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March 2nd, 2020

Randy Pate
Director, Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Comments on *HHS Notice of Benefits and Payment Parameters for 2021* Proposed Rule, CMS-9961-P

Comments submitted electronically at www.regulations.gov

Dear Mr. Pate,

Thank you for the opportunity to submit comments on the Department of Health and Human Services (HHS or "the Agency") Notice of Benefit and Payment Parameters for 2021 (NBPP) proposed rule (CMS-9961-P). The Global Healthy Living Foundation (GHLF) writes to express our concern that revisions to §156.130(h) in this proposal will create unnecessary barriers for chronically ill patients to access needed therapies.

GHLF is a 20-year-old 501(c)(3) patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events and our online support and education. GHLF works to improve the quality of life for patients living with chronic disease by making sure their voices are heard and advocating for improved access to care at the community level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease and migraine. As a result, these patients incur significant financial burden due to the high cost of the treatments that are necessary to manage their disease. It is on behalf of the patients we represent that we provide this information for your consideration.

GHLF is concerned that some of the strategies that HHS believes will reduce healthcare costs will instead create additional undue cost burdens for people living with chronic illness. In particular, GHLF opposes the revisions to §156.130(h) and asks the Agency to leave in place the provisions in the 2020 NBPP that allowed coupons to count toward deductibles in certain circumstances. The 2021 proposed rule gives plans flexibility to determine whether or not to include coupon amounts from the annual limitation on cost sharing, regardless if a generic alternative is available or not. Additionally, the proposed rule further interprets the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons, a type of copay assistance. Essentially, this means that amounts paid using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs may be excluded from the enrollee's annual limitation on cost sharing. GHLF is very concerned that these proposed changes will lead to dramatic increases in costs for the most vulnerable patients. Combined with the increase utilization of high-deductible health plans (HDHP), policies like these that force consumers to bear the full burden of prescription drug costs mean that patients with serious, chronic health conditions are at greater risk than ever before of not having access to life-altering therapies.

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Copay assistance programs have often become the only means for many patients covered by these types of plans to afford their medications and gain access to life saving therapies. **Typically, funds from copay assistance programs count toward the enrollee's deductible, ensuring that when their coupons run out, they are still able to access their treatment without exorbitant copayments.** This enables patients to plan for their medical expenses, maintain their prescribed therapies, and stay in control of their health.

Under the proposed rule, permitting insurers not to count payments made with coupons towards an annual limitation on cost sharing is in contrast to the goal of positive health outcomes, i.e. making sure that patients have access to the best treatment for them. For many serious chronic conditions, there are often only expensive brand name drugs available with no generic equivalent. This proposed policy is not just a bad decision, but it would force many patients to choose between maxing out credit cards they cannot pay, bankruptcy, or to go without taking their medications. A 2018 report found that when patient cost sharing exceeds $250, 69 percent of new prescriptions are not filled or are not picked up at the pharmacy.[1] Many biologic medications used to treat complex conditions cost between tens of thousands of dollars per treatment, far above that $250 threshold. Without the ability of copay assistance programs to count toward their deductible, the 2021 proposed NBPP rule is putting patients at greater risk of not having access to their medications and suffering needlessly.

Permitting patients to use funds from copay assistance programs to meet their annual limitation on cost sharing has clear benefits: insurance companies still receive their payments while those with chronic health conditions are able to access their treatments and retain autonomy over their healthcare spending. GHLF disagrees with the rationale provided in the proposed rule that the existence of financial assistance programs changes the patients' cost-sharing obligation. Rather, we view these programs as a means for those with chronic illnesses to meet their financial obligations that are no different than a patient using a gift, a Go Fund Me account, a tax refund, or other means to pay for their medications. We urge you, on behalf of our community members, to consider the millions of people who rely on copay assistance programs to access their needed medications and remove these provisions from the final NBPP 2021 rule.

Thank you for your consideration and we would be please to provide any further information that you need.
Sincerely,

Steven Newmark

Steven Newmark
Director of Policy and General Counsel
Global Healthy Living Foundation

[1] IQVIA. Patient Affordability Part Two: Implications for Patient Behavior & Therapy Consumption. https://www.iqvia.com/locations/united-states/patient-affordability-part-two.