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Republican Healthy Future Task Force Subcommittee on Treatments

The Honorable Bruce Westerman
202 Cannon House Office Building
Washington, DC 20515

The Honorable Brad Wenstrup, D.P.M.
2419 Rayburn House Office Building
Washington, DC 20515

The Honorable John Joyce, M.D.
1221 Longworth House Office Building
Washington, DC 20515

Dear Representatives Westerman, Wenstrup and Joyce,

Vizient, Inc. appreciates the opportunity to provide feedback on the Republican Healthy Future Task Force Subcommittee on Treatment's (hereinafter, "Task Force") Request for Information (RFI) on policy considerations and opportunities for improvement related to incentivizing and ensuring access to innovative treatments. The United States' health care system provides many of the leading innovations in cures, treatments and improvements in health care delivery. Through our collaborative engagement with health care providers and leading manufactures, Vizient is uniquely positioned to offer insights on care delivery and the health care marketplace. We thank the Task Force for its ongoing work in examining the more nuanced and complicated policy issues related to ensuring that medical innovation is available to patients across the country.

Vizient is pleased to provide feedback on several of the key issues that were raised in the RFI. While we do not provide feedback on every element of the RFI, we are happy to serve as an ongoing resource to the Task Force and Congress as a whole, as you continue to develop policy proposals to promote innovation and access to care.

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.

Goal 1: Evaluate potential innovative payment solutions for expensive curative therapies in Medicare and Medicaid

How should government payors use innovative payment methodologies to pay for expensive new drugs, diagnostics, and devices?

Vizient supports updates to current payment systems, including through the use of innovative payment methodologies, to pay for expensive new drugs, diagnostics and devices. However, Vizient also recognizes the need to consider how the provision of care may be impacted by these expensive new technologies, including the need to consider different sites of care and the variable impacts to patients. For example, CAR T-cell therapy is an expensive therapy that has variable sites of care, resource demands and outcomes. Vizient's research found that of 139 patients, nine patients received their infusion in an outpatient setting, demonstrating that there is variability in where patients receive care, which can impact cost. Also, the same research showed that for those patients treated in an inpatient setting, the median length of stay was 21 days and within 30 days, 28 patients (20.1%) had an unplanned readmission to the index hospital, as there can be a variety of unique adverse effects associated with high-cost medications that lead to readmissions.[1] Thus, innovative payment methodologies should be flexible to account for unique care needs and a range of patient outcomes.

Regarding devices, Vizient believes clear and adequate reimbursement is also critical to support up-take of innovative technologies. The Vizient® Tech Watch[2] informs hospital strategy, supports care delivery and fuels performance improvement in key high-impact areas: medical devices, pediatrics and diagnostic imaging. In each Tech Watch volume, Vizient shares data-driven insights on trends and dynamics affecting health care and providing clinical insights that drive innovation in care delivery. The marketplace and best practices are continually evolving for hospitals and, as such, as innovative payment methodologies are considered, Vizient believes it is important for policymakers to refrain from taking approaches that may limit opportunities to adjust to ensure adequate reimbursement to support new, effective products. Vizient encourages payment methodologies that reflect the utilization of best practices and, as more is being learned about innovative and expensive products, it is important to minimize financial risk for providers - particularly given initial costs to make such products and related services available.

Additionally, it merits consideration that hospitals and other providers are likely to have additional investments and ongoing costs to support the use of new products. Hospitals may need to develop new policies and procedures for handling certain medications, purchase complementary equipment or tools, train staff or enroll in programs (i.e., FDA Risk Evaluation and Mitigation Strategies). These additional costs are generally not reflected in Medicare reimbursement. Vizient suggests developing reimbursement opportunities to support providers looking to expand access to new drugs, diagnostics

[1] *See* Adkins, S. (2019). CAR T-Cell Therapy: Adverse Events and Management, *J Adv Pract. Oncol.* Suppl. 3, 21-28, doi: 10.6004/jadpro.2019.10.4.11

[2] https://www.vizientinc.com/our-solutions/supply-chain-solutions/tech-watch

and devices. More broadly, it is imperative that these additional costs and the costs directly associated with care are financially sustainable for hospitals and other providers.

Lastly, as Congress considers payment methodologies for new drugs, devices and diagnostics, Vizient notes our members' significant interest in learning more about the safety and efficacy of products after they are approved by FDA and use increases. For example, as new oncology products come to market, it is often not clear how their effectiveness differs from that of already approved products. This lack of information can make purchasing decisions more challenging, in addition to patient care decisions. Vizient recommends that Congress work with stakeholders to identify innovative payment solutions that encourage data sharing beyond adverse events and particularly related to patient outcomes for new, expensive products. As more information is learned about the effectiveness of such products, additional information or resources should also be provided to health care providers. Further, since some entities, such as academic medical centers, are already working to study new and innovative products, Vizient encourages additional funds be provided to such entities to develop or bolster current efforts.

Would a singular model for reimbursement of curative therapies help or hurt development?

Vizient has significant concerns with the concept of a singular model for reimbursement of curative therapies, as it could significantly limit patient access to care. As noted above regarding CAR T-cell therapy, Vizient research notes that patients may receive CAR T-cell therapy in an outpatient or an inpatient setting. Patient-specific factors often impact the setting in which a patient receives care and helps ensure patient safety. Thus, it is critical that providers be given the flexibility to consider the most appropriate care setting for patients and the reimbursement in each setting be adequate such that providing care is financially sustainable. Additionally, payment models that increase beneficiary co-pays represent another barrier that could emerge should a singular model be pursued. Vizient encourages models that lower the cost of curative therapies broadly while also considering variability in cost of care and unique patient needs.

Lastly, should Congress consider care settings in the context of access to innovative technologies, we encourage patient homes to be included as a possible alternative care setting. As demonstrated during the pandemic, with models like Hospital at Home, Vizient suggests Congress ensure that opportunities to safely expand access to care beyond the walls of a hospital are pursued in advance of the COVID-19 Public Health Emergency (PHE) ending.

Setting the Price of Drugs in Medicare

Vizient supports market-based approaches that would leverage competition to reduce prescription drug prices. Congress should reduce barriers to entry for generic and biosimilar medications, including targeting patent thickets, pay-for-delay settlements and other policies that discourage the entrance of new generic and biosimilar medications to the marketplace. Additionally, while considering policy updates, Vizient encourages Congress to ensure that provider reimbursement exceeds the cost of acquiring and administering the medications. Capping reimbursement rates is concerning given the

additional costs association with handling and administering certain high-cost drugs. As the Task Force considers policies to reduce the cost of drugs, Vizient recommends providing greater incentives for biosimilar medications, such as those provided in the BIOSIM Act.

Goal 2: Encourage innovation and make the Medicare system more flexible to be able absorb new innovative drugs, devices, diagnostics while being good stewards of taxpayer dollars

Barriers to Innovation

Vizient notes that the Unapproved Drugs Initiative (UDI) can serve as a barrier to innovation. Under UDI, older drugs that providers have long used and were on the market before they were required to undergo a full FDA approval process could volunteer to go through the approval process with an additional incentive. In the case of UDI, the incentive was that these products would receive a new, temporary exclusivity period. These newly approved products tend to rely on the 505(b)(2) pathway for approval, which allows applicants to rely on others' research, including clinical trials, for approval. While well intentioned, this represents one way that innovation is stifled, because applicants are able to receive exclusivities while investing less in research and development.

The UDI example highlights the challenge of creating new incentives for post-market data sharing. There are significant opportunities available through digital platforms or through performance-based payment models that could better identify clinical improvements and highlight safer and more effective products through post-market data sharing. However, in building that incentive, it is important to ensure that it would not be structured in such a way that could be exploited to delay or deny competition from accessing the market.

Reimbursement Pathways (Medicare Coverage of Innovative Technologies; Breakthrough Technologies)

While the RFI seeks feedback on specific elements related to the Medicare Coverage of Innovative Technology Final Rule and included definition of "reasonable and necessary", Vizient has not taken a position on the regulation or subsequent withdrawal. However, Vizient encourages the adoption – either through regulation or legislation – of policies that clarify and make consistent coverage and reimbursement determinations for new technology more widely across Medicare, particularly in circumstances where private payers cover such new technologies. In addition to enhanced consistency and predictability of coverage, Vizient believes it is essential that clear, public information is made available to support patient access and understanding related to the cost and coverage of new technology.

Medicare reimbursement for innovative new products is essential for them to impact the market. New Technology Add-on Payments (NTAPs) are a useful support mechanism to bolster adoption of new products, but often, even the enhanced reimbursement rates do not keep pace with the full costs of new products. This presents a meaningful barrier to access, as the high costs can make it financially unsustainable for hospitals to provide new treatments at a loss. Vizient encourages Congress to consider whether

alternative or additional add-on payments can be made available to support the use of new technologies.

Critical Flexibility to Improve Medicare Advantage and other Value-based Plans: Throughout the course of the COVID-19 pandemic, it has become clear that maintaining or even improving access to care can be accomplished by offering new flexibilities for patients and providers under Medicare and Medicare Advantage. Through virtual health, remote patient monitoring, greater use of virtual specialty care and supervision, new "hospitals without walls" flexibilities and more, patients have been able to receive high quality care conveniently through several new modalities.

Under the Medicare Advantage program, health plans have traditionally had significant flexibility to offer a broad array of services and approaches for patients that have been unavailable through traditional Medicare fee-for-service. Given MA plans' ability to utilize telehealth options widely, they should be incentivized to share greater detail around how telehealth deployment and utilization has been successful. While health care providers have learned a significant amount about the impact and effectiveness of virtual care during the pandemic, making real world data and information from MA plans more widely available would provide greater insights in considering how fee-for-service Medicare – as well as Alternative Payment Models – should provide waivers and expand services offered through telehealth following the COVID-19 PHE.

In recognition of the ongoing widespread expansion of telehealth and virtual care services, Vizient also encourages Congress to broadly consider the necessary investments not only to make telehealth services available, but to maintain, integrate with other products, update and ensure critical cybersecurity protections remain in place. While Congress and HHS have been broadly supportive of telehealth flexibilities and deployment, as they consider how to make these services more permanently available, Vizient encourages recognition of those costs in reimbursement determinations so long-term planning and capital investments in digital health strategies are not negatively impacted by uncertainty.

Revisions to Safe harbors, Anti-kickback Statute and Civil Monetary Penalties
Vizient remains supportive of ongoing efforts to ease barriers for hospitals and providers to provide coordinated, value-based care. One consistent obstacle that we have heard repeatedly from our members are concerns related to running afoul of the strict liability of Stark physician self-referral laws. Combined, the Stark and AKS framework exist to protect patients and taxpayers from abuses that could lead to referrals and other actions that have financial motives instead of the interests of patients in mind. While well-intended, these statutory limitations have not been fully updated to recognize the recent steps to move the nation's health care system away from fee-for-service to more collaborative and value-based approaches through Accountable Care Organizations and other alternative payment models.

The Department of Health and Human Services (HHS) and the HHS Office of the Inspector General (OIG) finalized regulations that would take steps to improve clarity around how providers in certain value-based arrangements could better coordinate care

without running afoul of Stark law and AKS restrictions. The final rule made meaningful improvements, but questions still exist, and uncertainty related to the potential risks of engaging in coordinated care may limit providers' willingness to pursue innovative models. Most notably, the strict liability associated with even unintentional violations of the statute is perhaps the most significant deterrent that discourages providers from entering into coordinated care and value-based arrangements. Altering that approach to recognize unintentional or documentation-related violations may ease some of the reluctance from providers to take steps to join in value-based arrangements. Similarly, Congress should consider providing for additional opportunities for drug and device makers to enter into value-based enterprises. While those arrangements would require further scrutiny, in the event they improve care outcomes and reduce cost, they should be considered.

Finally, as Congress and the administration consider ways to make improvements to current statutes, Vizient urges caution around making unnecessary changes that may narrow existing safe harbors that are currently being successfully utilized.

Goal 4: Increase access to medical innovation

Making more prescription products available over-the-counter
Vizient appreciates efforts to increase patient access to medications. As access is considered, it is important that physical access (e.g., OTC availability) be considered in addition to other factors that can impact access like pricing and coverage. Regardless of how policies are adapted, it is essential that additional costs are not pushed onto consumers.

One example of an opportunity to increase access to medication through different channels is for medication-assisted treatments, such as methadone, for opioid use disorders. Vizient endorsed the Opioid Treatment Access Act of 2022, which would allow greater access to OTC methadone for a limited subset of eligible patients. Vizient encourages the Task Force to consider including this policy in future proposals related to medication access and medical innovation. This bill would support a more modern approach to substance use disorder treatment based in part on learnings from the COVID-19 PHE.

Speeding Drug Development
In response to the pandemic, both vaccines and treatments have been made available via emergency use authorization and in some circumstances, approval. Given the rapid changes that have occurred regarding the clinical use of authorized products during this challenging period, Vizient believes that ongoing communication and greater transparency helped facilitate patient access to vaccines and new treatments for COVID-19. As drug development accelerates to treat a range of diseases and conditions, the effects of new products in the manufacturing and distribution process and other supply chain constraints should be considered to ensure that access to other medications is not interrupted.

Vizient also recommends greater tracking of patient outcomes and care needs as products are approved through expedited pathways to learn more about the

effectiveness and limitations of medications. During the pandemic, it was clear that the effectiveness of treatments varied depending on the strain of the virus. Such information may not have been learned if not for ongoing research. In addition, as seen with mRNA vaccinations, additional doses may be needed to maintain effectiveness. Thus, we encourage a broad view of drug development such that more information can be learned about drugs already approved or otherwise authorized by FDA.

Patient access to treatment for antimicrobial resistant infections

To promote antibiotic development and appropriate use, Vizient reiterates our ongoing support and recommends passage of the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act. Among other positive changes described in our prior comments, the PASTEUR Act would establish a subscription program that would provide a predictable return on investments for critically needed new antibiotics through federal payments that are delinked from antibiotic sales and use. In addition, it would also incentivize the development of antibiotic and diagnostic stewardship guidelines to encourage appropriate use of antibiotics.

Additional Policies

Vizient appreciates the Task Force's requests for additional policy proposals. We have long advocated for reforms to the Unapproved Drugs Initiative and related compliance plans. In addition, Vizient has developed a draft legislative proposal to help curb future, unnecessary price spikes that arise from retracted competition for legacy drugs. Vizient welcomes the opportunity to further discuss and refine this proposal.

In addition, Vizient notes our members' ongoing concerns related to payer-imposed white-bagging policies. A Vizient analysis has found that such policies impose an estimated labor expense of $310 million per year to manage the additional clinical, operational, logistical, and patient care work associated with white/brown bagging to prevent negative patient outcomes and medication waste. As noted above, Vizient believes it is imperative that treatment involving innovative medicines be viewed in the context of care provided. Thus, to help minimize costs, Vizient urges Congress to support hospitals' and health systems' efforts to address payer-imposed white bagging requirements.

Lastly, Vizient urges the task force to advance policies that support transparency and resiliency within the supply chain. As the administration and Congress take a hard look at learnings from the COVID-19 pandemic, Vizient also encourages policymakers to look more broadly at potential considerations related to where critical Active Pharmaceutical Ingredients and components of drugs and devices are sourced and products are manufactured to better recognize the risk of shortages or manufacturing challenges that may limit drug and product availability. Vizient continues to work aggressively with our suppliers to better understand those issues and build additional resilience and redundancies into the health care supply chain. These factors, in addition to drug prices, help support sustainable, cost-effective patient access to medications and hospital and health care provider access to critical medical supplies.

Conclusion

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.

Vizient appreciates depth and range of policy considerations raised by the RFI and is pleased to see the Healthy Futures Task Force discussing with appropriate nuance the challenging faced to ensure continued innovation and access to treatments. We look forward to seeing any proposals that may stem from the RFI and the Task Force's work and hope to continue serving as a resource for your efforts.

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 issues.

Respectfully submitted,

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