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Submitted electronically via: www.regulations.gov

The Honorable Jeff Wu
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; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (Docket No.: CMS-2024-0345)

Dear Acting Administrator Wu,

Vizient, Inc. appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (hereinafter "Proposed Rule"). Vizient appreciates CMS's efforts to address challenges that patients and providers experience related to Medicare Advantage (MA) plans, such as those related to use of Artificial Intelligence (AI), provider directories, and utilization management (UM). In addition, Vizient offers recommendations regarding several proposals to enhance clarity and prevent disruptions to care.

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

Vizient appreciates CMS's efforts to improve MA beneficiaries' protections and to promote equity in coverage and care. Vizient offers the following recommendations for the agency's consideration as related to AI guardrails, provider directories, medical loss ratio (MLR) standards, health equity, and prior authorization and utilization management in MA plans.

Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence (AI)

To help prevent enrollees from experiencing bias and discrimination, CMS proposes guardrails for use of AI by MA plans. These guardrails include: requiring AI and automated systems to be used in a manner that allows equitable access to MA services; requiring MA plans to disclose their use of AI tools; and requiring that the use of AI must follow existing Medicare regulations that prohibit discrimination and promote equal access to MA services. While Vizient works primarily with providers to support their use of health information technology (HIT), including the utilization of AI, we believe it is imperative that AI, when used by a range of healthcare stakeholders, does not worsen or further entrench disparities.

In the Proposed Rule, CMS proposes to define "automated system" as "any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques, and exclude passive computing infrastructure." Given the countless current and anticipated applications of AI, Vizient has concerns that the proposed definition of "automated system" is too broad and would result in too many systems being included and as a result, subject to CMS regulations. Further, an unnecessarily broad definition of automated system could also affect both the collection and evaluation of meaningful data. Instead of using a broad definition of automated system, Vizient suggests CMS consider using a different definition, such as "equitable algorithm," to develop a more targeted regulation that would still help reduce algorithmic discrimination and bias with the use of AI in MA plans. Should CMS consider a definition of "equitable algorithm" as we suggest, Vizient encourages CMS to work collaboratively with stakeholders to identify appropriate language for this definition.

Also in the Proposed Rule, CMS defines "patient care decision support tool" as "any automated or non-automated tool, mechanism, method, technology, or combination thereof used by an MA organization to support clinical decision-making in its health programs or activities.[1]" Similar to the proposed definition of "automated system", Vizient is also concerned the definition of "patient care decision support tool" is too broad and lacks clarity. For example – are automated tools distinct from automated systems? Does the definition of "patient care decision support tool" relate to the definition of "automated system"? It is also unclear what technologies are included in automated and non-automated tools. To effectively provide feedback to CMS, we encourage the agency to provide a more narrow and clear definition of "patient care decision support tool" to ensure AI challenges are addressed while not causing unnecessary disruption to the use of existing tools that do not rely on AI.

In addition, while not addressed in the Proposed Rule, Vizient has concerns about the limited data and the lack of transparency of instances where the use of AI causes an MA plan to make specific decisions that could affect a patient's medical care. For example, MA plans might depend on the use of AI in making decisions about prior authorization. Creating additional transparency will help to create greater oversight and lead to a reduction of bias and discrimination in the use of AI. Therefore, Vizient requests the agency require public reporting of the use of AI by MA organizations for prior authorization and any additional uses that directly impact care decisions. Furthermore, to help ensure MA plans and providers use tools that do

[1] According to the Proposed Rule, patient care decision support tools can range in form from flowcharts and clinical guidelines to complex computer algorithms, decision support interventions, and models.

not perpetuate bias, Vizient suggests that CMS support the development of tools or measures to validate non-bias in the use of AI. In some circumstances, there are legitimate differences in diagnostic, treatments and communication approaches for different demographics. Vizient believes such tools or measures would be helpful to ensure that the use of AI in healthcare promotes equitable access to care and culturally competent care for all MA enrollees.

Format Medicare Advantage Organizations' Provider Directories for Medicare Plan Finder (MPF)

In the Proposed Rule, CMS proposes to require MA organizations to submit their plan provider directory data to CMS to be integrated online for display on the MPF, to help simplify and streamline the patient experience when shopping for an MA plan. Vizient agrees with this aim to support and increase patient access to accurate provider directory information, so patients can make more informed choices for their care needs.

In addition, to ensure the accuracy of the data being submitted, CMS also proposes to require MA organizations to attest to the accuracy of the provider directory data being submitted. Vizient notes that patients and providers often experience challenges when directory information is not accurate or updated frequently. To better alleviate these issues, Vizient suggests CMS require MA plans to take additional steps that are not burdensome to providers to improve directory accuracy beyond attestation. For example, some third parties that compile directories can verify provider information by reviewing the billing addresses, service addresses and reviewing external sources to confirm information. These types of steps may help ensure the information in the directory is accurate, but plans may decide not to pursue these additional verification options since additional measures are not required. While Vizient supports efforts to improve the accuracy of information included in provider directories, we encourage CMS to provide additional ways for plans to verify directory information that is not burdensome to providers.

Proposed Regulatory Changes to Medicare Advantage (MA) and Part D Medical Loss Ratio (MLR) Standards

Proposal to Prohibit Administrative Costs from Being Included in Quality Improving Activities in the MA and Part D MLR Numerator

The Proposed Rule includes a proposal that only expenditures directly related to activities that improve health care quality may be included as quality improving activity expenses in the MA and Part D MLR numerators. This proposal prohibits administrative costs from being included in quality-improving activities for purposes of MA and Part D reporting. Inclusion of indirect expenses not directly related to activities that improve health care quality can inflate the MLR numerator, leading to inconsistent MLR reporting and undermining the integrity of the MLR programs. Vizient agrees with the agency's proposal to include only those costs attributable to activities that improve health care quality. In addition, we encourage CMS to monitor the implications of the policy on provider-owned plans, which tend to be smaller and operate differently from national plans, to ensure they are not unintentionally harmed because of this policy.

Proposal to Change Medicare MLR Regulations Authorizing Release of Part C and Part D MLR Data

The Proposed Rule updates Medicare MLR regulations that authorize the release of Part C and Part D MLR data by adding an exclusion from data release. Specifically, CMS proposes to

exclude the release of direct and indirect remuneration (DIR) information reported within the MLR data as part of incurred claims.[2] Vizient is concerned that allowing this exclusion will add an additional barrier to transparency even though CMS would still collect this through required reporting because such information would not be released more broadly. As a result, Vizient discourages CMS from adding an exclusion for DIR information in the context of data releases.

Request for Information on MLR and Vertical Integration

The Proposed Rule includes a Request for Information (RFI) on how the MA and Part D MLRs are calculated to help enable policymakers to address concerns surrounding vertical integration in MA and Part D. Vizient providers have continued to try and address challenges with MA, with some opting to create their own MA plans. This is not necessarily an option available to all, given the time, expense, and other administrative burdens it takes to create and implement an MA plan. However, as noted in Vizient's prior comments, providers who do have their own MA plans have reported much greater satisfaction and significantly fewer issues related to patient care delivery. As CMS contemplates additional rulemaking or future guidance based on information received from comments on this RFI, Vizient requests that CMS consider different ownership structures and provider-reported challenges with specific MA plans. For example, hospitals tend to report challenges with larger, national organizations, but the RFI seems broadly focused on vertical integration. Additionally, Vizient highlights the distinction between vertical integration where a provider creates a health plan, and the trend of large national plans integrating vertically by acquiring providers and PBMs. Given this information, it is unclear from the RFI whether CMS is equally concerned about vertical integration for all types of organizations. While Vizient appreciates efforts to address vertical integration, we encourage the agency to ensure that these efforts do not unintentionally disincentivize provider-sponsored health plans.

Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

Annual Health Equity Analysis of Utilization Management Policies and Procedures

In the Proposed Rule, CMS noted that during a public comment period for a past regulation,[3] stakeholders voiced concerns about the requirement that the metrics for the health equity analysis be aggregated for all items and services. Specifically, the concerns were that aggregated prior authorization (PA) data would not provide enough detail for true accountability and could allow plans to hide disparities.[4] As a result, in the Proposed Rule, CMS proposes to require the metrics reported for the health equity analysis to be reported by each item or service, rather than aggregated for all items and services. Consistent with prior comments, Vizient supports this new requirement because the additional granular data gathered will assist

[2] Currently, CMS excludes four categories of information from the release of Part C and Part D MLR data:
1) any narrative information that MA organizations and Part D sponsors submit to support the amounts that they include in their MLR Reports, such as descriptions of the methods used to allocate expenses.
2) any plan-level information that MA organizations and Part D sponsors submit in their MLR Reports.
3) any information that could be used to identify Medicare beneficiaries or other individuals.
4) any MLR review correspondence.

[3] The Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024- Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule, https://www.govinfo.gov/content/pkg/FR-2024-04-23/pdf/2024-07105.pdf

[4] Currently, MA plans are not required to submit data to CMS on PA requests, denials, or appeals by service type, despite indications that certain types of service types (e.g., the most costly procedures) may be denied at higher rates than others: https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf

in increasing transparency and ensure the most accurate data regarding PA is available. This policy, if finalized, will also give providers better information when working with MA plans.

Adding Mental Health or Substance Use Disorder (SUD) Diagnosis to the List of Social Risk Factors that MA Plans Must Use for the Annual Health Equity Analysis

CMS indicates that it is considering adding a mental health or SUD diagnosis to the list of social risk factors that MA plans must use to conduct the annual health equity analysis. To inform this decision, CMS solicits comment, including feedback on whether the addition of a mental health or SUD diagnosis to the list of social risk factors appropriately addresses a gap in the existing social risk factors. Vizient appreciates the agency's efforts to improve access to care and equity of care for patients with mental illness and SUDs. While Vizient recognizes the need to address current gaps in the collected social risk factor data, we seek additional information regarding both the intent and use of the mental health and/or SUD diagnosis data if this provision is finalized.

In the Proposed Rule, CMS does not explain the reasoning for the proposal to create a separate reporting category for mental health or SUD diagnoses or why CMS decided that having a mental health or SUD should be considered a social risk factor. Since existing social risk factors for the health equity analysis MA plans must perform already include having a disability,[5] Vizient questions whether it is the intent of the agency to expand the included conditions beyond those that would be considered disabilities and whether individuals may be counted under both disability status and under mental health and SUD. While not every individual with a mental health or SUD will meet the definition of disabled, Vizient does encourage CMS to clarify why the agency wants to have reporting based on mental health or SUD status in this context to avoid confusion regarding interpretation of the additional data and so we can provide additional feedback.

Similarly, the agency does not indicate the criteria it is using to define social risk factors. Given that mental health and substance use disorder diagnoses are clinical in nature, Vizient suggests CMS ensure that careful attention is paid to appropriately identifying social risk factors. In addition, Vizient suggests CMS clarify this information, as it would help inform future comments. Further, the 2024 MA Final Rule implies that the data collected through the health equity analysis was for informational purposes to help understand whether the use of prior authorization practices relates to enrollee disparities. The Proposed Rule does not include information on how the agency plans to use the additional data collected on mental health and SUD in the health equity analysis for MA plans. Vizient requests the final rule clarify whether this additional data will only pertain to information collection on whether the use of prior authorization causes persistent disparities or whether the agency plans to use the additional data to help address the gap in the existing social risk factors.

Lastly, Vizient notes that there are currently many gaps in the existing social risk factors and 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

[5] § 422.137 (d)(6)(ii) Medicare Advantage Utilization Management Committee Responsibilities:
The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:
(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.
(B) Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-C/section-422.137

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.

Formulary Inclusion and Placement of Generics and Biosimilars

Given concerns, such as higher out-of-pocket costs stemming from plan formulary decisions related to generics and biosimilars, CMS proposes to enhance the agency's formulary review process to better consider access to these products. Specifically, among other actions, CMS would review whether a plan's formulary and utilization management (UM) practices with respect to these drugs are "cost-effective," "reasonable and appropriate," and inclusive of "incentives to reduce costs." Further, CMS indicates it would use its authority to negotiate with a Part D plan if the proposed formulary does not appear to provide broad access to generics, biosimilars and other low-cost drugs. Related to this issue, Vizient's 2022 biosimilar survey highlighted variable payer coverage decisions related to biosimilars, including that 13 percent of provider respondents prefer the brand originator and that the top barrier to biosimilar adoption for a certain, highly utilized product was payer placement. Given this information, Vizient supports the agency's efforts to more closely monitor payer placement of generics and biosimilars, as this can be critical in determining which medication a patient will take. However, Vizient also encourages CMS to work with providers, plans and patients to ensure that patient access to medications is not hampered.

Also, as CMS considers access to a range of biosimilars and generic products, Vizient notes an emerging trend where vertical integration may encourage more preferable formulary placement of a biosimilar that is not available through traditional channels (e.g., accessible only through a subsidiary). While Vizient has long encouraged competition and utilization of biosimilars, we are concerned that these types of models may exacerbate existing challenges where providers and patients have limited choice in the products patients receive. This is also challenging as patients may change payers and have more frequent changes to their medications. Under the proposal, it is unclear how CMS would view these scenarios since additional biosimilars would be listed on the formulary but may not consistently lead to reduced costs or competition in the same way as biosimilars that are more broadly available. Vizient encourages CMS to consider these models and work with providers to address challenges in future policy development.

Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings

In the Proposed Rule, CMS proposed several policies to strengthen the notice requirements to ensure that a provider who has made a standard organization determination or integrated organization determination request on an enrollee's behalf receives notice of the MA organization's decision. One proposal was that if the MA organization or applicable integrated plan fails to provide the enrollee, physician, or provider involved, as appropriate, with timely notice of an organization determination or integrated organization determination, this failure itself constitutes an adverse organization determination and may be appealed. Vizient is concerned that this proposal will encourage MA organizations to avoid reviewing patient determination requests because it will benefit the MA organizations for those requests to be denied. Instead of a proposal that will lead to automatic adverse determinations without timely notice, Vizient recommends CMS propose a policy requiring that a standard or integrated

organization determination be presumed approved should the standard or expedited decision timeframes not be met by the payer.

In addition, due to the ongoing issues CMS has seen with previously approved inpatient hospital admissions later being inappropriately revised or rescinded, CMS proposes policy to prevent MA plans from subsequent revisions or rescission. Specifically, CMS proposed that if an MA organization approved an inpatient hospital admission, any additional clinical information obtained after the initial determination cannot be used as new and material evidence to establish good cause for reopening the determination. Vizient agrees with the need to address revisions and rescissions in these circumstances since these decisions cause administrative burden and disruptions to care. In addition, Vizient agrees that curtailing an MA organization's authority to reopen and modify an approved authorization for an inpatient hospital admission should reduce the number of previously approved inpatient hospital admissions later being inappropriately revised or rescinded. However, Vizient is concerned that MA organizations may increase initial denials because of this provision, which could disrupt patient care and increase administrative burden. To prevent this unintended consequence, Vizient recommends that CMS provide an additional policy to ensure that MA organizations do not increase their rate of initial denials.

Promoting Informed Choice – Enhancing Review of Marketing and Communications

In the Proposed Rule, CMS proposes expanding the definition of marketing which would broaden CMS oversight of MA and Part D communication materials and activities. Specifically, CMS would rely only on the intent standard[6] to determine whether communications and activities are considered marketing. As noted in Vizient's prior comments, we have concerns that many of the marketing and communications tactics that MA and Part D plans use create confusion and unintended consequences for enrollees (e.g., confusion regarding enrollment decisions, scope of benefits, how to utilize those benefits). Vizient supports the agency's efforts to broaden oversight of marketing to help protect beneficiaries and deter plans from employing deceptive marketing and communications tactics.

Medicare Drug Price Negotiation Program: Medicare Transaction Facilitator (MTF) Requirements for Network Pharmacy Agreements

While not directly raised in the Proposed Rule, Vizient continues to emphasize to CMS that a retrospective rebate model will prove challenging for pharmacies and other providers for a range of reasons. To better identify and address these challenges, particularly as related to the MTF data module (DM), we suggest CMS engage pharmacies and other providers in additional testing of the MTF DM well before 2026. Vizient believes taking such proactive measures will help reduce disruption once the negotiated price goes into effect in 2026.

Medicare Drug Price Negotiation Program: Timely Submission Requirements for Prescription Drug Event (PDE) Records

In the Proposed Rule, CMS provides an overview of recently finalized guidance related to implementation of the Negotiation Program. Under the guidance, if a manufacturer opts to provide retrospective payments, there will be considerable delays in payments to pharmacies

[6] As noted in the Proposed Rule, "In evaluating the intent of an activity or material, CMS will consider objective information including, but not limited to, the audience of the activity or material, other information communicated by the activity or material, timing, and other context of the activity or material and is not limited to the MA organization's or Part D sponsor's stated intent."

and providers given existing submission timelines.[7] In the Proposed Rule, CMS aims to address stakeholder concerns regarding this timeline, which Vizient appreciates, as we had previously expressed concerns with the timeline to CMS.

To prevent unreasonable delay of payments and mitigate financial hardship to pharmacies, CMS proposes to codify a 7-day timeframe for the Part D sponsor to submit initial prescription drug event (PDE) records[8] for selected drugs. Specifically, the Part D sponsor must submit initial PDE records for selected drugs within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. For non-selected drugs, CMS clarifies that the existing 30 calendar day timeframe would still apply. Vizient agrees with the proposal to reduce the initial PDE timeframe, as this is one step that will reduce the time that pharmacies wait to receive refunds for products that were purchased above the maximum fair price (MFP). In addition, while addressing this timeline issue is critical, Vizient recommends that CMS take more significant steps to address provider concerns, including opportunities to shift to primarily prospective access to MFP, as noted in Vizient's prior comments.

Request for Information on Access to Pharmacy Services and Prescription Drugs

In the Proposed Rule, CMS seeks feedback in a request for information regarding additional data or information to consider in the context of the requirement that plans must offer a standard contract with reasonable and relevant contract terms.[9] As CMS considers additional data needs, we encourage the agency to consider whitebagging policies, which effectively steer patients to specific pharmacies, and are often affiliated with a given plan. In 2021, Vizient released a report based on survey data which highlighted numerous challenges providers and patients face as payers force physicians and health systems from a traditional buy-and-bill model to one where specialty medications are dispensed from a third party, such as a plan-affiliated pharmacy. While Vizient understands that such policies are primarily advanced by commercial payers, we have heard anecdotally of MA-PDs increasing this practice. Given this and the concerns related to patient care which are noted in the Vizient report, greater scrutiny of payer-mandated whitebagging will help ensure patient access to pharmacy services and prescription drugs. As a result, Vizient encourages CMS to seek additional data regarding the frequency with which whitebagging occurs and for which medications these policies are most common.

Conclusion

Vizient membership includes a wide variety of hospitals ranging from independent, community-based hospitals to large, integrated health care systems that serve acute and non-acute care needs. Additionally, many hospitals 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 the opportunity to share feedback on this important Proposed Rule.

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[7] As noted in the Proposed Rule, the existing submission timelines would be 30 calendar days for the Part D sponsor to submit PDE data to the Drug Data Processing System (DDPS), plus approximately one to three days for the PDE data to move from the DDPS to the Medicare Transaction Facilitator (MTF) to the Primary Manufacturer, plus up to an additional 14 days for the Primary Manufacturer to transmit an MFP refund payment

[8] In the Proposed Rule, CMS clarifies that the initial PDE records are submitted after a pharmacy claim is received by the Part D sponsor, adjustment and deletion of PDE records that have been accepted by CMS, and records to resolve PDE records that were rejected by CMS.

[9] For example, as noted in the Proposed Rule, existing plan requirements include that any willing pharmacy may participate as a network pharmacy and the contracted pharmacy network must be sufficient to ensure that Part D beneficiaries have convenient access to pharmacy services.

Please feel free to contact me, or Randi Gold at Randi.Gold@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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