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January 22, 2025

CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4208-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via <https://www.regulations.gov>

Re: CMS-4208-P 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,

On behalf of the American Academy of Dermatology Association, thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) proposed rule that would revise the Medicare Advantage (MA) Program, the Medicare Prescription Drug Benefit Program (Part D), the Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE).

The American Academy of Dermatology Association (Academy) is the leading society in dermatological care, representing more than 17,000 dermatologists nationwide. The Academy is committed to excellence in the medical and surgical treatment of skin disease; advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of skin disease.

The Academy appreciates CMS' efforts to evaluate and update MA, Part D, and Medicare cost plans, particularly on promoting informed choice through marketing and communications,

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health equity, drug coverage, utilization management, and network adequacy, and offers the following comments on proposals to these programs.

Promoting Informed Choice - Medicare Advantage Network Adequacy

The Academy believes provider networks should serve patient needs, specifically by ensuring that patients have adequate and timely access to providers with appropriate training and specialty or subspecialty expertise.

CMS notes that it is considering conducting network adequacy reviews at the MA plan benefit package level rather than continuing its current practice of conducting the reviews at the contract level. **AADA supports this change in methodology, which we believe would better ensure that patients in each plan benefit package service area have meaningful access to robust provider networks.**

Moreover, AADA highlights the need to further strengthen network adequacy requirements by requiring plans to consider availability of subspecialty providers. Lack of accountability for including dermatologic subspecialties can result in significant access problems as each subspecialty within dermatology provides unique services to distinct patient populations with varying care needs. **CMS should therefore establish network adequacy standards for dermatologic sub-specialties.**

Furthermore, MA plans should be required to publicly notify CMS, plan members and its provider network, of its rationale for significant reductions or closures of their networks. Physician practices have reported MA plans increasingly reducing or closing their networks without clear explanation, thereby impacting patient access. **We also call upon CMS to implement guardrails for MA plans to provide a meaningful appeal process whenever a physician is terminated or denied application to the provider network.** The appeal review should consider whether the removal of the physician from the network would result in network inadequacy, and this should be a basis for reinstatement. Additionally, plan members should be allowed to stay with a physician until the next open enrollment period if the provider is eliminated from a network mid-year.

Finally, AADA supports additional changes that would increase access to dermatologic care for MA enrollees. For example, we urge CMS to support the principle that any willing, qualified physician should be allowed to participate in MA plan managed care networks. The Academy also supports all patients having direct access to dermatologic care delivered by dermatologists. Direct access to dermatologists is the easiest and most cost-effective method of providing quality dermatologic services in managed care settings.

Promoting Informed Choice – Format Provider Directories for Medicare Plan Finder (MFP)

CMS is proposing to require MA organizations to submit provider directory data for integration into the MFP and attest that such information is accurate and consistent with data submitted to comply with CMS's MA network adequacy requirements. We appreciate CMS's effort to provide consumers ready access to provider network information and ensure provider directories are accurate. As CMS considers how to best balance the need for accountability for accurate data with the burden of the attestation, we are concerned about potential downstream impacts to physician practices imposed by MA carriers. We continue to hear from dermatology practices reporting increasing demands from MA plans to provide information for a range of reasons, for example related to credentialing, prior authorization, and step therapy, as well as to justify the plans' risk scores. To force compliance, health plans impose penalties that impact payments or network participation. There is concern that MA plans will employ similar harsh measures on physician practices to support the provider directory attestation. CMS and payers need to recognize that poorly designed information requirements and administrative burdens increase practice administrative costs, take clinical staff away from patient care, and contribute to professional burnout. In order to prevent the shifting of the attestation burden to physician practices, **we encourage CMS to provide oversight to ensure that MA plans do not impose financial penalties or undue administrative burdens on physician practices in support of their obligation to attest to the accuracy of their provider network data.**

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

We applaud CMS' decision to revise the required metrics for the annual health equity analysis of the use of prior authorization to require the metrics be reported by each item or service, rather than aggregated for all items and services, and **we recommend that CMS finalize this policy as proposed.** This aligns with the Academy's prior recommendations for prior authorization reporting by payers. This deeper level of granularity will ensure that potential disparities can be more readily identified. **Similarly, we urge CMS to mandate that MA plans also publicly report prior authorization data for each item and service, rather than at the aggregate level as currently required.** Such increased transparency will enable stakeholders to review and assess plans' use of utilization management tools and their impact on access to care.

Clarifying MA Organization Determinations to Enhance Enrollee Protections in Inpatient Settings

We strongly support CMS' intent that once prior authorization of an inpatient stay is granted, the payer cannot deny coverage later (Section 422.138 paragraph (c)). Specifically, CMS proposes that "if an MA organization approved an inpatient hospital admission under the rules at § 412.3(d)(1) or (3), any additional clinical information obtained after the initial organization determination cannot be used as new and material evidence to establish good cause for

reopening the determination.” CMS’s proposal ensures physicians and patients can rely on such approvals prior to inpatient admissions. All too often, MA plans have attempted to obfuscate prior authorization approvals to justify later denying care and payment. The AADA appreciates CMS attempt to halt this practice and encourages CMS to limit MA plan’s ability to use a “good cause” exception.

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

CMS proposes to ensure services are provided equitably irrespective of delivery method or origin, whether from human or automated systems. CMS also clarifies 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.

The Academy supports the development of artificial intelligence (AI) technology provided that it is designed and evaluated in a manner that enables the delivery of high-quality care to patients. However, AI should not impede access to medically necessary and appropriate dermatologic care.

As the validity and generalizability of AI technology are dependent on the quality and source of the data that are used to develop AI models, data used to train AI models must be fully representative of the target population and auditable, and all data sources must be clearly and accurately identified.

Enhancing Rules on Internal Coverage Criteria

The Academy supports expanded efforts to preserve access to basic benefits for MA enrollees. To that end, we support CMS’ proposals to prohibit the use of coverage criteria when they do not have any clinical benefit and merely exist to reduce utilization of an item or service and when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination. **With respect to the latter prohibition, we encourage CMS to specify that any internal coverage criteria that relies on AI cannot be used to deny coverage or payment without having further review by a physician of the same specialty.** The Academy also supports CMS’ proposals to update public availability of information related to plans’ internal coverage criteria, which we agree will facilitate stakeholders’ ability to access and understand the criteria that plans apply.

Formulary Inclusion and Placement of Generics and Biosimilars

CMS highlights concerns that Part D sponsors and their pharmacy benefit managers (PBMs) engage in formulary and manufacturer rebate practices that favor brand-name drugs and reference products over generics, biosimilars, and other lower cost drugs. In light of these concerns, CMS clarifies that Part D plan formularies must provide broad access to generics, biosimilars, and other lower cost drugs as a necessary component of having a reasonable, appropriate, and cost-effective drug utilization management program. Further, CMS plans to check that Part D sponsors provide broad access to generics, biosimilars, and other lower cost drugs, including reviewing utilization controls, as part of its formulary review process.

The Academy applauds CMS' efforts to ensure beneficiaries have broad access to generics, biosimilars, and other lower cost drugs. The Academy affirms that Americans should have access to affordable, quality dermatologic health care, including medications and treatments. We oppose the imposition by insurance companies of restrictive formularies that exclude medications considered necessary in the provision of high-quality medical care and believe that strategies used to tier drugs should take into account the clinical efficacy as established through scientific evidence, the equivalence of alternatives, and the cost implications to patients. Further, we have called for more transparency and monitoring of financial arrangements with PBMs to avoid a conflict of interest when developing formularies and/or tiers. Considering that multiple recent reports have raised concerns about formulary placement and rebate practices, **the Academy supports CMS' plans to review access to generics, biosimilars, and other lower cost drugs, and to use its authority to negotiate the terms and conditions of submitted Part D sponsors' bids if formularies do not appear to provide broad access.**

Reducing Burden of Medicare Advantage Medical Record Requests

The Academy is concerned about substantial burden imposed upon physicians by MA plans related to medical record requests. These requests are numerous and place a significant burden on our members, especially for those who are solo practitioners or part of a small practices as they have limited resources that can be diverted from patient care.

MA plans routinely request an excessive volume of records, with members reporting that requests for 100 or more records are not uncommon. To accommodate these requests, office staff must dedicate time and financial resources to research, abstract, print or copy, and transmit records – activities that are particularly disruptive for small practices. In addition to the large volume of requests, MA plans routinely impose additional requirements or restrictions related to the production of the requested records that further place burden on physician practices. For example, MA plans often impose unreasonable and rigid timelines for returning requested records, with limited flexibility for practices facing extenuating circumstances. MA plans may also limit providers' ability to submit medical records through submission methods

that are least burdensome to practices. In addition, practices must also contend with an array of disparate processes for receiving, processing, and submitting medical record requests across all of their contracted MA plans.

Finally, MA plans often fail to provide a clear rationale for requesting medical records. While we are aware of MA plans' requirements under CMS' Risk Adjustment Data Validation (RADV) program, in many cases, we are concerned that the request is not for purposes of validating diagnoses previously submitted to CMS, but for mining for additional diagnoses to submit to CMS in order to increase their risk adjustment scores and secure higher Medicare payments for their enrollees.

We urge CMS to mitigate these unnecessary administrative burdens on physician practices. While we understand that CMS is generally reluctant to intervene in the relationship between MA plans and their contracting physicians, we believe that changes are necessary to curtail egregious plan practices that do not support patient care and place unnecessary burden and costs on the physicians who furnish care to MA beneficiaries. Particularly for solo and small practices, who are least likely to have leverage in contract negotiations and most likely to have limited resources to accommodate the record requests, the changes outlined above would better enable physicians to maximize their limited resources on furnishing high-quality care, rather than on meeting onerous administrative requirements. Equally importantly, it would assist CMS in addressing longstanding challenges with MA "coding intensity," protecting the Medicare Trust Funds from potential fraud and abuse.

Supporting Appropriate Provider Payment

The Academy calls upon CMS to require MA plans to explicitly provide detailed information on its provider payment arrangements and methodologies. **All payers are urged to align their payment policies with current established coding conventions and guidelines.** Payment policies that improperly reduce payment by failing to adhere to established coding principles, such as inappropriately bundling separately identifiable services and lowering the value of an appropriately documented claim (downcoding), should be avoided. **The Academy urges CMS to oppose reimbursement policies implemented by MA plans that reduce payment for separately valued services when appropriately reported by current coding guidelines.**

The Academy appreciates the opportunity to provide comments on proposed revisions to regulations governing MA, Part D, Medicare cost plans, and PACE. If you have any questions

about the recommendations in this letter, please contact Associate Director of Practice and Payment Policy, Lou Terranova, at lterranova@aad.org or (202) 340-2875.

Sincerely,

A handwritten signature in black ink that reads "Seemal R. Desai MD FAAD". The signature is written in a cursive, flowing style.

Seemal R. Desai, MD, FAAD

President, American Academy of Dermatology / Association