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Submitted electronically via: www.regulations.gov

The Honorable Mehmet Oz
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 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) calendar year (CY) 2026 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, including 97% of the nation's academic medical centers, and more than 35% of the non-acute market. The Vizient contract portfolio represents $140 billion in annual purchasing volume enabling the delivery of cost-effective, high-value care. With its acquisition of Kaufman Hall in 2024, Vizient expanded its advisory services to help providers achieve financial, strategic, clinical and operational excellence. Headquartered in Irving, Texas, Vizient has offices throughout the United States. Learn more at www.vizientinc.com.

Recommendations

In our comments, we respond to various policies 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.

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

Calculation of the Proposed CY 2026 PFS Conversion Factor

In the Proposed Rule, CMS estimates two conversion factors (CFs) for CY 2026, one for items and services furnished by a qualifying Advanced Alternative Payment Model participant (qualifying APM CF) and another for other items and services furnished by a non-qualifying APM participant (referred to as the non-qualifying APM conversion factor). The proposed qualifying APM CF is 33.5875 and the proposed non-qualifying APM conversion factor is 33.4209. While each of these CFs is slightly higher than the CY 2025 CF (33.3465), this is largely due to a one-year 2.5% payment adjustment provided

by Congress.[1] As such, Vizient believes that a longer-term solution to ongoing reimbursement challenges faced by providers is needed.

Practice Expense Relative Value Units (RVUs) Between Facility and Non-facility Settings

CMS proposes changing how it allocates the indirect practice expense (PE) when setting PE RVUs by proposing to provide different indirect PEs for certain services depending on whether those services are provided in a facility or non-facility setting. As proposed, for each service valued in the facility setting under the PFS, the portion of the facility PE Relative Value Units allocated based on work RVUs would be reduced to half the amount allocated to the non-facility PE RVUs beginning in CY 2026. Due to this proposal, reimbursement for facility-based services would be reduced. While CMS justifies this approach by citing physician consolidation and recommendations of the Medicare Payment and Advisory Commission (MedPAC), the agency does not clearly justify the value of the proposed reduction, making the amount appear arbitrary. Since CMS does not provide data to support the reduction to half the amount allocated to the non-facility PE RVUs, and for other reasons noted below, Vizient recommends the agency withdraw the proposed change to how the agency allocates the indirect PE.

Also, in the Proposed Rule, CMS does not clearly articulate the anticipated implications of the proposed reduction to the facility PE RVUs and therefore, Vizient is concerned the agency has not carefully considered the implications for patient access to care. Such a significant change in the methodology would be highly disruptive to providers in facility settings and would have more substantial, negative financial implications for certain types of specialists whose services would be directly impacted by the proposed policy (e.g., infectious disease physicians, oncologists). As provider reimbursement is already financially unstable, changes that would further reduce reimbursement for certain specialties add even more financial pressure that could limit providers' ability to continue to provide care.[2,3] As such, to maintain stability and reimbursement accuracy, Vizient recommends that CMS withdraw this flawed policy proposal.

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

In considering data to update the inputs related to the PE, CMS is straying from longstanding policy and is not proposing to utilize the latest data from the American Medical Association (AMA) Physician Practice Information (PPI) Survey (i.e., PE per hour data or cost shares). Consistent with prior feedback to CMS, Vizient believes the AMA's PPI Survey helps improve the accuracy of PE estimates. While we are concerned that the agency has not proposed utilizing the AMA's survey data, we appreciate that the agency indicates it will work with interested parties, including the AMA, to understand whether and how such data should be used in PFS ratesetting.

Valuation of Specific Codes: Proposed Efficiency Adjustment

For CY 2026, CMS proposes an efficiency adjustment of -2.5% that would be applied to all non-time-based services. CMS justifies this policy based on the agency's concerns about the quality of certain survey data and the agency's belief that work RVUs have not adequately accounted for certain

[1] https://www.congress.gov/bill/119th-congress/house-bill/1/text
[2] https://www.ama-assn.org/practice-management/medicare-medicaid/ama-urges-alternative-approaches-two-flawed-cms-proposals
[3] https://www.ama-assn.org/system/files/ama-medicare-reform-grassroots-insert.pdf

efficiencies (e.g., technology, procedural workflows, practitioner experience) for non-time-based services. Historically, CMS has relied on survey data from the AMA/Specialty Society Relative Value Scale (RVS) Update Committee (RUC) to estimate practitioner time, work intensity and PE for the purpose of establishing RVUs for the codes used for payment under the PFS. Vizient questions the agency's conclusion that existing valuation approaches do not account for certain efficiencies for non-time-based services.

To inform the efficiency adjustment, CMS proposes a new methodology, which accumulates Medicare Economic Index (MEI) productivity adjustments[4] from the past five years, to account for efficiency gains that would then be reflected in the valuation of work RVUs. As CMS is aware, the MEI productivity adjustments are dependent on data from the Bureau of Labor Statistics (i.e., the average growth of private non-farm business total factor productivity), which does not provide data relevant to specific types of services. Vizient disagrees with the agency's proposed use of the MEI since it does not provide sufficiently detailed data that aligns with the agency's aim to account for specific types of efficiencies for specific types of services. Vizient recommends that CMS withdraw the proposed efficiency adjustment given these methodological concerns.

Also, CMS proposes to apply the efficiency adjustment to the intraservice portion of physician time and work RVUs every three years and seeks input as to whether efficiencies stop accruing for services after a predefined number of years. As noted above, Vizient has concerns regarding the agency's assessment that an efficiency adjustment is needed, so we similarly raise concerns with the proposed policy to apply the efficiency adjustment in future years. As different technologies and services evolve, so does the care that is provided. Vizient cautions CMS from overgeneralizing how technology may impact care and encourages the agency to do further research to better understand the impact of technology on care, including considerations where technology may help streamline certain components of care but add work to others.

Lastly, considering the new efficiency adjustment, certain specialties that bill more often for procedures and diagnostic imaging and radiology services (e.g., radiation oncology, radiology, certain surgical specialties) would be disproportionately impacted. While other specialties may see increases due to the proposed efficiency adjustment, we are concerned that those facing reductions may be inappropriately under-reimbursed for care given the imprecise nature of the proposed adjustment. As such, we recommend that CMS work closely with providers to identify a more targeted approach to identify efficiencies within certain procedures should the agency reconsider this policy in future years. We discourage CMS from making broad efficiency presumptions to inform reimbursement, as done in the Proposed Rule.

Use of Outpatient Prospective Payment System (OPPS) Data for PFS Ratesetting

As noted in the Proposed Rule, CMS has concerns with the quality of recent AMA survey data (i.e., AMA's PPI and Clinician Practice Information Surveys). As a result, CMS proposes to use hospital OPPS data to either set relative or absolute rates, especially for technical services paid under the PFS (i.e., radiation treatment delivery and superficial radiation therapy services, remote patient monitoring and remote therapeutic monitoring services and skin substitutes). Generally, Vizient has

[4] To calculate the efficiency adjustment, CMS proposes using the Medicare Economic Index (MEI) productivity adjustment. The MEI productivity adjustment used for the final MEI update reflects the most recent historical estimate of the 10-year moving average growth of private nonfarm business total factor productivity, as calculated by the Bureau of Labor Statistics.

concerns with the agency's growing interest in using OPPS data to inform PFS rates. As CMS is aware, there are different statutory frameworks for payment under OPPS and PFS which should be followed by the agency, as these are distinct payment systems. In addition, Vizient cautions CMS against presuming certain similarities exist between hospital outpatient departments and physician offices and advancing efforts related to site neutral payment policy, which are disruptive and harmful to providers.

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

Vizient appreciates the measures the agency took during the COVID-19 Public Health Emergency (PHE) to expand access to telehealth services, and we are concerned that telehealth flexibilities, both statutory and regulatory, may expire. These care delivery changes have 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, highlighted effective strategies for sustaining and optimizing 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 September 2025 (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 patient 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 fiscal year.

Despite these telehealth flexibilities potentially expiring, in the Proposed Rule, CMS offers various policies that would 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.

Proposal to Modify the Medicare Telehealth Services List and Review Process

CMS maintains a Medicare telehealth services list, where services are assigned either a "permanent" or "provisional" status after a 5-step review process. For CY 2026, CMS proposes to eliminate two steps of the review process related to service element mapping and evidence of clinical benefit that is analogous to the clinical benefit of the in-person service. Vizient agrees with the need to reduce barriers to services being included on the telehealth list and believes the proposed changes are aligned with that goal.

In addition, CMS proposes to remove the "permanent" and "provisional" designations so that all services on the Medicare Telehealth Services List would be included on a permanent basis. The current distinction of "permanent" and "provisional" telehealth services can be a source of confusion and adds burden. Vizient supports the proposal for all services on the Medicare Telehealth List to be included on a permanent basis.

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, CMS suspended these limitations for certain codes[5] through CY 2024. In CY 2025, CMS removed the frequency limitations for these codes but did not address subsequent years, though Vizient was supportive of the agency making the policy permanent. For CY 2026, CMS proposes to permanently remove frequency limitations on the following services furnished via telehealth: Subsequent Inpatient Visits (CPT 99231-99233), Subsequent Nursing Facility Visits (CPT 99307-99310) and Critical Care Consultation Services (G0508-G0209). Vizient supports the agency's proposal to permanently remove frequency limitations, as this will help improve access to care.

Distant Site Practitioner's Currently Enrolled Practice Location

In the Proposed Rule, CMS does not address practitioner location in the context of enrollment. In the CY 2025 PFS Final Rule, CMS finalized 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 during CY 2025 only. As a result, Vizient is concerned about the implications of requiring distant site practitioners to use their home location for enrollment purposes, as their personal information (i.e., home address) would be more widely available. Broader access to a provider's home address poses privacy and security risks which CMS can prevent. In addition, there would be substantial administrative burden on providers to update this information with CMS. To avoid such risks and burden, Vizient recommends CMS make permanent the agency's current policy of allowing practitioners to use their currently enrolled practice location when providing telehealth from their home.

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

Direct Supervision Flexibilities

In the Proposed Rule, CMS proposes to permanently adopt a definition of direct supervision that allows ''immediate availability'' of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for all incident-to services, diagnostic tests and certain cardiac services, except for services that have a global surgery indicator of 010 or 090. Since the PHE, CMS has permitted direct supervision to be provided virtually (e.g., via audio-video real-time communications technology), which has helped increase patient access to care, as noted in Vizient's prior comments. In addition, practitioners have found that virtual direct supervision is a safe and effective alternative to in-person supervision. Vizient supports the agency's proposed permanent definition of direct supervision.

Teaching Physician Billing for Services Involving Residents with Virtual Presence

For CY 2026, CMS is not proposing policy to extend flexibility that allows the teaching physician to have a virtual presence during the key portion of the Medicare telehealth service for which payment is sought in any residency training location. Instead, for CY 2026, CMS proposes that for services provided within

[5] The codes include: Subsequent Inpatient Visit CPT Codes 99231-99233, Subsequent Nursing Facility Visit CPT Codes 99307-99310, Critical Care Consultation Services HCPCS Codes G0508-G0509.

Office of Management and Budget (OMB)-defined metropolitan statistical areas (MSAs), physicians must maintain physical presence during critical portions of all resident-furnished services to qualify for Medicare payment, not just in-person services. CMS proposes this policy only for those within MSAs to provide greater flexibility for rural healthcare providers. Vizient is concerned that the proposal will adversely affect providers, both residents and teaching physicians, along with patients, as it will be more challenging to provide supervision. For example, when a patient is at home, multiple providers, including different specialty types, can join the patient remotely and may utilize different devices to connect with the patient. If finalized, virtual supervision within MSAs would be stopped without justification despite the agency recognizing the benefit of virtual supervision to increase access to care by allowing this flexibility to continue in rural areas. Vizient urges CMS to refrain from finalizing this proposal. Instead, Vizient recommends CMS permanently permit teaching physicians to bill for services involving residents with virtual present in all locations where residency training occurs.

Remote Physiological Monitoring (RPM)

In the Proposed Rule, CMS proposes policy in response to the American Medical Association's Current Procedural Terminology (CPT) editorial panel's new and revised CPT code set for RPM, as provided in September 2024. Vizient appreciates the agency's efforts to update policy related to RPM and support providing additional flexibility for providers furnishing RPM services.

Among other proposals, for CY 2026, CMS proposes that a new device code (99XX4) would be available to cover RPM for 2-15 days in a 30-day period and code 99XX5 would also be available for the first 10 minutes of a real-time interactive communication with the patient/caregiver during the calendar month. As CMS is aware, current RPM reimbursement requires 16 out of 30 days of data transmission. As a result of the proposed change, providers would be able to provide RPM services to more patients for more clinical scenarios. As such, Vizient supports the agency's proposal to make the new device code (99XX4) available.

Regarding reimbursement for 99XX4, CMS acknowledges that as RPM device applications evolve, issues involving the use of software and other forms of digital tools become more difficult to account for in the agency's standard PE methodology. Due in part to this challenge, CMS proposes to use OPPS cost data to establish the valuation for the PE portion of 99XX4, since the agency believes OPPS cost data is more accurate than the PE inputs recommended by the RUC. While Vizient appreciates the agency's interest in providing accurate reimbursement, we have concerns with the agency's proposal to use OPPS data to set PFS rates. As CMS is aware, PFS and OPPS are governed by different parts of the law and CMS should not use data between settings interchangeably. In addition, CMS should not presume that vendor agreements that hospitals obtain are also available to physician offices and vice versa. Vizient encourages CMS to more carefully consider the approach to valuing RPM services, including 99XX4, to ensure reimbursement under the PFS is adequate.

Remote Therapeutic Monitoring (RTM)

Similar to the changes CMS proposes for RPM, CMS provides a similar policy for RTM. Specifically, CMS proposes adding new codes for certain RTM services for 2-15 days of data transmission and including a code for 11-20 minutes of services. Collectively, these changes will allow providers to offer a broader array of RTM services, including less frequent services. However, to value these codes, CMS proposes RVUs that are less than the RUC's recommendation and does not provide strong justification to stray from these recommendations. Also, consistent with Vizient's recommendations for RPM, we suggest that CMS not rely on OPPS data for ratesetting purposes in the PFS and work with providers to refine valuation of RTM codes.

Evaluation and Management (E/M) Visits

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

Although CMS does not address prior overestimates of the utilization of G2211 in the Proposed Rule, which impacts budget neutrality adjustments, Vizient urges CMS to correct this issue. Due to the 2024 utilization overestimate, providers continue to suffer, with the AMA finding that providers will be under-reimbursed by $1 billion annually.[6] To help address this under-reimbursement issue, for CY 2026, Vizient recommends that CMS make a prospective budget neutrality adjustment to the proposed CFs.

For CY 2026, CMS proposes to broaden use of the O/O E/M visit complexity add-on code (HCPCS code G2211) by extending use to the home or residence E/M visits code family (CPT codes 99341, 99342, 99344, 99345, and 99347- 99350). In the CY 2024 PFS Final Rule, CMS finalized separate payment for the G2211 code but provided limitations on its use. Based on data from the Clinical Practice Solutions Center (CPSC)[7], as noted in Figure 1, utilization of G2211 is less than CMS projected in CY 2024 rulemaking. Specifically, in the CY 2024 PFS Final Rule, CMS projected G2211 would be billed with 38% of all E&M services initially (i.e., 2024) with full usage at approximately 54%.[8] Based on Figure 1, utilization of G2211 appears to be significantly lower than CMS projected. Vizient appreciates that CMS proposes changes that would allow the code to be billed more frequently and supports finalizing this policy. However, should CMS reconsider budget neutrality changes due to G2211 as recommended above, Vizient cautions CMS from continuing to overestimate utilization of the code based on this CY 2026 proposal.

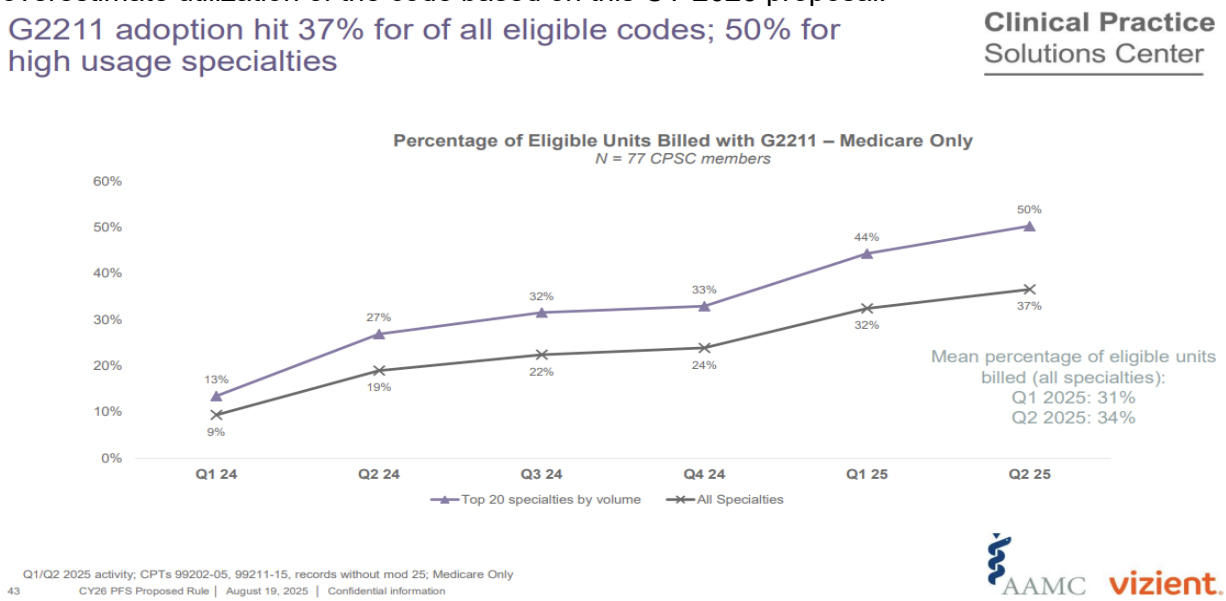

Figure 1. Graph showing the percentage of eligible units billed with G2211 (Medicare only) among Clinical Practice Solutions Center members which includes faculty practice organizations.

[6] https://www.ama-assn.org/practice-management/medicare-medicaid/overestimate-tripled-budget-neutrality-medicare-physician-pay
[7] The Clinical Practice Solutions Center (CPSC), developed by the Association of American Medical Colleges (AAMC) and Vizient, is the result of a partnership that works with member practice plans to collect data on provider practice patterns and performance.
[8] https://www.federalregister.gov/documents/2023/11/16/2023-24184/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other

Enhanced Care Management

For CY 2026, CMS proposes to create optional add-on codes (GPCM1-GPCM3) for advanced primary care management (APCM) services that would facilitate providing complementary Behavioral Health Integration (BHI) services by removing the time-based requirements of the existing BHI and Collaborative Care Model (CoCM) codes. CMS indicates the proposed add-on codes would be considered a "designated care management service" and, as such, could be provided by auxiliary personnel under the general supervision of the billing practitioner. Vizient appreciates the agency's proposed policy, as it is consistent with our prior recommendations to ensure that codes can be more readily used by a range of providers.

Comment Solicitation on Payment Policy for Software as a Service (SaaS)

In the Proposed Rule, CMS seeks input on how SaaS and artificial intelligence (AI) tools' associated costs should be integrated into evolving payment models like Advanced Primary Care and risk-based arrangements under the PFS. CMS notes that there have been rapid developments in the use of software-based technologies to support clinical decision-making in the outpatient and physician office settings, some of which may be devices requiring Food and Drug Administration clearance, approval or authorization. Also, in the Proposed Rule CMS identifies several challenges in evaluating SaaS for clinical use and payment (e.g., wide and unverifiable cost variations among similar products, limited comparability to existing medical services due to their novelty, and a lack of sufficient Medicare claims data to assess utilization and value). Vizient thanks CMS for seeking comments related to payment for SaaS, including what factors CMS should consider when paying for SaaS.

Among other factors, Vizient encourages CMS to consider value, including potential time savings, when paying for SaaS, particularly as some SaaS may not require FDA clearance, approval or authorization. As CMS gathers feedback, we encourage the agency to share information on how a product's value may be considered when establishing reimbursement policies to support utilization and to work with providers to refine how the agency determines a product's value. Considering value in the context of reimbursement initially may also help encourage utilization of SaaS given the various costs associated with SaaS that are not associated with other devices and existing data limitations.

CMS also seeks input on how to enhance the agency's ability to provide consistent and accurate payment for procedures incorporating SaaS. Vizient appreciates the agency's interest in addressing this issue, as factors like start-up costs and uncertain reimbursement may deter providers from furnishing services involving SaaS. Vizient encourages CMS to provide additional provider education regarding how various SaaS and artificial intelligence technologies may already be reflected in different components of payment policy (e.g., separate reimbursement, reflected in the work RVU or intra-service time) before providing proposed policies, as this could potentially reduce reimbursement for certain services (e.g., the Proposed Rule's efficiency adjustment).

Also, Vizient suggests that CMS identify reimbursement opportunities for SaaS and AI technologies that can help improve care but may not be reimbursed under existing frameworks. For example, SaaS and AI tools can improve quality, but are not eligible for reimbursement by CMS. This lack of reimbursement can limit providers' willingness to invest in certain SaaS or AI tools.

Payment for Skin Substitutes

In the Proposed Rule, CMS proposes significant changes for skin substitute supplies to provide a consistent payment approach for skin substitute products across the physician office and hospital outpatient department (HOPD) settings. In addition, CMS proposes to use hospital utilization patterns

to inform payment rates for skin substitutes. As noted in Vizient's OPPS comments regarding site neutral payment policy, there are several differences between HOPDs and physician offices, including how prospective payments for each setting are determined. Vizient encourages CMS to carefully consider whether these differences should prompt alternative methodologies and approaches to reimbursement.

In addition, Vizient notes that a Local Coverage Determination (LCD) is expected to go into effect January 1, 2026.[9] With potentially other, concurrent policy changes, both physicians and hospital outpatient departments may need to provide additional resources to effectively implement changes, such as new coding and billing practices.

Ambulatory Services Model

In the Proposed Rule, CMS proposes a new mandatory Center for Medicare and Medicaid Innovation (CMMI) model, the Ambulatory Specialty Model (ASM). The ASM would begin January 1, 2027, last for five performance years and would be mandatory for specialists who commonly treat Medicare fee-for-service beneficiaries in an outpatient setting across selected regions (i.e., roughly one-quarter of core-based statistical areas and metropolitan divisions). While CMS proposes some exclusion criteria for the ASM (e.g., low-volume providers, certain practice settings, non-physician practitioners), Vizient is concerned with the mandatory nature of ASM, particularly given the large volume of providers and episodes that would be impacted by the model. CMMI models often increase burden on providers, as they need to carefully review the model's design, adapt to meet a model's various requirements and redesign their care strategy to attempt to improve their outcomes in the model. For voluntary models, providers can make an informed participation decision based on their circumstances. Given these concerns, Vizient recommends that CMS refrain from finalizing the ASM or consider making the model voluntary.

Medicare Prescription Drug Inflation Rebate Program

In the Proposed Rule, CMS proposes policy to support the implementation of the Medicare Prescription Drug Inflation Rebate Program. Specifically, CMS proposes approaches to exclude drugs provided through the 340B program from the total number of units used to calculate the total rebate amount for Medicare Part D. Vizient offers recommendations for the agency's consideration regarding both proposed approaches, but emphasizes the importance of ensuring the agency makes clear that the amount of 340B units identified for purposes of this program are not accurate values, and so, such 340B unit data should not be used for other policy purposes.

Estimation Methodology

Under the first approach for CY 2026, CMS proposes removing 340B units from the Part D drug inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered 340B covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE as a 340B contract pharmacy. CMS also acknowledges that this proposed approach may overestimate the number of units that are potentially 340B-eligible and that other approximations associated with the methodology may vary

[9] https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041

significantly across different Part D rebatable drugs. Given these limitations and our concerns about inaccurate data related to the 340B Program being proliferated, Vizient is concerned that the proposed approach poses more concerns than the estimation approach contemplated in the CY 2025 PFS Proposed Rule.[10]

As noted in the Proposed Rule and in the CY 2025 PFS Proposed and Final Rules, CMS previously considered an alternative estimation methodology to remove 340B units from the total number of units dispensed. Under this alternative estimation methodology, CMS would remove units from the total number of units dispensed of a Part D rebatable drug for each applicable period that would be based on a calculated percentage that reflects the portion of 340B purchasing relative to total sales. Under this previously proposed methodology, CMS would determine the estimation percentage using Prime Vendor Program Data and average manufacturer price (AMP) data. With both the proposed and previously proposed methodologies having limitations, Vizient acknowledges that neither would provide completely accurate data, but we recognize the importance of establishing policy to exclude drugs provided through the 340B program to implement the Medicare Prescription Drug Inflation Rebate Program. Therefore, Vizient recommends that CMS reconsider using the previous, alternative estimation methodology since we believe this approach would be more accurate than the proposed methodology, though both have limitations. Further, Vizient suggests CMS work with stakeholders to identify whether additional modifications to the alternative estimation methodology could be made to improve accuracy.

To support selection of the best approach in the short term, Vizient suggests CMS share estimates for each potential approach related to over-inclusions and under-inclusions to better inform decision making. A longer-term option could be for CMS to test different methods with a small subset of covered entities (CEs) to validate a process for long-term use, particularly if the 340B repository, which is noted below, remains optional. Vizient notes that for such testing to occur, the agency may need to provide incentives to CEs to encourage CE participation if the agency were to test different estimation methods.

340B Voluntary Repository

In the Proposed Rule, CMS proposes a second, voluntary approach to identify 340B units. Specifically, CMS proposes to establish a 340B repository, which would launch in Fall 2026, to receive voluntary submissions from 340B covered entities of certain data elements from Part D 340B claims. As noted by CMS, this approach would require that CEs submit certain data elements from Part D 340B claims to the 340B repository on a retrospective basis. However, at least initially, CEs would optionally begin submitting information the 340B repository for Part D 340B claims with dates of service on or after January 1, 2026. Vizient supports the establishment of a 340B repository and agrees that it should be optional and validated.

In addition, CMS indicates that it does not expect concerns about the privacy of data submitted to the repository, as this data would not be made available to external parties, including manufacturers and Part D plan sponsors. Vizient appreciates this clarification and encourages the agency to finalize policy to reinforce the privacy and security protections associated with the data submitted to the repository.

[10] https://www.govinfo.gov/content/pkg/FR-2024-07-31/pdf/2024-14828.pdf

Medicare Shared Savings Program

Calculation of Accountable Care Organization's Population and Income Adjustment Bonus Points

In the Proposed Rule, CMS proposes to remove the phrase "health equity adjustment bonus points" and, in its place, add the phrase "population and income adjustment bonus points", but does not consider other potential changes to the adjustment. Consistent with Vizient's prior comments, we have concerns regarding the use of the Area Deprivation Index (ADI) for purposes of this adjustment and recommend the use of the patent pending Vizient Vulnerability Index™ instead. 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. Vizient welcomes the opportunity to further discuss the Vizient Vulnerability Index and its potential use in the Medicare Shared Savings Program (MSSP) with CMS.

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 regarding 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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Vizient, Inc.