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September 9, 2024

Submitted electronically via: www.regulations.gov

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: Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2025 Medicare Physician Fee Schedule (PFS) and Quality Payment Program (QPP) Proposed Rule, as many of the proposed policies have a significant impact on our provider members and the patients they serve.

Background

Vizient, Inc., the nation's largest provider-driven healthcare performance improvement company, serves more than 65% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 35% of the non-acute market. Vizient provides expertise, analytics and consulting services, as well as a contract portfolio that represents $140 billion in annual purchasing volume. Solutions and services from Vizient improve the delivery of high-value care by aligning cost, quality and market performance. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

In our comments, we respond to the various issues raised in the Proposed Rule and offer recommendations to constructively improve the final rule. We thank you for the opportunity to share our views on CMS's proposals. Vizient believes the following areas are important for CMS to consider when finalizing the provisions for the CY 2025 Medicare PFS, Medicare Shared Savings Program (SSP) and QPP Proposed Rule.

Changes to the Physician Fee Schedule and Other Changes to Part B Payment Policies

Calculation of the Proposed CY 2025 PFS Conversion Factor

In the Proposed Rule, CMS estimates a conversion factor (CF) of $32.3562, which is approximately a 2.8% reduction from 2024. Due to this significant reduction, Vizient is concerned that providers will endure even greater financial challenges during CY 2025 absent changes by CMS or Congress.

Vizient urges CMS to advance policies that reduce financial strain on providers and to support any legislative efforts that prevent these harmful payment reductions.

Development of Strategies for Updates to Practice Expense Data Collection and Methodology

In the CY 2024 PFS proposed rule, CMS solicited public comment on strategies to update the practice expense data collection and methodology. Among other sources, CMS uses the American Medical Association's (AMA's) Physician Practice Information Survey (PPIS) to inform PFS rates. In the Proposed Rule, CMS notes that AMA expects updated analysis, reporting and documentation related to the PPIS to be complete by the end of CY 2024, despite updated information being available soon. Vizient appreciates the agency's mention of the AMA's PPIS to inform PFS rates, as we believe such information helps improve the accuracy of practice expense (PE) estimates.

In addition, CMS indicates that it has started new work under contract with the RAND Corporation to analyze and develop alternative methods for measuring PE and related inputs for implementation of updates to payment under the PFS. CMS seeks information regarding scheduled, recurring updates to PE inputs for supply and equipment costs in an effort to improve the stability and predictability of any future updates. While Vizient supports efforts to improve the stability and predictability of future payments, we request that the agency ensure that providers are included in the RAND Corporation's process.

In addition, we note our concern with a prior RAND Report recommendation[1] which suggested that comparisons between PFS PE relative values and Outpatient Prospective Payment System (OPPS)-based relative values for procedures could be used to identify potentially misvalued procedures in the two systems and help address site-of-service differentials. Vizient cautions CMS from this approach, as there are numerous reasons why expenses between these two settings vary. While CMS did not directly discuss such prior recommendations in the Proposed Rule, we note our strong opposition to site neutral payment policies that would ultimately under-reimburse providers, including hospital outpatient departments, for care. However, we do appreciate that CMS has taken additional measures to ensure the stability and predictability of future payments.

Medicare Economic Index

Consistent with the agency's position in the CY 2024 PFS final rule and given the agency's policy goal to balance PFS payment stability and predictability, CMS is not proposing to incorporate the 2017-based Medicare Economic Index (MEI) in PFS rate setting for CY 2025. Vizient agrees with this approach, as it is critical that recent and accurate data be used to update the MEI, such as the anticipated AMA's PPIS.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

Vizient appreciates the measures the agency took during the COVID-19 Public Health Emergency (PHE) to expand access to telehealth services. Such changes were critical to preventing the spread of COVID-19 and have also helped ensure continuous access to care. For example, a March 2023 report from the Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, has highlighted effective strategies for sustaining and optimizing

[1] https://www.rand.org/pubs/research_reports/RRA1181-1.html

telehealth in primary care, but also indicates that legislative and regulatory concerns by providers are a significant hinderance to adoption and acceptance of telehealth by more providers.

As CMS is aware, there are numerous COVID-19 PHE-related telehealth flexibilities that are set to expire at the end of CY 2024 (e.g., geographic location and originating site flexibilities, waiver of the in-person visit requirement for mental health services, scope of eligible telehealth providers). Once these flexibilities expire, Vizient is concerned that patients' access to telehealth will be severely limited and disrupted. As such, Vizient urges CMS to work with Congress to permanently extend the COVID-19 PHE-related telehealth flexibilities that will, without congressional intervention, expire at the end of the year. Despite these telehealth flexibilities expiring, in the Proposed Rule, CMS offers various policies that would generally help maintain access to telehealth services. Vizient offers additional comments related to our support for extending several of the telehealth flexibilities that are within the agency's authority, among other recommendations.

Frequency Limitations on Medicare Telehealth Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations

Before the COVID-19 PHE flexibilities eased frequency restrictions, CMS imposed restrictions on how often practitioners could furnish services via Medicare telehealth (e.g., one subsequent hospital care service furnished through telehealth every 3 days; one subsequent nursing facility visit furnished through telehealth every 14 days; and one critical care consultation service furnished through telehealth per day). Although the frequency limitations resumed on May 12, 2023 (upon expiration of the PHE), through enforcement discretion through CY 2024, CMS suspended these limitations for certain codes (e.g., Subsequent Inpatient Visit CPT Codes 99231-99233, Subsequent Nursing Facility Visit CPT Codes 99307-99310, Critical Care Consultation Services HCPCS Codes G0508-G0509). Through CY 2025, CMS proposes to remove the frequency limitations for these codes. Vizient supports the agency's proposal to remove frequency limitations. However, to better support patient access to care and provide stability, we recommend that these limitations be removed permanently.

Audio-Only Communication Technology to Meet the Definition of "Telecommunications System"

Through regulation, CMS has defined "interactive telecommunications system" as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. During the COVID-19 PHE and through subsequent legislation, through December 31, 2024, audio-only communications technology could be used to furnish services described by the codes for audio-only telephone evaluation and management services and behavioral health counseling and educational services. As noted in the Proposed Rule, CMS now believes that it would be appropriate to permanently allow interactive audio-only telecommunications technology for telehealth services. As such, CMS proposes to change the definition of "interactive telecommunications system" to state that an interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a beneficiary in their home if the distant site physician or practitioner is technically capable of using an

interactive telecommunications system[2]. Vizient appreciates the agency's recognition of the important role that audio-only telehealth services play in connecting patients to providers. As noted in the March 2023 CPSC report, from January-September 2022 and as illustrated in Figure 1, there is a significant range of audio-only versus video visit rates across CPSC member organizations. Thus, while organizations are capable and regularly providing video visits, patients still rely on audio-only care. As such, Vizient supports the agency's proposal to permanently extend access to audio-only technology for covered telehealth services.

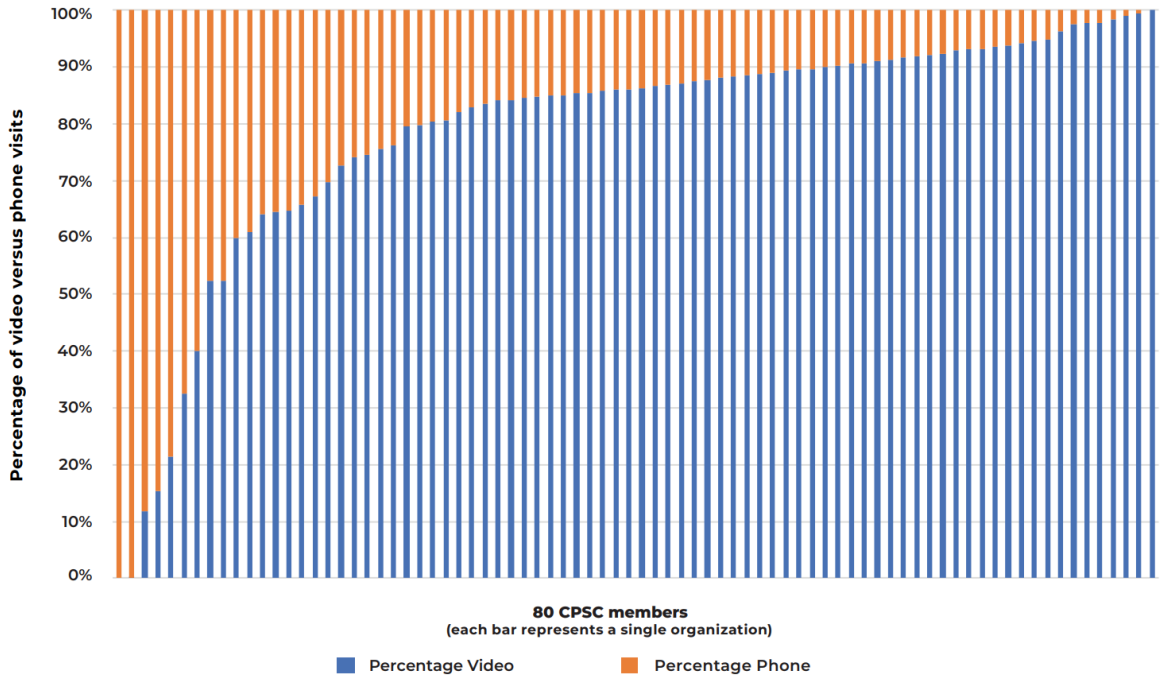

Figure 1. Video versus phone telehealth use in primary care, quarters 1-3 (January-September 2022). Graph from "Effective Strategies for Sustaining and Optimizing Telehealth in Primary Care", Vizient Inc-AAMC Clinical Practice Solutions Center ©.

Distant Site Practitioner's Currently Enrolled Practice Location

In the CY 2024 PFS final rule, CMS continued policy to permit a distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. CMS proposes to continue this policy through CY 2025. Vizient strongly supports the proposal to extend this policy, as it helps support practitioner privacy and prevents their personal information (i.e., home address) from being publicly available. Further, this policy helps minimize administrative burdens that would emerge should enrollment forms need to be updated. Although CMS proposes to extend this policy through CY 2025, which we appreciate, Vizient suggests that the agency permanently extend this policy.

[2] Interactive telecommunications system as defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication, but the patient is not capable of, or does not consent to, the use of video technology.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Direct Supervision Flexibilities

Since the PHE, CMS has permitted direct supervision to be provided virtually (e.g., via audio-video real-time communications technology). In the Proposed Rule, CMS proposes to extend the virtual supervision option for direct supervision through December 31, 2025. As noted in Vizient's prior comments, allowing virtual direct supervision has helped improve access and practitioners have found that it is a safe and effective alternative to in-person supervision. While Vizient appreciates the agency's proposal to extend this flexibility for an additional calendar year, we recommend that the agency permanently allow virtual direct supervision.

Also, CMS proposes to adopt a definition of direct supervision that allows the presence of the physician (or other practitioner) to be met through virtual presence using audio/video real-time communications technology (excluding audio-only) but only for a certain subset of incident-to services.[3] For all other services required to be furnished under the direct supervision of the supervising physician or other practitioner, such as diagnostic x-ray tests, CMS proposes to continue current policy through December 31, 2025, where direct supervision includes virtual presence through real-time audio and visual interactive telecommunications technology (excluding audio-only). Vizient supports the agency's proposals to extend the direct supervision flexibilities, including as related to virtual supervision, as it will help support patient access to care. We encourage CMS to continue to monitor this policy to determine whether the broadened definition of direct supervision would be appropriate for other services in the future.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

CMS proposes to continue the current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished involving residents in all teaching settings, but only when the service is furnished virtually (e.g., a 3-way telehealth visit, with the patient, resident, and teaching physician in separate locations). CMS clarifies that this would permit teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location through December 31, 2025. While Vizient supports the proposed extension and agrees that virtual direct supervision is likely not appropriate for certain services (e.g., high risk and complex procedures), we suggest the agency consider working with providers to broaden the policy to include virtual supervision of certain in-person services.

[3] The proposed subset of services are: (1) services furnished incident to a physician or other practitioner's service when provided by auxiliary personnel employed by the billing practitioner and working under their direct supervision, and for which the underlying HCPCS code has been assigned a PC/TC indicator of '5'; and (2) services described by CPT code 99211 (Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional).

Evaluation and Management (E/M) Visits

Office/Outpatient (O/O) Evaluation and Management (E/M) Visit Complexity Add-on

In the CY 2024 PFS final rule, CMS finalized separate payment for the O/O E/M visit complexity add-on code (HCPCS code G2211[4]). CMS made clear that the O/O E/M visit complexity add-on code is not payable when the O/O E/M visit is reported with CPT Modifier -25, which denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service. In the Proposed Rule, CMS acknowledges previous stakeholders' concerns that denying payment of the add-on code when the O/O E/M base code is reporting on the same day as a Medicare preventive service is disruptive to the way care is usually furnished. In response, CMS proposes to the allow payment of the O/O E/M visit complexity add-on code when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient setting. Vizient supports this proposal, as we believe it will better align with current delivery practices and support access to preventive services.

Enhanced Care Management

In the Proposed Rule, CMS outlines its proposal to recognize the "advanced primary care" delivery model[5] and related resources involving in furnishing services using an "advanced primary care" approach[6] to care under the PFS. Notably, building from elements of Innovation Center models related to primary care, CMS proposes to adopt coding and payment policies to recognize advanced primary care management (APCM) services (i.e., HCPCS codes GPCM1, GPCM2 and GPCM3). CMS notes these codes are for use by practitioners who are providing services under this specific model of advanced primary care, when the practitioner is the continuing focal point for all needed health care services and responsible for all primary care services. In addition, the APCM codes aim to pay for certain care management and communications technology-based services. Vizient appreciates the agency's efforts to better address advanced primary care but offers additional recommendations for the agency's consideration.

To determine the payment rate, CMS proposes to crosswalk HCPCS codes GPCM1 and GPCM2 to existing CPT® codes (e.g., GPCM1 is crosswalked with CPT® 99490, which is for chronic care management service) and for GPCM3, CMS proposes to provide an increase from GPCM2. While Vizient appreciates the challenge in determining appropriate reimbursement for such services, we are concerned that the valuation approach CMS has taken does not adequately reflect the demanding list of practice-level capabilities (e.g., 24/7 access to care, population-level management, performance management), upfront investments and resources utilized should these APCM services be provided, as proposed. Vizient suggests CMS ease various practice-level requirements to better ensure such

[4] The full descriptor for the O/O E/M visit complexity add-on code, HCPCS code G2211, is (Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).

[5] CMS proposes to define "advanced primary care" as propose to define using the 2021 National Academies of Sciences, Engineering, and Medicine (NASEM) report on Implementing High-Quality Care as: "whole-person, integrated, accessible, and equitable health care by interprofessional teams that are accountable for addressing the majority of an individual's health and wellness needs across settings and through sustained relationships with patients, families, and communities.

[6] Under this approach, the delivery of care is supported by a team-based care structure and involves a restructuring of the primary care team, which includes the billing practitioner and the auxiliary personnel under their general supervision, within practices.

codes can be more readily used by a range of providers. Further, Vizient suggests CMS more carefully consider its approach to valuing the APCM codes, as the payment rate may be inadequate, which would likely limit provision of APCM services.

Request for Information: Advanced Primary Care Hybrid Payment

In the Proposed Rule, CMS also seeks comments regarding care delivery and incentive structure alignment and five foundational components. "Health equity, clinical and social risk" are one of the five foundational components and CMS seeks to learn how advanced primary care and billing policy could be used to reduce health disparities and social risk. Specifically, CMS seeks feedback on what non-claims-based indicators could be used to improve payment accuracy and reduce health disparities. Vizient encourages CMS to consider utilizing the patent pending Vizient Vulnerability Index™ which identifies social needs and obstacles to care in neighborhoods that may influence a person's overall health. The Vizient Vulnerability Index is publicly available, utilizes publicly available data sources, includes nine domains of vulnerability, and, unlike other indices, flexes to ensure the index values are location appropriate. While Vizient believes accurate data collection and screening are critical to patient care, there is much work that needs to be done to collect this data, particularly if the agency wishes to ensure the data is consistently collected. Vizient continues to welcome the opportunity to further discuss and partner with CMS on potential opportunities to use the Vizient Vulnerability Index.

Strategies for Improving Global Surgery Payment Accuracy

Current policies related to global surgery require the use of transfer of care modifiers only where there is a formal documented agreement between practitioners to provide specific portions of the global package. In the Proposed Rule, CMS aims to address instances where there are informal, non-documented anticipated transfers of care. Beginning for services furnished in CY 2025, CMS proposes to require the use of the transfer of care modifiers for the 90-day global packages in more circumstances. Specifically, CMS proposes to require the use of the appropriate transfer of care modifier (i.e., modifier -54[7], -55[8], or -56[9]) for all 90-day global surgical packages in any case when a practitioner plans to furnish only a portion of a global package (including but not limited to when there is a formal, documented transfer of care as under current policy, or an informal, non-documented but expected, transfer of care).[10] While Vizient appreciates the agency efforts to improve global payment accuracy, we are concerned that the proposal may be premature, particularly as the agency seeks to learn more about how practitioners in separate group practices furnish different portions of care included in global packages. Vizient believes stakeholder input could significantly help inform the agency's proposal and potential future changes related to global surgery payment accuracy.

Should the agency finalize the policy as proposed, we recommend that additional education and outreach to providers is performed to ensure their understanding of the policy and related changes. In

[7] Modifier -54 Surgical Care Only: this modifier is appended to the relevant global package code to indicate that the proceduralist performed only the surgical procedure portion of the global package.
[8] Modifier -55 Post-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the post-operative management portion of the global package.
[9] Modifier -56 Pre-operative Management Only: this modifier is appended to the relevant global package code to indicate that the practitioner performed only the pre-operative portion of the global package.
[10] CMS notes that practitioners billing for a global package procedure code with modifier -54 and other practitioners in the same group practice as that practitioner would still be able to bill during the global period for any separately identifiable E/M services they furnish to the patient that are unrelated to the global package procedure. To do so, the practitioner would append modifier -24 to the claim line for the E/M service.

addition, we suggest the agency work with providers after implementation to gain more immediate feedback regarding potential challenges or needed clarifications and to monitor for any unintended consequences.

Advancing Access to Behavioral Health Services

Vizient appreciates the agency's efforts to continue to advance policies to increase access to behavioral health services, including the proposed add-on code for safety planning intervention (SPI) services, a code for post-discharge telephonic follow-up contacts and the three new G-codes related to digital mental health treatment (DMHT) devices (GMBT1, GMBT2, GMBT3). Should the agency finalize these codes, we encourage it to closely monitor utilization and provider experiences to ensure payment adequacy. For example, SPI services could be more time-intensive when more complex patient circumstances exist.

In addition, regarding reimbursement for services related to DMHT devices, CMS proposes to require that the patient complete treatment for payment to be provided. Vizient suggests CMS ease this policy as it may discourage providers from initiating treatment with DMHT devices as they risk being under-reimbursed. Also, CMS proposes to include only DMHT devices that are cleared by the Food and Drug Administration (FDA) which may limit use of other types of devices, such as those subject to enforcement discretion, among other potential pathways. Vizient suggests CMS consider whether it would be appropriate to broaden the scope of DMHT devices and to work more closely with the FDA regarding different ways to structure this proposal.

Medicare Part B Payment for Preventive Services

Hepatitis B Vaccine

In the Proposed Rule, CMS proposes to expand coverage of the hepatitis B vaccination series for an expanded range of Medicare enrollees. Specifically, those who have not completed a hepatitis B vaccine series and those with an unknown vaccination history would be at intermediate risk of contracting hepatitis B and eligible to access the vaccine. Vizient supports this policy, as vaccines play a critical role in public health and preventing disease.

Payment for Drugs Covered as Additional Preventive Service

In the Proposed Rule, CMS notes that it has not yet covered or paid for any drugs or biologicals (hereinafter, referred to as drugs) under the benefit category of additional preventive services. Notably, in July 2023, CMS released a Proposed NCD for Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Infection Prevention. As a result and in anticipation of a finalized NCD, CMS proposes a fee schedule for Drugs Covered as Additional Preventive Services ("DCAPS drugs") that uses existing Part B drug pricing mechanisms.[11] CMS proposes that the payment limit for a DCAPS drug be determined using ASP methodology, or if ASP data is not

[11] In addition, specific to PrEP for HIV, CMS propose national rates for HCPCS code G0012 (Injection of pre-exposure prophylaxis (PrEP) drug for HIV prevention, under skin or into muscle) that are crosswalked from CPT code 96372 (Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular).

available for a particular drug[12], to use an alternative pricing mechanism which may eventually rely the on the Federal Supply Schedule (FSS) should other metrics not be available. Vizient notes that should CMS rely on the FSS to determine pricing, the agency may need to work more closely with providers to ensure that reimbursement is adequate since providers may not have access to the FSS pricing.

Payment Limit Calculation When Manufacturers Report Negative or Zero Average Sales Price (ASP) Data

In the Proposed Rule, CMS provides additional guidance regarding how the agency will handle payment for drugs separately payable under Part B when the reported manufacturer's ASP for at least one national drug code (NDC) within the billing and payment codes of the drug is negative or zero. CMS proposes to consider ASP data to be "not available" for the purposes of calculating a payment limit in circumstances in which negative or zero manufacturer's ASP data is reported.

In addition, CMS proposes different methodologies to set payment limits based on the type of product and data available. For biosimilars, if the ASP for all NDCs is negative or zero, CMS proposes to determine reimbursement for the biosimilar on the ASP data of other biosimilars, with the same reference product. Reimbursement would be based on the volume weighted ASPs of the other biosimilars with the same reference product. It is unclear to Vizient why the agency proposes to potentially base biosimilar reimbursement on other biosimilars with the same reference product when such biosimilars have their own codes, particularly since the agency could propose policy that is similar to the policy proposed for single source drugs. Given the ongoing need to support competition and bolster biosimilar use as a means of reducing expenditures, Vizient is concerned the proposed policy could have unintended consequences on the biosimilar landscape more broadly. Vizient encourages CMS to better clarify the impacts of the proposed policies before finalizing such proposals.

Medicare Prescription Drug Inflation Rebate Program

The Inflation Reduction Act (IRA) established new requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. For Part B drugs, CMS considers the rate of inflation for a calendar quarter, starting with the first quarter of 2023. For Part D drugs, CMS considers the rate of inflation over a 12-month period beginning with October 1, 2022. Given differences related to the inputs used to calculate the rebate amounts for Part B and Part D, CMS proposes to use different methodologies to calculate inflation rebates for Part B rebatable drugs and Part D rebatable drugs. Vizient appreciates that the agency recognizes differences between Part B and Part D processes that warrant a separate policy to be implemented.

[12] As noted in the Proposed Rule, manufacturers of DCAPS drugs are not required to report ASP data to CMS. If ASP data is not available for a DCAPS drug, CMS proposes to use the most recently published amount in the Medicaid's National Average Drug Acquisition Cost (NADAC) survey. When using NADAC data, CMS proposes to determine the payment limit per billing unit, which would be an average of NADAC pricing for all NDCs for the drug. If a drug is available in generic and brand formulations, CMS proposes all NDCs will be averaged together to determine the payment limit. If NADAC information is not available, CMS proposes to rely on the Federal Supply Schedule (FSS), are further detailed in the Proposed Rule (pg. 942) and if FSS pricing is not available, CMS proposes that MACs would determine the payment limit for the drug according to the invoice.

Reducing the Rebate Amount for Part B and Part D Rebatable Drugs in Shortage and When there is a Severe Supply Chain Disruption

In the Proposed Rule, CMS further details the process by which CMS will reduce or waive the rebate amount owed by a manufacturer for rebatable drugs in shortage and when there is a severe supply chain disruption. Regarding a severe supply chain disruption for biosimilars, CMS proposes to require the biosimilar manufacturer to submit to CMS a written rebate reduction request but indicates that it would keep confidential certain information provided by the manufacturer (e.g., trade secret or confidential commercial or financial information if certain requirements under the Freedom of Information Act are met). However, it is unclear what information CMS will share and when stakeholders could learn more about a given potential severe supply chain disruption. Vizient has long supported greater transparency regarding drug shortages and encourages CMS to provide greater detail regarding requests when there is a severe supply chain disruption.

Medicare Part D Drug Rebates for Drugs, Biologicals, and Sole Source Generic Drugs with Prices that Increase Faster than the Rate of Inflation

In the Proposed Rule, CMS proposes numerous policies that are provided in the revised Medicare Part D Drug Inflation Rebate Guidance. In addition, CMS proposes new definitions and policies not addressed in the revised Medicare Part D Drug Inflation Rebate Guidance to implement the Medicare Part D Drug Rebate Program, such as proposals related to exclusions from the total number of units dispensed under Part D. Regarding exclusion of 340B acquired units, CMS proposes an estimation methodology which would not, under Part D, require the use of a 340B modifier on pharmacy claims to identify when a 340B drug was dispensed to a Part D beneficiary. Vizient supports an approach such as this proposal because it would minimize burden on providers and is more operationally feasible, since 340B-eligble prescriptions are not identified at the point of sale under Part D at this time.

In the Proposed Rule, CMS notes that the proposed estimation policy is temporary and will allow CMS to implement the exclusion of 340B units from Part D inflation rebates by January 2026. Vizient recommends that CMS work closely with the provider community on alternative policy, particularly should the agency further consider a Medicare Part D claims data repository.

In the Proposed Rule, CMS seeks comments on requiring covered entities to submit 340B claims data to the repository and notes that it could require or encourage 340B third-party administrators (340B TPAs) to submit certain data elements to the repository on behalf of the covered entity. Vizient is concerned that the agency is considering mechanisms to compel a 340B TPA to submit data on behalf of the covered entity as the covered entity would have limited control under this scenario, including the opportunity to review data for accuracy. While Vizient appreciates that 340B TPAs can help reduce administrative burdens on covered entities, we believe it is critical that covered entities ultimately have control regarding how their data is shared.

Although CMS notes that it could require an attestation from covered entities that the data element from all claims submitted to the repository are verified 340B claims in compliance with the 340B statute and HRSA OPA Guidance, Vizient encourages the agency to provide additional information regarding such a process. While Vizient agrees that the responsibility to identify 340B claims should rest solely with the covered entity, it is unclear from the Proposed Rule how often CMS would require such attestations and whether there would be any corrections process should an error be identified. Vizient also suggests CMS further clarify that manufacturers could not influence the process to identify 340B claims for purposes of this policy, including by requesting additional information from the covered entity.

Medicare Shared Savings Program

Financial Methodology

In the Proposed Rule, CMS proposes modifications to the financial methodologies under the Medicare Shared Savings Program (SSP). Specifically, CMS proposes creating a health equity benchmark adjustment (HEBA), to provide an upward adjustment to an ACO's historical benchmark based on the proportion of beneficiaries they serve who are dually eligible or enrolled in the Medicare Part D low-income subsidy (LIS). CMS proposes the HEBA be applicable to ACOs in agreement periods beginning on January 1, 2025 and in subsequent years. To identify beneficiaries from underserved communities for purposes of the HEBA, CMS would identify those who are enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid and only ACOs with a proportion of assigned beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid of 20% or greater would be eligible for the HEBA. Vizient is concerned that the proposed approach targets a very narrow population and may not adequately reflect the scope of underserved patients served.

Although Vizient believes more beneficiaries should be identified for purposes of the policy, we applaud CMS for not relying on the use of the Area Deprivation Index (ADI) to identify beneficiaries. However, in the Proposed Rule, CMS seeks comments on potential use of the ADI, so we reiterate our prior concerns with the ADI. Although the ADI includes seventeen different factors related to education, income, employment, housing, and household characteristics, the relationships among the specific variables chosen result in an index that is heavily weighted toward income and home values with very little contribution from the other variables. The estimates provided by this algorithm can underestimate the vulnerability of neighborhoods where housing prices do not reflect broader trends and other specific obstacles to health and healthcare. In particular, much of the rural South and rural Midwest are estimated as less vulnerable than their life expectancy would suggest, while the Northeast and parts of the Midwest are estimated as more vulnerable.

Additionally, as shown in Figures 2-5, cities with extreme housing costs are broadly estimated to be of very low vulnerability regardless of actual variability in specific neighborhoods. Among these are neighborhoods with some of the lowest life expectancies and highest burden of chronic disease in the nation.

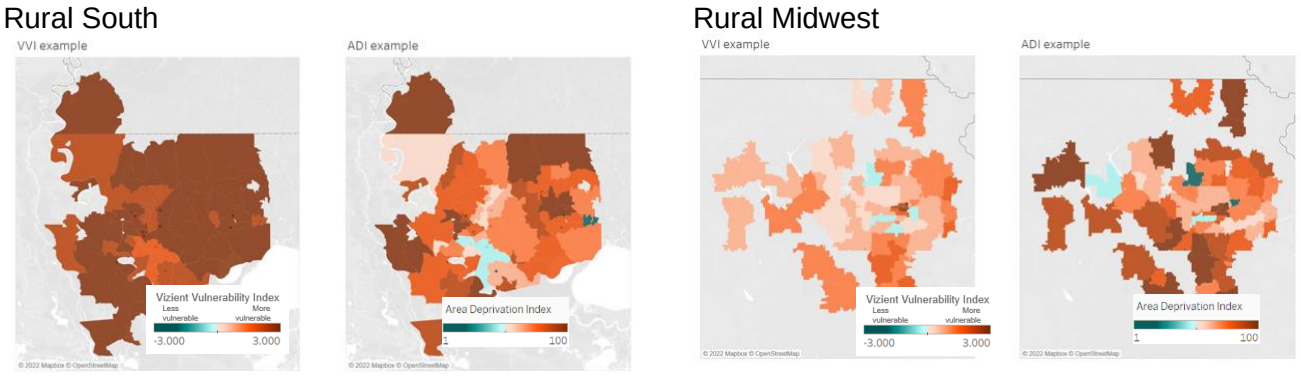

Figure 2. Maps comparing the Vizient Vulnerability Index's insights with the Area Deprivation Index's insights.

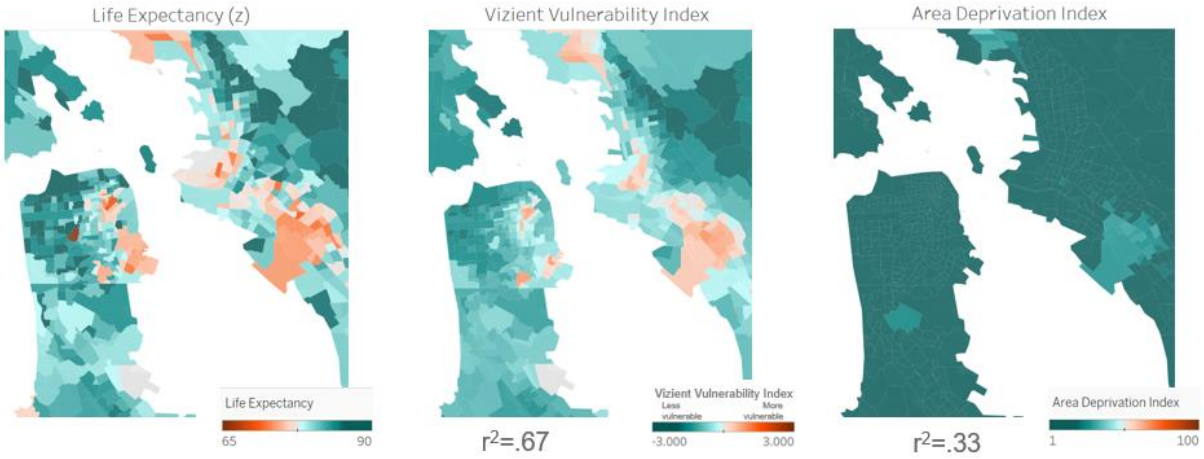

Figure 3. Maps showing San Francisco's life expectancy and insights from the Vizient Vulnerability Index and ADI.

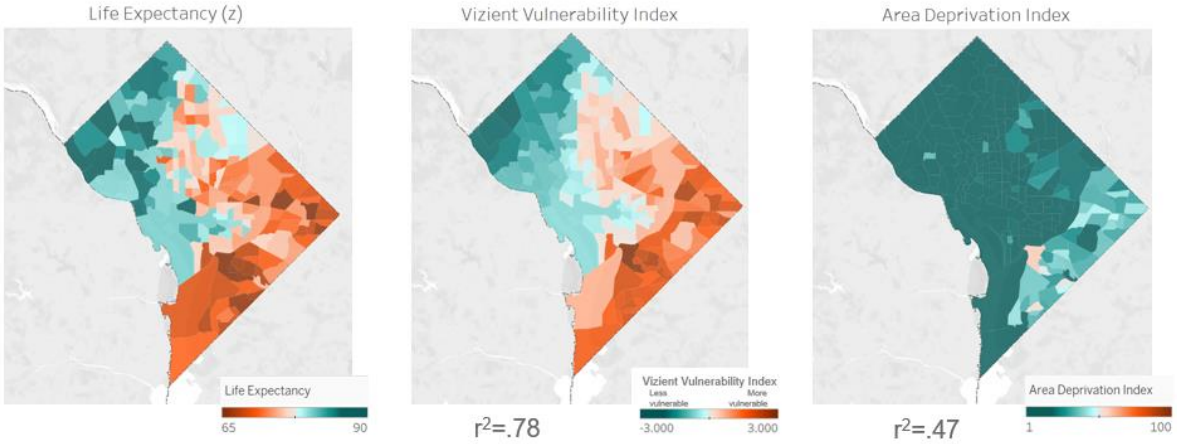

Figure 4. Maps showing Washington, D.C.'s life expectancy and insights from the Vizient Vulnerability Index and ADI.

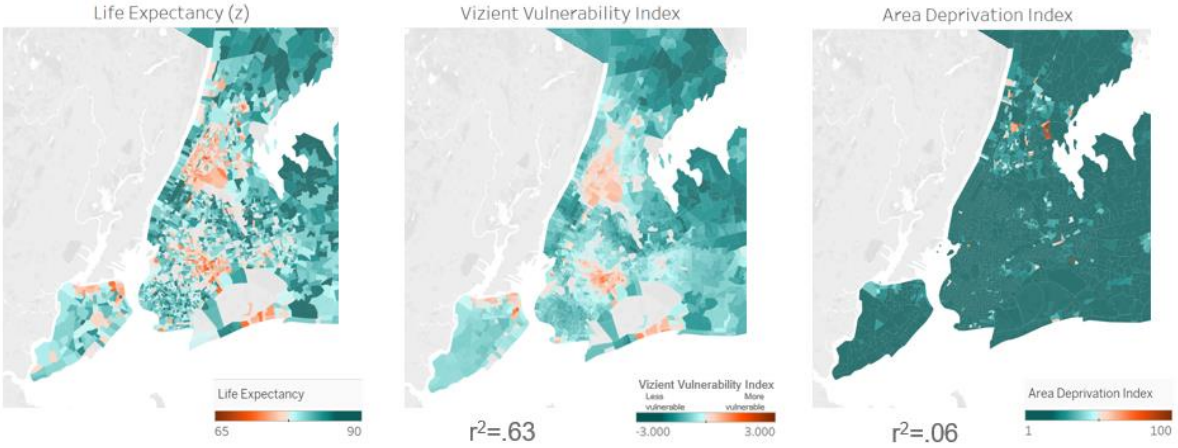

Figure 5. Maps showing New York City's life expectancy and insights from the Vizient Vulnerability Index and ADI.

Recent research reinforces these concerns about the ADI. Vizient urges CMS to reconsider its use in this and all other CMS programs. In place of the ADI, Vizient encourages the agency to consider utilizing the Vizient Vulnerability Index, which correlates much more closely with life expectancy and also flexes geographically, among other benefits, when compared to the ADI and other indices.

Prepaid Shared Savings

Building upon the agency's advanced investment payment (AIP) policy, CMS proposes policy to allow certain ACOs with a history of earning shared savings to receive shared savings as a prepayment with conditions regarding how such funds could be used. In Vizient's prior comments regarding AIPs, Vizient encouraged CMS to expand the eligibility pool for AIPs, among other recommendations. While not specific to AIPs, Vizient supports the agency's proposal to provide prepaid shared savings, as it will help support earlier investments in care similar to AIPs.

Quality Payment Program

Transforming the Quality Payment Program

In the Proposed Rule, CMS includes additional insights regarding the agency's plans to sunset traditional MIPS for the 2029 performance period and require MIPS Value Pathways (MVP) reporting. In addition, CMS poses numerous questions to stakeholders related to their experiences with MVPs, as the agency aims to achieve full MVP adoption and subgroup participation as it moves towards sunsetting traditional MIPS. Consistent with our prior comments regarding the potential sunsetting of traditional MIPS, Vizient emphasizes to CMS that much remains to be seen regarding the transition to voluntary MVP reporting and also the mandatory changes in 2026 for multi-specialty groups to form subgroups. As such, we are concerned that it is premature for the agency to plan on requiring MVP reporting for the 2029 performance period. However, Vizient greatly appreciates the agency's efforts to gain insights from current MVPs to better understand their perspectives regarding the transition to MVPs. We encourage the agency to also do outreach to those continuing to participate in traditional MIPS to determine why MVP reporting was not selected. Also, we suggest that the agency consider sharing information regarding clinician readiness and experiences to better inform potential MVP participants about the transition to MVP reporting.

In the Proposed Rule, CMS notes that with the proposed addition of six MVPs that approximately 80% of specialties participating in the program could submit applicable MVPs. While the number of MVPs and array of MVPs continues to grow, Vizient cautions CMS from assuming that the opportunity to submit applicable MVPs will mean that additional challenges would not be encountered, particularly once reporting occurs or as new MVPs are established. Further, we note that challenges in reporting MVPs may vary by geography and practice size, among other reasons. Vizient strongly encourages the agency to ensure establishment of a broad array of MVPs to ensure robust provider participation, including providers serving a range of patient populations and geographic locations. Also, well before sunsetting traditional MIPS, CMS should ensure that different types of providers, including those serving different geographies and operating in different practice structures, are comfortable reporting such MVPs.

In addition, we appreciate the agency's efforts to examine approaches to developing MVPs to ensuring that all MIPS eligible clinicians have MVPs to report. In the Proposed Rule, CMS notes that existing gaps in quality and cost measures limit the ability to make MVPs available to all MIPS eligible clinicians. While, in the Proposed Rule, CMS seeks comments on different potential approaches, Vizient recommends that traditional MIPS reporting be available, as it could be harmful for the agency to force a more immediate solution with pitfalls to achieve the goal of broader MVP coverage. Further, without more meaningful MVPs, the agency's broader goals related to quality improvement, more meaningful measures and burden reduction will be limited.

Also, CMS seeks feedback regarding potential limits for subgroups reporting MVPs (e.g., limits on size, composition based on Medicare claims data). As CMS is likely aware, large multi-specialty

practices are commonplace, yet they are often structured and function differently, particularly given different staffing structures and team-based care. As a result, limiting subgroups reporting for MVPs may have unintended consequences of disrupting operations for such practices. Vizient recommends that the agency ensure that subgroup reporting of MVPs not be disruptive to care delivery. Further, as subgroup reporting becomes more commonplace in future years and before the sunset of traditional MIPS, we believe that the agency can better understand these dynamics in the coming years. Also, we note our concerns that future limitations on subgroups could also be disruptive to subgroups that have formed before such limitations are in place.

Traditional MIPS: Data Completeness Threshold

In the Proposed Rule, despite plans to increase the data completeness threshold in the future, CMS proposes to maintain the data threshold at 75%. Vizient strongly supports the agency's proposal to maintain the threshold, as this will prevent disruptions that could occur should a higher threshold be required and provide stability. Given this information, we encourage the agency to consider maintaining the threshold for future years.

Conclusion

Vizient welcomes CMS's efforts to update the PFS and other payment policies impacting providers. We appreciate the agency's various requests for comments, which provide an opportunity for stakeholders to inform the agency on the impact of specific proposals.

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 comment on this important Proposed Rule. 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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