Sound Policy. Quality Care.

February 13, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Dear Administrator Brooks-LaSure,

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 Organizations (MAOs) and their impact on access to specialty medical care.

Utilization Management Requirements

The Alliance greatly appreciates CMS' proposals to meaningfully improve utilization management (UM) in the Medicare Advantage (MA) program and urges CMS to finalize these policies. These proposed reforms come after years of provider and patient advocacy and multiple agency initiatives to reduce administrative burdens. We are extremely pleased that CMS has heard our concerns and recognizes the need to take action. These proposed reforms are particularly important for specialty physicians and their patients, who are often subject to prior authorizations and other UM tactics. They are particularly timely as the MA program continues to grow, with 60% of beneficiaries expected to be enrolled by 2032.[1] Again, ***we laud CMS for the proposed policies in this rulemaking and urge their finalization.***

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

Generally, UM processes delay enrollee access to medically necessary care and treatments and create considerable, unnecessary administrative burdens for specialty physicians. Equally concerning, these tactics are a leading cause of physician burnout, forcing many to retire early or leave the practice of medicine. While UM processes, such as prior authorization, may be appropriate in some situations, the Office of Inspector General found that MA plans use prior authorizations to deny *medically necessary* care, that is, care that met coverage requirements under traditional Medicare and was supported by the enrollee's medical records.

We understand that CMS' UM proposals for "items and services" will, if finalized, apply to physician-administered medications covered by MA plans but not to pharmacy benefit drugs covered by Part D (whether as part of an MA plan or as a standalone plan)*. *While patients needing provider-administered medications welcome these proposals, the Alliance urges CMS to institute more robust continuity of care provisions for Part D medications. Additionally, the Alliance asks CMS to rescind its 2018 step therapy guidance empowering MA plans to apply step therapy to Part B medications or at least ensure that the memo's continuity of care provisions are consistent with those in the proposed rule, as discussed in detail below. For many specialists and their patients enrolled in MA plans, prior authorization, step therapy, and non-medical switching are constant barriers to medically necessary drug therapies, regardless of whether these drugs are covered via the medical or pharmacy benefit. Enrollees that have complex, chronic diseases — including rheumatoid and psoriatic arthritis, ulcerative colitis and inflammatory bowel disease, and macular degeneration — require complex therapies to manage their condition effectively. Absent these therapies, patients with the aforementioned autoimmune diseases will face debilitating pain, and those with macular degeneration will face blindness. In fact, an article in PharmacoEconomics concluded that *"[c]ompared with patients in plans without access restrictions or with [prior authorization] only, [rheumatoid arthritis] and [psoriatic arthritis]* ***patients in insurance plans with step therapy had lower odds of treatment effectiveness*** *[emphasis added], mainly due to lower odds of adhering to treatment, during the 12 months following subcutaneous [biologic disease-modifying antirheumatic drugs] initiation."*[2]

CMS claims that step therapy puts MAOs in a stronger position to negotiate lower prices with drug manufacturers and reduce cost-sharing for enrollees. However, a 2020 *Health Affairs* article provides more color to this assertion, explaining that *"[a]pplying rebates to reduce premiums saves an equal amount for all enrollees, but* ***basing cost sharing on the list price of drugs (as is done in Part D) increases out-of-pocket costs for those using drugs with rebates, especially for those patients taking highly rebated drugs*** [emphasis added]."[3] Some of the most highly-rebated drugs are specialty medications, including the biologics used to treat the aforementioned conditions. Prohibiting step therapy on these medications would greatly improve access to them.

As noted, the Alliance has previously asked CMS to withdraw its 2018 step therapy guidance to MAOs, highlighting the problems associated with the policies described in the memo and how they harm enrollees, especially those who rely on complex medications that are most frequently subject to step therapy.[4] This

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[2] https://link.springer.com/epdf/10.1007/s41669-019-0152-1?author_access_token=wn16qxqmbu8Y_A-omSP0Zve4RwlQNchNByi7wbcMAY7RP9W-hCIFOibQHi4l6PB9b5joHSXGA0k7qbFjo6QnM0Ej28kBPej-vh8ykFXYLJMUTTqkvuDVm1VBKf0Bb_cQSxdQGJP3vTIux9AOlxUCUQ==
[3] https://www.healthaffairs.org/do/10.1377/forefront.20200911.841771/
[4] https://specialtydocs.org/wp-content/uploads/2019/05/Alliance_Part_B_Step_Therapy_Letter_Sept_2018.pdf

rulemaking presents an opportunity for CMS to withdraw the memo and reinstate the prohibition on step therapy for Part B drugs in MA. If CMS does not wish to withdraw the memo at this time, at a minimum, the agency should update the memo to be expressly consistent with the continuity of care policies (once finalized). That will streamline these patient protections by ensuring that any new enrollee undergoing an active course of treatment cannot be subjected to new or additional UM requirements, such as step therapy, for the first 90 days of enrollment. Such a policy would be consistent with the 2018 memo, which stresses the importance of continuity of care and prohibits step therapy for enrollees who are actively being treated with the affected product but stops short of clarifying that this provision applies to all enrollees — both existing enrollees and new enrollees who "come in with" an ongoing prescription covered by their previous plan.

Again, we appreciate the proposed policies, which respond to the patient and medical communities' concerns about the impact of utilization management on patient care and physician workforce. We urge CMS to finalize these policies but include all drugs — both medical and pharmacy benefits — in the final rule. We also urge CMS to withdraw the 2018 step therapy memo or make the aforementioned clarification to ensure that continuity of care is protected.

Gold Carding

Among its UM proposals, CMS encourages MA plans to adopt gold-carding programs. The agency notes that gold-carding enables certain providers to be exempt from prior authorization and provides a more streamlined medical necessity review process for providers who have demonstrated compliance with MA plan requirements. These programs also alleviate the burden associated with prior authorization and could facilitate more efficient and timely delivery of health care services to MA enrollees. ***We agree with CMS about the benefit of gold-carding programs but strongly urge the agency to establish requirements for them, as most plans are unlikely to do so on their own without a specific mandate.***

Review of Medical Necessity Decisions

CMS proposes to revise its regulations by adding that the physician or other appropriate health care professional conducting a medical necessity review for the MAO must have expertise in the field of medicine appropriate for the item or service being requested before the MAO issues an adverse decision. CMS' policy aim is appreciated, but ***we strongly urge the agency to require reviewers to be licensed physicians in the same or similar specialty or subspecialty as the treating physician.***

Most specialists and subspecialists have participated in so-called "peer-to-peer" UM review processes, only to be told by a non-physician or physician with limited or no expertise in the specialty or the delivery of the service subject to UM that the patient does not appear to be a candidate for the service. Although allied health professionals play a critical and necessary role in health care, it is inappropriate to, for example, have a nurse practitioner determine the medical necessity of intravitreal injections requested by a retina specialist for patients with neovascular (wet) macular degeneration, particularly as these health care professionals are not generally authorized to administer these medications.[5] It would also be inappropriate for a primary care

[5] The FDA label for EYLEA states that the medication "must only be administered by a qualified physician." https://www.regeneron.com/downloads/eylea_fpi.pdf

physician to determine the necessity of spine surgery or the medical necessity of biologic medication administrations by rheumatologists for rheumatoid arthritis.

We ask CMS to modify the regulatory language in the final rule to reflect that reviewers must be licensed physicians in the same or similar specialty or subspecialty as the treating physician.

Medicare Advantage Network Adequacy: Access to Services

CMS confirms MAOs' obligation to provide access to appropriate providers, including credentialed specialists, for medically necessary treatment and services and proposes to add to its regulations that MAOs must arrange for any medically necessary covered benefit outside of the plan provider network at in-network cost-sharing when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. The Alliance appreciates the intent behind this proposal but notes that it will not meaningfully improve access to medically necessary services. Many MAOs already have processes in place to provide access to out-of-network care, which are fraught with obstacles and unnecessary hurdles, prompting many enrollees to delay or forego needed care. The more appropriate solution to ensuring access to medically necessary covered benefits is requiring MAOs to have an adequate network of providers, including specialists and subspecialists.

As the Alliance has previously shared, ***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.*** CMS recognizes the importance of a robust MAO network to ensure access to care, particularly for underserved populations, but leverages its authority to "pick and choose" which specialists offer the most value based on the Administration's policy priorities rather than the health care needs of enrollees. This is evidenced by proposals elsewhere in this rule that would add behavioral health specialties to network adequacy requirements and revise provider directory requirements to include new elements (i.e., provider's cultural and linguistic capabilities, provider's waived to treat patient with medications for opioid use disorder), despite CMS data showing a very low prevalence of drug and substance abuse among the Medicare population, but extremely high rates of other conditions, such as heart disease, arthritis, and diabetes.[6]

Despite the provider community's repeated attempts to secure improvements to MAO network adequacy criteria, CMS continues to base MAO network adequacy on a narrow list of primary specialties and not any subspecialists.[7] In addition, CMS fails to require MAOs to provide physicians with any explanation or rationale for their exclusion or termination from the MAO network, including options for entering or re-entering networks. CMS has not responded to any of our requests through the annual notice-and-comment rulemaking, making it difficult to understand the agency's rationale for not adopting any of the recommended actions.

MAOs require the full range of specialty and subspecialty providers — those *best* equipped to manage a growing population of seniors with multiple chronic and acute health conditions — which will help reduce program costs and improve enrollee health and quality of life. To that end, ***we again ask CMS to act on the following recommendations aimed at improving access to specialty and subspecialty care:***

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[6] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Downloads/cc_charts.zip

[7] 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

- ***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,[8] 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.***

Enrollee Notification Requirements for Medicare Advantage Provider Contract Terminations

The Alliance appreciates CMS' proposals to establish enrollee notification requirements for MA provider contract terminations. However, we have asked across multiple rulemaking cycles that CMS establish *provider* notification requirements, so physicians who are either excluded or terminated from an MAO network (1) understand the rationale behind the MAO decision excluding or terminating them from the network, including any performance metrics used and the associated methodology, and (2) are provided options for entry or re-entry in the MAO network.

For many specialists and subspecialists, particularly in areas with high MAO penetration, participation in the network is essential to having a patient panel that ensures practice viability. However, specialty physicians — especially subspecialists — are frequently blocked or eliminated from networks without explanation. In fact, one subspecialty — Micrographic Dermatologic Surgeons (aka Mohs surgeons) — was wholly barred from MA networks in Missouri for several years.

It is not unreasonable for physicians to expect that adverse decisions related to their in-network participation are clearly explained and offer an opportunity for recourse. ***We again urge CMS to establish provider notification requirements that afford physicians an explanation for why they have been excluded or terminated from the network, including any performance metrics used and the associated methodology, and are provided options for entry or re-entry into the MAO network.***

Medicare Advantage and Part D Marketing

The Alliance supports CMS' reforms for MA and Part D plan marketing and urges the agency to finalize these policies. CMS shared in its 2023 Advance Notice that it reviewed MA plan complaints, finding that they "primarily originate from beneficiary confusion around misleading marketing materials and/or inadequate training of marketing personnel." Through policy proposals outlined in this rulemaking, CMS is meaningfully addressing the concerns raised, including those of specialty medical providers. We noted how many of our patients with specialty medical conditions learn after enrolling in an MA plan that their specialist is not in the

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

network, and their medications are not on the plan's formulary or are cost-prohibitive. This is particularly common for patients with autoimmune diseases, such as rheumatoid arthritis.

CMS proposals to modify the pre-enrollment checklist by requiring plans to explain the implications of choosing an MA or Part D plan and that they are better informed about the details surrounding the plan for which they are enrolling (e.g., whether their doctors are in the network, whether their medications are on the plan's formulary, etc.), are important improvements. ***We urge CMS to finalize these policies and to continue providing necessary oversight.***

Changes to an Approved Formulary

The Alliance agrees with CMS that formulary stability is extremely important to ensuring enrollees maintain access to a medication(s), which may be what leads them to select a specific MA plan. We also appreciate that CMS recognizes how formulary changes can lead to non-medical switching, which poses undue threats to enrollee health and outcomes. As many of our member organizations rely on biologic medications to treat specialty health conditions, we greatly appreciate CMS's proposal to limit reference biological product substitutions to *interchangeable* biological products. ***We urge CMS' to finalize its proposed provisions for the approval of formulary changes.***

Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

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 MAOs 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. As noted earlier, 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 requests are usually plan-initiated and designed to identify additional diagnosis codes, which increase the MA plan "risk score," with corresponding increases in their Medicare payments.

Preparing for these deceptive audits is daunting for already-burdened physician practices. More importantly, plans are overreaching to establish additional diagnoses. These concerns are not new to CMS, its policy advisors, or oversight agencies, and we believe this burden will increase now that CMS has issued final rules updating the RADV program.[9]

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.***

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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.

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[9] https://www.cms.gov/newsroom/press-releases/cms-issues-final-rule-protect-medicare-strengthen-medicare-advantage-and-hold-insurers-accountable

Sincerely,

American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
North American Spine Society