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Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW, Room 445-G
Washington, DC 20201

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs [CMS-5528-ANPRM]

Dear Administrator Verma:

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) advanced notice of proposed rulemaking (ANPRM) to solicit public comments on potential options the agency may consider for testing changes to payment for certain separately payable Part B drugs and biologicals – as published on October 30, 2018 in the Federal Register (Vol. 83 No. 210).

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 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 and customer 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.

Recommendations

Vizient's national infrastructure and presence, combined with geographic and local delivery, impacts beneficiaries in hospitals, clinics, ambulatory care and post-acute care delivery sites and communities across the United States. Vizient and its subsidiary companies – Provista, Aptitude, Sg2 and Apexus – have demonstrated the power of a transparent, mission-driven organization in improving patient care and driving down health care costs. Additionally, Vizient represents over $100 billion in annual health care expenditures, much of it associated with pharmaceuticals. As a result, we can validate the need our membership has for strategies to mitigate the accelerating expense of pharmaceuticals not only for themselves, but for the patient populations they serve.

Vizient applauds the work of CMS in facilitating the dialogue regarding the topic of increasing drug pricing and expense, and looks forward to continuing to engage with the agency. We appreciate CMS's stated intent to decrease the drug expenditure burden to beneficiaries including out-of-pocket costs, to maintain stability in revenue and reduce provider financial risk, and to enable additional competition for the acquisition of Part B drugs, while minimizing the disruption of the current supply chain.[1] However, based upon our assessment as well as insight gathered from our member organizations, the policies outlined in the ANPRM do not achieve these objectives. **Vizient believes that, as presently described, the policies do not directly alter drug pricing, would make a complicated pharmaceutical supply chain more difficult to manage, and would create additional financial and workload hardship for providers, which ultimately could limit beneficiaries' access to care.** We would like to enumerate the following challenges in support of creating a more successful methodology to rationalize drug costs.

The Potential International Pricing Index (IPI) Model – Challenges

The variation in the pricing of pharmaceuticals, particularly the increased costs to the U.S. market, is well documented in this proposal, in CMS's recent analysis of commonly prescribed Part B drugs, and in the clinical literature.[2,3,4] The recognition of this discrepancy and efforts to minimize this variation are needed. However, the mechanism articulated in this advanced notice does not actually alter the price that drug manufacturers charge, but instead mandates a dramatic alteration to the supply channel by which providers obtain drugs and limits the extent to which they are reimbursed for care delivery.

Various reasons have been put forth to account for the variation in pricing between the U.S. and other nations.[5] Part of the difference relates to the fact that single payer structures exist within some of these countries – granting these governments greater leverage to negotiate price. However, another critical difference is that most of these nations also support an entity that conducts comparative effectiveness analyses of medications to assess their value relative to outcomes.[6] Various private organizations and professional practice associations conduct such comparative effectiveness analyses and/or have developed "value frameworks" to advance the concept of "value based" purchasing.[7,8] Thus far, these assessments have shown that pharmaceutical prices do not correlate with their acquisition costs.[9] **As a result, Vizient believes any efforts to decrease prescription drug costs in the U.S. should begin with pharmaceutical manufacturer prices. Furthermore, we encourage the agency – as a first step – to consider developing a method (or demonstration) which involves an assessment of prescription drug value relative to the clinical outcomes that are derived from their use.**

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[1] Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2018, October 30). Medicare Program; International Pricing Program Index Model for Medicare Part B Drugs. 42 CFR Chapter IV [CMS-5528-ANPRM]. Retrieved from https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF.

[2] Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2018, October 30). Medicare Program; International Pricing Program Index Model for Medicare Part B Drugs. 42 CFR Chapter IV [CMS-5528-ANPRM]. Retrieved from https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF.

[3] Office of the Assistant Secretary for Planning and Evaluation. (2018, October 25). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. Retrieved from https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.

[4] Kesselheim, AS; Avorn, J; Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: Origins and Prospects for Reform. *JAMA*. *316*(8), 858-871. doi:10.1001/jama.2016.11237

[5] Kesselheim, AS; Avorn, J; Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: Origins and Prospects for Reform. *JAMA*. *316*(8), 858-871. doi:10.1001/jama.2016.11237

[6] Kesselheim, AS; Avorn, J; Sarpatwari, A. (2016). The high cost of prescription drugs in the United States: Origins and Prospects for Reform. *JAMA*. *316*(8), 858-871. doi:10.1001/jama.2016.11237

[7] Institute for Clinical and Economic Review. ICER Value Assessment Framework. Retrieved from https://icer-review.org/methodology/icers-methods/icer-value-assessment-framework/.

[8] Neumann, PJ; Cohen, T. (2015). Measuring the Value of Prescription Drugs. *The New England Journal of Medicine*. *373*, 2595-7. doi:10.1056/NEJMp1512009

[9] Vivot, A; Jacot, J; Zeitoun, JD; Revaud, P; et al. (2017) Clinical benefit, price and approval characteristics of FDA-approved new drugs for treating advanced solid cancer, 2000-2015. *Annals of Oncology, 28*(5), 1111-6. doi: 10.1093/annonc/mdx053

Concerns with the "Vendor" Structure and Detrimental Impact on the Supply Chain

As shown in Figure 1 of the advanced notice (and in other references), the pharmaceutical supply chain involves a complex interaction between multiple stakeholders to ensure medications are available at the exact point in time required for patient care.[10,11] The increasing costs of pharmaceuticals have further elevated the scrutiny of the efficiency of these processes, and have prompted manufacturers and payors to implement limited distribution mechanisms that further restrict the ease of accessibility of products. Some medications require limited distribution processes to ensure safety and appropriate prescribing in accordance with FDA Risk Evaluation and Mitigation Strategies (REMS).[12] As a result, providers must interact with an increasing number of stakeholders to acquire prescription drugs. Introduction of an additional intermediary to this process for a subset of pharmaceuticals could further exacerbate the ordering, acquisition, and inventory management of these processes, particularly if minimal qualifications and conflict resolution standards are not set for possible new vendors.

In November 2013, Congress enacted the Drug Quality Security Act (DQSA), including Title II, the Drug Supply Chain Security Act or DSCSA.[13] The intent of this legislation was to create a supply channel for pharmaceuticals that is resistant to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.[14] Through this electronic and interoperable system, the detection and removal of potentially dangerous drugs from the supply chain can be facilitated. The foundational aspect of this process involves creation and exchange of "T3" information (i.e. transaction data) that identifies the medication and captures and assures the safety of its distribution and management.[15] All trading partners in the supply chain including manufacturers, wholesalers, and pharmacies are required to provide this information upon selling product to another trading partner.[16]

One aspect of the potential model (as proposed) involves the creation of a "vendor", which would take title to and assume the expense on behalf of providers for the Part B drugs included in the IPI model. Vizient has concerns that this mechanism could further contribute to the complexity of an already complicated supply chain, and may have the unintended result of increasing the workload of providers to ensure appropriate distribution and billing to CMS and to beneficiaries.

Additionally, under the proposed structure of this model, the "vendor" supplies, but does not sell Part B pharmaceuticals to the provider. As a result, it appears that the "vendor" would remain liable for the integrity of the product – even after delivering it to the provider. It remains unclear if prospective "vendors" would be willing to assume that level of accountability and risk, in addition to product costs. Thus, Vizient believes that this potential model could substantially disrupt the mechanisms to prevent the introduction of counterfeit and/or contaminated products.

Negative Impact of Changes to "Add-On Payment" Process

Vizient has significant concerns regarding the payment structure of the potential model; specifically, changes to the "add-on" payment structure from a "buy and bill" methodology to a

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[10] Department of Health and Human Services, Centers for Medicare and Medicaid Services. (2018, October 30). Medicare Program; International Pricing Program Index Model for Medicare Part B Drugs. 42 CFR Chapter IV [CMS-5528-ANPRM]. Retrieved from https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF.

[11] Huggett, B. (2016) America's drug problem. *Nature Biotechnology, 34*(12), 31-41. doi: 10.1038/nbt.3734

[12] U.S. Food & Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS). Retrieved from https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm.

[13] U.S. Food & Drug Administration. (2018, October 30). Drug Supply Chain Security Act (DSCSA). Retrieved from https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

[14] U.S. Food & Drug Administration. (2018, October 30). Drug Supply Chain Security Act (DSCSA). Retrieved from https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

[15] U.S. Food & Drug Administration. (2018, October 30). Drug Supply Chain Security Act (DSCSA). Retrieved from https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

[16] U.S. Food & Drug Administration. (2018, October 30). Drug Supply Chain Security Act (DSCSA). Retrieved from https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.

situation where providers are reimbursed only for the management and administration of the prescription pharmaceutical. While the stated intent is to eliminate any incentive to select higher cost drugs given the potential for generating greater revenue, the reality is that even the existing reimbursement methodology may not adequately cover the ordering, storage, handling, preparation, administration, and monitoring of pharmaceuticals. As stated above, the proposed introduction of additional intermediaries, including multiple "vendors", would create additional resource requirements and expense to manage a separate supply channel for included Part B medications. Furthermore, the requirements for the implementation of DSCSA have necessitated additional investment to support supply chain integrity.[17] These requirements exist to ensure the sterility of parenterally administered medications, as well as to prevent inadvertent exposure of health care workers to hazardous pharmaceuticals (i.e., United States Pharmacopoeia (USP) standards <797> and <800>, respectively). While essential for the integrity of the supply chain and patient safety, these requirements mean increased expenses for providers.[18,19]

Of the 27 medications included in CMS's analysis of relative prices, 22 products are administered via intravenous infusion – where sterility is of a paramount concern.[20] In addition, 6 of the 27 products evaluated would be classified as hazardous drugs, necessitating the use of additional personal protective equipment and other technologies to avoid inadvertent health care worker exposure.[21] As a result, even the existing mechanism of calculating reimbursement on the average sales price (ASP) of a medication may fail to adequately capture the totality of expense associated with administration for certain pharmaceuticals.

Adverse Impact on 340B

Many of Vizient's members qualify for participation in the 340B Drug Pricing Program. These members have had to adjust to the agency's recent dramatic decreases to Part B reimbursement.[22] Vizient strongly believes that, as proposed, the potential model would exacerbate an already tenuous environment. The value of the 340B Program is realized via the "buy and bill" methodology. By purchasing medications at a lower price, 340B eligible organizations can direct the additional margin to the delivery of uncompensated care. Reducing how Medicare reimburses hospitals that participate in the 340B Program for these drugs will not address the underlying issues impacting the rising costs of prescription drugs. Rather, it has the opposite and detrimental effect of impeding hospitals' ability to utilize 340B savings to maintain programs that provide services to vulnerable populations, including Medicare beneficiaries. Vizient strongly encourages CMS to protect providers that are positively impacting patients and our health care system by continuing to adequately reimburse drugs and biologicals purchased under the 340B 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. If CMS chooses to move forward with this potential model, Vizient strongly urges the agency to exclude 340B covered entities from this demonstration.

[17] U.S. Food & Drug Administration. (2018, October 30). Drug Supply Chain Security Act (DSCSA). Retrieved from https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/.
[18] United States Pharmacopeia. General Chapter <797> Pharmaceutical Compounding – Sterile Preparation. Retrieved from http://www.usp.org/compounding/general-chapter-797.
[19] United States Pharmacopeia. General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. Retrieved from http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare.
[20] Office of the Assistant Secretary for Planning and Evaluation. (2018, October 25). Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures. Retrieved from https://aspe.hhs.gov/pdf-report/comparison-us-and-international-prices-top-medicare-part-b-drugs-total-expenditures.
[21] Centers for Disease Control and Prevention. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. Retrieved from https://www.cdc.gov/niosh/docs/2016-161/default.html.
[22] Department of Health and Human Services, Centers for Medicare & Medicaid Services. (2017, November 13). Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs. 42 CFR Parts 414, 416, and 419. [CMS-1678-FC]. Retrieved from https://www.gpo.gov/fdsys/pkg/FR-2017-11-13/pdf/2017-23932.pdf.

Other Questions and Concerns

In addition to our responses concerning the fundamental components of the proposed potential model, there remain other questions about the model in its current format. For example, while we recommend overt exclusion of 340B covered entities due to the detrimental impact on patient care, we also question if these organizations could participate in the model's existing structure. Would the "vendor" role be viewed as a group purchasing organization (GPO) and, as a result, be off limits to 340B entities? If the model is implemented with the proposed mandatory participation for providers, would 340B covered entities have to exit the program to adhere to the "vendor" model – and, as such, lose the essential drug discounts that enable uncompensated care for vulnerable populations? Furthermore, Vizient is concerned that while participation is mandatory for providers, the role of pharmaceutical manufacturers appears voluntary. What incentives exist for suppliers to enter negotiations to offer discounted prices to vendors?

Final Comments and Recommendations

Vizient appreciates the administration's ongoing efforts and stakeholder engagement around strategies to lower the costs of prescription drugs. Although we do not believe this proposed potential model will achieve this goal – for patients or providers – we encourage CMS to continue discussions and collaborating with health care stakeholders to find meaningful solutions to decrease the rising cost of prescription drugs and lower out-of-pocket costs for beneficiaries.

Vizient urges CMS to prioritize a potential model that incorporates a performance-based ratings system to measure, incentivize and reward improved patient outcomes, while focusing on increasing prescription drug competition. We strongly believe that a data-driven model would help to fill the gaps and improve shortcomings in our current health care system. Transparency, competition and standardization will be key elements of any program's success. Vizient would also like to emphasize the importance of the introduction and adoption of biosimilars – which could deliver consistent and meaningful savings.

Conclusion

Vizient welcomes CMS'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 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. Therefore, we respectfully ask that you consider the indispensable role played by America's hospitals and health systems in providing care for the patients and communities they serve. **Vizient strongly encourages CMS to consider policies to lower prescription drug costs that also protect providers that are positively impacting patients and our health care system. Vizient members adhere to the mission of providing high quality health care to everyone they serve, and believe CMS should adequately and appropriately reimburse providers.**

Furthermore, Vizient has a long history in government pricing programs and contract negotiation. We provide access to discounted medications, education and compliance support, and we work with all stakeholders, including manufacturers, wholesalers, distributors, consultants, trade organizations and health providers. Most importantly, every member of the Vizient team is committed to lowering the costs of prescription drugs for Americans by increasing competition, improving negotiation, and lowering list prices and out-of-pocket costs.

Vizient is concerned that this potential model could have a negative impact on access to care for the most vulnerable and complex patients. Communities with already limited sources of health care could bear the brunt of this potential model, as well as the many patients that rely on the invaluable services provided by our members. Vizient encourages the agency to properly account for the costs of providing care, and consider a model that would strengthen hospital and health systems' ability to continue to serve as access points for care in their communities.

In closing, on behalf of Vizient, Inc., I would like to thank CMS for providing us this opportunity to comment on this important proposal. Please feel free to contact me at (202) 354-2600 or Chelsea Arnone, Government Relations Director (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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