Alliance of Specialty Medicine

Sound Policy. Quality Care.

January 27, 2025

Jeff Wu
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2026 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs Proposed Rule (CMS-4192-P)

Dear Acting Administrator Wu:

The Alliance of Specialty Medicine (the "Alliance"), representing more than 100,000 specialty physicians from sixteen specialty and subspecialty societies, is deeply committed to improving access to specialty medical care by advancing sound health policy. On behalf of the undersigned members, we write to provide feedback on proposed policy changes for Medicare Advantage (MA) and Part D prescription drug plans and their impact on access to specialty medical care.

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

To promote equitable access to care, CMS proposes regulatory changes that would require MA organizations to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. In support of these requirements, CMS also proposes to adopt definitions for "automated system," and "patient care decision support tool," as outlined below:

- Automated system: *"any system, software, or process that uses computation as whole or part of a system to determine outcomes, make or aid decisions, inform policy implementation, collect data or observations, or otherwise interact with individuals or communities or both. Automated systems include, but are not limited to, systems derived from machine learning, statistics, or other data processing or artificial intelligence techniques, and exclude passive computing infrastructure. 'Passive computing infrastructure' is any intermediary technology that does not influence or determine the outcome of decision, make or aid in decisions, inform policy implementation, or collect data or observations, including web hosting, domain registration, networking, caching, data storage, or cybersecurity. As used in this part, automated systems that are within the scope of this definition are only those that have the potential to meaningfully impact individuals' or communities' rights, opportunities, or access."*

- Patient care decision support tool: *"any automated or non-automated tool, mechanism, method, technology, or combination thereof used by an MA organization to support clinical decision-making in its health programs or activities."*

The Alliance appreciates and supports CMS' proposals, which expand on prior finalized policies that aim to preserve equitable access to MA services. We appreciate and agree with CMS' clarification that AI tools, including but not limited to, machine learning, patient care decision support tools, and/or other algorithmic tools, must not violate CMS existing regulations rules, and where such tools are used, it is the responsibility of the MA plan to ensure compliance with all existing Medicare policies.

Finally, ***we strongly urge CMS to use its oversight and enforcement authority under 42 CFR part 422, subparts K and O, to conduct program audits and compliance activities as well as issue compliance and enforcement actions to MA organizations who fail to comply with CMS' regulations***. As we have suggested in other areas, ***enforcement must include financial penalties, and where plan behavior is more egregious, termination from the MA program altogether***.

Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures (§ 422.137)

To ensure the use of prior authorization does not disproportionately impact underserved populations, CMS proposes to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the following:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.
- The percentage of standard prior authorization requests that were denied, reported by each covered item and service.
- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.
- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

The Alliance supports these proposals and urges CMS to make them final. These proposed reforms are particularly important for specialty physicians and their patients, who are often subject to prior authorizations and other utilization management (UM) tactics, and very timely given the anticipated growth in Medicare Advantage, where more than 60% of beneficiaries are expected to be enrolled by 2032.[1]

[1] https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/

Similarly, we understand that CMS' current policies and aforementioned proposals do not apply to any medications, whether self- or physician-administered. ***Until the Agency has adopted policies to address challenges with other forms of utilization management, including step therapy and non-medical switching, we again ask CMS to rescind its 2018 step therapy memorandum***. Absent this action, ***at a minimum, CMS must incorporate step therapy and non-medical switching into the aforementioned health equity metrics***, given they equally delay patient care and pose significant barriers to treatment, particularly in specialties where the majority of treatments are subject to these tactics.

Finally, as a way to further ease burdens on patients and specialists, ***we urge CMS to extend previously finalized electronic prior authorization standards to include both physician- and self-administered drugs***. Medications represent a significant proportion of prior authorization requests, often requiring practices to hire full-time staff to work solely on obtaining them and delaying beneficiaries' access to care that is almost always approved. Implementing standards that facilitate the electronic exchange of information would increase efficiency, reduce system costs, and, most importantly, ensure patients receive timely access to care.

Medicare Advantage Network Adequacy (§ 422.116)

CMS proposes changes to its network adequacy requirements for Medicare Advantage plans, including a proposal to codify "valid rationales" for exception requests and eliminating those that are not valid (i.e., that the "*provider does not contract with any organization or contracts exclusively with another organization*" (meaning MA organization)). ***While the Alliance supports this proposal, we are concerned that CMS has taken no other meaningful steps to ensure enrollees have robust access to specialty medical care and treatment.***

As we have shared in numerous prior comments, most enrollees do not realize the limitations of their plan's provider network until they are faced with a critical need for specialty medical services. And, despite our repeated requests, CMS continues to base network adequacy on a narrow list of primary specialties and not any subspecialists[2] and does not require plans to provide an explanation or rationale for network exclusion or termination decisions. ***We again ask CMS to act on the following recommendations aimed at improving access to specialty and subspecialty care:***

- ***Require MAOs to accurately identify physician specialties and subspecialties when calculating network adequacy using the Healthcare Provider Taxonomy code set developed by the National Uniform Claims Committee,[3] which distinguishes between specialty and subspecialty physicians.***
- ***Develop Quality Rating System (QRS) measures for plans that:***
    - ***Account for specialty and subspecialty care, which may include aligning QRS measures with physician-level performance metrics in CMS' Quality Payment Program; and***
    - ***Tie maintaining an adequate network to a health plan's quality rating.***
- ***Require plans to provide detailed information on the cause for exclusion or termination from the network, including options for entering or re-entering the network.***
- ***Require plans to maintain accurate, real-time provider directories that include specialty and subspecialty designations.***

---

[2] According to its most recent guidance, CMS measures 27 provider specialty types and 13 facility specialty types to assess the adequacy of the network for each service area. https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance06132022.pdf

[3] https://taxonomy.nucc.org

As discussed in the rule, the Alliance also believes that CMS should conduct network adequacy reviews at the plan benefit package level rather than the contract level, and consistent with the above request to include all specialty and subspecialty providers as part of these reviews, supports CMS' proposals for applying existing time and distance standards at the plan benefit package level.

Format Medicare Advantage (MA) Organizations' Provider Directories for Medicare Plan Finder (§§ 422.111 and 422.2265)

To enhance the usability of the Medicare Plan Finder (MPF) and improve the accuracy and accessibility of MA provider directories to support informed decision-making and market competition, CMS proposes requiring MA organizations to submit accurate provider directory data for integration into MPF by the 2026 Annual Enrollment Period and to attest to the accuracy of the data. Specifically, CMS proposes to:

- expand on the existing requirements applicable to MA organizations regarding their provider directories at a newly established § 422.111(m) to include a new provision to require MA organizations to submit or otherwise make available their plan provider directory data, that is the requirements found under § 422.111(b)(3)(i), available to CMS/HHS in a format, manner, and timeframe that CMS/HHS determines in order for the MA organization's provider directory data to be integrated online by CMS/HHS for display on MPF.
- include a requirement that MA organizations update the provider directory data that is submitted or otherwise make available to CMS for this purpose within 30 days of receiving information from providers of a change, which mirrors the current standard for updating provider directory data found under § 422.2267(e)(11).
- add new subparagraph § 422.111(m)(4), which would require an MA organization to attest that the information being submitted to CMS/HHS under this new requirement is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements at § 422.116(a)(1)(i).

CMS notes that its proposals closely mirror the provider directory submission requirements at 45 CFR § 156.230(c) for Qualified Health Plan (QHP) issuers on the federally facilitated Exchange (FFE).

As noted above, we continue to be disappointed that CMS has not meaningfully addressed challenges enrollees' face in accessing specialty medical care. The recommended actions listed in the section above would further improve and enhance provider directories for the benefit of potential and current MA plan enrollees.

Promoting Informed Choice – Expand Agent and Broker Requirements regarding Medicare Savings Programs, Extra Help, and Medigap (§§ 422.2274 and 423.2274) and Enhancing Review of Marketing & Communications (§§ 422.2260 and 423.2260)

Based on its review of many marketing and enrollment audio calls, CMS has found that agents and brokers fail to ask pertinent questions to help beneficiaries enroll in plans that best fit their health care needs (e.g., failing to confirm whether a preferred provider was in-network, to discuss pharmacy networks, or to address the trade-offs between premiums and out-of-pocket costs). Other feedback provided to the Agency suggest that beneficiaries are often unaware of their guaranteed issue (GI) rights or the rules around Medigap underwriting when switching from an MA plan to Traditional Medicare, leading to significant confusion.

As a reminder, CMS previously finalized a list of topics that must be discussed with beneficiaries during the marketing and sale of an MA or MA-PD plan or PDP and prior to their enrollment in a new plan. Now, CMS is proposing additional discussion topics based on information gaps it has identified. Specifically, and along with other regulatory text changes, CMS proposes to:

- modify §§ 422.2274(c)(12) and 423.2274(c)(12) to include low-income subsidy (LIS) eligibility criteria as an additional topic that agents and brokers must address before enrolling a beneficiary in an MA, MA-PD, or Part D plan.
- create §§ 422.2274(c)(12)(v) and 423.2274(c)(12)(iv) to add the phrase 'resources for state programs, including Medicare Savings Programs,' to the existing list of required topics.
- require that an agent or broker convey that the beneficiary generally has a 12-month period under Federal law in which they can disenroll from the MA plan and switch back to Traditional Medicare and purchase a Medigap plan with Medigap Federal GI rights.

The Alliance strongly supports these proposals. Enrollees report being grossly misled by plan representatives (i.e., brokers and agents) about the impact of their enrollment, particularly when it comes to whether their physicians are in the plans network, and whether their medications will be covered or subject to utilization management policies. Once they realize the difficulty in continuing with their current care plan and physician, they attempt to return to traditional Medicare, but often cannot pass the medical underwriting required by supplemental insurers due to their conditions. These enrollees find themselves "stuck" in an MA plan that does forces them to find a new physician, new therapy, and frequently, winds up being cost-prohibitive despite promises of substantial savings and enhanced benefits.

In addition to the proposals CMS has outlined above, ***we strongly urge CMS to use its oversight and enforcement authority to impose financial penalties, and in some cases, termination from the MA program, for misleading marketing practices.***

Finally, ***we support CMS proposed revisions to its marketing and communications standards and definitions***, as follows:

- eliminating the content standard, as described in §§ 422.2260(2) and 423.2260(2) of the marketing definition, so that all communications materials and activities that meet the existing intent standard are considered marketing for purposes of CMS's MA and Part D marketing and communications regulations.
- conforming edits to the definition of 'Advertisement (Ad)' in §§ 422.2260 and 423.2260 to align with the proposed updates to the definition of marketing.

These policies, if finalized, will greatly improve transparency in marketing practices by plans.

Enhancing Rules on Internal Coverage Criteria (§ 422.101)

CMS proposes several policies aimed at building upon and enhancing its previously finalized policies related to the use of internal coverage criteria. Specifically, CMS proposes to define the phrase "internal coverage criteria," establish policy guardrails to preserve access to basic benefits, and add more specific rules about publicly posting internal coverage criteria content on MA organization websites. ***The Alliance strongly supports these proposals.*** We are particularly supportive of the proposed prohibitions (i.e., coverage criterion that does not have any clinical benefit, and therefore, exists to reduce utilization of the item or service; coverage criterion that is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination as required) which have been challenging for enrollees that require specialty medical care. ***We urge CMS to clarify that these policies would equally apply to medications, both self- and provider-administered.***

Formulary Inclusion and Placement of Generics and Biosimilars

Given challenges accessing biosimilar and other medications, CMS seeks comment on: (1) the prevalence of manufacturer rebates and the extent to which such rebates influence formulary decisions that reduce Part D beneficiaries' access to generics, biosimilars, and other lower cost drugs; and (2) whether further programmatic actions within CMS's current statutory authority are necessary to prevent Part D formularies from excluding or disfavoring coverage of generics, biosimilars, and other lower cost drugs. CMS may consider this feedback for future rulemaking.

Biosimilar medications are critical to many Alliance specialties in the care and treatment of patients with autoimmune diseases managed by specialty medical physicians. Unfortunately, they are increasingly challenging to access because – to secure "fail first" positioning – manufacturers have "over-rebated" these medications to the point that their average sales price (ASP), on which Part B reimbursement is based, has diminished well below the cost borne by physicians to purchase them. Physicians that typically administer biosimilars in the office must now refer their patients who have relied on these drugs to the more expensive hospital setting for care; they can no longer afford to purchase these medications in the current fiscal environment of high inflation and declining Medicare payment rates, nor can they offer an alternative medication given step therapy requirements. Referring enrollees to the hospital setting for infusions increases program spending and enrollee out-of-pocket costs, and more importantly, disrupts care continuity and puts enrollees with weakened immune systems at greater risk of contracting serious infections. Until Congress adjusts the ASP methodology to address reimbursement challenges, ***CMS must withdraw the 2018 step therapy memorandum and allow enrollees to by-pass "fail first" requirements and access an alternative therapy when the biosimilar is "underwater."***

Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System (§§ 422.166 and 423.186)

The Alliance has previously commented on additional quality measure concepts that would improve access and quality, including measures that would transform care and drive quality through value-based initiatives. We continue to believe additional measures are essential to address challenges observed in MA and urge CMS to:

- ***Establish a star measure awarding points to MA plans that maintain an adequate network of specialty and subspecialty physicians.*** As we explain in our comments, MA plans impede access to medically necessary services by maintaining "narrow networks" that prevent specialty and subspecialty physicians from participating as in-network providers. Specialty and subspecialty physicians continue to be eliminated from MA plans, frequently in the middle of a plan year, leaving enrollees with limited or no access to care for chronic health conditions, such as glaucoma, macular degeneration, rheumatoid arthritis, lupus, and skin cancer, which are best managed by specialists with expertise in those disease areas. When a plan does not have an adequate network of specialty and subspecialty providers, it is impossible for seniors to access the full range of providers and treatments they may need, thus diminishing quality and outcomes. Often, enrollees may not realize they need specialty medical care until after they have enrolled in a plan and new symptoms present or an existing condition worsens. Establishing a measure tied to network adequacy would incentivize MA plans to retain specialty and subspecialty physicians as "in-network."
- ***Establish a star measure based on a survey of physicians' experiences with MA plans, which could be developed in collaboration with the Alliance and other professional associations.*** Questions should focus on the following:

- Network adequacy, including the accuracy of physician directories and physician termination and reinstatement practices;
- Payment and reimbursement practices, including the sufficiency of payment rates, the volume of denials and post-payment medical reviews, and other tactics that deny or slow payment after services are rendered;
- Utilization management, including prior authorization practices, step-therapy requirements, non-medical switching of medications, and other administrative barriers that inappropriately diminish or slow beneficiary access to medically necessary diagnostic and therapeutic services and treatment; and,
- Other administrative burdens, including the number and type of medical record documentation requests.

Other Concerns

CMS previously sought feedback on the nature and extent of medical record documentation requests by MA plans, including ideas to address this burden. Specialty physicians report that MA plans continue to misrepresent medical record requests to specialty physician practices as CMS-initiated mandatory Risk Adjustment Data Validation (RADV) audits. In reality, these plan-initiated requests are designed to identify additional diagnosis codes, a problem that was highlighted by the Office of Inspector General in 2019.[4]

As we have previously shared, the scope and volume of medical record requests are tremendous, with some seeking hundreds of records per physician. Furthermore, these requests include untenable submission deadlines, sometimes just days after the request. Practices that fail to comply have been told their contracted rates will be lowered, or worse, that they may be terminated as in-network providers.

To address these issues, ***we urge CMS to require MA plans to:***

- ***Follow a standardized process for all medical record requests;***
- ***Clearly identify the nature of their medical record request (e.g., RADV, other purpose, etc.) and provide written documentation when requests are mandated as part of CMS-initiated audits;***
- ***Provide reasonable deadlines for medical record submissions, as well as a process for extending the submission deadline for extenuating circumstances;***
- ***Limit the number and volume of medical record requests (e.g., no more than once per year and no more than 20 records per physician);***
- ***Allow practices to submit medical records through a secure web portal, on CD/DVD, or by fax when possible; and***
- ***Reimburse practices for completing medical record requests at a rate no less than is set under State law.***

***

We appreciate the opportunity to provide feedback on the proposals in this rule that aim to improve access to specialty and subspecialty care. Should you have any questions or would like to meet with the Alliance to discuss these recommendations further, please contact us at info@specialtydocs.org.

Sincerely,

[4] https://oig.hhs.gov/oei/reports/OEI-03-17-00474.pdf

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American Academy of Otolaryngology – Head and Neck Surgery
American College of Mohs Surgery
American College of Osteopathic Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society of Dermatologic Surgery Association
American Society of Echocardiography
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society
Society of Interventional Radiology