiter. Given Congress did not provide a benchmark but did identify a variety of factors for the certified IDR entity to consider when selecting an offer, Vizient believes it is clear that the QPA presumption runs counter to Congress's explicit direction.[4] As mentioned in our previous comments, the QPA methodology favors payors over providers in the IDR process.[5] Given Vizient's range of concerns with both the use of the QPA, the Departments' statutory interpretation and the QPA methodology, we urge the agency to withdraw elements of the regulation that result in the QPA being excessively weighted during the IDR process.

In addition, the IFC provides that the certified IDR entity may also consider other factors (e.g., if experience or level of training of a provider was necessary for providing the qualified IDR item or service to the patient or if the experience or training made an impact on the care that was provided, retrospective payment penalties, patient acuity or complexity, teaching status, case mix and scope of services, or good faith efforts to enter into network agreements) when making a payment determination. The IFC provides conditions when these additional circumstances should be considered, namely if the supporting evidence meets a "credible information" standard and clearly demonstrates that the QPA is "materially different" from the out-of-network rate. That said, the Departments indicate that they still intend to provide

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[3] *See* Public Health Services Act (PHSA) § 2799A–1(c) listing factors that the IDR entity "shall consider" in making its payment determination. These factors include, the QPA; the level of training, experience, and quality and outcomes measurements of the provider or facility; market share of each party; acuity of the individual; teaching status, case mix and scope of services of the provider/facility; demonstration of good faith efforts by the parties to enter into network agreements over the previous four years; and any other factors that the parties may wish to submit for consideration with several explicit prohibitions.

[4] Public Health Services Act (PHSA) § 2799A–1(c)(5)(A).

[5] https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20210907_surprise_billing_comments_vizient.pdf

additional guidance to certified IDR entities, potentially, to clarify how these allowable factors should be considered. However, given the vagueness of these conditions and general uncertainty regarding the arbitration process, Vizient is concerned that this framework sets up a situation in which the QPA is again excessively relied upon and overweighted during the IDR. Vizient urges the Departments to withdraw the current IDR payment determination policy and to work more closely with stakeholders on a more amenable interpretation of the statute, particularly regarding the weighting of the QPA and other factors.

Treatment of Batched Items and Services

The Departments note that a plan or issuer may pay a provider or facility a single payment for multiple services an individual received during a single episode of care (bundling). In the IFC, the Departments provide various limits on when batching of claims is permitted. Those limitations include when the item or service was billed by the same providers or groups of providers or facility, when the items or services were billed using the same service code and when the items or services occurred within the same 30-day period or within a 90-day suspension period[6] between IDR requests for same or similar services. Vizient is concerned these limitations excessively narrow the circumstances in which batching will be permitted and depletes the utility of batching. Vizient urges the Departments to work with hospitals and other providers to develop a more flexible batching framework.

Extension of Time Periods for Extenuating Circumstances

In the IFC and a separate notice[7], the Departments indicate a disputing party may submit a request for an extension to the IDR process timeline because of extenuating circumstances. However, the notice expires on April 30, 2022, and the IFC provides little additional insight regarding extensions, noting that extensions may be provided in the case of extenuating circumstances at the Departments' discretion and that requests can be made through the Federal IDR portal. Given the COVID-19 public health emergency (PHE) is currently in place with new information emerging daily, including new variant information, Vizient is concerned the current policy will expire too quickly. Vizient urges the Departments to extend this policy and ensure it is easy for hospitals to submit extension requests. Vizient believes that the current timeline to implement the surprise billing regulations is too fast and should be delayed or a broader enforcement discretion policy provided, as outlined below.

Implementation

The Departments indicate the surprise billing requirements, including IDR processes, will be in effect by January 1, 2022, despite various interim final regulations being released over the past six months and the IFC's release on September 30, 2021. Vizient is concerned that this short timeline is not conducive to effectively developing and implementing regulations. Given the uncertainty regarding implementation, it will be difficult for hospitals and other providers to interpret and rapidly adapt to these changes, especially given the additional challenges and demands posed by the ongoing PHE. For example, should plans underpay providers, there is a risk that providers will not have the systems, processes and resources, including staff time, to review and engage in the IDR process. There is also limited time to provide education to those who will be involved in such processes moving forward and issues will likely emerge,

[6] As provided in the IFC, the party that initiates the IDR process may not bring the same party to arbitration for the same item or services for 90 days following a decision.

[7] https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/no-surprises-act/surprise-billing-part-ii-information-collection-documents-attachment-10.pdf

particularly given the technical elements (e.g., IDR portal) are new and therefore, not broadly used or tested by providers. While Vizient appreciates that some elements of the surprise billing regulations will have a delayed implementation, Vizient believes enforcement discretion should be provided broadly and timelines should be extended.

Protections for the Uninsured

Good Faith Estimates for Uninsured (or Self-Pay) Individuals
The NSA requires that providers and facilities furnish good faith estimates to uninsured (or self-pay) individuals upon their request and at the time of scheduling the item or service. The IFC details the requirements for providing such a good faith estimate, such as the specific timeframes to provide the estimate and the contents of the estimate, including any reasonably expected charge associated with the scheduled or requested care and charges from all providers and facilities who are reasonable expected to provide care. Vizient is concerned HHS underestimates the difficultly and burden associated with developing good faith estimates. It is not information that can be thoughtfully provided in mere minutes. Given the various price transparency resources now available and challenges associated with short-term compliance, Vizient encourages HHS to better streamline the surprise billing regulations in the context of hospitals' other requirements.

Vizient also suggests the agency provide enforcement discretion regarding all good faith estimates for uninsured and self-pay individuals due to various requirements associated with the good faith estimate and the limited implementation period. For example, under the IFC, providers and facilities still need to develop future compliance plans and processes. It is foreseeable that a hospital or health system may utilize the same plans and processes, including technical solutions, to compile all types of good faith estimates. Imposing variable deadlines will result in different systems and processes being developed and implemented, which creates confusion and redundant work as other deadlines approach. Hospitals should be granted more time to have the opportunity to more meaningfully contemplate effective compliance plans that can also remain relevant in the long-term.

Vizient also notes our concern with the difficulty providers and suppliers may have in identifying items and services to include in the good faith estimate. In the IFC, HHS provides that the good faith estimate would be for the expected charges[8] for furnishing the items or services that are reasonably expected to be provided in conjunction with such scheduled or requested items or services.[9] While HHS acknowledges that unforeseen factors during the course of treatment could result in higher billed amounts than anticipated, HHS indicates it does not expect the good faith estimate to include charges for unanticipated items or services that occur due to unforeseen events. Given different factors, including patient-specific factors, can impact what is foreseeable, Vizient is concerned that this element of the regulation will also be difficult to implement and could be difficult for patients to understand, should estimates for foreseeable but not planned events be included in the estimate. Vizient encourages HHS to work with hospitals and other providers regarding how best to utilize other regulatory

[8] "Expected charges" means, for an item or service, the cash pay rate or rate established by a provider or facility for an uninsured (or self-pay) individual, reflecting any discounts for such individuals, where the good faith estimate is being provided to an uninsured (or self-pay) individual; or the amount the provider or facility would expect to charge if the provider or facility intended to bill a plan or issuer directly for such item or service when the good faith estimate is being furnished to a plan or issuer.
[9] The good faith estimate is also to include items or services reasonably expected to be provided by another health care provider or health care facility.

requirements (e.g., price transparency requirements) to help with compliance efforts related to the good faith estimate.

Per the IFC, a convening provider or facility is responsible for providing the good faith estimate to an uninsured (or self-pay) individual and may receive information from co-providers or co-facilities regarding a good faith estimate of the items and services it may furnish. The IFC indicates that HHS will provide enforcement discretion until January 1, 2023 for incorporating all co-providers and co-facilities in good faith estimates. There are many unknowns regarding implementation of the surprise billing regulations and additional technical changes (e.g., technology or transaction standards) that would need to be in place to effectively implement the good faith estimate requirement for self-pay or uninsured individuals. Vizient encourages the Departments to work with hospitals and other providers to identify mechanisms and standards to enable automation of the good faith estimates. Also, Vizient suggests HHS extend timelines for good faith estimates more broadly.

Financial Assistance
The IFC provides that the good faith estimate must also include the expected billing and diagnostic codes for items or services and take into consideration expected discounts or adjustments that the provider or facility expects to apply to an uninsured (or self-pay) individual's billed charges. However, it is unclear when financial assistance assessments should occur, if at all. Vizient encourages HHS to clarify that financial assistance assessments do not need to be conducted for each patient before providing a good faith estimate.

Should a provider offer financial assistance and decide to consider this in a good faith estimate, Vizient is concerned that the IFC's timeline (e.g., individuals scheduling care at least three business days in advance, must receive the good faith estimate within one business day after the date of scheduling) for providing the good faith estimate does not account for additional time needed to complete financial assistance assessments. In addition, the timeline may not be feasible if the provider needs more information from the patient, particularly since it is unclear from the IFC whether the provider would needed to have had an in-person visit with the patient before scheduling a procedure. Vizient encourages HHS to give more flexibilities to providers regarding the good faith estimate, including delaying implementation until these types of issues can be collaboratively addressed.

Lastly, Vizient is concerned that patients may forego needed care should good faith estimates be too confusing or otherwise deter patients from receiving care. While HHS provides certain requirements regarding the readability of good faith estimates and language requirements, patients may still have questions or issues understanding the estimate. To help inform future policy decisions, Vizient suggests HHS monitor the effect of good faith estimates on patient decisions to receive care.

State and Federal Laws
The Departments' surprise billing regulations are generally structured to supplement state balance billing laws, allowing any state law or state All-Payer Model Agreement to still apply. Consistent with Vizient's Part I surprise billing comments,[10] we are concerned that significant confusion currently exists and will only be worsened as the surprise billing protections are

[10] https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/aboutus/20210907_surprise_billing_comments_vizient.pdf

quickly implemented. Vizient urges the Departments to work with states to clarify elements of the surprise billing protections, including when patients travel across state lines or when providers practice in multiple states.

Patient-Provider Dispute Resolution
In the IFC, the Departments create a process for uninsured and self-pay patients to dispute provider charges. This process is triggered when such charges are at least $400 more than the good faith estimate that was provided in advance of the services. Given the complexities that can be associated with providing comprehensive care, Vizient is concerned the $400 threshold is not appropriate and may result in an excessive number of patient-provider disputes. Vizient encourages HHS to work with hospitals and other providers to identify a more appropriate threshold, such as a percentage in excess of the good faith estimate as opposed to a flat rate.

Conclusion

Vizient welcomes the opportunity to comment on the Departments' IFC to help inform the agencies on how specific policies related to surprise billing will impact our members. On behalf of Vizient, I would like to thank HHS, DoL, Treasury and OPM for providing us the opportunity to comment on this important IFC. Please feel free to contact me at (202) 354-2600 or Jenna Stern, Sr. Director of Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

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Vizient, Inc.