

January 8, 2024

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

Re: 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 [CMS–9895–P; RIN 0938-AV22]

Dear Administrator Brooks-LaSure,

On behalf of The Patient Access Network (PAN) Foundation, one of the nation's largest charities, I write to provide comment on the Department of Health and Human Services' (HHS) 2025 Notice of Benefit and Payment Parameters (NBPP) proposed rule. We laud the Biden administration for making progress to increase access to health care and coverage, but more is needed to ensure that people living with a chronic illness are not discriminated against and are able to get the ongoing care they need.

PAN is an independent, national 501(c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out-of-pocket (OOP) costs for their prescribed medications. PAN provides patients with direct assistance through more than 70 disease-specific programs and collaborates with national patient advocacy organizations to provide patients with education and additional support. Since 2004, we have helped more than 1 million underinsured patients.

### **Allowing States to Add Routine Adult Dental Benefits as Essential Health Benefits (EHBs)**

PAN commends CMS for acknowledging the vital role that oral health plays in enhancing overall health outcomes and improving patients' quality of life. PAN strongly supports CMS' proposal to remove the regulatory prohibition on issuers from including routine non-pediatric dental services as an EHB, which would allow states to add routine adult dental services as an EHB by updating their EHB-benchmark plans. Removing the regulatory prohibition on non-pediatric dental services aligns state EHB-benchmark plans more closely with the private marketplace. Given the expanding dental benefit offerings in employer-based plans, it is essential that the scope of EHBs be extended to Americans obtaining Marketplace coverage.

This proposal would also give states the opportunity to improve adult oral health and overall health outcomes, which could help reduce health disparities and advance health equity since these health outcomes are disproportionately low among marginalized communities. People of color are less likely than whites to receive dental care, in part because of lack of coverage. Moreover, lack of access to dental services also leads to other serious conditions, including cardiovascular disease and low birthweights, which are more prevalent in underserved communities. By allowing states to require dental care coverage, the 2025 NBPP opens the door to the possibility that states will use the benchmarking process to require dental care as a way to address health disparities regarding dental care and related conditions.

Former US Surgeon General David Satcher said more than 20 years ago that “you cannot be healthy without oral health.”<sup>1</sup> But for working-age adults disparities in oral health outcomes and in access to dental care have widened by income and race. Treating dental care as essential health benefit is the only way to address these challenges.

Further, PAN also supports removal altogether of provision that prohibits health plan issuers from offering routine non-pediatric dental care, routine non-pediatric eye exam services, long-term/custodial nursing home care benefits, or non-medically necessary orthodontia as EHB. Like dental care, significant disparities in vision health and eye care exist. Vision benefits are also routinely offered in employer-based plans and therefore should be an option for states to include in their EHB-benchmark plans.

### **§ 156.122 Amendment to Codify Drugs in Excess of State Benchmark as EHB**

We applaud and strongly support the proposal to add paragraph (f) to §156.122 to codify that prescription drugs in a plan that are in excess of those covered by a State’s EHB-benchmark are considered EHBs. The 2025 NBPP proposed rule states:

*“If the plan is covering drugs beyond the number of drugs covered by the benchmark, all drugs in excess of the drug count standard at § 156.122(a) are considered EHB, such that they are subject to EHB protections and must count towards the annual limitation on cost sharing”*

PAN supports CMS’ intention to codify current policy that establishes that, when plans cover prescription drugs beyond the bare minimum, those additional medications are still considered EHBs. This ensures that cost sharing protections apply to the whole spectrum of a plan’s drug formulary, rather than being limited to those medications the plan is required to provide. Many issuers across the country have tried to exclude some drugs from the EHB cost-sharing protections, imposing exorbitant financial burdens on consumers. As expected, the heaviest burden falls on individuals with complex health needs who use costly prescription drugs. Codifying HHS’ policy would protect these patients and strengthen health equity regarding access to prescription drugs. While this does not address copay accumulator programs specifically, it does clarify that any prescription drug covered by a plan must be considered an EHB and therefore, copay accumulator programs are not allowed.

Copay accumulators are discriminatory toward those with chronic illnesses and harm patients while benefiting insurers and PBMs. Copay accumulator adjustment policies unfairly target people with serious, chronic illness, undermining the Affordable Care Act (ACA) protections that prohibit insurers from charging people with pre-existing conditions more for health insurance than healthier enrollees. Copay assistance is available generally for high-cost brand and specialty medications without a medically equivalent generic alternative and is used by people with serious and complex chronic illnesses.<sup>2</sup> These policies subvert the benefit of copay assistance, thereby discriminating against people living with chronic conditions. People with low incomes and people of color are more likely to be living with a

<sup>1</sup> US Department of Health and Human Services. *Oral Health in America: A Report of the Surgeon General*. National Institute of Dental and Craniofacial Research, National Institutes of Health; 2000. <https://www.nidcr.nih.gov/sites/default/files/2017-10/hck1ocv.%40www.surgeon.fullrpt.pdf>

<sup>2</sup> K. Van Nuys, G. Joyce, R. Ribero, D.P. Goldman, A Perspective on Prescription Drug Copayment Coupons. Leonard D Schaeffer Center for Health Policy & Economics. (February 2018), <https://healthpolicy.usc.edu/research/prescription-drug-copayment-coupon-landscape/>

chronic illness;<sup>3</sup> therefore, these policies target the most vulnerable patients, enabling insurance issuers to essentially underwrite insurance policies for people who require specialty or brand medications.

When copay assistance is not counted toward a patient's deductible and out-of-pocket costs, the patient alone is left responsible for paying what is often an exorbitant amount in out-of-pocket costs that can inhibit access to a needed prescription medication. This means that the insurer is often accepting payments above and beyond the maximum cost sharing requirement required by the ACA, as the dollars from third-party payments are not counted towards the calculation of the patient's deductible or annual out-of-pocket maximum. PBMs are potentially collecting the payments twice - once via copay assistance, and again when the patient requires other care, or when their copay assistance runs out and they need to get their prescriptions refilled assuming they can afford to do so.

#### **Plans' Designation of Excess Prescription Drugs as "Covered Non-EHB"**

PAN is concerned that the proposed rule does not clarify that plans cannot designate certain medications "non-EHB" based on their definition of prescription drugs as an EHB. The proposed rule states:

*"In addition, a small number of commenters noted concerns regarding some plans in the individual, small group, and large group markets that have stated that some drugs in excess of the drug count standard at § 156.122(a) are not EHB and have developed programs to provide some drugs as "non-EHB," outside of the terms of the rest of the coverage. We seek comment regarding how widespread these practices are."*

This must be clarified. The "covered non-EHB designation" has harmful consequences to patients, particularly to patients relying on specialty medications to treat and/or manage serious, complex, and chronic conditions. The lack of clarity has allowed some plans or Pharmacy Benefit Managers (PBMs) to categorize additional drugs they cover beyond these minimum standards as "non-EHB." This has allowed for plans to designate certain medicines as "non-essential" and steer enrollees to alternative funding programs provided by outside vendors. In alternative funding programs, patients who use certain medications are directed to enroll in an alternative program, which is not insurance, in order to by-pass ACA laws and regulations relative to patient cost-sharing limits and other patient protections. They remove these drugs from the formulary and the entity finds alternative funding mechanisms to pay for the drugs. If the patient does not comply, they will be left paying the full cost of the drug. Further, plans conceal these policies in plan documents leaving patients unaware. We urge CMS to bar plans from designating certain medications as "non-EHB" based on the plan's definition of prescription drugs as an EHB.

#### **HHS Authority and Applicability of § 156.122 Amendment to Large Group and Self-Insured Plans**

While PAN understands that this proposal specifically requires plans subject to the requirement to cover EHB to count all prescription drugs as EHB for the purposes of coverage and cost-sharing, we urge CMS, Treasury, and the Department of Labor to further clarify that this protection extends to prescription drugs covered in large group and self-insured plans. We are fully aware and understand that the proposed amendment does not change the core premise that large group and self-insured plans are not required to offer EHBs. However, we interpret the proposed amendment as being applicable to these

<sup>3</sup> The Center for American Progress, Fact Sheet: *Health Disparities by Race and Ethnicity*. (May 7, 2020), <https://www.americanprogress.org/article/health-disparities-race-ethnicity/>

plans if they offer prescription drugs and include drugs in excess of the benchmark plan they have selected as their defined EHB.

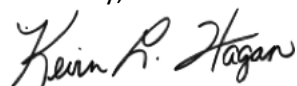
## **Conclusion**

While PAN strongly supports the proposal to require plans to count all prescription drugs as EHB for cost-sharing purposes, we note that CMS continues to oppose efforts to require PBMs and insurers to count copay assistance payments made by or on behalf of an enrollee toward that enrollee's annual deductible and out-of-pocket limit. In light of the U.S. District Court for the District of Columbia's September 29, 2023 decision<sup>4</sup> and subsequent clarification on December 22, 2023,<sup>5</sup> we urge CMS to revert to the 2020 Notice of Benefit and Payment Parameters Rule which permitted manufacturer assistance to be excluded from cost-sharing only for "specific prescription brand drugs that have an available and medically appropriate generic equivalent"<sup>6</sup> and ensure enforcement of the copay assistance provision.

**In summary, PAN strongly supports the proposal to codify its current policy to ensure that prescription drugs in excess of those covered by a state's EHB-benchmark plan are considered EHBs such that they are subject to EHB protections, including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits. We also encourage CMS to use its enforcement authority when plans fail to comply with this regulation. We also urge CMS to require issuers and PBMs to count all payments made by or on behalf of the beneficiary (including patient copay assistance) toward patients' annual deductible and out-of-pocket limit. Additionally, CMS must prohibit the harmful strategies by plans of designating certain drugs as non-essential health benefits and then collecting the copay assistance from drug manufacturers and the growing practice of alternative funding programs. Keeping medications out of the reach of patients who need them is not good or effective policy.**

The PAN Foundation appreciates your leadership to increase equitable access to and affordability of health care for more Americans. Thank you for your consideration of our comments. If you have questions about the issues raised, please contact Amy Niles, Chief Advocacy and Engagement Officer at [aniles@panfoundation.org](mailto:aniles@panfoundation.org).

Sincerely,



Kevin L. Hagan  
President and Chief Executive Officer

<sup>4</sup> <https://hivhep.org/wp-content/uploads/2023/09/HIV-Hepatitis-Policy-Institute-v.-HHS-DDC-opinion.pdf>

<sup>5</sup> <https://hivhep.org/wp-content/uploads/2023/12/Clarification-decision.pdf>

<sup>6</sup> Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020. 84 FR 17454. April 25, 2019. <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>