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December 20, 2023

Ms. Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4205-P  
P.O. Box 8016  
Baltimore, MD 21244-8016

**RE: Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program and Medicare Prescription Drug Benefit Program**

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.

**Plan Marketing**

**AAAAI supports and urges CMS to finalize the proposed changes concerning Medicare Advantage (MA) and Part D Prescription Drug Program communication and marketing,** which would expand on the policies the Agency finalized in its Contract Year 2024 final rule. Deceptive marketing practices have led many A/I patients to enroll in MA plans only to face extreme challenges accessing the care and treatment they need, as the providers they see may be out-of-network and the therapies they depend on may be off-formulary or subject to burdensome utilization management.

We agree with CMS that enhanced disclaimers for Special Supplemental Benefits for the Chronically Ill (SSBCI) are necessary to increase transparency for those considering MA plan enrollment. SSBCI heavily contribute to beneficiary decision making when it comes to plan selection and enrollment, therefore, it must be clear if and how these SSBCI would – or would not – be available to them.

We also appreciate and support CMS' proposals to address financial incentives paid by MA plans to its agents and brokers.

Compensation is a primary motivator driving agents and brokers to push prospective enrollee toward one plan over another, reducing their ability to objectively assess and make plan recommendations based on the beneficiary's needs.

## Benefits

Consistent with the above, **AAAAI also supports the establishment of standards to ensure adequate notice is provided by MA plans to their enrollees regarding supplemental benefits coverage.** We support CMS' proposals for what a plans' notice should include, but recommend the following improvements:

- That the notice is delivered quarterly – not just mid-year – so enrollees have ample notice and opportunity to take advantage of the benefits for which they are due.
- That the notice is included as part of every explanation of benefits (EOB) mailed or electronically delivered to enrollees.
- That plans maintain “real time” information about supplemental benefits coverage and use as part of the enrollees online account.

Expanding when and how information about supplemental benefits coverage is shared with enrollees would also address concerns about the timing of notices for those beneficiaries that have an enrollment effective date after January 1.

## Changes to an Approved Formulary

**AAAAI opposes CMS' proposals that would remove the discernable distinction between biosimilars and interchangeable biosimilars for purposes of mid-year formulary changes by Part D plans.** CMS touts its proposals as a way for Part D plans “to more quickly substitute lower cost biosimilar biological products for their reference products” and “to support competition in the prescription drug marketplace.” However, what CMS characterizes as simple substitutions or “maintenance changes” could have a detrimental impact for enrollees who rely on biosimilars to treat and manage complex A/I conditions as biosimilarity and interchangeability are *not* one-and-the-same. Moreover, this policy empowers insurers to implement switching policies that ignore the regulatory paradigm of section 351(k) of the Public Health Service Act and implementing guidance by the US Food and Drug Administration (FDA) specific to these medications.

As proposed, CMS' policy blurs the distinction between biosimilars and interchangeable biosimilars in a way that will leave insurance companies and pharmacy benefit managers in charge of making a finding that Congress expressly and exclusively empowered FDA to make: namely, when patients can routinely switch back-and-forth between reference products and biosimilars without any safety concerns or loss of efficacy. Absent a change in law and FDA regulation concerning these products, **CMS should not finalize this policy.**

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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](mailto:sheitzig@aaaai.org) or (414) 272-6071.

Sincerely,

A handwritten signature in black ink that reads "Jonathan Bernstein". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

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

