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February 13, 2023

Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4201-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

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 Chiquita Brooks-LaSure,

Thank you for the opportunity to provide comments on the proposed rule that would revise Medicare Advantage (MA or Part C), the Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) for contract year 2024.

As the leading society in dermatological care, representing nearly 16,500 dermatologists nationwide, the American Academy of Dermatology Association (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 disease.

The Academy appreciates CMS' efforts to strengthen MA, Part D, Medicare cost plans, and PACE, and we have provided our comments below.

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Utilization Management Tools

The Academy applauds CMS for its efforts to address the inappropriate use of utilization management tools and its impact on beneficiary access to care. As we have shared in previous comments, patients face significant barriers to treatment when MA and Part D plans use utilization management policies such as prior authorization and step therapy. These types of policies can delay the initiation or continuation of medically necessary treatments, which ultimately jeopardizes patients' health and increases the risk of poor health outcomes.

The Academy's 2020 Prior Authorization Survey found that approximately 25% of patients that come to a dermatology practice require prior authorization. On average, dermatology offices have spent \$40,000 on additional staff to help manage the prior authorization process, which takes 3.5 hours each day. In fact, dermatologists could see an additional 5 to 8 patients daily if no prior authorization was required. Needless to say, unwarranted prior authorization policies, especially those implemented for high-volume treatments, are a tactic used to exhaust providers, particularly those in small or solo practices who may not be able to devote the time and energy to the prior authorization process. Ultimately, unnecessary prior authorization policies delay patients' access to medically necessary treatments and cost the health care system more than it saves.

Gold-Carding Program

While we appreciate the Agency's efforts to address the toll that prior authorization is taking on patients, physicians, and medical practices, we urge CMS to take additional steps by working with Congress to implement a gold-carding policy to assure beneficiaries timely access to care. "Gold-carding" is a type of program to improve efficiency and reduce burden on practices by exempting providers from prior authorization requirements if they have demonstrated a consistent pattern of approvals. In the proposed rule, CMS states that "gold-carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more efficient and timely delivery of health care services to enrollees." In fact, CMS notes the success they have seen with similar programs they have implemented, such as the one they use in the Medicare Fee-for-Service Review Choice Demonstration for Home Health Services.

Based on the increased efficiencies that a gold-carding program could provide in delivering care that is recognized by CMS, the Academy recommends that the Agency work with Congress to implement a gold-carding policy similar to the Getting Over Lengthy Delays in Care as Required by Doctors (GOLD CARD) Act of 2022 (H.R. 7995). This legislation would exempt physicians from prior authorization requirements for the plan year if at least 90% of prior authorization requests were approved the preceding year.

Reviews for a Gold Card exemption would be limited to no more than once every 12 months, and the 90% threshold includes approvals granted after appeal. Gold-carding is a common-sense reform that will help reduce barriers to care, allow physicians to spend more time with patients, and put treatment decisions back where they belong – in the hands of physicians and patients. **We urge CMS to work with Congress in developing a gold-carding policy that would protect beneficiaries' access to timely medically necessary treatments in addition to reducing the unnecessary administrative burdens placed on providers and payers.**

Step Therapy

The Academy is disappointed that CMS neglected to address step therapy or “fail first” strategies in this proposed rule, as these policies have been shown to negatively impact patient outcomes and quality of life. By avoiding issues with step therapy, patient outcomes are jeopardized, as well as the relationship between a doctor and a patient, as dermatologists' clinical judgment is overridden. The Academy urges CMS to include guardrails on the use of step therapy protocols in MA and Part D to ensure that beneficiaries have access to the most appropriate medical treatment determined by their physician.

Step therapy protocols, a cost containment tool used by MA and Part D plans, require patients to try one or more prescription drugs before coverage is provided for a drug selected by the patient's health care provider. We understand the need to contain health care costs, but we are concerned that step therapy strategies for medication and other treatments will adversely impact patient outcomes as well as the quality of life, which ultimately increases the total cost of care.

Requiring MA and Part D plan enrollees to try and fail treatments jeopardizes the health of patients, potentially resulting in dangerous consequences. In some instances, MA plans force patients to return to the same treatments that have proven to be ineffective when tried previously under a different health plan.

Further, step therapy interferes with the patient-physician relationship by preventing dermatologists from prescribing drugs they know will provide the best treatment results in the most effective manner. Physicians know their patients' medical history, which enables them to identify potential contraindications and life-threatening adverse reactions. Retaining physicians' medical judgment in patients' treatment plans is a cost-effective way to prevent health care dollars from being used on medications that are not effective. Relying on the medical expertise and judgment of the physician also prevents patients from enduring a prolonged course of treatment that includes scheduling multiple visits to

their doctor's office and spending money on prescription medications that are not effective. **Therefore, the Academy urges CMS to establish guardrails for step therapy protocols that will preserve the physician's right to make treatment decisions in the patient's best interest.**

Utilization Management Committee

The Academy encourages CMS to establish requirements on member participation in Utilization Management Committees and to guarantee CMS oversight of committee policies to certify consistency in the Medicare program and that beneficiaries receive timely access to medically necessary care. In the proposed rule, CMS requests feedback on its proposal to require that all MA plans establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines. We encourage CMS to create requirements that when the Utilization Management Committee reviews policies applicable to an item or service, at least one committee member who has expertise in the use or medical need for that specific item or service is allowed to participate in the decision-making process.

Additionally, we urge CMS to provide appropriate oversight of policies and procedures determined by the Utilization Management Committee to make certain that MA plans are acting in ways that comply with national coverage determinations (NCD), local coverage determinations (LCD), and general coverage and benefit conditions included in Traditional Medicare statutes. Dermatologists have shared numerous stories detailing patients who have been denied coverage and payment for services that are in compliance with Medicare coverage criteria and MA billing policies. In addition to hindering beneficiaries from receiving timely access to medically necessary care, rejecting requests that meet Medicare coverage criteria burdens providers and their practices. Although some denials are ultimately reversed, these inefficiencies within MA plans create unnecessary delays in accessing care. Further, these inefficiencies lead to providers spending excessive time and resources trying to obtain prior authorizations and disputing denied requests. **Therefore, we urge CMS to use its oversight authority of MA plans and Utilization Management Committees to ensure they comply with traditional Medicare coverage and utilization policies and not implement policies that unnecessarily delay or deny beneficiaries' access to care.**

Health Equity

The Academy supports CMS's goal of improving equity for those historically underserved, marginalized, and adversely affected by poverty and inequality. We maintain that all Americans should have access to affordable, efficient, quality health care. However, insurers are increasingly creating payment issues with modifier 25, used to bill

for preventive and problem-focused evaluation and management (E/M) services in the same encounter. As a result of payment issues associated with modifier 25, physicians ability to provide efficient care is being restricted, which disproportionately impacts underserved communities. **To further promote health equity, we urge CMS to create policy to eliminate inappropriate payment reductions for modifier 25 to ensure patients, especially those from underserved communities with limited resources, can access efficient care and achieve better health outcomes.**

Dermatologists practice efficient, patient-centered care – one of CMS goal's when promoting health equity. As the skin is the most visible and apparent organ system in the body, it is not uncommon for patients to present to the dermatologist with multiple, unrelated complaints during a visit. As such, a dermatologist may need to indicate that on the day a procedure or service identified by a CPT code was performed, the patient's condition required a significant separately identifiable E/M service. Modifier 25 indicates that on the day of a minor procedure, the patient's condition required a significant, separately identifiable E/M service, above and beyond the usual pre-and postoperative care associated with the procedure or service performed. However, despite the appropriate use of modifier 25, **insurers are implementing improper restrictions and are developing policies that eliminate or reduce payment associated with the modifier, which ultimately contradicts the national payment standard for Traditional Medicare.**

By failing to address insurer-created issues that affect efficient care delivery, patients with lower socioeconomic status are negatively impacted. Barriers to proper payment can influence the way care is provided to patients. For example, patients may be required to schedule additional doctor's visits, which will increase their out-of-pocket expenses, due to copays, transportation to and from doctor's appointments, as well as time off from work. Out-of-pocket costs are a more significant burden on underserved communities, as poverty levels are higher, and individuals in these communities are less likely to have extra income to visit the doctor frequently. **To further promote health equity of vulnerable and underserved populations, we urge that when an E/M code is appropriately reported with a modifier 25, that both the procedure and E/M codes are paid at the non-reduced, allowable payment rate.**

Conclusion

Again, we applaud CMS' continued focus on improving beneficiary protections and for proposing revisions to regulations governing MA, Part D, Medicare cost plans and PACE. We appreciate the opportunity to provide feedback to ensure beneficiaries have timely access to dermatological care. If you need additional information, please contact Jillian Winans, Associate Director of Healthcare Economics, at jwinans@aad.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark D. Kaufman". The signature is written in a cursive style with a large, stylized initial "M".

Mark D. Kaufman, MD, FAAD
President, American Academy of Dermatology