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The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 600-E
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

Vizient, Inc. appreciates the opportunity to comment on the Department of Health and Human Services' (HHS) policy statement and request for information (RFI) regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, as published on May 7, 2018 in the Federal Register (83 FR 22692).

Background

Vizient, Inc. is the largest member-driven health care performance improvement company in the country. At Vizient, our purpose is to ensure our members deliver exceptional, cost-effective care. Vizient is member-driven and member-minded, working tirelessly to amplify each provider organization's impact by optimizing every interaction along the continuum of care.

Vizient provides innovative data-driven solutions, expertise and collaborative opportunities that lead to improved patient outcomes and lower costs. Vizient serves a diverse membership base including academic medical centers, pediatric facilities, community hospitals, integrated health delivery networks, and non-acute health care providers. Vizient is headquartered in Irving, TX with locations in Chicago, Washington, D.C., and other cities across the country.

One of our core capabilities is our sourcing services. As one of the leading group purchasing organizations (GPOs), Vizient negotiates prices for drugs, devices, and other products and services on behalf of our member healthcare providers, including hospitals, ambulatory care facilities, physician practices, and other non-acute providers. "The central purpose of GPOs is to enhance the quality of the services delivered and lower their members' operating costs by reducing transaction costs and negotiating lower prices for supplies than providers might otherwise obtain on their own. As part of improving efficiency in the supply chain, GPOs also provide a range of additional services to healthcare providers that may lower costs or improve operations[1]." Vizient echoes the concerns of the administration that rising drug costs are

[1] Group Purchasing Organizations: How GPOs Reduce Healthcare Costs and Why Changing Their Funding Mechanism Would Raise Costs – A Legal and Economic Analysis. Dan O'Brien, Jon Leibowitz, and Russell Anello. July 2017.

"spiraling out of control" and believes that our critical role in the health care supply chain can offer useful insights and recommendations on ways in which the administration can accomplish our mutual goals.

Recommendations

At a time when rising drug costs are putting an increasing strain on our members' bottom lines, we applaud the Administration and its efforts to understand the complexities of the U.S. pharmaceutical market and look for solutions to curb rising drug costs. Vizient supports the agency's overall goal of increasing competition, improving negotiation, and lowering list prices and out-of-pocket costs.

Additionally, Vizient is also a member of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition consisting of physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. Vizient and its members are committed to efforts that will improve the delivery of care and remove unnecessary cost from the U.S. health care market. We are grateful for the opportunity to lend our voice to this important discussion and look forward to continuing to work with HHS as they examine these critical issues.

Increasing Competition

Vizient believes that biosimilars represent one of the most important avenues for cost mitigation within the pharmaceutical supply chain in the near future. We strongly support the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics. Vizient endorses continued initiatives that foster a robust and diverse market of biosimilars and remove barriers that might inappropriately and unnecessarily curtail the adoption of these products. We believe in an approach that balances patient safety concerns and further reinforces the fact that biosimilars should be managed as agents that have similar safety, efficacy, and potency as the originator biologics to which they are compared.

Vizient has supported and appreciates many of the recent actions the Food and Drug Administration (FDA) has taken to promote innovation and competition for biologics. Vizient agrees with HHS in their concern that Risk Evaluation and Mitigation Strategies (REMS) have been used to prevent generic competition. This assessment is in line with the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which Vizient strongly supports.

The Blueprint notes that the "FDA is working to identify areas in which additional information resources or development tools may facilitate the development of high quality biosimilar and interchangeable products". Vizient strongly agrees that "physician and patient confidence in biosimilar and interchangeable products is critical to the increase market acceptance of these products". We appreciate that the FDA intends to build on the momentum of past education efforts by developing additional resources for health care professionals and patients – and encourage resources specifically dedicated to biosimilar and interchangeable products as the agency seeks to increase awareness of these important new treatments. However, while general awareness of the biosimilar concept has improved for physicians, pharmacists, and clinicians, a complete appreciation of the regulatory nuances of approval and marketing remains

elusive. Based on our experiences, we would like to offer some specific suggestions regarding educating providers and patients.

Throughout Vizient's work at increasing the understanding of biosimilars across its membership, one of the most useful tools in these educational efforts has been the meeting materials that accompany the FDA's Advisory Committee meetings. The ability for our members to read the FDA's comments and perspectives on critical factors of analytical similarity and clinical data evaluation has been invaluable in making concepts such as "totality of the evidence", "stepwise approach", bridging, and extrapolation easier to appreciate and understand. It would be helpful if the Agency made these types of meeting materials (e.g., briefing material, slides, etc.) available at the time of product approval (for all biosimilars, regardless of whether or not an advisory committee meeting is convened) in order to increase the general understanding of biosimilars.

Another critically useful element in improving the understanding of biologic licensing has been the historical basis of comparability of originator biologics. The information made available in the published literature through review of data published by the European Medicines Agency has helped clinicians understand that biologic variability (and the application of analytical characterization to monitor the extent of changes) is not novel to biosimilars. Vizient would likely support the Blueprint's proposed enhancements to the FDA's *Purple Book* and looks forward to learning more about what changes the administration plans to make. Whether the information would be included in the *Purple Book* or via the FDA website, specific information that would be helpful is regarding enforcement and monitoring of the comparability of originator branded biologics. Increased disclosure of information would help diminish concerns that the characteristics of biosimilars are different from the originators to which they are compared.

Biologic competition is a critical step in controlling the trajectory of drug costs – and ultimately lowering prices for patients. Vizient will continue to support the education of physicians, pharmacists, and other providers through its evidenced-based resources (e.g. infliximab-dyyb white paper), its budget projection tools (e.g. the twice annual Vizient Drug Price Forecast report), continuing educational web conferences, and other communication vehicles. In addition, Vizient continues to implement sourcing strategies to support members in their efforts to lower costs through biosimilar adoption. Vizient supports the introduction and adoption of biosimilars as safe and effective alternatives to originator biologics, and continues to provide education to physicians and other providers to minimize barriers to product acceptance. We are committed to minimizing health care costs and mitigating increasing drug expenditures to preserve access to care.

Better Negotiation

Vizient appreciates the overall goal of better negotiation, and applauds HHS for making value-based transformation of health care a top priority. This goal and priority is shared by Vizient, which, as a GPO, offers our members considerable value and cost reduction through negotiation. In Vizient's role as one of the nation's leading GPOs, we create value by lowering transaction costs and negotiating lower prices. Customer surveys show that providers realize savings of 10 percent to 18 percent by using GPOs, measured relative to the costs providers would have incurred if they negotiated prices on their own. Providers then pass these savings on to patients – and ultimately to our nation's taxpayers[1].

Our academic medical centers, integrated health systems, pediatric organizations, and non-acute providers frequently provide care for those patient populations most at risk for limited access to treatment. They are best positioned to ensure the continuity of care across different treatment settings. Vizient endorses strategies that support the appropriate use of these

increasingly expensive therapies and supports continued investigation of ways to align treatment costs and reimbursements with patient outcomes.

Vizient agrees with HHS's goal of ensuring adequate payment but strongly opposes any continuation of site-neutral payment policies, including those with respect to drug administration. Vizient members adhere to the mission of providing high-quality health care to everyone they serve, and believe CMS should adequately and appropriately incentivize providers to achieve health equity.

Vizient is concerned with the two site-neutral payment policies that are raised in the Blueprint and believes that, if implemented, both could lead to a substantial and devastating impact on access to care for the most vulnerable and complex patients. Communities with already limited access to health care services will bear the brunt of this proposal, as well as the many patients that rely on the invaluable services provided by our members. Additionally, hospital-level outpatient care is essential in all communities, and provides reasonable and necessary services to Medicare beneficiaries – especially in urban and rural areas where access to care is limited. There are significant differences between hospitals/hospital outpatient departments and physician offices (including, but not limited to, EMTALA requirements, case-mix differences, increased licensing, accreditation, and regulatory requirements) – all of which can greatly contribute to differences in the payment amounts for a wider range of services.

By reducing payments to hospitals for physician-administered drugs, patient access to appropriate, timely, life-saving treatments could be threatened. Additionally, the administration's previous (and ongoing) strategies to decrease reimbursement to lower the total expense of pharmaceuticals have had a negative impact on our member institutions. This makes it increasingly challenging for hospitals to preserve treatment options for all patients, especially the most vulnerable and complex. Reimbursement models for drugs administered in a hospital setting versus physician office cannot truly be compared – or equaled – due to the completely different payment structure in each setting. Hospital-administered drugs are accompanied with significantly more packaged costs versus simply the cost of the drug itself.

The Blueprint asks: "Which elements of the inpatient or outpatient setting lead to naturally differential payments, and why?" The short answer is that they are paid under different payment systems, using completely different methodologies. One reason for this is that patients in the inpatient setting tend to be sicker and often require more complex care that cannot necessarily be performed in the outpatient setting. This is reflected in the different payment methodologies for inpatient and outpatient reimbursement. Most hospitals – paid under the hospital inpatient prospective payment system (IPPS) – generally receive payment on a per-discharge or per-case basis for Medicare patients with inpatient stays. Discharges are assigned to diagnosis-related groups (DRGs), a classification system that groups similar clinical conditions (diagnoses) and the procedures furnished by the hospital during the stay. In other words, hospitals are paid a single pre-determined amount that is based on a national base payment rate. The Centers for Medicare & Medicaid Services (CMS) reviews the DRG definitions annually to ensure that each group continues to include cases with clinically similar conditions that require comparable amounts of inpatient resources[2]. Under the outpatient prospective payment system (OPPS), the unit of payment in most cases is the ambulatory payment

[2] Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network Booklet. Acute Care Hospital Inpatient Prospective Payment System. March 2018.

classification (APC). CMS assigns individual services (HCPCS codes) to APCs based on similar clinical characteristics and similar costs. “Packaging”, or grouping payment of dependent, ancillary, supportive, and adjunctive items and services into the payment for the associated primary procedure or service, is a critical feature of the OPPS. Packaging encourages efficient use of hospital resources. Separate payments are not made for packaged services, which are considered an integral part of another service that is paid under the OPPS. Additionally, the Bipartisan Budget Act of 2015 revised the OPPS so that certain items and services furnished by off-campus provider-based departments (PBDs) are not considered covered outpatient services for purposes of OPPS payment. Non-excepted items and services furnished in a non-excepted, off-campus PBD on or after January 1, 2017, are paid under the Medicare Physician Fee Schedule (PFS)[3].

Regardless of the complexities in the Medicare payment systems, Vizient strongly believes that decisions as to whether a patient should receive a drug in the inpatient or outpatient setting should be made solely by his or her prescribing physician based on their clinical judgment alone. If a drug can be safely administered in the outpatient setting, hospitals support this decision, but then should not be penalized by decreased reimbursements when there are significant factors that contribute to the overall cost of care. We strongly oppose any reduction to hospital reimbursement for drug administration procedures which do not properly account for the costs of providing care, and could threaten hospital and health systems’ ability to continue to serve as access points of care in their communities.

As HHS considers working in conjunction with the Department of Commerce and The Office of the U.S. Trade Representative (USTR) to address the “unfair disparity between the drug prices in America and other developed counties”, Vizient urges the agencies to use caution on their approach, especially if they are examining utilizing tariffs as a solution. In particular, we urge agencies to use caution in applying these penalties to the active pharmaceutical ingredients (API) used in the manufacture of finished pharmaceuticals for American consumers. We are concerned that tariffs may disrupt the supply of API, which could, in turn, upend pharmaceutical manufacturing and create new medication shortages or exacerbate existing shortages. Hospitals, health systems, and other health care facilities are constantly facing intermittent shortages of critical medications, often due to manufacturing delays, but sometimes attributable to natural disasters or supply and demand problems[4].

While supply of API is not the cause of current drug shortages, application of tariffs to API could result in significant unintended consequences, including manufacturing disruption or delay. Any resulting shortages could have serious ramifications for patient care in the United States. Vizient respectfully requests that the administration and federal agencies continue to work with health care industry stakeholders to take steps to ensure that any action taken does not unintentionally result in higher prices for products and services being paid by our nation’s hospitals, patients, and all American taxpayers.

Create Incentives to Lower List Prices

The 340B Drug Pricing Program (340B program) was established by Congress in 1992 and requires that to remain eligible for participation in the Medicaid program, drug manufacturers

[3] Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network Booklet. Hospital Outpatient Prospective Payment System. December 2017.

[4] American Society of Health-System Pharmacists (ASHP). Drug Shortage Statistics, available at https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics.

must provide outpatient drugs to eligible health care providers – also known as covered entities – at reduced prices[5]. These covered entities include community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations. According to the 1992 House Report accompanying the legislation, the 340B program was intended "to enable [covered] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services[6]."

The 340B Drug Pricing Program is essential for our safety-net hospital members to provide critical health care services to the patients and communities they serve. Furthermore, it enables many of our members to provide access to life-saving prescription drugs to low-income patients. The 340B Drug Pricing Program "is a small program with big benefits. It accounts for only 2.8 percent of the $457 billion in annual drug purchases made in the U.S.[7]" and requires no taxpayer dollars. Participating hospitals have extensive compliance requirements for which they bear the full cost, with no federal funding used. Tax-exempt hospitals participating in the 340B program report more than $51 billion in total benefit to their communities[8]. Vizient strongly encourages HHS to protect providers that are positively impacting patients and our health care system by ensuring adequate reimbursement for drugs and biologicals purchased under the 340B Drug Pricing Program – so that our nation's safety-net hospitals and health systems can continue to operate in the areas of our country that need them most.

Vizient supports 340B Drug Pricing Program integrity efforts to ensure this crucial program remains available to safety-net hospitals and health systems. The statute that created the 340B Program also requires the establishment of a prime vendor program (PVP). The 340B PVP helps participants comply with the requirements of the program, including the prohibition on duplicate discounts. The 340B PVP helps to lowers drug prices by collectively leveraging the purchases of all participating hospitals and clinics nationally to secure the lowest pricing on outpatient drugs for all participants, regardless of size. The prime vendor negotiates discounted pricing for 340B covered entities that is lower than the 340B ceiling price. Recent discounted PVP sales represent more than an 18 percent savings below the 340B ceiling price. Additionally, as part of its agreement with the Health Resources & Services Administration (HRSA), the current 340B PVP provides a multitude of tools to aid with program compliance, including a national call center. The PVP also provides ongoing education, training, and support to all 340B stakeholders through 340B University Live and OnDemand. Covered entities join the PVP on a voluntary basis, at no cost to them or the government.

HHS has requested information on whether the prime vendor program increases or decreases drug prices. Having a singular PVP better enables HRSA to efficiently and effectively manage the 340B program without additional inefficiencies or duplication of functions and costs to the PVP – or to the federal government. Inserting additional third parties into the contracting process will further complicate this process, adding waste and additional cost which will ultimately be paid for by suppliers, thus increasing costs to PVP participants. The current structure of the PVP allows for one point of efficiency and integrity for suppliers, distributors, and

[5] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b.
[6] H.R. Rep. 102-384, Pt. 2 (1992).
[7] American Hospital Association (AHA). Fact Sheet: The 340B Drug Pricing Program. February 2018.
[8] American Hospital Association (AHA). Fact Sheet: 340B Hospital Community Benefit Analysis. March 2018.

HRSA, further driving down costs to covered entities and patients. Additionally, the current structure of the single prime vendor increases competition in the marketplace by offering participants the choice of 29 different distributors as well as contracts with nearly 100 suppliers. This model leverages competition in the free market to lower drug prices for safety-net providers.

Conclusion

Our members believe and practice that every patient who seeks care should receive the same high-quality care. We respectfully ask that you consider the indispensable role played by America's hospitals and health systems, and the impact that potential policy changes may have on their ability to continue providing the care for patients and communities they serve. Vizient looks forward to continuing to work with HHS and offering support for efforts that appropriately and effectively address issues at the core of growing prescription drug costs. At a time when rising drug costs are putting an increasing strain on our members' bottom lines, we strongly support meaningful solutions to curb rising drug costs.

Vizient welcomes HHS's extensive discussion of options and its emphasis on requesting comments, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. Vizient looks forward to working with HHS and the administration to support efforts that lead to affordable and innovative improvements to the nation's health care system.

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, Inc., I would like to thank HHS for providing us this opportunity to comment. Please feel free to contact me at (202) 354-2600 or Chelsea Arnone, Director of Regulatory Affairs and Government Relations (chelsea.arnone@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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