

January 28, 2022

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The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities (RIN: 0938-AU55)**

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations (OPO), and End-Stage Renal Disease (ESRD) Facilities (RIN 0935-AU55) (hereinafter, "RFI"), as many of the topics included in the RFI have a significant impact on our members and the patients they serve.

**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 questions raised in the RFI to help inform the agency as it considers creating system-wide improvements and changes to the requirements that transplant programs, OPOs and ESRD facilities must meet to participate in Medicare and Medicaid. We thank you for the opportunity to share our views on future policies, particularly in advance of proposed rulemaking. Vizient notes our appreciation of CMS's decision not to finalize several of the organ acquisition payment policies that were included in the fiscal year 2022 inpatient prospective payment system (IPPS) proposed rule. Consistent with Vizient's prior comments, we

reiterate the importance of the agency relying on stakeholder feedback as it considers potential changes to Medicare organ acquisition payment policies. In addition, it is critical that CMS consider the complete care continuum as it develops policy that impacts transplant hospitals and the patients they serve. Vizient believes the following areas are important for CMS to consider should the agency propose additional regulations.

## **Transplant Program Conditions of Participation**

### Initial Approval Requirements

Vizient appreciates CMS's efforts to consider opportunities to improve transplant programs. In the RFI, CMS requests feedback regarding whether initial approval requirements create barriers to the establishment of new transplant programs. Vizient understands that it can be challenging to develop a new transplant program, as it can be resource-intensive to start. An alternative to modifying initial approval requirements would be for CMS to provide additional resources to current and prospective transplant hospitals to help support the expansion or development of new transplant programs.

As CMS considers potential changes to the conditions of participation (CoPs), we discourage CMS from making changes that will impose additional burdens on transplant programs, which are already highly regulated. To the extent CMS considers easing or removing burdens on transplant hospitals, Vizient would appreciate such an effort and encourages the agency to work closely with transplant hospitals in identifying those potential changes before going forward with rulemaking.

### Quality

In the RFI, CMS requests comment on whether the CoPs could be improved to incentivize and ensure performance quality in organ transplantation. As noted above, Vizient would have concerns with additional CoPs or modifications to existing CoPs that increase the burden on transplant hospitals. In addition, since there can be significant variability in how transplant programs operate, a one-size-fits-all approach through CoP modifications could unnecessarily limit or divert resources from effective practices within transplant hospitals.

As transplant hospitals continue to innovate and focus on quality improvement, it is important that their learnings and best practices be shared and considered by others. Further, as technology advancements can enable a broader pool of organ donors or prolong the viability of organs, it is important that providers are aware of this information so that they can consider whether and how to update their practices. To help improve quality, Vizient recommends CMS consider how it can help facilitate more timely information sharing and communication. Such information sharing could also help transplant programs learn how to more effectively communicate risks and benefits to patients.

To help support transplant hospitals and health care providers more broadly, Vizient encourages enterprise-wide, data-driven strategies to improve quality and patient

outcomes.<sup>1</sup> Such efforts can include the use of benchmarks to measure program performance. Also, while outside the scope of questions listed in the RFI, Vizient reiterates our [comments](#) to CMS regarding Hospital Star Ratings, where we encourage the agency to utilize criteria including relevant volume thresholds that differentiate patient comorbidities and surgical complexity, including the number of solid organ transplants, among other factors, for purposes of like-hospital peer-grouping. This approach is similar to what Vizient utilizes within its own [Quality & Accountability Hospital ranking](#) and provides a more effective comparison of hospitals.

## **Transplant Patient Rights**

Vizient understands there are many different approaches transplant programs, ESRD facilities and OPOs are utilizing to provide education and information to patients and their families regarding organ transplantation. Vizient believes education is critical in helping patients understand their options, including their ability to access a lifesaving organ transplant. As CMS is aware, patients may become eligible for certain transplants based, in part, on the severity of their disease. Since some disease progression can be lengthy, such as for kidney disease, it is important that communications with patients regarding their health take place before a transplant is needed, including in communications with primary care doctors and through public health service announcements.

In addition, Vizient understands that it may be challenging for patients, particularly those in underserved communities, to access providers and be evaluated for a transplant. While Vizient would be concerned with modifications to the CoPs as a means to ensure appropriate education is provided to patients, we do believe there is a need to consider resources and education needs for individuals who are not receiving regular care but are in need of a transplant or communication with a specialist. Therefore, as CMS considers patient education, we encourage the agency to consider approaches that can help support prevention efforts and connections to underserved patients.

## **Equity in Organ Transplantation and Organ Donation**

In the RFI, CMS indicates its aim to better consider equity in organ transplantation and organ donation. Vizient appreciates this goal and commends the various efforts CMS has initiated to identify and close health equity gaps. A key step towards addressing health equity is improving demographic data collection, particularly by using standard definitions and data collection approaches, as outlined in Vizient's FY 2022 IPPS proposed rule [comments](#). Vizient's comments cautioned the agency in using certain estimation methods and algorithms, as they may lead to less accurate information, particularly when trying to glean information from quality measures.

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<sup>1</sup> [https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/enterprise\\_wide\\_data\\_driven\\_strategy\\_whitepaper.pdf](https://www.vizientinc.com/-/media/documents/sitecorepublishingdocuments/public/enterprise_wide_data_driven_strategy_whitepaper.pdf)

In conversations with Vizient’s members, we have heard frustrations about the lack of consistent national data and definitional standards with respect to social determinants of health. There are currently a multitude of measurement instruments evaluating various need and outcome domains. Generally, without consistent measurement, it is difficult to appropriately determine whether specific programmatic investments are producing improved quality outcomes. To support collection of self-reported data, Vizient has identified the following topics for CMS’s consideration which are applicable across CMS programs.

### Demographic Data Collection Guidelines

Working with stakeholders, CMS should provide data collection guidelines on REAL (Race, Ethnicity, and Language) and SOGI (Sexual Orientation, Gender Identity), as well as other data points (i.e., income, employment status), to help providers understand what data is most meaningful to collect. Leveraging existing standards and developing national standards where needed would provide a comprehensive and standardized approach to capturing representative data for the communities that transplant hospitals serve.

### Social Needs Screening Standards

Currently, health care providers use a variety of social needs screening tools, each with different categories and questions. Standards can ensure that the social needs screening questions that Medicare and Medicaid beneficiaries are being asked are more consistent across providers and would afford CMS a more standardized view of social needs. Further, such factors can be more effectively and consistently considered in care plans with patients.

### Training Opportunities

In addition to knowing what data is most meaningful to collect and more consistent screening, there is also a need to train providers on how to collect self-reported demographic or social needs data. To address current gaps in training, Vizient has developed a Health Equity Leadership Education Series that addresses topics such as establishing common definitions and common understanding, establishing organizational structures to support health equity efforts, and data and analytics to plan and measure progress. Instead of modifying CoPs, CMS could make available or encourage providers to implement additional education and training related to health equity.

### **Research**

Vizient appreciates CMS’s interest in learning more about transplant programs, and applauds the agency for seeking more data, research and studies to inform future policy decisions. One way in which Vizient helps our member hospitals and health systems is through the Vizient Clinical Data Base (CDB). The CDB is a health care analytics platform for performance improvement which provides high-quality, accurate and transparent data on patient outcomes — such as graft failure, tissue rejection, other complications of transplants, kidney failure, mortality, length of stay, complication and readmission rates, and hospital-acquired conditions. The CDB is

unique in that it also provides cost data, which can be relevant in considering organ transplant financing.

Notably, the CDB has been used by our member hospitals, in collaboration with Vizient's experts, to develop numerous peer-reviewed research articles. There is a significant range of research underway and completed on topics including equity and quality outcomes as related to organ transplants. Regarding prior research, the CDB has been used in numerous articles,<sup>2,3,4,5,6,7,8</sup> which may help inform CMS's perspectives regarding organ transplants.

## **Conclusion**

Vizient welcomes CMS's aim to improve systems of care for patients in need of a transplant and to better identify opportunities to ensure each segment of the health care system aims to address disparities and improve to patient outcomes associated with organ transplants.

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 respond to this RFI. Please feel free to contact me, or Jenna Stern at [jenna.stern@vizientinc.com](mailto:jenna.stern@vizientinc.com), if you have any questions or if Vizient may provide any assistance as you consider these issues.

Respectfully submitted,



Shoshana Krilow

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<sup>2</sup> [Variability in postoperative resource utilization after pancreaticoduodenectomy: Who is responsible.](#) Ertel AE, Wima K, Hoehn RS, Chang AL, Hohmann SF, Ahmad SA, Sussman JJ, Shah SA, Abbott DE. *Surgery*. 2016 Dec;160(6):1477-1484. doi: 10.1016/j.surg.2016.08.031. Epub 2016 Oct 4. PMID: 27712874

<sup>3</sup> [Risk of Reoperation Within 90 Days of Liver Transplantation: A Necessary Evil?](#) Ertel AE, Wima K, Chang AL, Hoehn RS, Hohmann SF, Edwards MJ, Abbott DE, Shah SA. *J Am Coll Surg*. 2016 Apr;222(4):419-28. doi: 10.1016/j.jamcollsurg.2016.01.007. Epub 2016 Jan 23. PMID: 26905185

<sup>4</sup> [Organ quality metrics are a poor predictor of costs and resource utilization in deceased donor kidney transplantation.](#) Stahl CC, Wima K, Hanseman DJ, Hoehn RS, Ertel A, Midura EF, Hohmann SF, Paquette IM, Shah SA, Abbott DE. *Surgery*. 2015 Dec;158(6):1635-41. doi: 10.1016/j.surg.2015.05.014. Epub 2015 Jun 19. PMID: 26096564

<sup>5</sup> [Variation by center and economic burden of readmissions after liver transplantation.](#) Wilson GC, Hoehn RS, Ertel AE, Wima K, Quillin RC 3rd, Hohmann S, Paterno F, Abbott DE, Shah SA. *Liver Transpl*. 2015 Jul;21(7):953-60. doi: 10.1002/lt.24112. PMID: 25772696

<sup>6</sup> [Neighborhood level effects of socioeconomic status on liver transplant selection and recipient survival.](#) Quillin RC 3rd, Wilson GC, Wima K, Hohmann SF, Sutton JM, Shaw JJ, Paquette IM, Woodle ES, Abbott DE, Shah SA. *Clin Gastroenterol Hepatol*. 2014 Nov;12(11):1934-41. doi: 10.1016/j.cgh.2014.05.020. Epub 2014 Jun 4. PMID: 24907503

<sup>7</sup> [Healthcare utilization after liver transplantation is highly variable among both centers and recipients.](#) Bittermann T, Hubbard RA, Serper M, Lewis JD, Hohmann SF, VanWagner LB, Goldberg DS. *Am J Transplant*. 2018 May;18(5):1197-1205. doi: 10.1111/ajt.14539. Epub 2017 Nov 17. PMID: 29024364

<sup>8</sup> [Factors Associated With Major Adverse Cardiovascular Events After Liver Transplantation Among a National Sample.](#) VanWagner LB, Serper M, Kang R, Levitsky J, Hohmann S, Abecassis M, Skaro A, Lloyd-Jones DM. *Am J Transplant*. 2016 Sep;16(9):2684-94. doi: 10.1111/ajt.13779. Epub 2016 Mar 29. PMID: 26946333