American Academy of
Allergy Asthma & Immunology

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,

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases.

In the paragraphs that follow, we provide perspectives on proposals included in the aforementioned proposed rule.

Utilization Management Requirements

We are supportive of CMS' proposals that would improve utilization management (UM) processes for "items and services" – including physician-administered drugs – covered by Medicare Advantage (MA) organizations and urge CMS to finalize these policies. However, we are concerned that CMS has excluded Part D medications from its utilization management requirement proposals. All forms of UM, such as prior authorization, step therapy, and non-medical switching, are deeply problematic for A/I patients and providers; they delay access to medically necessary therapies, resulting in poor patient outcomes and harm.

More disappointing is CMS' decision to *specifically continue allowing* step therapy on Part B medications. The Agency states this tactic puts MA organizations in a stronger position to negotiate lower

prices with drug manufacturers, reducing the cost sharing for the beneficiary. It is well documented that MA organizations, via pharmacy benefit managers (PBMs), promise to steer volume to the drug maker that offers the highest rebate, which only benefits the plan and its shareholders – not the MA organizations' enrollees or the Medicare program.

In 2018, CMS established that MA Organizations could apply step therapy to Part B medications. However, the Agency also stressed the critical importance of continuity of care by prohibiting step therapy for enrollees who are "actively receiving" the affected drug. We understand CMS' continuity of care provisions to apply to physician-administered ("Part B") drugs, but this is not well explained in the rule. ***We urge the Agency to clarify in its final rule that its continuity of care proposals, and the aforementioned step-therapy memo, includes all new enrollees who are actively receiving affected physician-administered drugs, not just existing enrollees.***

Gold Carding

We strongly agree with CMS that the use of 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. AAAAI has long supported legislation at the federal and state level to facilitate gold card approaches to UM requirements. We appreciate that CMS encourages MA plans to adopt gold-carding programs, allowing providers to be exempt from prior authorization and providing a more streamlined medical necessity review processes for providers who have demonstrated compliance with MA plan requirements.

Medical Necessity Reviews

We generally support CMS' proposal to revise its regulations by adding that the physician or other appropriate health care professional who conducts the medical necessity review must have expertise in the field of medicine that is appropriate for the item or service being requested, before the MA organization issues an adverse decision. However, we disagree with CMS that the physician or other appropriate health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. ***CMS should ensure its finalized policies require that the reviewer is, at a minimum, a licensed physician in the same primary specialty as the treating physician.***

Changes to an Approved Formulary

AAAAI agrees with CMS that formulary stability is extremely important to ensuring enrollees maintain access to an item or service that may have led them to select the specific MA plan, and appreciates the Agency's recognition that formulary changes that force enrollees to change medications for non-medical reasons (i.e., non-medical switching) pose undue threats to enrollee health. We also strongly support CMS' proposal that would limit reference biological product substitutions to *interchangeable* biological products – an important and necessary clarification. ***We support CMS' proposed provisions for approval of formulary changes and urge their finalization.***

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

We appreciate and support CMS' proposal for a health equity index reward to further incentivize Part C and D plans to focus on improving care for enrollees with social risk factors (SRFs). We have shared previously that MA plans are well-resourced and equipped to capture SRFs through their annual health risk assessments (HRA) and enrollee experience questionnaires. CMS should ensure MA plans are

making the most of these opportunities to collect SRFs and tailor their program offerings to ensure health disparities and inequities are meaningfully addressed.

AAAAI also urges CMS to establish additional measures that would capture physicians' experiences with MA plans, a concept that CMS previously sought feedback on. As we've shared through formal comments and other venues, A/I providers face a host of challenges interacting with MA plans on contracting and network status; utilization management protocols, including prior authorizations and step therapy; and plan-driven "chart reviews" that serve as a data mining exercise to establish additional diagnoses and increase payments from Medicare.

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We appreciate the opportunity to provide our perspectives on the aforementioned proposed rule. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@AAAAI.org or (414) 272-6071.

Sincerely,

David A. Khan, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology