



1700 K Street, NW | Suite 740 | Washington, DC 20006

T 202.293.2856

[www.agingresearch.org](http://www.agingresearch.org)

[@Aging\\_Research](https://twitter.com/Aging_Research)

May 29, 2024

Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-8013

## **Re: Medicare Program; Request for Information on Medicare Advantage Data**

Dear Administrator Brooks-LaSure,

The Alliance for Aging Research (“Alliance”) appreciates the opportunity to respond to the request for information on improving the collection of data in Medicare Advantage. The Alliance for Aging Research is the leading nonprofit organization dedicated to changing the narrative to achieve healthy aging and equitable access to care.

### **Data Collection as a Tool to Prevent Utilization Management Abuse**

Since the Inflation Reduction Act (IRA) was passed in 2022, the Alliance has worked with CMS and other impacted stakeholders to share concerns about unintended consequences of provisions of the IRA which are likely to have detrimental impacts on patient access to care. Thoughtful reform and implementation can help mitigate these concerns. The Alliance has previously shared our concerns, outlined in additional detail below, with the Agency in other requests for information, responses to draft guidance, and in meetings.<sup>1</sup>

Accurate data collection in the Medicare program is crucial for supporting the health and well-being of older adults. It enables policymakers and healthcare providers to make informed decisions that enhance the quality of care, ensure timely access to necessary treatments, and address the specific health needs of this population. Comprehensive data that is available in real-time (or as close to real-time as possible) helps identify trends and gaps in care, guiding interventions that can prevent chronic disease progression, reduce

---

<sup>1</sup> Alliance for Aging Research. “Alliance + 45 Organizations Submit Comments on Needed Guardrails, Other Provisions of Medicare Advantage Rule.” <https://www.agingresearch.org/news/alliance-45-organizations-submit-comments-on-needed-guardrails-other-provisions-of-medicare-advantage-rule/>

hospital readmissions, and improve overall patient outcomes. Additionally, accurate data collection promotes transparency and accountability within Medicare Advantage plans, empowering older adults to choose the best possible coverage for their needs.

In the press release accompanying the release of the MA Advance Notice, HHS Secretary Xavier Becerra noted, “The Biden-Harris Administration is committed to making sure the millions of people who have managed care plans called Medicare Advantage get the best care possible, and that taxpayer dollars are used efficiently.”<sup>2</sup> Accurate, thoughtful, timely, and proactive data collection aid in ensuring that there is sufficient time to protect patients when issues emerge.

### **The Need for Stronger Data**

The Part D redesign escalates insurers' responsibility from fifteen percent of costs in the catastrophic phase of the benefit in 2023 to sixty percent in 2025 (45 percent total increase).<sup>3</sup> On top of that, the IRA limits premium growth to six percent each year through 2029.<sup>4</sup> As a result, payers have limited levers in the near term to shift costs. While Medicare beneficiaries have typically experienced fewer utilization management (UM) barriers in comparison to commercial plans, observers widely expect this to change as payers experience greater financial responsibility. Plans are expected to find ways to compensate for these increasing costs by controlling expenses more closely, including through the potential use of UM techniques such as more restrictive formularies, step therapy requirements, and prior authorization processes.<sup>5,6</sup> As a result, beneficiaries face a growing risk of potential treatment delays or loss of coverage altogether.

Additionally, if plans narrow access to certain medicines due to these dynamics, patients who are stable on a given medication may lose access and be forced to switch to an

---

<sup>2</sup> Centers for Medicare and Medicaid Services. “CMS Releases Proposed Payment Updates for 2025 Medicare Advantage and Part D Programs.” <https://www.cms.gov/newsroom/press-releases/cms-releases-proposed-payment-updates-2025-medicare-advantage-and-part-d-programs>

<sup>3</sup> Cubanski, Juliette and Neuman, Tricia. “Changes to Medicare Part D in 2024 and 2025 Under the Inflation Reduction Act and How Enrollees Will Benefit.” 20 Apr 2023. Kaiser Family Foundation. <https://www.kff.org/medicare/issue-brief/changes-to-medicare-part-d-in-2024-and-2025-under-the-inflation-reduction-act-and-how-enrollees-will-benefit/>

<sup>4</sup> Avalere. “Part D premiums Increasing Despite Stabilization Program.” 17 Oct 2023. <https://avalere.com/insights/part-d-premiums-increasing-despite-stabilization-program>

<sup>5</sup> Virta Health. “True catastrophic coverage and shifting liability: Preparing for IRA changes.” Fierce Healthcare. 20 March 2023. <https://www.fiercehealthcare.com/sponsored/true-catastrophic-coverage-and-shifting-liability-preparing-ira-changes>

<sup>6</sup> Shah, Suchita, et al. “Navigating the Inflation Reduction Act’s Impact on Drug Pricing and Innovation.” Boston Consulting Group. 14 Sep 2023. <https://www.bcg.com/publications/2023/navigating-inflation-reduction-act-impact-on-drug-pricing-innovation>

alternative medicine that was not originally prescribed by their clinician and may not be optimal for their unique circumstances. This is because CMS allows Part D plans to switch a beneficiary's medication from what was originally prescribed—sometimes called 'non-medical switching' since the practice excludes the beneficiary's healthcare provider or is performed for reasons other than efficacy, side effects, or adherence—in order to save costs.

While this series of events is extremely likely absent intervention given the underlying dynamics, so far, the Agency has indicated that it will only go so far as to "monitor" the situation. However, this is not sufficient. Increased application of UM – particularly when not clinically appropriate – puts patients at risk of delayed care and life-threatening adverse outcomes. For example, step therapy protocols require beneficiaries to take (often a series of) less expensive and potentially less efficacious medications first. In this case, beneficiaries must fail to show the desired clinical improvement before becoming eligible for coverage for the medication their physician or medical provider initially prescribed. Such impacts will disproportionately harm Medicare beneficiaries in underserved rural communities and communities of color, as noted below. This oversight would represent a direct conflict with CMS' strategic pillar commitment to health equity.

Further, many beneficiaries may have selected their current plan because it resulted in a lower out-of-pocket (OOP) cost burden. However, given the new OOP cap on beneficiary costs in Part D, changes to plans' benefit parameters may result in a different plan returning lower expected OOP costs in future years. As a result, more beneficiaries are expected to switch plans in 2025 than in a typical year. However, when beneficiaries switch plans, they may be required to go through their new plan's UM structure (or, to have the process knowledge and capability to file for an exception with their new plan) to maintain continued access to drugs on their care plan. This is particularly problematic with step therapy, where a beneficiary may be required to stop their current medication and take a medicine they have previously used but that has not been efficacious. These scenarios are likely to be seen in the real-world, given the increased "churn" in MA plan enrollment and projected expansion in UM protocols following from plans' increased liability in the catastrophic phase of the benefit.

If CMS relies solely on a reactive stance without establishing clear guidelines for the appropriate use of UM, it will be challenging to prevent potentially irreversible patient harm before it occurs. It is crucial that CMS adopts a proactive approach that safeguards patient access from UM tactics driven by plan sponsors' financial considerations rather than best practices that support the health of beneficiaries. Accurate and thoughtful data collection plays a pivotal role in this effort, enabling CMS to anticipate and address issues promptly.

Prioritized, precise data collection ensures that potential problems are identified early, allowing for timely interventions that protect beneficiaries from negative outcomes.

### **Data Improvements that would Support Increased Beneficiary Access to Care**

We have outlined below several specific improvements that CMS can make in its data collection processes to aid in protecting and improving beneficiary access to care through the implementation of the IRA and beyond. These include comprehensive monitoring of formulary changes, better evaluation of the use of AI and algorithms in claim denials, and detailed tracking of appeals data related to prior authorization and step therapy.

1. **Formulary Changes and Utilization Management of Drugs and Therapeutics:**

Data collection and monitoring plays a crucial role in scrutinizing formulary changes by providing the necessary information to identify, analyze, and address potential issues that could affect beneficiary access to medications. It allows CMS to track patterns and trends in formulary adjustments, including which medications are added or removed, and the impact of these changes on patient care. With accurate, timely, and robust data collection CMS can quickly identify areas for improvement and take proactive steps to address any concerns related to access, affordability, or quality of care for Medicare beneficiaries and stop the use of UM that does not align with clinical guidelines before it begins.

CMS should scrutinize the proposed formulary design for each Medicare Advantage plan in CY 2025 and following years to identify any potential shortcomings or disparities that may arise as an unintended consequence due to shifting financial incentives for payers given increased financial liability in the catastrophic phase of the Part D benefit or misaligned incentives for formulary placement for drugs selected for price negotiation. Further, CMS can more effectively ensure that formulary changes have a “reasonable justification”, the standard that the Agency has placed on any formulary changes resulting from the IRA. We also encourage CMS to provide resources toward real-time data monitoring during this important period of transition to identify and address undue barriers to access that may be attributable to formulary design or other factors.

2. **Data on Algorithms/AI/Automatic Denials of Care:**

CMS must better evaluate how MA plans are using artificial intelligence (AI) and algorithms to deny claims. It is currently unclear how CMS is monitoring and evaluating MA plans’ use of such tools, and monitoring is necessary as

algorithms are increasingly implemented and technology improves.<sup>78</sup>

Recommendations from House Democrats in November 2023<sup>9</sup> include measures for CMS to require MA plans to:

- a. Provide detailed explanations of denials, including patient conditions and denial timelines.
- b. Assess the frequency and reasons for denials.
- c. Examine the role of AI and algorithms in the denial process.
- d. Ensure algorithms do not use discriminatory factors such as race.<sup>10</sup>
- e. Evaluate whether algorithms are self-adjusting based on appeal reversals.

The Alliance also encourages CMS to not only evaluate whether plans' use of AI uses discriminatory factors but determines whether factors like algorithmic bias that may be present in AI tools have impacts that reinforce historical inequities. CMS should not permit the use of such tools without first being validated to ensure that all Medicare offerings comply with Section 504 of the Rehabilitation Act.<sup>11</sup>

3. **Appeals Data:** Data collection on appeals, particularly those related to prior authorization and step therapy, is essential. This data should include:
  - a. Frequency of Appeals: Understanding how often beneficiaries appeal UM decisions.
  - b. Outcomes of Appeals: Evaluating the success rate of appeals and the reasons for overturned decisions.
  - c. Timeliness: Monitoring the time taken to resolve appeals, as delays can adversely affect patient care.

---

<sup>7</sup> Tong, Noah. "Amid concerns about claims denials, Democrats seek greater oversight of Medicare Advantage plans' use of AI." Fierce Healthcare. 3 Nov 2023. <https://www.fiercehealthcare.com/payers/noticing-prior-authorization-surge-democrats-demand-better-ai-oversight>

<sup>8</sup> Ross, Casey and Herman, Bob. "UnitedHealth faces class action lawsuit over algorithmic care denials in Medicare Advantage plans." STAT News. 14 Nov 2023. <https://www.statnews.com/2023/11/14/unitedhealth-class-action-lawsuit-algorithm-medicare-advantage/>

<sup>9</sup> Chu, J., et al. "Letter to The Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services." 3 Nov 2023. Retrieved from: <https://chu.house.gov/sites/evo-subsites/chu.house.gov/files/evo-media-document/chu-nadler-ma-ai-oversight-letter-11.3.2023.pdf>

<sup>10</sup> Obermeyer, Ziad et al. "Dissecting racial bias in an algorithm used to manage the health of populations." *Science*. 25 Oct 2019. <https://www.science.org/doi/10.1126/science.aax2342>

<sup>11</sup> Department of Health and Human Services. "Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance." Federal Register / Vol. 89, No. 91. 9 May 2024. <https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf>

- d. Change in Number of Appeals Over Time: If appeals are happening more or less often as time progresses, that would serve as a useful indicator of areas in which more robust reform is needed.

The Alliance believes it would be beneficial for CMS to collect of survey data that evaluates beneficiaries' familiarity with their right to appeal a non-coverage determination, how to initiate the process, and whether beneficiaries would feel comfortable or empowered to file an appeal. This information would provide valuable context to CMS in terms of assessing the effectiveness of the appeals system and identify potential topics for education and outreach.

#### 4. **Data On Utilization Changes for Underserved Communities and Underrepresented Minority Populations:**

Collecting data on how UM practices impact underserved and minority populations is crucial for several reasons. First, it helps identify specific disparities in how these populations are affected by UM techniques such as prior authorization, step therapy, and formulary restrictions. For instance, non-White patients might face higher denial rates for certain treatments or longer delays in accessing necessary medications compared to other groups. By systematically gathering and analyzing this data, CMS can pinpoint where inequities exist and understand the underlying causes. This data is instrumental in guiding targeted policy adjustments aimed at mitigating these disparities. For example, if data shows that a particular UM practice disproportionately impacts a minority group, CMS can develop specific guidelines or regulations to address this issue, ensuring that UM practices are applied equitably across all populations. Additionally, comprehensive data collection can highlight successful strategies in certain areas or among certain plans that could be scaled or adapted to improve equity elsewhere. In the strategic plan, CMS states that the overarching health equity goals include, "Expand and standardize the collection and analysis of data, including data on race, ethnicity, preferred language, sexual orientation, gender identity, disability, income, geography, health-related social needs, and other factors."<sup>12</sup> Comprehensive data on the impact of UM techniques on these populations would align with this goal.

#### 5. **Areas that the Agency Notes in the RFI:** We support the RFI's focus on various data collection points, including:

---

<sup>12</sup> CMS Strategic Plan: Health Equity Fact Sheet. Centers for Medicare and Medicaid Services. Updated May 2024. <https://www.cms.gov/files/document/health-equity-fact-sheet.pdf>

- a. Supplemental Benefit Costs and Utilization: Understanding the costs and usage of additional benefits provided by MA plans.<sup>13</sup>
- b. Value-Based Payment Arrangements: Evaluating how these arrangements impact care quality and costs.
- c. Network Adequacy and Provider Directory Accuracy: Ensuring beneficiaries have access to necessary providers.
- d. Competitive Forces in the Market: Analyzing the effects of market shifts, vertical integration, and consolidation on consumers and care outcomes.
- e. Medicare Loss Ratios: Understanding the financial performance of MA plans and impacts on patient care.

### **Increased Transparency of Data**

An additional crucial question that CMS must address is who will have access to the data collected, and when access should be made available. The Alliances encourages CMS to mandate increased transparency from MA and Part D plans regarding their UM practices. Annual disclosure of all new and ongoing UM techniques for every covered prescription medication should be made openly available by plans at the time of enrollment and throughout the coverage period on the MA Plan Finder platform to enable beneficiaries to make informed decisions. This should be done comprehensively and in a way that is easily understood by beneficiaries to ensure they are able to select the insurance plan that best matches their individual care needs and circumstances. This would increase competition between plans at the time of enrollment and incentivize plans to avoid abusive UM practices that would harm patients.

### **Conclusion**

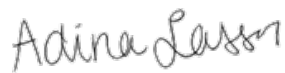
While robust data collection is fundamentally beneficial and needed, it is not sufficient on its own to ensure optimal patient care within the Medicare program. CMS must be prepared to act on the insights gained from this data and swiftly address any findings that reveal practices contrary to the best interests of beneficiaries. Effective data collection should be complemented by a readiness to implement corrective measures, policy adjustments, and interventions as needed. When data indicates that certain UM techniques or formulary changes are negatively impacting patient care, CMS must react promptly to mitigate these effects. Proactive monitoring, combined with decisive action,

---

<sup>13</sup> Freidman, Julia and Mary Yeh. "State of the 2024 Medicare Advantage Industry: General enrollment plan valuation and benefit offerings." Milliman White Paper. 16 Jan 2024.  
<https://www.milliman.com/en/insight/state-of-the-2024-medicare-advantage-industry-general-enrollment>

is essential to protect beneficiaries from unintended potential harms that may result from implementation of the IRA.

Thank you again for the opportunity to comment on needed reform for the collection of Medicare Advantage data. We look forward to continuing to partner with CMS to ensure that beneficiaries can easily access and benefit from these essential reforms. If CMS has questions about these recommendations or to discuss further, please contact Adina Lasser, Public Policy Manager at the Alliance for Aging Research, at [alasser@agingresearch.org](mailto:alasser@agingresearch.org).

A handwritten signature in cursive script that reads "Adina Lasser".

Adina Lasser  
*Manager of Public Policy*