



January 27, 2025

Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, DC 20201

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

Dear CMS Administrator:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the proposed rule to modify Medicare and Medicaid Programs in the 2026 plan year. In implementing the proposed changes, we urge the Centers for Medicare & Medicaid Services (CMS) to:

- I. Promote equitable access to treatments for Inflation Reduction Act (IRA) negotiated prescription drugs, and establish an ongoing oversight system to monitor IRA implementation and access challenges; and**
- II. Ensure transparency in artificial intelligence driven coverage determinations.**

I. Promote Equitable Access and Ensure Oversight of IRA Implementation

The Inflation Reduction Act of 2022 is a bipartisan bill that permits the Secretary of the Department of Health and Human Services (HHS) to negotiate select prescription drug prices on behalf of Medicare.¹ The IRA has the potential to lower prescription drug costs for the Medicare program. However, it is critical to ensure that negotiated prescription drugs do not result in utilization management policies that create access barriers to necessary medications.

The IRA Part D prescription drug negotiation program is a novel program that has not been previously implemented in Medicare, or any other federally regulated program. As such, the consequences of implementing the negotiated drug program are not completely known. However, surveys of payers have highlighted that potential consequences to prescription drug negotiations could include non-coverage of new drugs in a negotiated drug class; prior authorization, utilization management, and step therapy for protected classes; stricter formulary management; increased white bagging; and removal of established drugs from formularies.²

¹ Juliette Cubanski, et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023),

<https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/>.

² Saxena V. et al., *Impact of the Inflation Reduction Act on Payer Drug Coverage and Utilization Management – Insights from a Quantitative Survey*, CLARIVATE (May 2023), https://www.ispor.org/docs/default-source/intl2024/ispor24chaudharypt11posterv2138901-pdf.pdf?sfvrsn=9a65dcc5_0.



Thus, given the novelty of this program and its implementation, AImed Alliance urges CMS to implement an oversight and monitoring system that imposes a robust reporting system on health plans to allow CMS to monitor how formularies are impacted when negotiated prices come into effect. This monitoring system should also conduct regular analysis of key metrics, such as drug utilization rates among Medicare beneficiaries and out-of-pocket costs for prescription medications. These efforts will ensure that negotiated prices do not negatively impact access and affordability for consumers, reduce the impact of unintended consequences, and inform future policy decisions.

Lastly, we urge CMS to implement safeguards to mitigate the risk of narrow formularies and arbitrary utilization management policies. For example, CMS could establish a clear communication pathway for patients and providers to report access challenges relating to negotiated prescription drugs. Ultimately, imposing additional reporting requirements can help ensure CMS has the appropriate data to inform future policy decisions and protect access to necessary treatments for health care consumers.

II. Ensure Transparency in the Use of Artificial Intelligence in Coverage Determinations

We appreciate CMS's acknowledgment that it is necessary to ensure that the use of artificial intelligence (AI) does not result in inequitable treatment, bias, or both within the healthcare system, and instead is used to promote equitable access to care and culturally competent care for all enrollees.

The increasing use of AI in healthcare has the potential to improve the efficiency and accuracy of coverage determinations, however, it is essential to ensure that, in addition to being fair and unbiased, these determinations are also transparent. Recently, two class action lawsuits have alleged that Medicare Advantage plans were using AI to deny a substantial number of claims.³ Notably, the complaint alleges that these AI algorithms had a known 90 percent error rate.⁴ Moreover, when AI is used in rendering a benefit decision, health plans may not disclose that AI was used in providing the coverage decision.

Therefore, we urge CMS to require plans to disclose in denial letters whether AI was used as part of the review or coverage decision process. By requiring this transparency, CMS can ensure that beneficiaries and providers understand how AI is being used to make coverage decisions and have the ability to challenge those decisions if necessary.

III. Conclusion

CMS plays a critical role in ensuring that Medicare and Medicaid beneficiaries receive fair, transparent, and continued access to healthcare services. By taking the actions outlined above, including promoting equitable access to care after IRA pricing implementation,

³ *The Estate of Gene B. Lokken and The Estate of Dale Henry Tetzloff, et al., vs. United Health Group, Inc. Et al.*, 0:23-cv-03514 (Minn. 2023), https://litigationtracker.law.georgetown.edu/wp-content/uploads/2023/11/Estate-of-Gene-B.-Lokken-et-al_20231114_COMPLAINT.pdf.

⁴ *Id.*



establishing ongoing monitoring by CMS, and ensuring transparency in AI-driven coverage determinations, CMS can protect beneficiaries from bias and discriminatory treatment while promoting access and affordability in an era of drug pricing reform and AI-driven healthcare.

Thank you for your attention to this important matter. Please contact us at policy@aimedalliance.org if you have any questions.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance

Based on the following provisions, draft a letter to CMS that urges them to ensure equal access after IRA pricing implementation; ensure there's monitoring by CMS; and require plans disclose in denial letters whether AI was used as part of the review or coverage decision process:



“Ensuring Equitable Access to Medicare Advantage Services—Guardrails for Artificial Intelligence (AI)”

On October 30, 2023, the Biden-Harris Administration released an Executive Order, “Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence,” directing agencies to ensure that artificial intelligence tools do not impede the advancement of equity and civil rights, and that the use of AI within health care organizations does not deny equal opportunity and justice for the American people.^[3] Given the growing use of AI within the healthcare sector, such as, but not limited to, AI-based patient care decision support tools, vision transformer-based AI methods for lung cancer imaging applications, and AI and machine learning based decision support systems in mental health care settings, we believe it is necessary to ensure that the use of AI does not result in inequitable treatment, bias, or both, within the healthcare system, and instead is used to promote equitable access to care and culturally competent care for all enrollees. As such, we propose to revise § 422.112(a)(8) to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. We also clarify that in the event that an MA plan uses AI or automated systems, it must comply with section 1852(b) of the Act and § 422.110(a) and other applicable regulations and requirements and provide equitable access to services and not discriminate on the basis of any factor that is related to the enrollee's health status.”

“On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) ([Pub. L. 117-169](#)) was signed into law. It established the Negotiation Program to negotiate maximum fair prices (MFPs) for certain high expenditure, single source drugs and biological products (*i.e.*, selected drugs). The requirements for this program are described in sections 1191 through 1198 of the Act, as added by sections 11001 and 11002 of the IRA.

Under section 1193(a) of the Act, participating manufacturers must not only provide access to the MFP for a selected drug to MFP-eligible individuals (as defined in section 1191(c)(2) of the Act), but they must also provide access to the MFP to pharmacies, mail order services, and other dispensing entities with respect to such MFP-eligible individuals who are dispensed the selected drug during a price applicability period (as defined in section 1191(b)(2) of the Act).”