AIMEDALLIANCE

January 8, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Aimed Alliance 2025 NBPP CMS-9895-P

Dear Secretary Becerra and Administrator Brooks-LaSure:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the opportunity to comment on the 2025 Notice of Benefit and Payment Parameters (CMS-9895-P). We support:

I. Clarifying the scope of EHB coverage requirements;
II. Requiring minimum standards for network adequacy assessments; and
III. Requiring P&T committees to include a consumer representative.

In addition, we urge the Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") **to prohibit copay accumulator programs** in the final 2025 NBPP or in future rulemaking.

I. Prohibit Copay Accumulators and Protect Consumers with Chronic Conditions

In 2023, the HIV + Hepatitis Policy Institute, Diabetes Patient Advocacy Coalition, and the Diabetes Leadership Council collectively initiated legal proceedings against HHS alleging the 2021 NBPP improperly permitted health plans to adopt their own definition of "cost-sharing," thereby enabling plans to implement copay accumulators.[1] When a health plan employs a copay accumulator, it accepts third-party assistance for a prescription drug but excludes this assistance from contributing toward the enrollee's annual limit on cost-sharing.

In September 2023, the United States District Court for the District of Columbia held that the 2021 NBPP was unlawful because it permitted two distinct and contradictory definitions of "cost-sharing."[2] The Court did not determine if the definition of cost-sharing was required to include third-party assistance, but rather it defer to the agency to provide an interpretation of the definition of cost-sharing in the first instance.

[1] Aimed Alliance, *HHS's 2021 NBPP Rule and Copay Accumulators,* https://aimedalliance.org/hhss-2021-nbpp-rule-and-copay-accumulators/ .
[2] U.S. Dist. Ct. D.C., *Memorandum Opinion,* Sept. 29, 2023, https://aimedalliance.org/wp-content/uploads/2023/10/final-decision.pdf .

Subsequently, in December 2023, the Court reaffirmed that, with the 2021 NBPP being deemed unlawful, the current governing law defaults to the 2020 NBPP.[3] Under the 2020 NBPP, HHS specified that all cost-sharing, including third-party contributions, must contribute toward the annual limit on cost-sharing, except for brand-name medications with a medically-appropriate generic equivalent available.[4]

HHS has expressed its intention to address the unresolved issues left open by the Court's September 2023 decision concerning the definition of cost-sharing. While the 2025 NBPP does not address the question of cost-sharing, in future rulemaking Aimed Alliance urges HHS to adopt a definition of cost-sharing that requires all costs paid by or on behalf of the consumer to count when calculating their annual limit on cost-sharing.

Consumers with chronic conditions often rely on third-party assistance from drug manufacturers and non-profits to afford prescription drugs and meet their cost-sharing requirements. It is crucial that the value of this assistance be included in the cost of their treatments at the pharmacy counter and counted toward their annual limits on cost-sharing. Failing to include this assistance towards consumer's annual limits imposes significant financial burdens on consumers, necessitating thousands of dollars in additional payments to reach their annual limit. Inclusion of this assistance towards consumers annual limits not only ensures access to treatments and prevents disease progression, but also promotes equity for consumers with chronic conditions who have disproportionate healthcare costs compared to non-chronic consumers. Ultimately, Aimed Alliance encourages HHS to prohibit the use of copay accumulators in any future rulemaking related to the 2023 decision.

II. Closing the Non-EHB Loophole

Aimed Alliance applauds the actions taken by HHS and CMS in the 2025 NBPP to prohibit the use of the non-essential health benefit (non-EHB) designation. In recent years, health plans have defined certain covered prescription drugs as non-EHBs, strategically directing patients toward third-party programs.[5] Under the non-EHB designation, health plans notify enrollees that failure to work with third-party companies, and apply to third-party assistance programs will result in a 30 to 70 percent coinsurance responsibility, and this coinsurance will not contribute towards the consumer's annual limits on cost-sharing, given the drug's non-EHB designation.[6] This non-EHB designation is coercive and confusing for consumers who carefully selected their health plan with the expectation that their cost-sharing for covered drugs would count towards their annual out-of-pocket limits.[7] The non-EHB designation induces unnecessary financial stress

[3] Aimed Alliance, *DC Court Clarifies 2020 NBPP Is Current Law,* https://aimedalliance.org/dc-court-clarifies-2020-nbpp-is-current-law/ .
[4] HHS, *Patient Protection and Affordable Care Act; Notice of Benefit and Payment Parameters for 2020,* https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020.
[5] Aimed Alliance, *Copay Accumulator 101,* https://aimedalliance.org/copay-accumulator-101/
[6] *Id.*
[7] *Id.*: The proposed rule also requested commentors provide feedback on the prevalence of the non-EHB designation. Aimed Alliance believes this is a widespread practice used by health plans. Examples include PWGA, Iona University, University of Pittsburg, Northwestern University, County of San Luis Obispo, University of Kentucky,

and anxiety among consumers, potentially leading some consumers to either forgo or ration their medication due to affordability concerns or challenges.

Lastly, it is worth noting that the proposed 2025 NBPP clarifies the question, ***"What is an EHB?"*** This query is distinguishable from the one raised in the earlier 2023 litigation, which asks, ***"What is required to count towards cost-sharing for an EHB?"*** While these questions are related, they are, are in fact distinct. Therefore, Aimed Alliance urges CMS and HHS to ensure clarity in the finalization of the proposed rule, clearly specifying the questions addressed and indicating the plans to which these answers are applicable.

A. HHS Has Authority to Define EHBs as it Applies to Individual, Small, and Large Group Plans.

Large group plans, including employer-sponsored plans, are not required to cover essential health benefits ("EHBs").[8] 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 annual limits on cost-sharing and prohibition on annual and lifetime limits.[9] One of the ten EHBs is prescription drugs.[10]

To determine which benefits are subject to the annual limits on cost-sharing, a health plan must identify which benefits are considered EHBs. Employer-sponsored plans can select their own definition for EHBs, but they must use a definition authorized by HHS, "including any available benchmark option."[11]

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).[12] The FDA defines prescription drugs as "any human drug required by Federal law or regulation to be dispensed only by a prescription. . . "[13] Thus, the baseline definition for prescription drugs as an EHB includes ***all*** drugs dispensed via a prescription. A drug's designation as a medication that is dispensed via a prescription does not change because the drug is a "brand name," "generic," or "specialty" drug. Although these terms are often used to distinguish cost-sharing amounts for health insurance beneficiaries, they don't alter the fact that all these drugs are FDA-approved medications that can only be dispensed via a prescription. As such, all these types of prescription drugs are within the HHS and FDA definitions of prescription drugs.

George Washington University, National IAM Benefit Trust Fund, Ohio University, New York University, and Ruby Tuesday. This list is intended to be illustrative of the variety of plans using the non-EHB designation. This list is not intended to be exhaustive.

[8] Congressional Research Service, *Federal Requirements on Private Health Insurance Plans,* https://crsreports.congress.gov/product/pdf/R/R45146

[9] 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

[10] 42 U.S.C. § 18022.

[11] CMS, *Frequently Asked Questions on Essential Health Benefits Bulletin,* https://www.cms.gov/cciio/resources/files/downloads/ehb-faq-508.pdf;

[12] 45 CFR §156.122.

[13] 21 CFR §205.3.

Thus, if plans were solely obligated to consider how the FDA defines prescription drugs, then *all FDA-approved drugs that are dispensed via a prescription* would be considered an EHB. However, HHS has recognized that a health plan does not fail to provide EHB coverage solely because it does not cover all prescription drugs.[14] Consequently, the analysis must then shift to the extent of EHB coverage mandated by HHS.

Under §156.122, a plan offers 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 EHB benchmark plan.[15] Per 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 if the exception request is granted.[16] As such, state benchmarks must cover the following prescription drugs as an EHB (1) at least one drug in a category and class; and (2) all drugs deemed medically necessary via the exceptions process.

The proposed 2025 NBPP clarifies that the "*at least the greater of"* language is intended to be interpreted as a floor not a ceiling for EHB coverage. Consequently, all drugs covered in addition to at least one drug in a class and category are also EHBs. Thus, with this clarification in the 2025 NBPP, a plan would provide EHB coverage for prescription drugs if it includes (1) at least one drug in each category and class; (2) all drugs deemed medically necessary via the exception process; and (3) all additionally covered drugs in a category or class.

While employer sponsored health plans can select <u>*any state benchmark definition of an EHB*</u>, they must consider all state benchmark covered EHBs as EHBs under the employer's plan. Thus, if a benchmark plan designates 15 drugs in a category and class as EHBs, the employer-sponsored plan using the state benchmark plan must also consider at least 15 drugs as EHBs in that category and class. Moreover, because the benchmark plan is required to consider all additionally covered drugs and all drugs deemed medically necessary via the exceptions process as EHBs, these same rules should extend to the employer-sponsored plans using the state benchmark to define EHBs. This interpretation is supported by language in the proposed 2025 NBPP concerning other EHB coverage requirements:

"This proposal, if finalized, may impact plans that are not directly subject to the EHB requirements, such as self-insured group health plans and fully-insured group health plans in the large group market, that are required to comply with the annual limitation on cost sharing and restrictions on annual or lifetime dollar limits in accordance with applicable regulations with respect to such EHBs.[] ***If a State updates its EHB-benchmark plan to add coverage of routine non-pediatric dental services as an EHB and the sponsor of a self-insured group health plan or fully-insured group health plan in the large group market selects that EHB-benchmark plan, any routine non-pediatric dental services covered by such a group health plan would generally be subject to the limitation on cost sharing and restrictions on annual or lifetime dollar limits****."*

[14] 45 CFR §156.122 (b).
[15] 45 CFR §156.122.
[16] 45 CFR §156.122.

The commentary accompanying the proposed rule recognizes that if a benchmark plan exceeds the EHB requirement mandated by the ACA, a self-insured group health plan utilizing that benchmark plan must also incorporate all additional benchmark EHBs into its own EHB coverage. It would be inconsistent for this commentary to apply to the EHB benefits of "routine non-pediatric dental services" and not prescription drugs as an EHB.

Therefore, because the proposed rule would require a state benchmark plan to consider as EHBs: (1) at least one drug in each category and class; (2) all drugs deemed medically necessary via the exception process; and (3) all additionally covered drugs in each category and class, this same interpretation must be applied to employer-sponsored plans utilizing the state benchmark plans definition of EHBs.

FAQ 19, jointly prepared by the Department of Labor, HHS, and the Department of Treasury ("Departments"), further underscores that the additional rules imposed on state benchmark plans for defining EHBs are intended to extend to large group and self-funded plans. For example, under Q-3, the Departments recognize that brand-name medications can be excluded from the definition of EHB if a *medically appropriate* generic is available.[17] The response consistently emphasizes that such exclusion is suitable **only if** the generic is medically appropriate, and if under an exception process akin to 156.122(c), the medication is not deemed medically appropriate, then the brand-name medication should not be excluded from the definition as an EHB. FAQ-19's reference to 156.122(c) confirms that the Departments did not intend for large group and self-funded plans to provide narrow prescription drug coverage that excludes coverage for additional drugs deemed medically necessary.

Aimed Alliance commends CMS and HHS for prohibiting plans from defining medically necessary prescription drugs as non-EHBs, and for specifying that all drugs covered by the plan, beyond the minimum required in the state benchmark, are considered EHBs. If HHS and CMS intend for the 2025 NBPP to have a more limited interpretation, HHS and CMS ***must explicitly clarify the scope in the final rule.*** The absence of additional clarity may result in inconsistent plan policies regarding EHB coverage of prescription drugs, with some plans adopting Aimed Alliance's interpretation while others adopt a more limited view of the final rule.

III. Ensuring Network Adequacy

During the first three weeks of open enrollment in 2023, 4.6 million consumers selected their health plan from a state or federal marketplace.[18] Consumers rely on state and federal health insurance exchanges to obtain affordable health insurance coverage for both themselves' and their families. To effectively realize the intended objectives of these exchanges as sources for obtaining affordable coverage, it is vital that these plans not only prioritize affordability but also provide comprehensive coverage. Therefore, Aimed Alliance supports the network adequacy

[17] CMS, *FAQs About Affordable Care Act Implementation (Part XIX),* https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs19

[18] CMS, *More than 4.5 Million Select Affordable Health Coverage in ACA Marketplace Coverage Since Start of Open Enrollment Period,* https://www.cms.gov/newsroom/press-releases/more-45-million-select-affordable-health-coverage-aca-marketplace-coverage-start-open-enrollment.

requirements established in the 2025 NBPP, as they aim to ensure consumers receive accessible, high quality, and affordable healthcare coverage.

IV. Consumer Representatives on Pharmacy and Therapeutics Committees

Pharmacy and Therapeutics (P&T) Committees provide a number of functions, including the development of evidence-based formularies for medications and medication-associated products.[19] These formularies aim to capture the most current clinical judgment of medical staff, pharmacists, and other health care experts. However, a notable gap exists, as P&T Committees often lack consumer or caregiver perspectives.[20] Caregivers and consumers managing chronic conditions bring a unique perspective on the value of specific treatments. For example, one study found that consumer considerations in drug selection encompass non-traditional factors such as impact on quality of life and complexity of treatment regimen (i.e., site of care, treatment length, dosage, scheduling, etc.).[21]

Under the proposed 2025 NBPP, it is recommended that P&T Committees be required to include a consumer representative. The consumer representative would be required to be affiliated with a community-based organization and have experience in data analysis. Aimed Alliance supports this requirement, emphasizing its role in ensuring that the formulary development process incorporates the lived experiences of consumers with chronic conditions. Aimed Alliance also advocates for the inclusion of a health equity representative on P&T Committees to ensure formularies represent diverse treatment options for diverse consumer populations.

V. Conclusion

Thank you for providing us the opportunity to comment on 2025 NBPP. Please contact us at policy@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Ashira Vantrees
Counsel

[19] ASHP, *ASHP Statement on the Pharmacy and Therapeutics Committee and the Formulary System,* https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/pharmacy-and-therapeutics-committee-and-formulary-system.ashx .
[20] Avalere, *Infusing the Patient Perspective into Value Assessment,* https://avalere.com/insights/infusing-the-patient-perspective-into-value-assessment#:~:text=If%20the%20patient%20perspective%20is,value%20assessment%20has%20been%20minimal.
[21] Avalere, *Infusing the Patient Perspective into Value Assessment: A Case Study: Triple Negative Breast Cancer,* https://avalere.com/wp-content/uploads/2023/04/Infusing-the-Patient-Perspective-into-Value-Assessment.pdf.