AIMEDALLIANCE

July 14, 2026

Robert F. Kennedy Jr.
Secretary
Department of Health and Human Services

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services

Via Electronic Communication

Re: Request for Information CMS-9874-NC

Dear Secretary Kennedy and Administrator Oz:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. Aimed Alliance appreciates the opportunity to share our perspective with the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) on how coverage of essential health benefits (EHB) impacts consumers' access to necessary care and treatments.

I. Background

A. Annual Limits on Cost-Sharing

When patients cannot afford their medications, they may rely on financial assistance from pharmaceutical manufacturers and other third parties to meet their health plan's cost-sharing responsibilities and fill their prescriptions. The value of this financial assistance typically counts toward the health plan's deductible or maximum out-of-pocket limit, unless the health plan has implemented a copay accumulator program. Copay accumulator programs exclude the value of financial assistance distributed by third parties from counting toward the health plan's deductible or maximum out-of-pocket limit. These programs may increase consumers' annual out-of-pocket costs and force patients to switch or stop taking their treatment once their financial assistance has been exhausted and their medications become unaffordable.[1]

In recent years, health plans have expanded upon copay accumulator programs to create copay maximizers. Under a copay maximizer, certain covered prescription drugs are designated as non-EHBs, strategically directing patients to third-party companies that ensure consumers are enrolled in copay accumulators.[2] Because these drugs are designated as non-EHBs, health plans notify enrollees that failing to work with the third-party company will make them responsible for 100 percent of the cost of the medication, and those expenses will not count toward their annual limits on cost-sharing.[3] This practice is both coercive and confusing, particularly for consumers who carefully selected their health plan with the expectation that their cost-sharing for covered

[1] Aimed Alliance, *Copay Accumulator 101*, https://aimedalliance.org/copay-accumulator-101/.
[2] *Id.*
[3] *Id.*

drugs would count toward their annual out-of-pocket limits.[4] Moreover, the non-EHB designation can induce unnecessary financial stress and anxiety among consumers, potentially leading some consumers to either forgo or ration their medication due to affordability concerns or challenges. HHS and CMS should address the use of copay maximizers, as these programs define EHBs in a manner that has not been authorized by the Secretary of HHS.

B. Definition of EHB

Large group plans, including employer-sponsored plans, generally are not required to cover EHBs.[5] However, under Public Health Service ("PHS") Act section 2707(b), if employers are offering one of the ten EHBs, then they are required to comply with the ACA's protections, including the annual limit on cost-sharing and the prohibition on annual and lifetime limits.[6] Prescription drugs are one of the ten EHB categories.[7] Accordingly, to determine which benefits are subject to the annual limits on cost-sharing, a health plan must identify which covered benefits qualify as EHBs. Although employer-sponsored plans have flexibility in defining EHBs, they must use a definition authorized by HHS.[8]

The term "prescription drugs," has never been defined by HHS in the context of EHBs; however, the ACA broadly refers to prescription drugs as drugs approved by the Food and Drug Administration (FDA).[9] The FDA defines prescription drugs as "any human drug required by Federal law or regulation to be dispensed only by a prescription. . . "[10] Thus, the baseline definition of prescription drugs as an EHB includes all drugs dispensed via a prescription. A drug's status as a prescription medication does not change because it is classified as a "brand name," "generic," or "specialty" drug. Although these categories are commonly used by health plans to differentiate cost-sharing obligations for health insurance beneficiaries, they don't alter the fact that each is an FDA-approved medication that can only be dispensed via a prescription. As such, all these types of prescription drugs fall within the definition of "prescription drugs" recognized by both HHS and FDA. Thus, if plans were required to rely solely on the FDA definition of prescription drugs, all FDA-approved drugs that require a prescription would qualify as EHBs.

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[4] *Id.*
[5] Congressional Research Service, Federal Requirements on Private Health Insurance Plans, https://crsreports.congress.gov/product/pdf/R/R45146
[6] CMS, Frequently Asked Questions on Essential Health Benefits Bulletin, https://www.cms.gov/cciio/resources/files/downloads/ehb-faq-508.pdf; CMS, FAQs About Affordable Care Act Implementation (Part XIX), https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs19
[7] 42 U.S.C. § 18022.
[8] CMS, Frequently Asked Questions on Essential Health Benefits Bulletin, https://www.cms.gov/cciio/resources/files/downloads/ehb-faq-508.pdf.
[9] 45 CFR §156.122.
[10] 21 CFR §205.3.

However, Aimed Alliance recognizes that HHS did not intend for plans to be required to cover all FDA-approved drugs.[11] Consequently, the analysis must then shift to the extent of EHB coverage mandated by HHS.

Under §156.122, a plan provides EHB coverage for prescription drugs if it covers at least the greater of: (1) one drug in every United States Pharmacopeia (USP) category and class, or (2) the same number of prescription drugs in each category and class as the applicable EHB benchmark plan.[12] In addition, under section 156.122 (c), state benchmark plans must also provide a process for consumers to access clinically appropriate drugs not otherwise covered by the plan and to treat these drugs as EHBs when an exception is granted.[13] As such, EHB coverage must include at minimum: (1) one drug in each category and class; and (2) all drugs deemed medically necessary via the exceptions process.

In the 2025 Notice of Benefit and Payment Parameters (NBPP), HHS confirmed this interpretation, clarifying that all drugs covered in addition to the benchmark drug are considered EHBs. However, HHS did not extend this clarification to large-group and self-insured plans voluntarily covering EHBs. As a result, plans in the individual and small group markets are subject to different EHB requirements than large group and self-insured plans. This uneven treatment is inconsistent with the ACA's goal of ensuring that all plans subject to annual limitations on cost-sharing apply those limits equally to EHBs.

Importantly, in FAQ 66, the tri-agencies, the Department of Labor, the Department of the Treasury, and HHS, recognized the need for a uniform definition of EHB prescription drugs across all markets.14 The tri-agencies explicitly stated their intent to pursue rulemaking to ensure consistent application of the annual limits on cost-sharing requirements for EHBs across all markets.[15] Yet, since the FAQ's publication in 2024, HHS has failed to make the necessary clarification and ensure equal application of the EHB limits on cost-sharing. Therefore, Aimed Alliance urges HHS to finalize the promised regulation and ensure all health plans treat all covered drugs in addition to the EHB benchmark, as EHBs subject to the annual limits on cost-sharing under the ACA.

II. Question 3.2 – How do issuers, employers, and other interested parties manage costs associated with benefits included as EHB, including through benefit design, utilization management techniques, network design, or payment approaches? How do such tools affect affordability and enrollee access to medically necessary care?

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[11] Aimed Alliance, *Aimed Alliance 2025 NBPP CMS-9895-P,* https://aimedalliance.org/wp-content/uploads/2024/01/Aimed-Alliance-2025-NBPP.pdf.
[12] *Id.*
[13] *Id.*
[14] Dept. of Labor, *FAQ about Affordable Care Act Implementation Part 66 (April 2, 2024),* https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66.
[15] *Id.*

Health plans use a variety of utilization management strategies to contain costs. Common utilization management strategies include prior authorization and step therapy. Prior authorization requires consumers to receive approval from the health plan before accessing a prescribed medication,16 while step therapy requires patients to try and fail on one or more medications before the health plan will cover the originally prescribed treatment.[17] Both practices can delay consumers' access to medically necessary medications, resulting in disease progression, poorer health outcomes, and increased health care costs.

Importantly, prior authorization and step therapy do not always generate cost savings for plans. For example, Connecticut requires health plans to report the savings associated with their utilization management policies.[18] The state's 2025 Consumer Report found that Aetna Health's utilization of prior authorization *increased* the plan's annual costs.[19] Similarly, in 2024, Connecticut's 2024 Report found that "other utilization management," including step therapy, only saved health plans on average $4.50 a month per beneficiary.[20] These limited "savings" do not account for the additional costs these policies pose on the health care system, such as administrative burdens placed on health care providers to complete prior authorization paperwork or the increased risk of hospitalizations that result from delayed or denied treatments.

The value of utilization management tools is further challenged by a 2025 study examining open access formularies for individuals living with serious mental illness.[21] The 2025 study compared health care costs in a state Medicaid program with an open-access formulary against those with more restrictive formularies. Importantly, the study found that open access formularies had lower overall healthcare utilization, including hospitalizations, despite higher prescription drug costs.[22] These findings demonstrate that timely access to appropriate treatments can improve health outcomes while reducing health care expenditures by avoiding costly downstream complications.

While prior authorization and step therapy are used across all health insurance markets, some utilization management techniques are only associated with large-group and self-insured health plans. Specifically, alternative funding programs (AFP) are primarily used by large-group and

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[16] Aimed Alliance, *Step Therapy,* https://aimedalliance.org/step-therapy/.
[17] Aimed Alliance, *Prior Authorization,* https://aimedalliance.org/prior-authorization/.
[18] Connecticut Department of Insurance, *Consumer Report Card on Health Insurance Carriers in Connecticut* (Oct. 2025), https://portal.ct.gov/cid/-/media/cid/reports/consumer-report-card/2025-consumerreportcard.pdf?rev=a7011890673a4936abcc63e9c8eeda39&hash=4DCFD402562787FEDFB87A6A2798D799.
[19] *Id.*
[20] Connecticut Department of Insurance, *Consumer Report Card on Health Insurance Carriers in Connecticut* (Oct. 2024), https://portal.ct.gov/cid/-/media/cid/reports/consumer-report-card/2024-consumerreportcard.pdf?rev=94d0c6b1e170408b974006006dbe6751&hash=81474DB06393007646988C1A5C55116F.
[21] Rashmi Patel, et al., *Open Access to Antipsychotics in State Medicaid Programs: Effect on Healthcare Resource Utilization and Costs among Patients with Serious Mental Illness* (June 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12178157/.
[22] *Id.*

self-insured health plans. When a health plan adopts an AFP, certain *covered prescription drugs* are diverted into an alternative coverage process. Under this process, consumers must first obtain prior authorization establishing that the medication is medically necessary. If the drug is approved, the health plan then requires the consumer to work with a third-party company to access the medication.

The third-party company typically requires the consumer to apply to pharmaceutical manufacturer patient assistance programs (PAPs), which are intended to provide free medications to individuals who are uninsured or underinsured. In some cases, when consumers are deemed ineligible for the PAP, AFPs also require the consumer to obtain the medication through an international pharmacy. If neither option is available, the prescription is sent back to the health plan and covered through the typical pharmacy benefit. Although AFPs may appear financially advantageous to plans because AFP vendors charge plans 20 to 30 percent of the savings generated when a drug is obtained through an alternative source, these programs can create significant challenges for consumers.[23] For consumers, these programs are confusing and result in harmful delays in accessing their necessary treatments.

First, AFPs are often difficult for consumers to understand and navigate. In many cases, a consumer receives a determination that the prescribed medication is medically necessary, only to be told that they must work with an AFP to access the drug. During this process, consumers do not receive a formal denial letter stating the drug is not covered. As a result, consumers have no opportunity to appeal the requirement to work with the AFP to access their medications. Instead, consumers may be required to disclose personal, financial, and health information to the AFP and, in some cases, at the direction of the AFP, provide inaccurate information to patient assistance programs (PAPs) to qualify for these programs that were designed for uninsured or underinsured individuals.[24] For consumers who do not qualify for a PAP, some AFPs require them to import their medications from pharmacies located outside the United States, even when the medication is readily available in the United States.[25] Importantly, in 2026, the Food and Drug Administration confirmed that this type of mandatory importation is not consistent with FDA's personal importation policy or Section 804 programs.[26]

Second, AFPs also create substantial delays in access to treatments. A 2024 survey of consumers enrolled in AFPs found that, on average, consumers waited over two months to

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[23] Anastassia Gliadkovskaya, *A new wave of middlemen offers 'alternative funding' for specialty drugs. Patients bear the risk* (Oct. 14, 2025), https://www.fiercehealthcare.com/payers/new-wave-middlemen-promise-savings-specialty-drugs-patients-bear-risks.
[24] *Id*
[25] Aimed Alliance, *FDA Confirms AFPs Not Permissible Under Section 804,* https://aimedalliance.org/fda-confirms-afps-not-permissible-under-section-804/.
[26] *Id.*

receive their covered prescription drugs.[27] Similarly, a study by Vanderbilt Specialty Pharmacy found that consumers enrolled in an AFP were 47 percent more likely than non-AFP consumers to experience a treatment gap, and nine times more likely to experience a poor clinical outcome, such as disease progression or hospitalization, because of delays in treatment.[28]

These findings underscore the significant risks AFPs pose to patient health and continuity of care. Delaying access to necessary medications can worsen health outcomes, increase the likelihood of preventable complications, and ultimately lead to higher overall health care spending. Ultimately, AFPs do not serve the best interests of consumers and may increase long-term health care costs. As such, Aimed Alliance urges HHS and CMS to take action to address the use of these programs and ensure consumers can access their necessary treatments in a timely and affordable manner.

III. Question 7.3 – How might potential refinements to the EHB framework affect consumer continuity of coverage during transition periods?

Consumers carefully evaluate their coverage options during open enrollment to ensure they have access to affordable premiums and coverage for their necessary treatments and services. Once open enrollment ends, consumers generally cannot change health plans unless a qualifying event occurs. Consequently, any changes to the EHB framework that impact consumers must only take effect at the start of a new plan year and should not be implemented mid-year. In addition, if health plans adopt changes to EHB coverage requirements, they should be required to clearly and transparently disclose those changes before open enrollment so that a reasonable consumer can understand whether a change will take effect in the upcoming plan year. Disclosures buried in footnotes or small print should not be considered sufficient notice.

IV. Question 7.5 – Following implementation of any future EHB refinements, what targeted monitoring framework should CMS use to assess market impacts over time without duplicating broader affordability and data analyses addressed elsewhere in this RFI?

To ensure that proposed changes do not increase costs or result in arbitrary denials of benefits for consumers, CMS and HHS should strengthen reporting and transparency requirements related to utilization management and appeals processes.

With limited exceptions, health plans are not required to demonstrate in a quantifiable manner that utilization management policies, like step therapy and prior authorization, reduce

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[27] William B. Wong, et al., *A descriptive survey of patient experiences and access to specialty medicines with alternative funding programs,* J. Manag Care Spec Pharm. (Nov. 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC11522444/.

[28] Karen Blum, *AFPs Affect Access to Specialty Medications,* Specialty Pharmacy Continuum (Oct. 2025), https://www.specialtypharmacycontinuum.com/Online-First/Article/10-25/AFPs-Affect-Access-to-Specialty-Medications/78765.

health care costs.[29] Similarly, many health plans are not required to publicly report how many claims are approved, denied, appealed, and the outcome of those appeals. Aimed Alliance's 2025 report found that only nine states make this data publicly available, despite 24 collecting this type of information from health plans.[30] Without public reporting, consumer groups and advocates have limited ability to evaluate whether claims are being covered, denied, or appealed. The absence of transparency places the burden on individual consumers to identify and report potential violations, requiring them to navigate lengthy administrative processes to receive the benefits they are entitled to. To improve oversight and accountability, HHS and CMS should establish annual reporting requirements that require health plans to publicly report (1) the total claims approved and denied; (2) the total number of appeals; and (3) the outcomes of appeals. These data will help ensure plans comply with existing laws, regulations, and future reforms.

V. Conclusion

In conclusion, Aimed Alliance appreciates the opportunity to provide feedback on the necessity of EHBs for consumers and the importance of ensuring prompt access to necessary treatments. Aimed Alliance urges CMS to ensure that all reforms to the EHB coverage requirements do not impair consumers' ability to access and afford their necessary treatments. Please contact us at avantrees@aimedalliance.org if you have any questions.

Sincerely,
Ashira Vantrees
Director of Legal Strategy & Advocacy

[29] Aimed Alliance, Step Therapy, Oversight, and AI (June 2025), https://aimedalliance.org/wp-content/uploads/2025/06/AA-2025StateReport_June_2025.pdf.
[30] *Id.*