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January 25, 2023

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

Dr. Ellen Montz
Deputy Administrator and Director
Center for Consumer Information & Insurance Oversight
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW
Washington, D.C. 20201

Re: HHS Notice of Benefit and Payment Parameters for 2024 Proposed Rule, CMS-9899-P RIN 0938-AU97

Dear Administrator Brooks-LaSure and Deputy Administrator Montz:

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) 2024 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. We are extremely disappointed that the 2024 NBPP proposed rule does not include any reference to copay accumulator adjustment policies, which financially benefit insurance issuers and pharmacy benefit managers (PBMs), while making crucial treatments unaffordable for patients. PAN urges you to reconsider and include in the final rule a requirement that insurers and PBMs count all copays made by or on behalf of an enrollee toward their annual deductible and out-of-pocket limit, as well as address other harmful insurer schemes to circumvent Affordable Care Act requirements related to patient cost sharing limits.

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 costs for their prescribed medications. PAN provides patients with direct assistance through nearly 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.

PAN is pleased that HHS has taken meaningful steps to ensure beneficiaries on the federal exchange can afford their prescription drugs by requiring issuers to offer standardized plans that, for the most part, include reasonable copays. While minor improvements have been proposed, some of the

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copay amounts, particularly on the specialty tier, still need to be lowered for patients. Additionally, for many drug tiers, beneficiaries are still required to meet a high deductible threshold before taking advantage of the capped copays.

PAN is also pleased CMS has strengthened regulations that address discriminatory plan design, including adverse tiering, that results in discrimination against beneficiaries with chronic health conditions. However, we are disappointed that there has been a lack of enforcement and actions against insurers and PBMs that discriminate against beneficiaries with chronic health conditions.

PAN is a strong advocate for copay assistance which help patients cover the cost of copays and coinsurance, as imposed by the health issuer's benefit design. Copay assistance is financial assistance provided by manufacturers, charitable assistance foundations, or from a family member that helps a patient cover the cost of their copays and co-insurance, ensuring older adults and people living with disabilities can afford and access their prescriptions. It does not change how much a patient must pay toward the cost of their care; it is simply a source of funding to pay those costs.

Copay Accumulators

Copay accumulators, permitted through the 2021 NBPP, 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. 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 chronic illness; 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

¹ 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/

² 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/



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when their copay assistance runs out and they need to get their prescriptions refilled assuming they can afford to do so.

Non-Essential Health Benefits Drugs & Alternative Funding Programs

There are other schemes insurers, PBMs, and other new actors in the drug supply chain are implementing that seek to get around the requirements of the ACA that further restrict access to prescription medications that CMS must address. Some plans that must follow the essential health benefits designate certain medicines as "non-essential" and then raise the cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer, but do not count it towards the beneficiary's cost-sharing obligation. Under this arrangement, the plans often collect payments far exceeding the out-of-pocket maximum. Plans that follow essential health benefits cannot cover certain drugs or medical benefits and then pick and choose which ones will count towards a beneficiary's out-of-pocket obligations. We strongly urge CMS to enforce the law and essential health benefits regulations that require all cost-sharing associated with covered benefits and services be included as part of cost-sharing.

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 address these schemes and at a minimum require plans to be transparent by displaying this information on the Statement of Benefits and Coverage document.

In summary, we 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 investigate and 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 in seeking solutions to increase access to and affordability of health care for more Americans. Thank you for your consideration of our comments. If you would like further information or have questions, please contact Amy Niles, Executive Vice President at aniles@panfoundation.org.

Sincerely,

Kevin L. Hagan

Kein R. Hagan

President and Chief Executive Officer

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