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Submitted via regulations.gov

November 12, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–9888–P

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program (CMS–9888–P)

Dear Administrator Brooks-LaSure:

On behalf of the estimated 50 million Americans living with one or more autoimmune or immune-mediated diseases, the Autoimmune Association appreciates the opportunity to comment on the proposed rule titled *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2026; and Basic Health Program* (CMS–9888–P) (Proposed Rule), issued by the Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS or the agency).[1]

The Autoimmune Association is dedicated to the eradication of autoimmune diseases, the alleviation of suffering, and the socioeconomic impact of autoimmunity. Autoimmune diseases are a major cause of serious and chronic health conditions for millions of individuals. The Autoimmune Association is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of 64 organizations representing numerous diseases, such as lupus, psoriasis, rheumatoid arthritis, multiple sclerosis, Sjögren's, celiac disease, relapsing polychondritis, and many others. The NCAPG's mission is to convene, support, and amplify the voice of autoimmune disease patients and patient groups.

These comments focus on the following two issues:

- **Serious concerns about the agency continuing to allow issuers to exclude certain third-party assistance from patients' annual cost-sharing limit, despite a clear federal court ruling requiring inclusion of these amounts.** In 2023, the U.S. District Court for the District of Columbia vacated the 2021 Notice of Benefit and Payment Parameters (NBPP) rule[2] that had allowed issuers to decide whether to count certain assistance provided to patients by drug manufacturers toward a patient's annual cost-sharing limitation, and expressly reinstated and confirmed the current applicability of the 2020 NBPP rule[3] requiring issuers to count such assistance toward the annual cost-sharing limit when

[1] 89 Fed. Reg. 82308 (Oct. 10, 2024).
[2] 85 Fed. Reg. 29164, 29230–35, 29261 (May 14, 2020) (codified at 45 C.F.R. § 156.130(h)) (2021 NBPP).
[3] 84 Fed. Reg. 17454, 17568 (Apr. 25, 2019) (codified at 45 C.F.R. § 156.130(h)) (2020 NBPP).

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there is no generic equivalent available or medically appropriate.[4] Despite this ruling, the agency has failed to enforce the 2020 NBPP rule, instead allowing the harmful practice of excluding manufacturer assistance from patients' annual cost-sharing limitation to continue unchecked—at the significant expense of and detriment to patients and their families. It has been over a year since the court issued its decision vacating the 2021 NBPP provision. We are deeply disappointed that the agency continues to refuse to enforce the 2020 NBPP rule that is plainly in effect under the court's order. Failure to enforce severely and unfairly impairs medication access and affordability for patients, creating barriers for those with chronic conditions to adhere to the therapy regimens prescribed by their physicians. These harmful consequences often result in negative health outcomes for patients and increased costs for our health care system. We strongly urge CMS to act consistently with the court's ruling and enforce the 2020 NBPP rule; we also urge CMS to issue guidance expressly clarifying and confirming that it will be enforcing this rule. Although the Proposed Rule states that HHS and the Departments of Labor and Treasury "intend to issue a future notice of proposed rulemaking" to address "the applicability of drug manufacturer support to the annual limitation on cost sharing,"[5] an intention for future rulemaking does not excuse the agency from enforcing the existing and effective 2020 NBPP rule.

- **Request to expressly clarify and confirm that protections against the harmful practice of eliminating certain specialty medications from formularies and designating them as "non-essential health benefits" ("non-EHB") apply to large group and self-insured plans.** We greatly appreciate that the 2025 NBPP final rule[6] addressed this "non-EHB" issue for individual and small group market plans by expressly clarifying and codifying the requirement that prescription medications covered in excess of a state's EHB-benchmark plan are considered EHB, and are thus subject to the ACA's EHB protections, including annual cost-sharing limits. However, we are disappointed that the Proposed Rule did not expressly confirm and clarify that this policy also applies to large group and self-insured plans. The practice of designating certain drugs as non-EHB creates serious medication access and affordability issues for patients with autoimmune diseases and other chronic conditions, whose health and well-being suffer when their treatment regimens are interrupted, delayed, or changed. It is also inconsistent with applicable existing EHB regulations. In the 2026 final rule, we urge CMS to expressly confirm that the policy it already has confirmed is in place for individual and small group plans also applies to large group and self-insured plans.

We address these points in further detail below, with particular focus on the needs and circumstances of individuals living with autoimmune diseases.

I. Importance of Ensuring That Assistance Amounts from Any Third Party Count Toward Patients' Annual Cost-Sharing Limitation

We implore CMS to follow the 2023 District Court for D.C.'s ruling reinstating the 2020 NBPP rule that "[w]here there is no generic equivalent available or medically appropriate," then third-party manufacturing assistance "must be counted toward the annual limitation on cost sharing."[7] In addition to prompt agency enforcement that is consistent with the court's ruling, CMS should also issue guidance that expressly confirms and reminds health plans and other stakeholders that the 2020 NBPP provision is in now in effect and must be followed. As we explain below, this issue is urgent, and the agency must not delay enforcement any longer.

[4] *See HIV & Hepatitis Pol'y Inst. v. U.S. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-2604 (D.D.C. Sept. 29, 2023) (opinion granting plaintiffs' motion for summary judgment); *HIV & Hepatitis Pol'y Inst. v. U.S. Dep't of Health & Hum. Servs.*, Civ. A. No. 22-2604 (D.D.C. Dec. 22, 2023) (opinion & order on agencies' motion for clarification).
[5] 89 Fed. Reg. at 82308.
[6] 89 Fed. Reg. 26218 (Apr. 15, 2024).
[7] 84 Fed. Reg. at 17545.

We are gravely disappointed that the agency is failing to comply with the court's decision by refusing to enforce the 2020 NBPP provision that is currently in effect. Without this enforcement, issuers continue to exclude third-party assistance received from manufacturers from patients' annual cost-sharing limits. As we have emphasized in prior comments, this practice significantly harms patients, inappropriately hinders physicians' independent clinical treatment decisions, and unnecessarily impedes our important collective efforts to address the negative impact of chronic diseases across the country. At a time when policymakers should be focused on improving access to and affordability of prescription drugs for patients, this practice does the opposite.

Cost-sharing assistance from manufacturers, like other types of cost-sharing assistance, helps patients and their families cover their out-of-pocket costs for medicines. The agency has sought to rationalize a policy permitting exclusion of cost-sharing assistance received from manufacturers from counting toward patients' annual cost-sharing limits as an attempt to prevent a market distortive effect caused by patients choosing more expensive brand-name medications in lieu of cheaper generic alternatives.[8] However, the facts and data do not support this asserted rationale. Indeed, data indicate that only 0.4% of claims using manufacturer copay assistance were for brand name medications that had an available generic equivalent.[9] And, in any event, the currently effective policy under the 2020 NBPP rule accounts for this consideration even in the small number of instances where it may be relevant, by providing that the assistance must count toward patients' out-of-pocket limit *unless* there is a medically appropriate and available generic equivalent.[10]

Cost-sharing assistance received from third parties, including but not limited to assistance from manufacturers, helps patients maintain stability in their health conditions, avoid exacerbations or relapses, and achieve continuity of care. Those positive outcomes, in turn, reduce overall health care expenditures. Data and studies have shown that appropriate access to medications reduces, not raises, medical spending.[11]

Permitting issuers to exclude this assistance from patients' annual cost-sharing limitations is unfair to patients, and it undermines CMS's important goals of improving access and affordability for patients. Particularly for patients with serious and chronic conditions, including patients with autoimmune diseases, affordable access and continuity of care are imperative in order to manage their conditions, which often are progressive, debilitating, or life-threatening, especially in the absence of appropriate treatment. Accordingly, it is of paramount importance that patients with these conditions be able to obtain and maintain reliable access to the medically necessary therapies that their physicians prescribe.

Research has shown that, when patients face affordability challenges, increased out-of-pocket costs, or other barriers to accessing their prescribed medications, they are less likely to be able to adhere to their prescribed therapy regimens; prescription abandonment, therapy disruptions, discontinuations, and other issues are likely to occur.[12] Those obstacles to starting or continuing therapy have negative consequences for patients in terms

[8] 85 Fed. Reg. at 29234.
[9] IQVIA, *An Evaluation of Co-Pay Card Utilization in Brands After Generic Competitor Launch* (2018), https://www.iqvia.com/locations/united-states/library/fact-sheets/evaluation-of-co-pay-card-utilization.
[10] 84 Fed. Reg. at 17545.
[11] *See, e.g.*, Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (Nov. 2012); J. Michael McWilliams et al., *Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage*, JAMA, 306(4):402–409 (2011) (finding that Medicare beneficiaries' increased access to and use of prescription drugs through expanded coverage under Part D was linked to reduced non-drug medical spending).
[12] *See, e.g.*, Patrick P. Gleason et al., *Association of Prescription Abandonment with Cost Share for High-Cost Specialty Pharmacy Medications*, Journal of Managed Care and Specialty Pharmacy (Oct. 2009); 15(8): 648–658; *available at* https://pubmed.ncbi.nlm.nih.gov/19803554/.

of clinical outcomes,[13] which also leads to increased health care expenditures and other costs.[14] That, in turn, undermines cost-containment goals in light of the very high costs of hospitalizations and other clinical interventions and consequences that occur when patients' chronic conditions are not effectively managed.[15]

Patients should not be penalized for using the resources available to them to assist with that access; it also seems arbitrary to penalize certain types of assistance but not others. We believe that continuing to allow issuers to exclude certain assistance from patients' annual cost-sharing limitations imposes an unfair and unnecessary barrier to patients' ability to access, afford, and adhere to the treatment plans prescribed by their physicians. Addressing and removing this barrier is fully consistent with CMS's important goals to ensure appropriate access for patients, to "empower consumers," and to "improve affordability."[16]

Moreover, these issues continue to grow increasingly urgent as the annual out-of-pocket limit continues to increase. For example, when comparing the changes over time for the maximum out-of-pocket limit of ACA plans and employer-based Health Savings Account-qualified health plans, the former is increasing more rapidly than the latter due to differences in the applicable methodology. While certain aspects of that methodology are determined by statute, we urge HHS to advance policy options that reduce the impact of growing cost-sharing obligations on patients—not policy options that amplify and exacerbate that impact.

For these reasons, we strongly urge CMS to act consistently with the federal court's ruling and to immediately begin enforcing the 2020 NBPP rule and issue guidance expressly confirming and clarifying that it is pursuing such enforcement. Continued failure to do so is inconsistent with the agency's own policy priorities seeking to empower patients and to improve access to medically necessary care.

II. Request to Expressly Clarify and Confirm That the Practice of Designating Certain Medications as "Non-EHB" Is Prohibited in Large Group and Self-Insured Plans

We strongly urge CMS to clarify and confirm that insurance companies and pharmacy benefit managers (PBMs) are not allowed to eliminate certain specialty medications from their formularies and designate them as "non-EHB," and thus not subject to the ACA's EHB protections, including annual cost-sharing limits. We appreciate that the 2025 NBPP final rule addressed and clarified that this problematic practice is prohibited in

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[13] *See, e.g.*, Jalpa A. Doshi et al., *Impact of Cost Sharing on Specialty Drug Utilization and Outcomes: A Review of the Evidence and Future Directions*, American Journal of Managed Care (Mar. 2016); 22(3): 188–197, *available at* https://pubmed.ncbi.nlm.nih.gov/27023024/; Teresa B. Gibson et al., *Cost Sharing, Adherence, and Health Outcomes in Patients with Diabetes*, American Journal of Managed Care (Aug. 2010); 16(8): 589–600, *available at* https://pubmed.ncbi.nlm.nih.gov/20712392/; Marie T. Brown & Jennifer K. Bussell, *Medication Adherence: WHO Cares?*, Mayo Clinic Proceedings, (April 2011); 86(4): 304–314, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3068890/.

[14] *See, e.g.*, Stephan Kanzler et al., *Duration of Immunosuppressive Therapy in Autoimmune Hepatitis*, J. Hepatology, 34:354–355 (2001) (describing the importance of immunosuppressive therapy to sustained remission and prevention of relapse in patients with autoimmune hepatitis); Christopher C. Afendulis et al., *The Impact of Medicare Part D on Hospitalization Rates*, Health Servs. Res., 46(4):1022–38 (2011) (finding that implementation of Part D reduced hospitalization rates); Liisa Palmer et al., *Impact of Patient Cost Sharing on Multiple Sclerosis Treatment*, The American Journal of Pharmacy Benefits (2012) ("Suboptimal treatment adherence is common and associated with a higher risk of relapse, emergency department (ED) visits, hospitalizations, and medical costs."), *available at* https://www.pharmacytimes.com/publications/ajpb/2012/AJPB_2012_Nov/Impact-of-Patient-Cost-Sharing-on-Multiple-Sclerosis-Treatment.

[15] *See, e.g.*, Massachusetts Health Policy Commission, *Prescription Drug Coupon Study: Report to the Massachusetts Legislature* (July 2020), at 14 (noting, with citations to supportive studies, that "[r]esearch indicates that increasing medication adherence has the potential to reduce emergency department visits, hospitalizations, and overall health care costs for patients managing chronic conditions" and that "[p]rohibitive out-of-pocket drug costs are one factor contributing to poor medication adherence"); John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, NEJM, 354(22):2349–59 (2006) (finding that Medicare+Choice beneficiaries with a capped drug benefit had higher relative rates of ER visits, non-elective hospitalizations, and death, compared to those with unlimited drug coverage).

[16] 87 Fed. Reg. 584, 585 (Jan. 5, 2022).

individual and small group plans.[17] In that rule, the agency also stated that it would address the applicability of this policy to self-insured health plans and large group market health plans in future notice-and-comment rulemaking.[18] We are extremely disappointed that this year's Proposed Rule does not address this issue, and we strongly encourage CMS to expressly clarify and confirm these protections in the final rule.

In recent years, insurance companies and PBMs have increasingly been working with third-party vendors to eliminate certain specialty medications from their formularies and designate them as "non-EHBs" and thus not subject to the ACA's cost-sharing requirements. Third-party specialty medication vendors typically do this through schemes such as copay maximizer programs[19] or alternative funding programs (AFPs).[20] Under both types of programs, amounts paid for these "non-EHB" medications—either through manufacturer assistance or other forms of assistance provided to patients—do not count toward the patient's annual cost-sharing limits. As a result, patients are forced to incur thousands of dollars in other out-of-pocket health care costs that should be satisfied by payments made through patient assistance programs.

CMS has already acknowledged the harms that these programs cause to patients. In the 2025 NBPP final rule, the agency stated that "coverage is diminished if a drug is no longer considered EHB," and consumers would "be most negatively impacted by additional out-of-pocket costs and loss of consumer protections."[21] Because of these harmful effects, the agency added explicit language confirming and codifying the requirement that prescription drugs covered in excess of a State's EHB-benchmark plan are considered EHB and thus subject to the ACA's protections for EHB, including cost-sharing limitations.[22] Consistent with this policy and with existing EHB regulations, this policy applies to all plan types, and we strongly urge the agency to expressly clarify and confirm that this this requirement applies self-insured and large group plans as well as individual and small group plans.

Specialty medications are used to treat many chronic conditions, including autoimmune diseases like multiple sclerosis, rheumatoid arthritis, and psoriasis. Each autoimmune disease patient requires highly individualized care, with physicians personalizing each patient's therapies and treatment plans. The different available treatments are not interchangeable, and patients on a medication regimen depend on uninterrupted access to their prescribed therapies. However, when a patient's medication is designated as "non-EHB," their access can be disrupted or even discontinued altogether. For example, some patients having to use AFPs to obtain their specialty medications have experienced significant delays in the enrollment process, causing disruptions in their continuity of care and creating issues with treatment adherence.[23] Other patients who were subjected to copay maximizers have been told to switch their medications mid-year when their copay assistance has been exhausted or becomes unavailable—a dangerous practice known as "non-medical switching."[24]

Given the cost and access issues patients have faced with these programs, a patient may be inclined not to enroll. However, they do not really have a choice because opting out means facing significant co-insurance

[17] 89 Fed. Reg. at 26350–26352.
[18] 89 Fed. Reg. at 26351–26352.
[19] Under a copay maximizer program, a health plan determines and accepts as payment the annual maximum amount of manufacturer copay assistance available, but those payments are not counted towards the beneficiary's deductible or out-of-pocket maximum.
[20] Through an AFP, a patient effectively becomes selectively uninsured for certain specialty drugs, and payment for these medications are covered by a patient assistance program (PAP), which are not subject to the ACA's EHB protections and thus do not count toward the patient's annual cost-sharing limitations.
[21] 89 Fed. Reg. at 26351.
[22] 89 Fed. Reg at 26350–26351 (codified at 45 C.F.R. § 156.122(f)).
[23] *See, e.g.*, *The Looming Threat of Alternative Funding Models*, IPG Health (2022), https://ipghealth.com/news/the-looming-threat-of-alternative-funding-models.
[24] *How a Loophole in the Patient Protection and Affordable Care Act Can Impact Access to Your Necessary Treatments*, Aimed Alliance (2022), https://aimedalliance.org/wp-content/uploads/2022/07/Aimed-Alliance-Non-EHB-Fact-Sheet-FINAL-1.pdf; Seth J Baum, *Non-medical switching an unmitigated threat to patient care*, Am J Prev Cardiol (2023), https://pubmed.ncbi.nlm.nih.gov/36845664/.

rates (as high as 30% to 50% of the cost of the specialty drugs[25]) or even paying for the full cost of the medicine.[26] Even once enrolled in an AFP, patients still may need to pay significant out-of-pocket costs for their medications. This is because AFPs seek money from patient assistance programs (PAPs) to cover the cost of a patient's specialty medications, but PAPs are designed to help uninsured and low-income people access their medications. Therefore, an AFP-enrolled patient—who is otherwise insured and does not meet the income requirements—may be found ineligible for PAP funds.[27] The patient then must begin the arduous and protracted process of re-seeking insurance from their original health plan, which contributes to further disruption in treatment.[28]

We echo other stakeholders in urging the agency to act now to confirm the applicability of important protections for patients in large group and self-insured health plans, and to expressly state that this harmful "non-EHB" practice is prohibited. Doing so is urgently necessary, as the use of copay maximizers and AFPs is proliferating across all types of health plans and is harming patients. In 2023, 49% of commercially insured beneficiaries had plans with copay maximizers implemented, an increase from 6% in 2018.[29] The same expansion is found when looking at the numbers by therapeutic class: in 2022, 14% of commercially insured autoimmune patients had one or more of their drugs subjected to a copay maximizer, an increase from 4% in 2019.[30] AFP use is expanding in self-insured (i.e., employer-based) insurance plans, with 14% of these plans using an AFP in 2022, an increase from 6% in 2021.[31] The HIV+Hepatitis Policy Institute has compiled a list of 128 employers and 25 issuers who use third party vendors to designate certain specialty medications as "non-EHB,"[32] and has provided this information to the agency. We urge HHS to act promptly to protect patients from these harmful practices and programs.

At a time when we should all be working to help patients with complex diseases to obtain and maintain access to the prescribed care and treatment that they need, we should adopt policies that improve access to treatment. Effective treatments greatly improve quality of life for millions of Americans, increase productivity, and assist in containing overall health care costs. Yet, many individuals living with serious and chronic conditions routinely face substantial financial challenges in managing their health, including as a result of having their life-sustaining therapies designated as "non-EHB."

For these reasons, we implore CMS to expressly clarify and confirm—and enforce—its current regulations and policies to ensure that specialty medications for patients in self-insured and large group plans are

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[25] *PrudentRx Copay Program Frequently Asked Questions*, PrudentRx, https://membershealthplannj.com/wp-content/uploads/2020/11/Member-FAQ_PrudentRx-Copay-Program.pdf; *2024 Copay Assistance Benefit Drug List*, SaveOnSP, https://www.saveonsp.com/wp-content/uploads/2023/10/AllOther012024.pdf.

[26] David Choi et al., *A primer on copay accumulators, copay maximizers, and alternative funding programs*, J Manag Care Spec Pharm, 30(8):883–896 (2024), available at https://pmc.ncbi.nlm.nih.gov/articles/PMC11293768.

[27] *Alternative funding programs hinder access to medications*, Immune Deficiency Foundation (2024), https://primaryimmune.org/resources/news-articles/alternative-funding-programs-hinder-access-medications; Shelby Smoak, *The New Bully on the Insurance Playground: Alternative Funding Programs*, BIOMATRIX (2024), https://www.biomatrixsprx.com/news/the-new-bully-on-the-insurance-playground-alternative-funding-programs; Alliance for Patient Access, *The High Costs of Alternative Funding Programs* (2023), https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA_High-Costs-of-Alternative-Funding-Programs_June-2023.pdf.

[28] Alliance for Patient Access, *The High Costs of Alternative Funding Programs* (2023), https://allianceforpatientaccess.org/wp-content/uploads/2023/06/AfPA_High-Costs-of-Alternative-Funding-Programs_June-2023.pdf.

[29] Adam J. Fein, *Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow*, Drug Channels (2024), https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html.

[30] Adam J. Fein, *Copay Accumulator and Maximizer Update: Adoption Plateaus as Insurers Battle Patients Over Copay Support*, Drug Channels (2023), https://www.drugchannels.net/2023/02/copay-accumulator-and-maximizer-update.html.

[31] Adam J. Fein, *Employers Expand Use of Alternative Funding Programs—But Sustainability in Doubt as Loopholes Close*, Drug Channels (2023), https://www.drugchannels.net/2023/05/employers-expand-use-of-alternative.html.

[32] HIV+HEP Policy Institute, *Employers and Issuers Using "Non-Essential Health Benefit" Prescription Drug Vendors* (2024), https://hivhep.org/testimony-comments-letters/employers-and-issuers-using-non-essential-health-benefit-prescription-drug-vendors/.

appropriately designated as EHB and thus subject to the ACA's important EHB protections, including annual cost-sharing limitations.

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Thank you for your consideration of our comments. We look forward to continuing to work with you on these important issues.

Sincerely,

Molly Murray
President and Chief Executive Officer
Autoimmune Association