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January 8, 2024

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-9895-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

Re: 2025 Notice of Benefit and Payment Parameters

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 feedback on key proposals and policies in the aforementioned rule.

Non-Standardized Plan Option Limits (§ 156.202)

We read with interest the Agency's proposal to expand the number of non-standardized plan options that issuers can offer in order to promote consumer access to plans with design features that facilitate the treatment of chronic and high-cost conditions at a lower cost. Our specialty diagnoses, treats and manages multiple different chronic, complex conditions, such as asthma and primary immune deficiency disease (PIDD), which would be suitable for non-standardized plan options.

However, our experience with issuers in the Marketplace since passage of the Affordable Care Act and finalization of implementing regulations, is that access to care and treatment is increasingly limited. AAAAI is concerned that – despite the Agency's good intentions – issuers will use non-standardized plan options as a way to further hinder access to A/I providers and therapies – directing consumers away from their provider of choice and therapies they are actively taking – as a way to lower plan costs and with little regard to quality. As this agency is away, issuers continue to “narrow” their provider networks and

increase their reliance on utilization management tools, including prior authorization and step therapy. Should this policy be finalized, **AAAAI urges the Agency to provide enhanced oversight of non-standardized plan options to ensure consumers who opt to enroll in one of these plans do not lose access to care and treatment.**

Prescription Drug Benefits (§ 156.122)

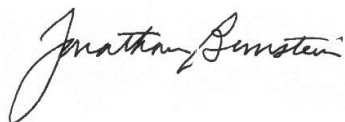
AAAAI is increasingly concerned about consumer access to prescription medications for A/I conditions in Exchange plans and urges the Agency to take the following steps to improve this circumstance.

First, our members have reported that some patients' specialty drugs are being excluded from coverage. It is unclear how exactly this occurs, but labeling these drugs as "non-Essential Health Benefits" seems to enable this behavior. When this happens, the patient hears from a third-party administrator that offers to secure "alternative funding" for coverage of these medications. It appears these entities are engaging in practices that circumvent the spirit of statutory and regulatory protections meant to protect patients. It is our expectation that your proposal to codify in regulation that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB would make these drugs subject to certain patient protections, including the annual limitation on cost sharing. **We urge the Agency to finalize this policy, and perhaps more importantly, to closely monitor alternative funding entity practices and provide enhanced oversight to keep consumers safe.**

Second, many of the conditions we treat in the Exchange population are vastly different from those we treat in the Medicare population. As many of our conditions rely on medication therapies, it makes sense that the Agency would adopt a prescription drug standard that is focused on consumers in the Health Insurance Marketplace, rather than those covered by Medicare. For this reason, **we urge the Agency to – in a future rulemaking – propose and finalize the adoption of the United States Pharmacopeia Drug Classification (USP DC) to assist with formulary support, in place of the USP Medicare Model Guidelines (MMG).** This is also important given the pace of innovation and advancement in A/I treatments that more frequently rely on biologic and biosimilar medications. The USP MMG is only updated every three years, whereas the USP DC is updated yearly, which would better accommodate and account for the newer medications that are coming to market.

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

Sincerely,



Jonathan A. Bernstein, MD, FAAAAI
President, American Academy of Allergy, Asthma & Immunology