January 27, 2022

The Honorable Xavier Becerra Secretary
U.S. Department of Health and Human Services (HHS)
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: Comments on *Notice of Benefits and Payment Parameters for 2023* Proposed Rule [CMS-9911-P]

Dear Secretary Becerra:

On behalf of the Hepatitis B Foundation, a national nonprofit organization dedicated to finding a cure and improving the quality of life for people affected by hepatitis B worldwide, and Hep B United, our national coalition of 50 organizations across the United States with more than 1,000 local partners, we appreciate the opportunity to comment on the *Notice of Benefits and Payment Parameters for 2023* Proposed Rule. The patients we represent appreciate all you are doing to make healthcare more accessible and affordable. This letter focuses on the issues that impact access and affordability of prescription drugs.

Hepatitis B is the most common liver infection in the world. In the United States, up to 2.4 million Americans are chronically infected. If left untreated, hepatitis B can lead to serious complications, such as cirrhosis, liver cancer, and liver failure in 15-40% of infected individuals. Significant disparities are associated with hepatitis B. Asian American, Pacific Islander, and African communities are disproportionately affected by hepatitis B, with these communities comprising up to 80% of all chronic hepatitis B infections in the U.S.

As hepatitis B has no cure, access to affordable medication is critical to preventing end-stage liver disease and liver cancer, and improving the quality of life for those living with chronic hepatitis B. Over the past several years, the Hepatitis B Foundation has heard from an increasing number of patients expressing an inability to afford their hepatitis B treatments despite insurance coverage. One of the most common generic hepatitis B medications, entecavir, costs patients with high-deductible health plans an average of $133 dollars for a 30-day supply in 2018 – a number associated with higher rates of prescription abandonment. Failing to take hepatitis B medication as prescribed can cause the virus to flare, further increasing the risk of liver damage. Additionally, the average out-of-pocket spending per year for a 30-day supply of entecavir increased from $81 to $476 (generic) and $931 to $1,534 (brand-name) between 2014 and 2018.

We are extremely pleased that you have 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. Additionally, we are pleased you are including regulations that address discriminatory plan design and warn insurers and pharmacy benefit managers (PBMs) about designing benefits that include adverse tiering which results in discriminating against beneficiaries with chronic health conditions. However, we are extremely disappointed that the proposed rule does not require issuers and PBMs to count copay assistance for prescription drugs towards beneficiary deductible and out-of-pocket maximum obligations, thus allowing the continuation of copay accumulator adjustment programs. We also urge you to take action against employer plans that offer essential health benefits and designate certain drugs as non-essential health benefits and excluding any cost-sharing associated with them from a beneficiary's cost-sharing obligation. Finally, we commend your actions to promote greater equity in healthcare. While many of your proposed actions will help achieve this goal, the lack of action on copay assistance will further impede progress towards equity.

Standard Plan Options

We are very pleased that CMS is following through on President Biden's Executive Order Promoting Competition in the American Economy which directed HHS to implement standardized options on the exchanges. As we have written before, patients today face significant prescription drug affordability challenges that have only grown worse due to the cost of medications along with insurance benefit design, including high deductibles and co-insurance. This negatively impacts patient adherence and leads to worse health outcomes and increased costs across the healthcare system. Standardized plans can greatly assist patients to afford the prescription drugs and health services they rely on to treat their health conditions and prevent others.

High Patient Cost-sharing for Prescription Drugs: Before we offer specific comments on what CMS has proposed, please consider the following:

- Out-of-pocket costs for non-retail medicines, according to an IQVIA analysis, reached $16 billion in 2020, up from $13 billion in 2015.
- That same study found that when out-of-pocket costs reach $75-$125, 31 percent of patients abandoned their brand name prescriptions at the counter; when those costs hit $250, that number rises to more than 56 percent of patients.
- According to the Kaiser Family Foundation, average deductibles for covered workers increased 212 percent from 2008 to 2018. About 40 percent of beneficiaries with employer-sponsored coverage have a high-deductible plan with deductibles exceeding $1,500 for 20 percent of those beneficiaries.
- For qualified health plans, CMS reports that the medium annual deductible for an individual on a Silver plan in 2022 is $5,115, which is an increase of 6 percent from 2021 and 23 percent from 2018.
- According to the Kaiser Family Foundation, the average payments towards coinsurance rose 67 percent from 2006 to 2016.
- According to an IQVIA analysis of brand medicines across seven therapeutic areas, anywhere from 44-95 percent of patients' total out-of-pocket spending for brand

medicines in 2019 was due to deductibles and coinsurance. For oncology and multiple sclerosis, deductibles and coinsurance accounted for more than 90 percent of total patient out-of-pocket costs.

- According to a review of CMS' National Health Expenditures Accounts data, in 2019 individuals were responsible for paying 14.5 percent of the total cost of prescription drugs. However, for hospital care, which accounts for more than three times more of the total spending, patients were responsible for paying only 3 percent. Despite the smaller total amount of spending for prescription drugs, the total out-of-pocket spending for prescription drugs was actually higher than all the out-of-pocket spending for hospitals.

While after premiums are paid, there are cost-sharing limits - they too are rising. For plan year 2023, CMS has set the maximum out-of-pocket responsibility at $9,100 for an individual and $18,200 for all others. Due to the proliferation of high deductible plans, depending on the drug, a patient may be required to pay the total amount of $9,100 all at once for their medication at the beginning of the year.

CMS Proposed Standardized Options: In order to limit patient cost-sharing and improve patient affordability and accessibility to prescription drugs, we are very pleased CMS will be requiring insurers to offer standardized plans that utilize copays rather than co-insurance and that for many metal levels, these costs are pre-deductible. While we are very supportive of what has been proposed, in some areas they fall short and we offer suggestions on how they can be improved.

In previous comments, the public health community has encouraged the establishment of standardized plans and have offered as examples several states that have successfully implemented them. In most respects, what you have proposed aligns with their recommendations. First, plans would be **required to offer standardized plans**, but they can offer alternatives plans with different benefit designs, as well. This provides insurers with the ability to offer variation and compete for beneficiaries. Second, for prescription drugs, the tiers are limited to four and all **include copays rather than costly co-insurance**. Third, for most metal levels, the **drug copayments are pre-deductible**, meaning the beneficiary does not have to meet a costly deductible in order to access their prescription drugs.

These three important elements are critical to implementing standardized plans and **we strongly urge CMS to move forward with them in 2023** to promote beneficiary drug affordability. **However, we do believe they can be improved, including 1) ensuring more of the drugs in the Silver and Bronze levels are not subject to a deductible and 2) lowering the copays for the Specialty Drug tier, particularly in the Bronze and Silver levels.**

It is extremely critical that prescription drugs for as many beneficiaries as possible be outside the deductible. Currently, beneficiaries must meet their annual deductible that is based on the full cost of the list price of the drug, which does not consider the substantial amount of rebates insurers and PBMs receive.

In 2019, a review of more than 200 silver-level health insurance plans in 14 states that participated in the federal marketplace showed that 52% of analyzed plans had deductibles that were greater than $3,000. Some deductibles were as high as $7,000. By including prescription drugs outside the deductible, beneficiaries will be able to better afford and access their medications, particularly at the start of each year, to remain healthy. This would be especially helpful to beneficiaries with chronic conditions who rely on prescription drugs from one year to the next.

The proposed $5,800 deductible in Standard Silver plans coupled with a $350 copay for Specialty Drugs would still make prescription drugs unaffordable for most patients, particularly those with chronic conditions like hepatitis B. We realize that benefit designs must meet the actuary value requirements in each metal level. However, using the CMS 2023 AV calculator, we calculate that if all drugs in the Standard Silver plan were outside the deductible and copays for non-preferred drugs were lowered from $80 to $70 per month and Specialty Tier drugs were lowered from $350 to $100 a month, the actuarial value would remain the same if all other benefits and cost-sharing remained the same except copays for Generic Drugs were increased from $20 to $22.50 per month. **We strongly urge you to establish the Standard Silver plan to remove all drugs from the deductible and lower the copays for the non-preferred tier from $80 to $70 and most importantly, Specialty Drugs from $350 to $100.**

As ASPE detailed in their report, "Facilitating Consumer Choice: Standardized Plans in Health Insurance Marketplaces", several states have implemented standardized plans. Some of them are using lower copays for prescription drugs and ensuring that they are outside the deductible.

Proposed Non-Discrimination Regulation

The ACA makes clear that health insurers must not discriminate against beneficiaries based on their health condition or design insurance benefits that discriminate against certain individuals. In the past, the public health community has repeatedly brought to your attention to potential violations and instances of issuers placing drugs for certain conditions on the highest drug tier and instituting medically unnecessary prior authorization, step-therapy requirements, and other utilization management techniques. Additionally, we have urged you to ensure that laws against discrimination in healthcare are upheld and enforced. Research demonstrates that despite current non-discrimination regulations, health insurance companies have continued to shift the cost of medications for chronic diseases like **HIV** and **hepatitis B** onto consumers, largely through benefit plan designs.

For those reasons, **we are extremely supportive of the proposed regulation § 156.125 on Prohibition on Discrimination,** which states that an issuer cannot discriminate through its benefit design or their implementation "based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions." Additionally, it states, "Non-discriminatory benefit design that provides EHB [essential health benefits] is one that is clinically-based, incorporates evidence-based guidelines into coverage and programmatic decisions, and relies on current and relevant peer-reviewed

medical journal article(s), practice guidelines, recommendations from reputable governing bodies, or similar sources."

We thank CMS for recognizing the ongoing problems associated with insurance benefit design and its impact on beneficiaries, especially those with chronic conditions. We are pleased that you have advised issuers that "instances of adverse tiering are presumptively discriminatory and that issuers and PBMs assigning tiers to drugs should weigh cost of drugs on their formulary with clinical guidelines for any such drugs used to treat high-cost chronic health conditions to avoid tiering such drugs in a manner that would discriminate based on an individual's present or predicted disability or other health conditions in a manner prohibited by § 156.125(a)."

It is important for the law and the rule to be enforced by both the federal and state regulators. CMS can play a role in ensuring there are sufficient tools provided to state regulators to conduct plan reviews. States also must take the responsibility to fully review plans and take enforcement actions against issuers that are not in compliance.

Counting Copay Assistance Towards Patients' Out-Of-Pocket Maximums

While we are pleased to support CMS' proposed standardized plans that limit patient cost-sharing for prescription drugs in the federal funded exchange plans, they will not address affordability for all plans and certainly not plans off the exchange. As a recent Commonwealth Fund report noted, "Employer health insurance coverage remains the backbone of health insurance in the United States, covering more than half of Americans under age 65—about 163 million people." Unfortunately, these beneficiaries will still be subject to potential high deductibles and high-cost sharing expressed in terms of co-insurance. In order for patients to afford their prescription drugs, they continue to rely on manufacturer copay assistance. According to IQVIA, the total amount of copay assistance reached $14 billion in 2020. Of commercially insured patients on branded medications, 14 percent of them used copay assistance to reduce their out-of-pocket costs in 2020.

However, more and more insurers and PBMs have instituted harmful policies that do not apply copay assistance towards beneficiaries' out-of-pocket costs and deductibles. This violates existing regulations that define "cost-sharing" as "any expenditure required by ***or on behalf of*** an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges, but excludes premiums, balance billing amounts for non-network providers, and spending for non-covered services" 45 CFR 155.20, (emphasis added).

This significantly increases out-of- pocket costs for patients, while allowing insurers to "double dip" and increase their revenue by receiving patient copayments twice. The 2020 *Notice of Benefit and Payment Parameters (NBPP)* prohibited this practice. However, the 2021 *Notice of Benefit and Payment Parameters* rule advanced by the previous administration walks back the 2020 rule and allows insurers to implement these policies, often referred to as "copay accumulator adjustment programs."

Despite the urging of numerous patient groups, the proposed *Notice of Benefit and Payment Parameters* rule for 2023 failed to even mention our request for CMS to include language

that reverts to the 2020 NBPP rule requiring insurers to count copay assistance towards a patient's annual deductible or out-of-pocket maximum, with limited exceptions. Patients rely on copay assistance to afford the drugs prescribed by their provider. For many patients with complex illnesses, there are no generics or low-cost alternative options available.

A recent study highlighted the negative impact of copay accumulator programs, finding that patients who are subject to the programs fill prescriptions 1.5 times less than patients in high deductible health plans. Additionally, patients subject to these programs experience a 13 percent drop in persistence between months three and four as they reach the cap in their annual benefits and terminate their therapies.

We continue to urge CMS to address this critical issue that is increasing patient costs for prescription drugs, which runs counter to the goals of the Biden administration to increase patient affordability.

If issuers are implementing these policies, beneficiaries must be made aware of them. Unfortunately, issuers continue to conceal them deep in plan documents and leave patients unaware of the increase in patient costs that they might be subject to. Additionally, there is no consistency among insurers on how the policies are displayed.

In the 2021 *Notice of Benefits and Payments Parameter* rule, CMS reminded issuers "to encourage transparency with regard to changes in how direct drug manufacturer support amounts count towards the annual limitation on cost-sharing. For example, we encourage issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits. If we find that such transparency is not provided, HHS may consider future rulemaking to require that issuers provide this information in plan documents and collateral material."

Despite these warnings, there has been no improvement in transparency and CMS has taken no action to correct the situation. We urge you to require plans to display this information on the Statement of Benefits and Coverage document.

Non-Essential Health Benefits Drugs

In another scheme that insurers and PBMs are implementing, large group plans that 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.**

Promoting Health Equity

We commend the Biden administration and your department for focusing on health equity. In your report, "Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy" you identified your first of three guiding principles for drug pricing reform as "mak[ing] drug prices more affordable and equitable for all consumers and throughout the health care system." We believe that several proposals contained in the proposed rule, including the establishment of standardized plans and non-discrimination regulations, will better achieve health equity across the country. However, allowing insurers and PBMs to continue to not count copay assistance for prescription drugs will increase beneficiary cost-sharing and exacerbate inequalities in healthcare. Since it mainly impacts beneficiaries with chronic conditions who rely on prescription drugs, if you follow the rules you have laid out, it constitutes discrimination in healthcare.

We thank you for the opportunity to share these comments and look forward to working with you and your department as you seek to make healthcare more affordable and accessible for all Americans.

If you have any questions or comments please contact Michaela Jackson, Prevention Policy Manager at the Hepatitis B Foundation at michaela.jackson@hepb.org.

Sincerely,

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