Sound Policy. Quality Care.

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: Notice of Benefit and Payment Parameters for 2025

Dear Administrator Brooks-LaSure:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from 16 specialty and subspecialty societies who are dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care. We appreciate the opportunity to provide feedback regarding the 2025 Notice of Benefit and Payment Parameters.

Establishment of Exchange Network Adequacy Standards (§ 155.1050)

Adequate networks of physicians is an ongoing issue, particularly for consumers that require specialty and subspecialty care, as the current quantitative standards fail to meaningfully consider most specialists. Most consumers do not realize the limitations of their plan's provider network until they are faced with a critical need for specialty medical services and the physicians who deliver them. Only then do the barriers to specialists and subspecialists become apparent. As a result, many patients forego critical, medically necessary specialty care because the obstacles to acquiring treatment are too significant. We continue to believe the Agency should take steps to ensure robust access to specialty medicine for consumers in the Exchanges and direct you to our prior comments that include detailed recommendations for addressing this issue.

While we continue to have broad concerns about network adequacy, the Alliance appreciates proposals aimed at ensuring network adequacy by way of quantitative time and distance standards in the State Exchanges and State-based Exchanges on the Federal platform (SBE-FP). However, ***we are deeply concerned that the Department did not propose that State Exchanges and SBE-FPs that are not yet conducting quantitative network adequacy reviews enforce appointment wait time standards or meet applicable standards specified for Federally-facilitated Exchanges (FFEs), to include providing access to a network directory, informing consumers of provider transitions, and appropriately counting out-of-network cost-sharing, among other requirements.***

Consumers purchasing healthcare insurance through the Marketplace – regardless of whether it is State or Federally-facilitated – should be assured the available plans meet the same federal "floor" when it comes to network adequacy. By holding some plans to a different, and arguably lower, set of standards and enforcement, consumers in some states will undoubtedly face increased challenges understanding their plan network, and more importantly, accessing medically necessary care from the most appropriate provider. All Exchange plans should, at a minimum, meet the standards that have been set for the FFEs. And, as we've explained above, this "floor" should be raised to afford needed access to specialists.

We urge CMS to reconsider its proposal and to hold all plans established under the Affordable Care Act (ACA) to the same quantitative network adequacy standards, including enforcement of appointment wait time standards and the standards outlined for FFEs at § 156.230(b) through (e).

Prescription Drug Benefits (§ 156.122)

Classifying the Prescription Drug Essential Health Benefit (EHB)

Currently, CMS uses United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) to classify the drugs required to be covered as EHB. However, in 2017, the USP developed a second drug classification system, the USP Drug Classification (DC), to assist with formulary support outside of Medicare Part D. For purposes of health plans subject to EHB requirements, ***the Alliance supports using the USP DC because it would provide more meaningful and robust coverage for the populations intended to benefit from the EHBs coverage requirement.***

The use of the USP MMG in this context is a legacy policy: when CMS was implementing the EHB policy, there was no system identified as an alternative, the USP MMG was publicly available, and the pharmacy benefit manager industry was familiar with it as an existing system. However, as CMS highlights, the MMG was created in 2004 specifically for the rollout of Medicare Part D. The Part D population has different health needs than those of the population in plans subject to the EHB coverage requirement, which includes children and people of reproductive age. Furthermore, the USP MMG does not account for medications that are categorically excluded from Part D coverage by statute, such as weight loss drugs, infertility treatment, and smoking cessation, among others. That necessarily results in those medications not being covered as EHB either, even though the same statutory coverage restrictions do not apply. Using the USP DC would strengthen the drug benefit by expanding coverage of such products for populations who will benefit from them.

This decision is especially timely given the new generation of anti-obesity medications. We thank CMS for its thoughtful approach to the coverage of these products and its thorough overview of the clinical guidelines on their appropriate use, including those of the American Gastroenterological Association, an Alliance member. ***We urge CMS to finalize policies that require insurers to abide by these clinical guidelines in their coverage of anti-obesity medications***.

Coverage of Prescription Drugs as EHB

CMS proposes to codify that prescription drugs in excess of those covered by a State's EHB-benchmark plan are considered EHB, which would make these drugs subject to certain patient protections, including the annual limitation on cost sharing. We acknowledge that CMS assumed this was already its existing policy, but some of our members have also received reports of specialty drugs being excluded from coverage as non-EHB, with third party vendors offering to seek alternative funding for coverage of these

products. How common this practice has become is unclear, but codifying this policy will hopefully help prevent it from becoming a standard business model.

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The Alliance appreciates the opportunity to share feedback on this guidance and the impact on specialty medicine and patients. Should you have any questions, please contact us at info@specialtydocs.org.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American College of Mohs Surgery
American Gastroenterological Association
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Echocardiography
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons
National Association of Spine Specialists
Society of Interventional Radiology