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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 201503

Re: Office of Personnel Management; Department of the Treasury; Department of Labor; Department of Health and Human Services: Interim Final Rules with Requests for Comments - Requirements Related to Surprise Billing; Part I (RIN 0938-AU63)

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 I" (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 aimed 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 constructive improvements to the regulations for the Departments to consider as additional rulemaking is anticipated. We thank the Departments for the opportunity to share our views on the

IFC. Vizient believes the following areas are important for the Departments to consider as the agencies work with stakeholders to implement the IFC.

Applicability and Enforcement Delay

In the IFC, the Departments indicate the regulations are effective September 13, 2021, with most provisions applicable on January 1, 2022. Vizient is concerned that not enough time is provided to comply with the regulations and urges the Departments to delay the applicability date and provide enforcement discretion for all the IFC's requirements. While Vizient believes the additional clarity regarding the Department's enforcement plans as described in a recent Frequently Asked Questions[1] (FAQ) document are helpful, we believe a broader enforcement discretion policy is needed given the numerous changes that are still to take effect January 1, 2022, and needed time to effectively implement the regulations.

The IFC includes provisions applicable to group health plans and health insurance issuers[2] (collectively "plans and issuers" for purposes of these comments) and HHS-only provisions applicable to health care providers, facilities and providers of air ambulance services (which may be referred to throughout this letter collectively as "providers"). These regulations detail the new patient protections from surprise medical bills and how communications and payments between plans and issuers and providers will be handled should a circumstance arise that previously would have caused a patient to receive a surprise medical bill. To satisfy these requirements, a significant amount of labor, planning and technological changes (e.g., transaction standards) are needed. In addition, the IFC addresses the interplay of state laws and regulations with these new federal regulations, which has been a source of confusion that ultimately hampers providers' ability to comply. Also, as noted in the FAQ and IFC, additional rulemaking is forthcoming. Despite the broad scope and complexity of the regulations, in addition to anticipated rulemaking and the FAQ, the Departments continue to indicate in the IFC that the majority of provisions in the regulations are applicable beginning January 1, 2022, which is mere months away. Vizient reiterates our concerns that this timeline is simply too short and urges the Departments to provide broad enforcement discretion regarding the IFC's requirements and applicability date.

In addition, Vizient is deeply concerned that hospitals and other health care providers will be unable to comply given their ongoing response to the COVID-19 Public Health Emergency (PHE). As the Departments are aware, COVID-19 cases persist across the country. Throughout the PHE, hospitals and health systems have been stretched thin. Providers have needed to learn and implement different laws and regulations during the pandemic to meet imminent patient needs. Additionally, while Vizient appreciates the importance of the IFC, the Departments should more carefully consider the burdens already placed on hospitals and other providers as enforcement plans are considered. Further, as additional requirements and information are released, the burden of implementation will only increase as hospitals are being asked to do more with less resources and competing priorities. Providing broad enforcement discretion will help alleviate this burden and allow hospitals and other health care providers to focus on treating patients and adapting to changes spurred by the COVID-19 PHE.

Lastly, Vizient is concerned the condensed timeline of the IFC's release, effective date and applicability period is inadequate for hospitals and other stakeholders to review and comment on the

[1] Departments of Labor, Health and Human Services, and the Treasury, (August 20, 2021). FAQs about Affordable Care Act and Consolidated Appropriations Act, 2021, available at: https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-49.pdf, last accessed: September 2, 2021.

[2] The IFC also includes information regarding regulations for Federal Employees Health Benefits (FEHB) Program carriers

IFC and related guidance, such as the FAQs. In addition, during this shortened period, hospitals in states with surprise billing laws already in effect have been challenged in interpreting both laws to understand what needs to be done to comply and where additional clarity is needed. As such, to better ensure stakeholders can meaningfully comment on the regulations, and in consideration of various state laws and subsequently released federal information, Vizient urges the Departments to delay enforcement of the IFC's requirements.

State Law

Throughout the IFC, the Departments indicate that different aspects of state law should be considered for implementation purposes where such state law exists. Vizient members have expressed confusion regarding the interaction between state laws and the IFC, including how to determine which elements of state or federal law are applicable. While some members have been in contact with state regulatory bodies and monitoring state activity to help ensure their understanding and compliance, there is an ongoing need to broadly clarify this information. In addition, determining the interaction of the IFC with state law will continue to take additional time and resources from hospitals and other providers, which ultimately delays planning and implementation. Therefore, in addition to delaying enforcement as described above, Vizient encourages the Departments to work closely with states and providers to provide additional information and resources regarding the interaction of the IFC with state laws.

Vizient also notes that some states may be considering reviewing or modifying current policies and encourages the Departments to work collaboratively with states to minimize disruption or significant changes, as there may be periods where different laws or regulations are in effect. Without such collaboration and coordination, Vizient is concerned compliance may vary, even within states, and that additional burdens may be unintentionally imposed on providers and other stakeholders.

Education and Resources

As previously noted, the IFC is complex and has a narrow implementation window, even with the recent flexibilities the Departments provided in the FAQ. Vizient appreciates the Departments hosting stakeholder calls and webinars but recommends that more information be provided. For example, the FAQ changed enforcement periods and clarified which elements of the NSA will be accompanied by rulemaking, however, no educational resources or infographics were provided to more effectively communicate regulatory requirements associated with the NSA. Vizient encourages the Departments to provide additional resources in a single location online to help support stakeholder compliance efforts and address questions. Also, as FAQs are developed, Vizient suggests the Departments clarify when new questions are added to those documents and make such information quickly available to others who may have the same or similar questions. Lastly, as resources and standards are developed to support future implementation, Vizient urges the Departments to seek stakeholder feedback, particularly from hospitals and health systems, before finalizing or otherwise making such information available.

Definition of "Emergency Services" and "Post-Stabilization Services"

In the IFC, the Departments provide several definitions to clarify the scope of services impacted by the NSA. Included among those definitions are "emergency services" and "post-stabilization services". The Departments seek comment on any additional conditions that would be appropriate to include under either of these definitions. Vizient requests the agency refrain from expanding either definition. Not only would adding services be disruptive to current implementation efforts, but stakeholders should also have the opportunity to meaningfully review and comment on broadened definitions, especially given the potential far-reaching consequences of the IFC on contract negotiations and network adequacy.

Definition of "Visit"
The Departments also propose a definition of "visit" and clarify that a visit may include the furnishing of equipment and devices, telemedicine service, imaging services, laboratory services and preoperative and postoperative services, regardless of whether the provider furnishing such services is at the facility. The Departments seek comment on whether other items and services would be appropriate to include within the scope of a visit. Similar to Vizient's concerns regarding expanding the terms "emergency services" and "post-stabilization services", Vizient discourages the Departments from adopting a broader interpretation of "visit".

Determination of the Out-of-Network Rate
The out-of-network rate is the total payment made to the provider or facility and must be equal to one of four amounts (i.e., an amount determined by an All-Payer Model Agreement; an amount based on specified state law; an agreed upon amount between the provider or facility and plan or issuer; or a payment amount determined by the Independent Dispute Resolution (IDR) entity). Notably, the out-of-network rate is not based on the Qualifying Payment Amount (QPA). Because this distinction may not be apparent given the potential use of the QPA in the IDR process, Vizient believes it is critical the Departments clarify and emphasize to plans and other stakeholders that the QPA should not be interpreted or viewed as the out-of-network rate. Also, Vizient offers various recommendations for the Departments' consideration related to different aspects of the out-of-network rate.

Agreed Upon Amount Between the Provider or Facility and Plan or Issuer and Open Negotiation
In the IFC, the Departments indicate one way the out-of-network rate may be determined is "if the nonparticipating provider or nonparticipating emergency facility and the plan or issuer agree on an amount of payment".[3] Also, the Departments indicate that when the initial payment is sent, the plan must provide notice to the provider or facility about initiating a 30-day open negotiation process for purposes of the determining the amount of the total payment. Vizient is concerned these policies may result in situations where providers' administrative burdens increase because they must consider the appropriateness of initial payments individually and collectively, should multiple initial payments be provided. Providers and facilities would also need to track timelines associated with each initial payment as they consider open negotiation and the independent dispute resolution (IDR) process. As such, Vizient requests the Departments provide greater deference to providers and facilities considering timelines for open negotiations and IDR.

Also, Vizient encourages the Departments to clarify both processes, including through the use of examples with multiple claims involving different patients and timeframes when initial payments are provided. As currently drafted, the IFC does not contemplate scenarios where multiple initial payments are provided from the perspective of a provider or facility. Vizient is concerned the open negotiation process is confusing, especially in the context of multiple claims, and that this may slow implementation and increase burden.

Alternatively, Vizient notes our concern that hospitals and other providers may passively accept initial payments despite being under-reimbursed should they not have the resources available to verify payments and undergo open negotiation or the IDR process. This concern is heightened as additional information would likely be requested of the plan and additional employee time would need to be devoted to those communications and any subsequent analysis. Providers may not have

[3] 86 FR 36951

such resources available or be reluctant to commit valuable staff time to review and negotiations, which unfortunately, may result in plans providing low initial payments, as they may factor in the cost of such burdens in initial payment amounts or negotiations. This concern is exacerbated by the current PHE, which is further stretching available resources at providers nationwide.

Initiating the IDR Process after the Open Negotiation Period
In the IFC, the Departments indicate that if the 30-day negotiation period does not result in a determination, generally, the provider or facility may initiate the IDR process within four days after the end of the open negotiation period. Vizient believes that this is an extremely short timeframe for providers to make a decision regarding the IDR process. In addition, it is unclear how batching may affect this timeline. Vizient recommends the Departments be highly deferential to the time providers and facilities may need to decide whether to initiate the IDR process.

Information to be Shared about the QPA from the Plan or Issuer
In the IFC, the Departments specify information the plans or issuers must provide upon request by the provider or facility regarding the QPA. While the Departments specify the information should be provided in a timely manner, Vizient is concerned "timely", from a plan's or issuer's perspective, may be too slow for the provider or facility. Providers would likely need information more quickly given their need to evaluate whether to initiate open negotiations or the IDR process (including for batching). Vizient encourages the Departments to prioritize provider and facility needs as the interpretation of "timely" is considered. In addition, to the extent a plan or issuer is noncompliant with this request or if there are inaccuracies with the information, the out-of-network amount identified by the provider or facility should be the decided out-of-network amount.

Application of the QPA in the IDR Process
In the IFC, the Departments indicate the arbiter will consider the QPA in the IDR process and that it may consider certain other factors when deciding on a payment amount. Those other factors include the provider's training and experience, the complexity of the procedure or medical decision-making, the patient's acuity, the market share of the insurer and provider, teaching status of the facility, scope of services, demonstrations of good faith efforts to determine a payment amount and contracted rates from the prior year. Although Vizient appreciates that other factors may be considered during the IDR process, it is unclear how the arbiter will ultimately weigh these factors, if at all. Vizient is concerned this framework could result in the QPA being more heavily weighted in the IDR process and that excessive burden will consistently be placed on the provider or facility to justify a payment rate that is greater than the QPA.

Further, given that arbitration fees fall on the losing party, the QPA methodology and vague arbitration process, Vizient is concerned providers and facilities will be disproportionately negatively impacted by this framework as they may be willing to accept lower payment rates solely to avoid the cost, burden and risk associated with the IDR process. This could have harmful downstream consequences, particularly considering contract negotiations and patient access to care. Therefore, Vizient recommends the Departments clarify that the QPA should not be heavily weighted during the arbitration process and that the Departments reiterate to arbiters that the QPA is not listed as a factor for purposes of determining the initial payment.

In addition, as described below, Vizient encourages the Departments to reconsider the QPA methodology given it is to serve dual purposes – to be considered as a factor during the IDR process and to determine cost-sharing.

Batching
Under the NSA, a provider or facility may batch together multiple items or services related to the treatment of a similar condition and attributable to the same health plan that occur during a 30-day

period. Since during this 30-day period some payments may be made to the provider or facility even though batching may still be considered, Vizient believes the Departments should provide flexibility to providers and clarify that a provider initially accepting a payment does not necessarily mean the IDR process would be unavailable.

Initial Payment Amount
In the IFC, the Departments seek comment on whether to set a minimum payment rate or methodology for a minimum initial payment. Vizient does not believe it is appropriate for the Departments to set such a payment minimum, as it may become the default amount provided, potentially resulting in harm to hospitals, increasing the frequency of IDR cases or negatively impacting network adequacy. Further, Vizient would be concerned with a policy setting minimum rates based on Medicare or Medicaid payment, as these payments are often inadequate. Also, additional payments or adjustments (e.g., add-on payments, value-based purchasing program payments, graduate medical education payments, etc.) may impact a hospital's payments but would be difficult to adequately capture if limited rates or unique facility characteristics are not considered.

Determination of the Cost-Sharing Amount
In the IFC, the Departments provide that the patient cost-sharing amount is generally determined based on as the "recognized amount". The recognized amount is based on the lesser of the amount billed by the provider or facility or the QPA, where a specified state law or All-Payer Model Agreement is not applicable. The IFC also provides detail regarding how the QPA will be determined, among other policies, which Vizient addresses below.

Methodology for Calculating the Qualifying Payment Amount (QPA)
Generally, for a given item or service, the QPA is the median of the contracted rates recognized by the plan or issuer on January 31, 2019 (adjusted for inflation), for the same or similar item or service that is provided by a provider in the same or similar specialty and provided in a geographic region in which the item or service is furnished. The median contracted rate is determined with respect to all group health plans of the plan sponsor or all group or individual health insurance coverage offered by the health insurance issuer that are offered in the same insurance market, consistent with the methodology established by the Departments and detailed further in the IFC. Vizient offers various recommendations to the Departments to improve the methodology for calculating the QPA to ensure critical differences between hospitals are adequately considered.

Notably, regarding the median contracted rate, the Departments indicate "these interim final rules do not allow plans or issuers to separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary, such as whether a hospital is an academic medical center or teaching hospital".[4] Vizient questions the need for the Departments' rigid perspective regarding other characteristics of a facility that may cause contracted rates to vary. For example, academic medical centers generally have higher costs than nonteaching hospitals, as they often treat more complex patients and drive innovation and research, among other distinctions. Further, Medicare and other payers have long provided payment adjustments (e.g., graduate medical education payments) to support teaching hospitals, given the importance of a trained health care work force. As such, it would be consistent with prior policy to ensure the QPA can be calculated by considering other factors that could impact payment broadly and not solely median contracted rates.

[4] 86 FR 36892

Vizient also recognizes that several other differences exist between hospitals and those differences may impact whether a hospital is selected for an emergency service. While the Departments note that patients may not have a choice in selecting an emergency department, a decision may be reached based on unique characteristics of a hospital and the patient's needs. As currently drafted, the IFC does not recognize that different settings may be more appropriate for certain emergency services and thus, certain types of facilities may receive more complex patients. Vizient is concerned that failure to consider such variation will negatively impact hospitals that are equipped to provide more specialized emergency care services. In addition, the Department's presume that different hospital characteristics are never factored into decisions regarding which emergency department to attend. This notion runs counter to several Centers for Medicare and Medicaid Services (CMS) and other industry initiatives aimed at increasing information about hospitals and other providers. As such, Vizient again urges the Departments to reconsider its policy of not allowing plans or issuers separately calculate a median contracted rate based on other characteristics of facilities that might cause contracted rates to vary.

Appeals

In the IFC, the Departments acknowledge that there may be instances where a beneficiary appeals an adverse benefit determination (e.g., a determination of cost-sharing amounts) "through the claims and appeals process concurrently with a provider's challenge to a payment amount through the IDR process".[5] Additional details regarding this situation, such as how enrollee appeals may impact providers' payments or communications to the provider, are not provided in the IFC. Vizient encourages the Departments to clarify such information and seek provider input before finalizing this policy.

Contract Negotiations

As the Departments are aware, the QPA may have downstream implications for contract negotiations. Vizient appreciates that under the NSA, a separate study from the Government Accountability Office (GAO) is required regarding the law's impacts on network participation. However, Vizient is concerned that impacts on contract negotiations may not be immediately apparent and the methodology to determine the QPA, if overly generalized, may have unintended consequences regarding contract negotiations between payers and providers. Given these considerations, and that in some states providers have experienced contractual shifts due to surprise billing[6], Vizient suggests the departments adopt provider and facility recommendations related to the QPA and other elements of the law to prevent unintended disruption to contract negotiations. While Vizient believes it is critical that patients be protected from surprise billing, it is also important the Departments work to minimize unintended consequences by taking a more targeted and cautious regulatory approach. As such, Vizient urges the Departments to heavily weigh providers' contracting concerns as it considers regulatory changes.

Notice and Consent

Information regarding the notice and consent process and documents are detailed in the IFC and CMS-developed forms.[7] The notice and consent process is required in certain circumstances where

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[5] 86 FR 36902

[6] La Forgia, Ambar, Bond, A.M. & Braun, R.T. (2021). Association of Surprise-Billing Legislation with Prices Paid to In-Network and Out-of-Network Anesthesiologists in California, Florida, and New York, An Economic Analysis, *Jama Intern. Med.* Published online August 16, 2021. doi:10.1001/jamainternmed.2021.4564.

[7] Centers for Medicare & Medicaid Services, July 1, 2021, CMS-10780 Requirements Related to Surprise Billing: Qualifying Payment Amount; Notice and Consent, Disclosure on Patient Protections Against Balance Billing and State Law Opt-In, available at: https://www.cms.gov/httpswwwcmsgovregulations-and-guidancelegislationpaperworkreductionactof1995pra-listing/cms-10780, last accessed August 31, 2021.

patients agree to waive their balance billing protections and be billed for out-of-network. Vizient appreciates the Departments' and the agency's effort to make available standard forms. Vizient encourages that these forms be adapted in accordance with hospital and health system recommendations, including that several translations be made available.

The NSA provides different timelines for when documents regarding notice and consent must be provided. Notably, nonparticipating providers are required to provide patients with notice and consent documents at least three hours before items or services are provided. Vizient is concerned this timeline may be too long for services that aim to be provided on the same day and may unnecessarily delay care. Further, it is unclear as to how the Departments selected this timeframe and whether alternatives were considered. Vizient encourages the Departments to be flexible in their approach regarding this specific requirement and recommends the agency consider different circumstances where the 3-hour requirement may be unnecessary.

Provider or Facility Notice to Plans or Issuers

For each item or service furnished by a nonparticipating provider or nonparticipating emergency facility, the provider (or participating facility on behalf of the nonparticipating provider) or nonparticipating emergency facility must provide timely notice to the plan or issuer. This notice must indicate whether balance billing or in-network cost sharing protections apply to the item or service. If applicable, the provider or facility must provide to the plan or issuer a signed copy (by the patient or their authorized representative) of any written notice and consent documents. HHS notes that this information sharing is required so the plan or issuer can process the claim appropriately.

Process and Timing

HHS seeks comment on whether additional rulemaking would be helpful regarding the process and timing for such notification, including the definition of "timely," and what processes for conveying the notification would be most efficient, including existing processes that could be leveraged to convey the information. Vizient appreciates the Department's efforts to improve the clarity of the regulations, and consistent with our comments above, believe "timely" should be interpreted in a manner most favorable to providers. Since providers' reimbursement requires a claim submission, work is already being done to submit claims. Further, given the new notice and consent requirements, there could be issues that emerge that cause delays, such as identifying a patient's authorized representative and additional administrative burden. Also, Vizient notes the current technological infrastructure does not currently support these types of communications, which may lead to additional delays. As such, Vizient encourages HHS to give the utmost deference to hospitals and other health care providers in their interpretation of "timely" and how they choose to process notifications to plans or issuers.

Regarding submission of these documents, including signed consent documents, Vizient believes technological and operational challenges may emerge should these regulations be hastily implemented. For example, how these forms are to be submitted represent just one challenge that providers and facilities will need to monitor, as plans or issuers may have different processes until a more standardized approach is in place. Vizient encourages the Departments to work closely with stakeholders to support a more streamlined and consistent method of transmitting information to plans to help limit burden on providers and facilities and minimize communication issues.

Good Faith Estimate and Explanation of Benefits

Vizient appreciates the Department's decision to delay rulemaking regarding requirements related the good faith estimate and advanced explanation of benefits (EOB) given the complexity associated with implementation. Vizient recommends the Departments work closely with hospitals and other providers before providing regulations on these topics, especially as there may be an opportunity to coordinate regulatory approaches with the hospital price transparency regulations.

Surprise Billing Complaints
The NSA directs HHS to establish a process to receive consumer complaints regarding violations by health care providers, facilities and providers of air ambulance services regarding certain balance billing requirements and to respond to such complaints within 60 days. The IFC includes HHS-only rules to establish a process by which HHS will receive complaints regarding violations of these balance billing requirements by health care providers, facilities and providers of air ambulance services. Given Vizient's concerns regarding the condensed implementation timeline and that additional information regarding the complaint process has yet to be released, we encourage HHS to provide enforcement discretion should complaints be received.

Audits and Enforcement
The IFC clarifies that existing processes will generally be used to ensure plans and issuers comply with NSA requirements. Also, the IFC includes an audit provision establishing that HHS's existing enforcement procedures will apply with respect to ensuring that a plan or coverage is in compliance with the requirement of determining and applying a QPA as described in the IFC. The IFC also notes that HHS intends to amend its enforcement regulations through future notice and comment rulemaking. Vizient believes additional detail regarding audits and enforcement will be critical to ensuring the goals of the NSA are met and that providers and facilities are not harmed as a result of the NSA.

As noted above, Vizient is concerned that the burden to verify the accuracy of the QPA may be excessive and, as a result, it may not be routinely done by providers and facilities. As such, Vizient believes it is critical that audits and oversight efforts are in place to ensure plans and issuers consistently comply with the QPA requirements. Since limited information is provided in the IFC and additional rulemaking is forthcoming, Vizient encourages the Departments and HHS more specifically to develop a robust audit plan and communication strategies with the Departments and states to better ensure plans and issuers meet the IFC's requirements. Failure to provide such oversight could have detrimental downstream impacts on contract negotiations and providers' abilities provide care, which ultimately impacts patient access and a properly functioning health care system. Further, given the need for patient protections from surprise medical bills ultimately underpins the NSA and IFC, it is imperative that high attention be paid to how the QPA is determined to also ensure patients are, in fact, protected from surprise medical bills.

Conclusion

Vizient welcomes the opportunity to comment on the Departments' IFC to help inform the agencies on how specific proposals will impact our members. On behalf of Vizient, I would like to thank HHS, DOL, Department of the 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