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November 12, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard Baltimore, MD 21244

Submitted Electronically via: regulations.gov

RE: Patient Protection and Affordable Care Act; Notice of Benefit and Payment Parameters for 2026 and Basic Health Program [CMS-9888-P]

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the *Patient Protection and Affordable Care Act; Notice of Benefit and Payment Parameters for 2026 and Basic Health Program* Proposed Rule. NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation.[1] We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients.[1] Our research helps inform important health care policy debates and supports the achievement of the best patient outcomes in the most efficient way possible.

We appreciate CMS's commitment to promoting patient-centered and high-quality health care across the country. We aim to provide CMS with feedback and guidance on research relevant to some of the key policies outlined in the Notice of Benefit and Payment Parameters (NBPP) Proposed Rule for 2026.

Our comments are as follows:

I. Announcement of Intention of Proposed Rulemaking Regarding the Applicability of Drug Manufacturer Support to the Annual Limitation on Cost-Sharing

NPC is concerned with the agency's inaction against the promulgation of copay accumulators, maximizers, and alternative funding programs (AFPs) by third party vendors and pharmacy benefit managers. NPC believes that health care benefit designs should be patient-centered and promote the health of all Americans. These programs distort patient access to appropriate medicines by shifting the value of manufacturers' funding support to health plans rather than patients. To date, twenty-one states and Puerto Rico have recognized the negative impacts of copay accumulator programs on patients and

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[1] About the National Pharmaceutical Council. National Pharmaceutical Council. 2024. Available at: https://www.npcnow.org/about

have enacted prohibitions against them; however, these state bans may not blunt the impacts of copay maximizers or AFPs.[2] As of 2023, data representing 118 million commercially insured lives demonstrates that roughly half of working adults are in health plans that utilize an accumulator or maximizer.[3]

Given the scale and the impact of copay accumulator and maximizer programs on patients' access to necessary medicines, we urge the Agency to take swift action to stop the growth of these programs. We urge the Agency to return to and enforce the 2020 NBPP policy on coupons in light of the Court's final opinion from the *HIV and Hepatitis Policy Institute et al. v. U.S. Department of Health and Human Services et al.*, that vacated the 2021 NBPP's policy.[4] As stated in the HIV and Hepatitis Policy Institute comment letter to CMS on the NBPP for the 2025 calendar year, the "the District Court for D.C. …. has struck down the section of the 2021 Notice of Benefits and Payment Parameters rule that allowed issuers to decide if copay assistance can count or not, and that same Court has clarified, at the government's request, that the 2020 Notice of Benefits and Payment Parameters rule is now in effect, issuers must count copay assistance in most instances and not implement copay accumulators."[5] We urge CMS to issue rulemaking to enforce the 2020 NBPP policy on coupons, which requires plans to count patient assistance programs towards deductibles unless a generic equivalent is available.

We were encouraged to see the Agency codify the policy on the status of essential health benefits for prescription drugs for small group and individual plans; the codified policy asserts that all covered prescription drugs, including those in excess of those covered by a state's essential health benefit (EHB) benchmark, are EHBs within the small group and individuals plans.[6] However, we urge the Agency to expeditiously release the Tri-Agency rulemaking to address the EHB loophole in the large group and self-insured group plans. The lack of rulemaking from the Agency on the classification of all covered prescriptions as EHBs has led to the rise of maximizer programs. EHB-status for covered prescription drugs ensures that a patient's copay and coinsurance expenditures are attributed to his/her deductible and maximum out-of-pocket limits. Health plans and pharmacy benefit managers that utilize maximizer programs classify certain medicines as non-essential health benefits, and "extract" the value of manufacturer patient assistance programs (without attributing that value to a patient's out-of-pocket requirements).[7] Therefore, a patient receiving a prescription through a maximizer program could experience unexpected out-of-pocket expenses during the year, administrative hurdles, and treatment disruptions.[8] We are also particularly concerned with the potential discriminatory nature of these

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[2] All Copays Count Coalition. State Legislation Against Copay Accumulators. https://allcopayscount.org/state-legislation-against-copay-accumulators/

[3] Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. Drug Channels. Feb 2024. Available at: https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html

[4] *HIV and Hepatitis Policy Institute v. United States Department of Health and Human Services.* Memorandum Opinion & Order. 23 Dec 2023. Available at: https://hivhep.org/wp-content/uploads/2023/12/Clarification-decision.pdf

[5] Comments on the NBPP for 2025 Proposed Rule. HIV and Hepatitis Policy Institute. Jan 2024. Available at: https://hivhep.org/testimony-comments-letters/comments-on-the-nbpp-proposed-rule-for-2025/

[6] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program. Final Rule. Centers for Medicaid and Medicare Services. April 2024. Available at: https://www.federalregister.gov/documents/2024/04/15/2024-07274/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2025

[7] Joszt L and Lutton L. Breaking Down Co-Pay Accumulators, Maximizers and the Impact on Patients. AJMC. Oct 2024. Available at: https://www.ajmc.com/view/breaking-down-co-pay-accumulators-maximizers-and-the-impact-on-patients

[8] Choi D, Zuckerman AD, Gerzenshtein S, et al. A Primer on Copay Accumulators, Copay Maximizers, and Alternative Funding Programs. JMCP. 2024; 30 (8). Available at: https://doi.org/10.18553/jmcp.2024.30.8.883

programs. Recent evidence, released in 2023, evaluated racial differences in the exposure to copay accumulator and maximizer programs among four million commercially insured adults.[9] The authors found that – after adjustment for demographics, the presence of a state ban on copay accumulator programs, and other factors – non-White patients using copay cards are 30% more likely to be exposed to copay accumulator and/or maximizer programs as compared to White patients. The Agency should, at a minimum, investigate why accumulators are more prevalent among non-White patients. One potential link could be the association between chronic illness and racial disparities; non-White patients bear a greater share of chronic illnesses compared to non-White patients.[10] The AIDS Institute has raised concerns about the discriminatory nature of copay accumulator policies, stating "At the most basic level, copay accumulator adjustment policies discriminate against people living with chronic illness, interrupting their access to needed treatment and threatening their health."[11] Copay accumulator and maximizer programs shift cost sharing on patients who have a higher burden of chronic illness; further, delaying or halting treatment for patients with chronic disease.

We are also concerned about the emergence of alternative funding programs as a newer cost containment strategy among commercial plans. Alternative funding programs eliminate coverage for select specialty medicines and divert patients to receive these drugs through manufacturer patient assistance programs, charitable foundations, or other sources - putting patients at risk.[3] Patient safety should be at the forefront of the Agency's priorities; we are concerned about the practices of alternative funding programs, including importation of medicines from other countries. [12] The Agency should take notice and stop these actions. In the July 2024 House Committee on Education & the Workforce hearing, Lisa M. Gomez, Assistant Secretary for Employee Benefits Security Administration at the Department of Labor said that alternative funding programs are a "growing issue," and the Department of Labor has the "statutory authority to address this issue."[13] Alternative funding programs are often run by third party administrators, who project significant savings for health plans; however, as stated by Assistant Secretary Gomez, "employers find that these programs are not what are being sold to them…"[13]

<u>We request that CMS prioritize patients and the following immediate actions on patient exposure to plan cost containment strategies:</u>

- Expeditiously propose rulemaking to address accumulators, maximizers and alternative funding programs.

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[9] Ingham M, Sadik K, Zhao X, Song J, Fendrick AM. Assessment of racial and ethnic inequities in copay card utilization and enrollment in copay adjustment programs. J Manag Care Spec Pharm. 2023 Sep;29(9):1084-1092. doi: 10.18553/jmcp.2023.23021. Epub 2023 Aug 7. PMID: 37548953; PMCID: PMC10510673.
[10] Minority Population Profiles. Office of Minority Health. Oct 2024. Available at: https://minorityhealth.hhs.gov/minority-population-profiles
[11] Discriminatory Copay Policies Undermine Coverage for People with Chronic Illness. The AIDS Institute. Feb 2023. Available at: https://aidsinstitute.net/documents/TAI-Report-Copay-Accumulator-Adjustment-Programs-2023.pdf
[3] Copay Accumulator and Maximizer Update: Adoption Expands as Legal Barriers Grow. Drug Channels. Feb 2024. Available at: https://www.drugchannels.net/2024/02/copay-accumulator-and-maximizer-update.html
[12] Alternative Funding Programs: Offshoring patients, importing risks. The Partnership for Safe Medicines. Available at: https://primaryimmune.org/resources/news-articles/alternative-funding-programs-hinder-access-medications
https://www.safemedicines.org/2024/04/afps-offshoring-patients-importing-risks.html
[13] Examining the Policies and Priorities of the Employee Benefits Security Administration. 118th Congress. House Committee on Education & the Workforce. July 24, 2024. Available at: https://www.youtube.com/watch?v=adM3jjdlZU8&t=1s.

- Enforce the 2020 NBPP policy on manufacturer cost-assistance that requires plans to count manufacturer patient assistance toward a patient's deductible and annual limits on cost sharing, unless a generic equivalent is available.
- Expeditiously release the Tri-Agency rulemaking to address the EHB loophole in the large group and self-insured group plans, and classify all covered medicines as essential health benefits (EHB) in these plans.[14]
- Investigate the potential discriminatory nature of accumulators, maximizers, and alternative funding programs; prohibit accumulators, maximizers, and alternative funding programs found in violation of the law.
    - Ensure that plans are compliant with Title VI of the Civil Rights Act of 1964, the Americans Disability Act of 1990, and the Age Discrimination Act of 1975, and Title IX of the Education Amendments of 1972, which collectively prohibit discrimination based on race, sex, color, national origin, age or disability.[15] Plans' participation in alternative funding programs, which eliminate plan coverage of select specialty medicines for lower income patients, who qualify for patient assistance programs, may violate one or more of these acts.
- The Tri Agencies should investigate if implementing alternative funding programs run afoul of income discrimination, HIPAA, or fiduciary responsibility laws and enforce the law accordingly.[16] The Tri Agencies should prohibit AFPs in the commercial market. At a minimum, the Department of Labor should outline all the potential harms on patients due to exposure to AFPs.
- Require plan issuers to publicly identify which commercial health plans include copay accumulator, maximizers, and alternative funding programs.

II. <u>Further Refining the HHS-Operated Risk Adjustment Program</u>

A. Proposal to Phase Out the Market Pricing Adjustment for Hepatitis C Drugs and Trend Them Consistent with Other Specialty Drugs

CMS believes it is appropriate to phase out the market pricing adjustment for Hepatitis C drugs and begin trending the cost of these drugs consistent with other similar drugs in the HHS risk adjustment model.[17] NPC appreciates CMS's efforts to annually re-evaluate the costs and market pricing subsequent adjustments for Hepatitis C medicines, as access to these medicines is critical to promoting public health.

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[14] Departments of Labor, Health and Human Services (HHS), and the Treasury. FAQ about Affordable Care Act Implementation Part 66. April 2024. Available at: https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66

[15] Civil Rights for Individuals and Advocates. U.S. Department of Health and Human Services. Available at: https://www.hhs.gov/civil-rights/for-individuals/index.html

[16] Shelton J, Niakan K, McBride K. Pharmacy Benefit Alternative Funding Programs: key considerations for self-funded plan sponsors. Milliman. April 2024. Available at: https://www.milliman.com/-/media/milliman/pdfs/2024-articles/4-26-24_alternative-funding-whitepaper_final_04262024.ashx

[17] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2026. Centers for Medicare & Medicaid Services, HHS. October 2024. https://www.federalregister.gov/documents/2024/10/10/2024-23103/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2026-and

Although CMS has stated it will use a phased-in approach to the transition, we urge CMS to continue to evaluate the effects of this policy on public health.

The Centers for Disease Control (CDC) has found barriers in access to care for Hepatitis C treatments, with only one in three individuals with insurance receiving timely treatment.[18] Few people receive treatment within one year of diagnosis, even though Hepatitis C is curable in more than 95 percent of cases.[18] The CDC has also noted that expanding treatment for Hepatitis C is "essential to reducing viral hepatitis-related disparities and eliminating hepatitis C as a national public health threat."[18] Moreover, access to Hepatitis C therapies is important for health equity, as deaths associated with Hepatitis C were higher for both Black people and Hispanic people, compared to White people.[18] Inadequately compensating issuers for enrollees with Hepatitis C could exacerbate these barriers to treatment and worsen health disparities, potentially disincentivizing issuers from enrolling certain patients or causing them to employ benefit design policies that make it more difficult for patients to access these medicines.

B. Proposal to Incorporate HIV pre-exposure prophylaxis (PrEP) as a New, Separate Factor Called an Affiliated Cost Factor (AFC) in Risk Adjustment Models

Currently, costs of PrEP are modeled alongside other preventive services in the HHS risk adjustment models. CMS proposes to use a new, separate ACF for exposure to PrEP among plan enrollees. We appreciate the Agency's attention to PrEP medication, as these medicines are an important tool to decrease the spread of HIV infection among younger and older adults. PrEP continues to be underutilized; the CDC reports that less than 40% of people indicated PrEP were prescribed the medicine.[19] As the Agency changes risk adjustments based on PrEP utilization and costs, we ask the Agency to consider the implications of changes on any potential changes to access and affordability of PrEP medicines under Marketplace plans.

NPC has concerns that a sweeping policy change may have unintended consequences. We are seeking clarity regarding the following:

- We seek further clarity on estimations of the ACF, including incorporation of rebates and/or medication adherence; we request that the Agency provide additional background and detail in this area before finalizing a proposal.
- If the ACF is finalized, we urge the Agency to closely and consistently monitor whether adoption of this policy has a positive impact on addressing public health through reduced adverse selection and improved access to PrEP.
- We suggest that generic PrEP should not be considered in the ACF to protect against adverse selection. As CMS is considering using the ACF for other preventive services and treatments across a range of conditions, we urge the Agency provide clarity around the scope of services and treatments that may be incorporated in future ACFs.

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[18] Centers for Disease Control. Too Few People Treated for Hepatitis C. September 2022. Available at: https://www.cdc.gov/vitalsigns/hepc-treatment/index.html

[19] Ending the HIV Epidemic in the US. Centers for Disease and Control. October 2024. Available at: https://www.cdc.gov/ehe/php/about/goals.html?CDC_AAref_Val=https://www.cdc.gov/endhiv/prevent.html

- In the development of future ACFs, we urge the Agency to not take a one-size-fits-all approach and be transparent in the development of these measures, as there may be differences in conditions that require different risk adjustment methodologies.

III. Advancing Health Equity and Mitigating Health Disparities

In this rule, CMS proposes policies that aim to advance health equity and mitigate health disparities. Under one proposal, CMS proposes to conduct reviews of Qualified Health Plans (QHPs) in federally facilitated marketplaces (FFMs) in states performing management functions to ensure issuers include a sufficient number and geographic distribution of essential community providers (ECPs). ECPs often provide services specifically designed to address health needs of low-income individuals and traditionally unmet medical needs, including language services, patient support services, service coordination for health and social services, and location in a low-income community.[20] Inclusion of ECPs in marketplace plans is particularly important for women's health, as clinic-based providers and family planning clinics and health centers are valuable sources of reproductive and sexual health care, particularly for women who are low-income and women of color.[20] We support CMS's proposal to ensure network adequacy of ECPs, and thank CMS for taking this step in promoting access to care for underserved communities.

CMS also proposes an adjustment to the medical loss ratio (MLR) calculation for qualifying issuers. Through this change, CMS intends to support plans with unique business models that focus on underserved communities, whose beneficiaries often have high health needs. Risk adjustment payments are particularly crucial for these plans. NPC supports this proposal given its impact on underserved communities, and the importance of adequately compensating issuers for the cost of care to promote stability in the health care insurance marketplace.

IV. Increasing Transparency of Data

In this rule, CMS proposes publicly releasing the annual State-based Marketplace Annual Reporting Tools (SMART) and accompanying financial and programmatic audits, as well as data on Open Enrollment. These shifts towards greater transparency are designed to foster greater public understanding of and confidence in Marketplace operations, promote transparent compliance activities, and boost Marketplace efficiency and accountability. Additionally, CMS proposes to share aggregated, summary-level Quality Improvement Strategy (QIS) information publicly on an annual basis. This proposal seeks to promote transparency and accountability among QHP issuers while encouraging the adoption of the best practices to enhance the quality of health care coverage.

NPC supports policies to increase transparency of marketplace and other health care data. Greater transparency of commercial insurance data will facilitate greater accountability of plans to patients and other stakeholders. For example, CMS hospital reporting data has allowed researchers to

[20] KFF. Federal and State Standards for "Essential Community Providers" under the ACA and Implications for Women's Health. January 2015. https://www.kff.org/womens-health-policy/issue-brief/federal-and-state-standards-for-essential-community-providers-under-the-aca-and-implications-for-womens-health/#:~:text=ECPs%20often%20provide%20services%20that,in%20a%20low%2Dincome%20community

demonstrate hospital markups of infusion prescription drugs.[21] As a health policy research organization, NPC appreciates publicly available data that support our ability to study the health care system. We thank the Agency for the proposals to increase transparency and the availability of data on the Marketplace. We offer the following recommendations on the release of data:

- Release public data in modalities that are patient-friendly and accessible - accounting for differences in languages, physical/mental abilities, and health literacy.
- Align release of data with reports that ultimately help patients make informed decisions about the best Marketplace plan for their health care needs.
- Make data publicly accessible in a timely fashion for researchers, patient organizations, and other entities/populations to conduct research on compliance of plans over extended years, while also protecting important patient information and HIPAA protections.

Conclusion

The National Pharmaceutical Council appreciates the opportunity to comment on this proposed rule. We would be happy to meet to expand upon our comments and share our research. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

John O'Brien, PharmD, MPH
President & Chief Executive Officer

[21] Examining 340B Hospital Price Transparency, Drug Profits, and Incentives. Community Oncology Alliance (COA). September 2022. Available at:https://communityoncology.org/wp-content/uploads/2022/09/COA_340B_hospital_transparency_report_2_final.pdf