AIMEDALLIANCE

July 28, 2025

Peter Nelson
Deputy Administrator & Director
The Center for Consumer Information and Insurance Oversight
U.S. Centers for Medicare & Medicaid Services

Amber M. Rivers
Director
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor

Re: Request for Rulemaking on Cost-Sharing and Essential Health Benefits

Dear Deputy Administrator Nelson:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing to urge the Center for Consumer Information and Insurance Oversight ("CCIIO") and the Department of Labor ("DOL") to issue the two promised rules related to cost-sharing and essential health benefits.

I. Clarify the Definition of Cost-Sharing Includes All Copayments by or on Behalf of the Beneficiary

On July 4, 2025, President Trump signed the Big Beautiful Bill Act ("BBBA").[1] As part of its effort to address the federal deficit, the BBBA does not renew subsidies that help lower the cost of health plan premiums for consumers.[2] As such, Americans will have to rely on this Administration to address health care affordability through other means. Clarifying that the definition of cost-sharing includes all payments made by or on behalf of consumers can directly improve health care affordability for consumers.

When patients are unable to afford their cost-sharing requirements, they often turn to financial assistance from pharmaceutical manufacturers or other third-party sources to help cover their health plan's cost-sharing obligations and access needed treatments.[3] Typically, the value of this assistance counts towards a patient's annual out-of-pocket maximum. However, consumers are deprived of this benefit when the health plan adopts a copay accumulator program.

Copay accumulator programs accept third-party assistance on behalf of a consumer, but exclude this assistance from counting towards their cost-sharing requirements and annual out-of-pocket limit.[4] As a result, once this assistance is exhausted, patients are left responsible for their full cost-sharing amount.[5] This can force individuals to abandon or interrupt treatment due to

[1] The White House, *President Trump's One Big Beautiful Bill Is Now the Law – The White House*, https://www.whitehouse.gov/articles/2025/07/president-trumps-one-big-beautiful-bill-is-now-the-law/.
[2] *Id*.
[3] David Choi, et al., A p*rimer on copay accumulators, copay maximizers, and alternative funding programs*, 40 JOURNAL OF MANAGED CARE & SPECIALTY PHARMACY 8 (Aug. 1, 2024).
[4] *Id*.
[5] *Id*.

cost, jeopardizing health outcomes and increasing their risk of hospitalizations and other costly health consequences.[6] Patients who rely on high-cost specialty medications, which typically involve significant out-of-pocket expenses, are especially vulnerable to the financial harm caused by accumulator programs. As such, Americans need the Trump Administration to clarify that copay assistance is included within the definition of "cost-sharing."

Under the first Trump Administration, CCIIO recognized in the 2020 Notice of Benefit and Payment Parameters ("NBPP") that copay assistance is included as part of the definition of cost-sharing under the Patient Protection and Affordable Care Act ("ACA") unless the assistance is used for a brand-name medication with a medically appropriate generic alternative available.[7] However, due to a perceived conflict with a 2004 IRS Notice, the Administration reversed its position in the 2021 NBPP, deferring to each plan's interpretation of "cost-sharing" and permitting states to prohibit the practice under state law.[8]

In 2023, three patient advocacy organizations filed suit against the Department of Health and Human Services ("HHS"), alleging that it was unlawful for the agency to permit health plans to accept manufacturer copay assistance without counting it toward an enrollee's deductible and annual out-of-pocket limit.[9] The U.S. District Court for the District of Columbia agreed, reasoning that HHS improperly allowed plans to choose how the definition of "cost-sharing" was interpreted under federal law.[10] As a result of this decision, the 2021 NBPP was revoked and the 2020 NBPP was reinstated.[11] The previous Administration refused to enforce this requirement under federal law and stated it would engage in a new rulemaking to clarify the definition of "cost-sharing" under the ACA. No such rulemaking has been initiated.

Ultimately, issuing a new rule on the definition of cost-sharing could directly improve health care affordability for consumers in 2026. In addition, clarifying that copay assistance is included as part of the definition of "cost-sharing" under the ACA would be consistent with standard rules of statutory and regulatory interpretation.

A. Statutory Interpretation Supports Including "Copay Assistance" in the Definition of "Cost-Sharing"

The ACA, and by incorporation the Public Health Service Act ("PHSA"), establishes an annual limit on cost-sharing for consumers that applies to all non-grandfathered health plans.[12] The ACA further defines cost-sharing as "deductibles, coinsurance, copayments, or similar

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[6] *Id*.
[7] 84 Fed. Reg. 17,543 (April 25, 2019).
[8] 85 Fed. Reg. 29164 (May 14, 2020).
[9] *HIV and Hepatitis Policy Institute et al. v. U.S. Department of Health and Human Services et al.,* No. 22-cv-02604 (D.D.C. Sept. 29, 2023).
[10] *Id*.
[11] *Id*.; *HIV and Hepatitis Policy Institute et al. v. U.S. Department of Health and Human Services et al.,* No. 22-cv-02604, Motion to Clarify (D.D.C. Dec. 22, 2023), https://hivhep.org/wp-content/uploads/2023/12/Clarification-decision.pdf.
[12] 45 U.S.C. § 156.130.

charges."[13] Section 156.20 further clarifies that the definition of cost-sharing is intended to include expenditures paid "by or on behalf of an enrollee."[14] Thus, under a plain reading of the two statutory provisions, any payment made to satisfy a patient's cost-sharing obligation, regardless of the source, must be applied toward the enrollee's annual out-of-pocket maximum.

Therefore, Aimed Alliance urges CCIIO and DOL to issue a new rule that clarifies that the plain reading of the statute requires all cost-sharing paid by or on behalf of an enrollee to count toward the consumer's cost-sharing requirements, including their annual out-of-pocket limits.

II. Apply the 2025 EHB Clarification to Large Group and Self-Insured Plans

The PHSA incorporates many provisions of the ACA to ensure core protections, like the annual limits on cost-sharing and essential health benefits ("EHBs"), are available to all Americans with health insurance.

A key tenet of the ACA is its requirement that all health plans offer at least 10 essential health benefits, one of which is prescription drugs.[15] To satisfy this requirement, a health plan must offer coverage for "at least the greater of: (1) one drug in every [United States Pharmacopeia] category and class, or (2) the same number of drugs in each category and class as the applicable state benchmark plan."[16] This "at least the greater" standard sets a minimum floor, not a ceiling, for what a plan must cover to meet EHB requirements.

In addition, the drafters of the ACA recognized that some consumers would need access to treatments that were not on the benchmark plan. To address this concern, the ACA also requires that plans provide a process for individuals to request clinically appropriate medications not covered under the plan (i.e., an exceptions process), and if approved, "must treat the excepted drug(s) as an essential health benefit, including by counting any cost-sharing toward the plan's annual limit on cost-sharing. . . .".[17]

Jointly, these requirements recognize how a health plan can satisfy its obligation to offer prescription drug coverage as an EHB. However, recent practices have led employers to misunderstand the standard for EHB coverage. Specifically, certain health plans have alleged that prescription drugs covered in addition to the EHB can be classified as non-EHBs, and that "specialty drugs," as a category, can be carved out of the definition of prescription drugs as an EHB.

In the 2025 NBPP, CCIIO clarified that both of these interpretations are incorrect. As such, the 2025 NBPP confirmed that existing policy requires all prescription drugs covered in

[13] 42 U.S.C §18022(c).
[14] 45 C.F.R. § 155.20.
[15] 42 U.S. Code § 18022.
[16] *Id*.
[17] 42 C.F.R. 156.122.

addition to the benchmark to be treated as EHBs.[18] In addition, in dicta, CCIIO also clarified that excluding "specialty drugs" from the definition of prescription drugs as an EHB was likely an impermissible definition.[19] While the 2025 NBPP only applies to individual and small group plans, in FAQ 66, HHS explicitly acknowledged the need to extend this policy to large group and self-insured plans and stated its intent to address the issue through rulemaking.[20]

Therefore, we urge CCIIO and HHS to follow through on its commitment and move forward with a rule, as it is necessary to ensure equitable patient protections across all markets and consistent regulatory and statutory interpretation of the ACA.

A. Clarify that all Covered Prescription Drugs are Considered EHBs and Cannot be Renamed to Avoid EHB Protections

The ACA does not define the term "prescription drugs" and allows employer plans to create their own definitions of EHBs. Consequently, health plans allege they can designate drugs, such as those labeled as "orphan drugs" or "specialty drugs," as non-EHBs, even though these are FDA-approved prescription drugs covered in excess of the benchmark plan.[21] This interpretation contradicts the plain language of the ACA. The ACA regulation governing prescription drugs as EHBs refers to "FDA-approved drugs."[22] According to the FDA, a "prescription drug" is defined as "any human drug required by Federal law or regulation to be dispensed only by a prescription. . . ."[23] Furthermore, the plain meaning of the word "prescription drug" is a "drug that can be obtained only by means of a [health care practitioner's] prescription."[24] Therefore, within the ACA, the term "prescription drug" should be interpreted to encompass all FDA-approved drugs that are required to be dispensed by a health care practitioner's prescription.

To address this practice, Aimed Alliance urges CCIIO to clarify that all prescription drugs are considered EHBs, regardless of how the plan designates the drug or its cost-sharing requirements. Without this clarification, health plans would be permitted to cover "prescription drugs" in excess of the benchmark plan but deem these drugs non-EHB by labeling them as "orphan drugs" or "specialty drugs" and claiming they fall outside the scope of the *in excess* requirement. We believe this clarification is crucial to ensure the successful application of 45 CFR 156.122 (f) in large group and self-funded plans.

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[18] Centers for Medicare & Medicaid Services, *HHS Notice of Benefit and Payment Parameters for 2025 Final Rule* (Apr. 2, 2024), https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2025-final-rule.
[19] *Id.*
[20] U.S. Dep't of Labor, *FAQ about Affordable Care Act Implementation Part 66* (Apr. 2, 2024), https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66.
[21] There are limited
[22] 42 C.F.R. §156.122.
[23] 42 U.S.C §18022(b); 42 C.F.R. §156.122.
[24] 21 C.F.R. 205.3(e).

Lastly, providing clarification on this matter falls squarely within the agency's obligation under PHSA section 2711. As established in FAQ 66, the tri-agencies are responsible for upholding PHSA provisions that pertain to lifetime and annual dollar limits on EHBs, as defined under Section 1302(b) of the ACA. This requires the agencies to clearly define EHBs to ensure that plans accurately count cost-sharing for EHBs towards the annual and lifetime limits. Therefore, it is reasonable for the agencies to utilize their authority under the PHSA to provide this necessary clarification.

III. Conclusion

In conclusion, we respectfully urge CCIIO and DOL to issue new rules on cost-sharing and EHBs to directly improve consumer health care affordability and lower health care costs in 2026.

We would greatly appreciate an opportunity to meet with your offices to further discuss this issue and our understanding of the law. Please contact us at avantrees@aimedalliance.org to arrange a time that works for your schedules to further discuss this issue.

Sincerely,

Ashira Vantrees
Director of Legal Strategy & Advocacy