799 9th Street NW
Suite 210
Washington, DC 20001

T (202) 354-2600
vizientinc.com

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January 5, 2024

Submitted electronically via: **www.regulations.gov**

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Medicare Program; 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; Health Information Technology Standards and Implementation Specifications (Docket No.: CMS-2023-0187)

Dear Administrator Brooks-LaSure,

Vizient, Inc. appreciates the opportunity to respond to the proposed rule regarding Contract Year 2025 policy and technical changes to the Medicare Advantage (MA or Part C) and Medicare Prescription Drug Benefit (Part D) programs (hereinafter "Proposed Rule"). Vizient applauds CMS for continuing efforts to help support biosimilar uptake, address health equity, and improve utilization management.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 60% of the nation's acute care providers, which includes 97% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $130 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Recommendations

Vizient appreciates the efforts of CMS to improve beneficiaries' protections and to promote equity in coverage and care. Vizient offers the following recommendations for the agency's consideration as related to biosimilars, prior authorization and health equity.

Additional Changes to an Approved Formulary – Biosimilar Biological Product Maintenance Changes and Timing of Substitutions

CMS proposes to permit biosimilar biological products other than interchangeable biological products to be substituted for their reference products as "maintenance changes", which do not

require prior approval from CMS. Also, CMS proposes that immediate formulary substitution of interchangeable biological products would be permitted. Vizient has long supported our healthcare provider members in their evaluation and use of biosimilars. In 2022, a Vizient member survey provided key insights regarding the importance of payer coverage in the context of biosimilar conversion planning for 2023. For example, regarding an institution's biosimilar conversion process, 59% of respondents indicated that individual patients are converted based upon payer demand. Based on the importance of these payer decisions on individual patients, Vizient believes the proposed policy will help encourage biosimilar uptake by reducing barriers payers face in adding biosimilars to formularies.

Also, the Proposed Rule includes a requirement that the plan provide a 30-day notice regarding the formulary change. In describing this proposed policy, CMS notes that during this period, patient prescriptions could be rewritten to the biosimilar, which is especially important in states that do not permit pharmacist substitution. Vizient agrees that patient care should not be disrupted should formulary changes occur, and we encourage CMS to consider whether additional communications may be warranted from plans to providers. Further, we encourage CMS to monitor patient and provider experiences should the proposal be finalized to better understand whether notice is necessary, particularly as state laws regarding substitution evolve. Generally, Vizient suggests CMS aim to align formulary policies for biosimilars and interchangeable products where possible to promote uptake and minimize confusion.

Lastly, Vizient encourages CMS to help ensure that patients' out-of-pocket costs are the same or lower as formulary changes occur. While CMS notes in the Proposed Rule that patient out-of-pocket costs are not expected to increase except in limited circumstances[1], Vizient suggests CMS monitor this issue to ensure its expectations are met.

Annual Health Equity Analysis of Utilization Management Policies and Procedures

In the Proposed Rule, CMS proposes several changes to the composition and responsibilities of the utilization management (UM) committee, including a requirement that the UM committee conduct an annual health equity analysis[2] of the use of prior authorization. Also, CMS proposes that MA organizations make the results of the analysis publicly available. Vizient appreciates the agency's ongoing efforts to address health inequities and to improve UM, including prior authorization. Vizient believes greater attention to health equity in the context of UM is a helpful step, but encourages CMS to also consider additional requirements should inequities be identified.

[1] For example, CMS notes that out-of-pocket costs may be higher if the reference product was on a preferred tier, but the formulary exception tier designated in the plan benefit package is the non-preferred tier, then affected enrollees who obtain a formulary exception may be subject to higher cost sharing than previously.

[2] As noted in the Proposed Rule, "The proposed analysis would examine the impact of prior authorization on enrollees with one or more of the following social risk factors (SRFs): (i) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (ii) having a disability."

In addition, as the agency considers other potential social risk factors, Vizient suggests CMS consider using the publicly available Vizient Vulnerability Index™, which identifies social needs and obstacles to care that may influence a person's overall health. Also, Vizient continues to encourage more significant changes to UM processes, such as the decision timelines noted in prior rulemaking that have yet to be finalized.[3]

Health Equity Index Reward

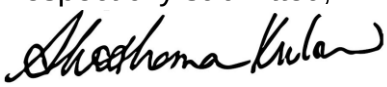
CMS proposes policy regarding the calculation of the Health Equity Index (HEI) Reward in the case of contract consolidations beginning with the 2027 Star Ratings, which will be the first Star Rating to include the HEI. While CMS does not propose revisions to the HEI Reward methodology, Vizient reiterates our prior comments regarding the HEI Reward and limited number of social risk factors. For example, we encourage CMS to consider whether the Vizient Vulnerability Index™, which is now publicly accessible, could be utilized in future policy related to the HEI Reward.

Conclusion

Vizient thanks CMS for releasing this Proposed Rule which would meaningfully help address challenges related to utilization management, health equity and biosimilar access.

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 the 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,



Shoshana Krilow
Senior Vice President of Public Policy and Government Relations
Vizient, Inc.

[3] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=0938-AU87