January 27, 2025

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-4208-P,
P.O. Box 8013,
Baltimore, MD 21244-8013

Re: Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program (CMS – 4208-P)

Submitted via www.regulations.gov.

Dear Deputy Director Rice,

Thank you for the opportunity to address changes in the Medicare Advantage (MA) program. AMIA's comments will focus on enhancing internal coverage criteria, enhancing health equity analysis of the Prior Authorization (PA) tool, and guardrails for Artificial Intelligence (AI).

AMIA is the professional home for more than 5,500 informatics professionals, representing frontline clinicians, researchers, and public health experts who bring meaning to data, manage information, and generate new knowledge across the health and healthcare enterprise. As the voice of the nation's biomedical and health informatics professionals, AMIA plays a leading role in advancing health and wellness by moving basic research findings from bench to bedside, and evaluating interventions, innovations and public policy across settings and patient populations.

In addition to the comments on CMS' specific proposals, it is important to clearly state AMIA's position that prior authorization must be eliminated to reduce the required onerous documentation needed to support it, maintain the healthcare workforce and reduce burnout, and improve patient access to necessary medical care as determined by their individual clinicians.

Enhancing Rules on Internal Coverage Criteria (§ 422.101(b)(6))
AMIA supports CMS' proposal that MA organizations must publicly display on their website a list of all Medicare items and services where the MA organization uses internal coverage criteria to make medical necessity decisions to ensure enrollees and potential enrollees of all plans can easily understand what would be accessible if they enrolled in a particular plan. Additionally, AMIA strongly encourages noting that MA organizations should publicly display this information in an easily accessible and obvious place on their websites to ensure enrollees and potential enrollees of all plans can easily understand what would be accessible if they enrolled in a particular MA plan. AMIA also encourages CMS to require MA organizations to include these lists in ways that are accessible for clinicians and providers, including at the end of claims documents and in a machine-readable format.

In addition to where the criteria should be available, AMIA recommends requiring a standardized format in which this information is shared to increase readability. This format must be user friendly for potential MA enrollees. This will allow potential MA enrollees to compare plans and understand which MA plan will meet their needs. This will also allow for automation of claim submissions, reducing burden on clinicians and providers

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

AMIA supports CMS' pursuit for more granular data and supports disaggregating the metrics for each item and service reported in the health equity analysis to identify services that may be disproportionately denied and whether there is a disproportionate impact on populations with one or more social risk factor (SRF). It's important to note that the data, even disaggregated, may be starting with biases because different groups have access to different levels of care. It is possible that different demographics are given different opportunities to pursue items that require prior authorization in the first place. For example, poorer Americans are less likely to pursue care in the first place. As such, they may be less likely to pursue an item or service that requires prior authorization. Another example is that in 2023, it was found that in a cohort of 1,406 gynecologic oncology patients, patients of Asian descent were associated with a 60% increased risk of experiencing prior authorization,[1] which would be a precursor to the data CMS is asking for here.

Regarding CMS' request for information on alternative ways to group items and services for the purpose of reporting on these metrics, AMIA recommends grouping items and services in a manner that matches the United States Core Data for Interoperability (USCDI) to allow for automation and keeping care providers from having to fill out additional information.
It is important that MA plans do not have the ability to push the data gathering for these required health equity analyses onto clinicians and providers, as this would add to the already overly burdensome requirements on clinicians and providers to submit this data. Matching to the USCDI would reduce the possibility that clinicians and providers would have to share information twice – for the USCDI and for the health equity analyses needed by the MA plans.

AMIA supports CMS' proposal to require the inclusion of an executive summary in the health equity analysis. AMIA does not suggest additional items for inclusion in the executive summary but does recommend standardized data collection and reporting across MA plans.

Regarding the concern that the disaggregated data may result in privacy issues for enrollees, AMIA recommends that cells of fewer than 10 people be suppressed.

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

AMIA supports CMS' goals to ensure that MA enrollees are provided equitable access to Medicare services regardless of the tools or methods used to provide that care. AMIA appreciates CMS proactively clarifying that AI tools used in MA may not violate CMS rules, including those focused on discrimination and access to care, and that MA plans are responsible for the use of these tools. Up front, AMIA requests that CMS require clarity from MA plans regarding use of predictive AI algorithms versus generative AI tools.

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[1] Smith AJB, Mulugeta-Gordon L, Pena D, Kanter GP, Bekelman JE, Haggerty A, Ko EM. Insurance and racial disparities in prior authorization in gynecologic oncology. Gynecol Oncol Rep. 2023 Mar 11;46:101159. doi: 10.1016/j.gore.2023.101159. PMID: 36942280; PMCID: PMC10024078.

- AMIA appreciates CMS' awareness that technology in this space is quickly evolving and thus policy, which moves much more slowly, must account for that fast evolution while protecting MA enrollees and participating providers and clinicians. AMIA supports the three recommendations for MA organizations maintaining compliance and have added three more to CMS' proposed list below:
    - (1) ensuring that they understand, recognize, and limit the impact of biased data inputs within any AI and/or automated system they utilize;
    - (2) that they create and follow a process to regularly review any automated system they utilize to ensure that the use of the automated system is nondiscriminatory and to address the need for algorithmic vigilance;
    - (3) that outputs with a known or suspected discriminatory bias (such as expected utilization or predictability of payment or both) are not used within a MA organization's automated system in a manner that discriminates in the delivery of services in violation of section 1852(b) of the Act or § 422.110(a);
    - (4) require third party evaluation and validation of algorithms;
    - (5) provide transparency as to the systems used, review process, and updates made;
    - (6) if a human is in the loop
        - require that the individual responsible for the work of the AI must be learned with respect to the AI system,
        - define what their responsibility is, and
        - determine the necessary qualifications for the human-in-the-loop based on the AI system and the steps for which they are responsible.

Finally, AMIA is curious as to how CMS plans to oversee MA plans follow these recommendations and instead suggests requiring the following methods of compliance.

- Define "automated system" as "any system, software, or process that uses computational methods without human input at the point of application/use as whole or as part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals, communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or AI techniques, and exclude passive computing infrastructure."
- Define AI as "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments. Artificial intelligence systems use machine and human-based inputs to – (A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action."

AMIA has concerns with the notion that AI tools can be "utilized to make care decisions" in isolation. CMS states that "MA organizations must provide enrollees with equitable access to services under the MA plan design or benefits or both *regardless of the tools or methods utilized to make care decisions* or to provide that care." AMIA encourages CMS to require MA plans using AI to use it only as a support tool in healthcare provision and not be given decision-making authority, especially given that, on average, 80% of MA denials are overturned upon appeal. Crucially, decision-making must rest with a human and their medical acumen/license.

This number is likely much higher, given many of the denied do not pursue appeal given the already onerous process of PA.

As CMS points out in the fact sheet for this proposed rule, there have been increasing calls for reforms to MA PA. AMIA is among those calling for PA reform, if not outright elimination.[2] PA is a major source of burden for clinicians, health systems, and patients in need of medically necessary care.

AI has the potential to improve the glaring issue of documentation burden currently devastating our healthcare workforce and delaying patient access to quality care, while fitting into clinical workflows.[3] Focusing on eliminating documentation redundancies while maintaining patient data accuracy is direly needed to avoid preventable errors and provide timely delivery of patient care.

To ensure AI has every opportunity to achieve this potential, AMIA recommends the following regarding payor use of AI tools in PA decisions.

1. Require transparency from payors on the function and use of the AI tool in their PA processes, including medical necessity determinations.
    a. Allow third-party auditors to review AI algorithms and decisions, dataset characteristics (e.g., data sources and demographics in context of representation of diverse populations), model training processes, and validation studies to ensure that AI is contributing to making fair, equitable, and clinically appropriate recommendations.
    b. Implement feedback mechanisms so that feedback from appeals can be used to refine the AI tools and improve accuracy.

2. AI tools alone may not be used by payors to deny PA requests.
    a. A PA decision made by AI alone cannot be used to override point-of-care clinical decision-making.
    b. Among the highest hopes for use of AI in healthcare has been the ability to create truly personalized care plans and decisions that consider all the variables in a patient's medical condition and circumstances. Instead, AI is being used by payors to do the opposite and create an approach that results in generalizations instead of person-centered approaches to care, delaying or denying delivery of care.
    c. When PA denials are appealed, adding to the healthcare system's excess documentation burden, over 80% of the denials are over-turned, demonstrating the initial PA request was medically necessary. AI has the potential to further exacerbate this problem by increasing the throughput of PA requests into the appeals queue.

3. Work with the Assistant Secretary of Technology Policy (ASTP) to improve interoperability standards for integrating AI tools with the Electronic Health Records (EHRs) such that AI tools within the EHR or clinical ecosystem can easily be used by clinicians to fill out PA requests.

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[2] 25x5 Recommendations to Reform Prior Authorization. https://amia.org/public-policy/public-comments/25x5-recommendations-reform-prior-authorization.

[3] Documentation Burden | Agency for Healthcare Research and Quality (AHRQ). June 3, 2022.

4. Regardless of the process for decision-making, reinforce transparency requirements of medical necessity criteria being used as the foundation for decision-making while recognizing that individual patient symptoms, conditions and demographics will not always fit cleanly into standard criteria.

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Thank you for your time and consideration of these comments. If you have questions or require additional information, please contact Reva Singh, AMIA's Vice President of Public Policy, rsingh@amia.org.

Sincerely,

Eileen Koski
Chair of the Public Policy Committee