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January 27, 2025

Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20001

Submitted Electronically at www.regulations.gov

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 (CMS-4208-P) [RIN 0938-AV40]

Dear Centers for Medicare & Medicaid Services,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the 2026 Medicare Advantage and Part D proposed rule (CMS-4208-P) that was released in the Federal Register on November 26, 2024.

ASCO is a national organization representing more than 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

We are pleased to offer our comments on select provisions below:

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Ensuring Equitable Access to Medicare Advantage (MA) Services – Guardrails for Artificial Intelligence (§ 422.112)

CMS proposes to revise the MA regulations to ensure services are provided equitably, irrespective of delivery method or origin, whether from human or automated systems. If an MA plan uses AI or automated systems, they must comply with applicable regulations and requirements and provide equitable access to services and not discriminate based on any factor that is related to the enrollee's health status.

Overall, ASCO supports CMS' proposed policy requiring MA organizations to provide all enrollees, without exception, equitable access to services, including

when MA organizations use AI or other automated systems to aid their decision-making. However, we would like to take this opportunity to emphasize the need to further clarify the specific metrics and technical requirements required of MA organizations to enable meaningful evaluation of AI systems performance. **While CMS’s intent to ensure equitable access and prevent algorithmic discrimination is commendable, the proposed rule lacks sufficient specificity in several critical areas that could impede effective implementation and oversight.**

ASCO is committed to addressing cancer health equity and continually works to improve understanding, advance scientific knowledge, and develop solutions to eliminate disparities in cancer care and outcomes. ASCO strives, through research, education, and promotion of the highest quality equitable patient care, to create a world where cancer is prevented, and every survivor is healthy. In this pursuit, cancer health equity remains a guiding institutional principle that applies to all its activities across the cancer care continuum. The Society’s statement¹ on health equity affirms its commitment to moving beyond descriptions of differences in cancer outcomes and toward the achievement of cancer health equity. This includes supporting policies focused on ensuring equitable access to care across the cancer care continuum.

In contrast to the perceived benefits of AI in oncology care, there is growing literature on the potential for this technology to both amplify existing problems of health disparities in oncology care and generate new biases, as previously highlighted by ASCO.² Although the impact and role of AI on health equity in oncology remains underexplored, AI has already demonstrated the potential for algorithmic bias and misuse in other areas of research.^{3,4,5,6} In a landmark study on racial bias, researchers found an algorithm widely used by payers systematically underestimated illness severity in Black patients and assigned the same level of risk as white patients, deprioritizing them for access to care.

A lack of understanding and oversight of AI opens the opportunity for misuse, can increase disparities, and can harm patient access to care. While biases in AI can arise through many mechanisms, one major

¹ <https://ascopubs.org/doi/full/10.1200/JCO.20.00642?af=R>

² Patel MI, Lopez AM, Blackstock W, Reeder-Hayes K, Moushey EA, Phillips J, Tap W. Cancer disparities and health equity: a policy statement from the American society of clinical oncology. *J Clin Oncol.* 2020 Oct 10;38(29):3439–48.

³ Istasy P, Lee WS, Iansavichene A, et al. The Impact of Artificial Intelligence on Health Equity in Oncology: Scoping Review. *J Med Internet Res.* 2022;24(11):e39748. Published 2022 Nov 1. doi:10.2196/39748.

⁴ Shanklin R, Samorani M, Harris S, Santoro MA. Ethical Redress of Racial Inequities in AI: Lessons from Decoupling Machine Learning from Optimization in Medical Appointment Scheduling. *Philos Technol.* 2022;35(4):96. doi:10.1007/s13347-022-00590-8. Epub 2022 Oct 20. PMID: 36284736; PMCID: PMC9584259

⁵ Obermeyer Z, et al. Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 366,447–453(2019).DOI:10.1126/science.aax2342.

⁶ Gianfrancesco MA, Tamang S, Yazdany J, Schmajuk G. Potential biases in machine learning algorithms using electronic health record data. *JAMA Intern Med.* 2018;178(11):1544–1547. doi:10.1001/jamainternmed.2018.3763

source of bias is the data used to train, evaluate, and monitor them.⁷ Reports have shown that payers use AI systems that rely on generalized or historical data to automate coverage decisions which can perpetuate bias that leads to discriminatory patterns.⁸

We recommend CMS require MA organizations to conduct regular bias impact assessments using standardized statistical measures across protected classes and historically marginalized populations, while maintaining comprehensive documentation of training data demographics and representation that remains readily available for review by CMS.⁹ Critical to these requirements is the establishment of clear definitions for what constitutes discriminatory impacts in automated coverage decisions.

Given the “black box” nature and technical complexity of AI tools and their potential impact on cancer care, CMS should require MA organizations to develop and implement robust standards for maintaining audit trails that document both AI-assisted and human coverage decisions—particularly those used in prior authorization. Expanding upon the compliance activities referenced in subparts K and O of 42 CFR part 422, these requirements should include mandatory disclosure of data elements that include outcome metrics and process validation. CMS could also provide additional guidance on standards for independent third-party evaluation of algorithms and establish remediation procedures and timelines for situations when bias is identified in automated coverage decisions.

In summary, the proposed rule in its current form lacks specific metrics and technical requirements that could result in inconsistent implementation and ineffective oversight of MA organizations. We recommend CMS establish clear, measurable standards that enable meaningful evaluation of AI systems performance and its potential impacts on cancer care access and outcomes. These guardrails should align with existing non-discrimination requirements while providing concrete guidance for implementation, evaluation, auditing, and compliance monitoring.

See ASCO’s *Principles for the Responsible Use of Artificial Intelligence in Oncology*¹⁰ for additional information.

Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures

In the April 2024 final rule, CMS finalized policy requiring the utilization management committee to conduct an annual health equity analysis of the use of prior authorization. The analysis must examine the impact of prior authorization at the plan level, on enrollees receiving the Part D low-income subsidy,

⁷ Alderman JE, Palmer J, Laws E, et al. Tackling algorithmic bias and promoting transparency in health datasets: the STANDING Together consensus recommendations. *Lancet Digit Health*. 2025;7(1):e64-e88. doi:10.1016/S2589-7500(24)00224-3

⁸ <https://www.ama-assn.org/system/files/ama-ai-principles.pdf>

⁹ National Institute of Standards and Technology. NIST Special Publication 1270. Towards a Standard for Identifying and Managing Bias in Artificial Intelligence. <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1270.pdf>

¹⁰ [ASCO-AI-Principles-2024.pdf](#)

who are dually eligible for Medicare and Medicaid, or who have a disability. The analysis must compare aggregated metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. By July 1, 2025, and annually thereafter, the health equity analysis must be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website. In response to ASCO and other stakeholder feedback, **CMS is proposing to require the health equity analysis be done and reported on by each covered item and service to more readily identify prior authorization trends and to better identify and address the impact of prior authorization on enrollees with the specified SRFs. ASCO strongly supports this proposal to make transparent disaggregated data for all enrollees.**

ASCO strongly supports transparency in prior authorization and the metrics outlined in the proposed rule. We believe that disaggregating prior authorization data across all items and services may provide meaningful and actionable information for specific specialties, patients undergoing complex treatments, and even for CMS. More granular data will better highlight how often specific treatments and services are impacted by payer policies, and CMS will be able to effectively monitor the adverse impact of plan prior authorization policies, including suboptimal clinical outcomes, increases in adverse events and disparities in treatments. Additionally, enrollees can be better informed when choosing plans that are best suited to their care needs.

Enhancing Rules on Internal Coverage Criteria § 422.101

CMS proposes to build upon and enhance the regulations from the April 2023 final rule, specifically those related to the use of internal coverage criteria, by defining the phrase “internal coverage criteria,” establishing policy guardrails to preserve access to basic benefits, and adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

ASCO supports policy that requires payers to disclose the process by which they evaluate and determine prior authorization, including the evidence on which these decisions are based;¹¹ therefore, **we support CMS’s proposal to adopt a clear regulatory definition of the term “internal coverage criteria” to prevent unnecessary denials of care. We support CMS’s proposal to require that MA organizations demonstrate through evidence that any additional criteria included in a MA plan’s internal coverage policies support patient safety.** MA plans should provide a publicly accessible summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations, a list of the sources of such evidence, and include an explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination.

Promoting Informed Choice

CMS proposes to enhance its oversight of misleading marketing materials by broadening the definition of “marketing” to increase the number and type of advertisements that are required to be submitted to

¹¹ <https://old-prod.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2022-PA-Statement-FINAL.pdf>

CMS. CMS also proposes to expand the number of required topics that agents and brokers must cover before an individual's enrollment. Topics include potential eligibility for the Low-Income Subsidy and Medicare Savings Programs, as well as the potential impact of MA enrollment on future Medigap guaranteed issue rights and where an individual might access additional information about these programs.

ASCO commends the Agency for its continued efforts to protect beneficiaries from predatory marketing tactics. The proposed rule aims to protect MA and Part D enrollees shopping for Medicare coverage from confusing and potentially misleading marketing while also ensuring they have accurate and necessary information to make coverage choices that best meet their needs.

Many beneficiaries rely on agents and brokers to help navigate complex Medicare choices as they comparison shop for coverage options. Medicare beneficiaries need accurate information from reliable sources about Medicare coverage without worry that they are being steered into a certain plan regardless of if a plan will meet enrollee needs. Enrollees should have a complete understanding of whether they will have access to their preferred providers and necessary prescriptions before enrolling in a plan. Enrollees applying for coverage should understand references to benefit information in plans and be able to use this information to make an informed plan selection with the help of a non-biased agent or broker. ASCO supports enhanced monitoring and oversight of Medicare Advantage plan marketing and communications.

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We appreciate the opportunity to comment on the 2026 Medicare Advantage and Part D proposed rule. Please contact Gina Hoxie (gina.hoxie@asco.org) with any questions or for further information.

Sincerely,



Eric P. Winer, MD, FASCO
Chair of the Board
Association for Clinical Oncology