January 30, 2023

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: Comments on *Notice of Benefits and Payment Parameters for 2024* Proposed Rule [CMS-9899-P]

Dear Deputy Administrator Montz:

We, the undersigned 71 organizations, on behalf of millions of patients and American consumers who live with complex conditions such as HIV, autoimmune diseases, cancer, diabetes, lupus, hemophilia, mental illness, hepatitis, neurological diseases, and other chronic illnesses, write to comment on the *Notice of Benefits and Payment Parameters for 2024 Proposed Rule*. The patients we represent appreciate all you are doing to make healthcare more accessible and affordable for beneficiaries. While there are several components of the *Proposed Rule* that many of us will comment on elsewhere, this letter focuses on those issues that impact access and affordability of prescription drugs.

1) **We are pleased that you are continuing to implement standardized plans in an effort to increase patient affordability of their healthcare, including prescription drugs, which for the most part, require the use of reasonable copays. While minor improvements have been proposed, some of the 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 before taking advantage of the capped copays.**
2) **Despite years of urging from the patient community and others, we are extremely disappointed that the proposed rule does not require issuers and PBMs to count copay assistance for prescription drugs towards the beneficiary deductible and out-of-pocket maximum obligations, thus allowing the continuation of copay accumulator adjustment programs.**
3) **We are also disappointed that despite the urging of the patient community and others, you have not taken action against plans that designate certain drugs as non-essential and exclude any cost-sharing associated with them from a beneficiary's cost-sharing obligation. You also have not taken action against plans that take drugs off formulary and seek alternative funding sources for them.**
4) **While we are pleased that you have strengthened the regulations that address discriminatory plan design, including the practice of adverse tiering, we are disappointed that there has been a lack of enforcement and actions against insurers and pharmacy benefit managers (PBMs) that discriminate against beneficiaries with chronic health conditions.**

Standard Plan Options

We are pleased that CMS reinstituted in 2023 standardized options on the exchanges that utilize copays, rather than co-insurance, for prescription drugs. Patients today face significant prescription drug affordability challenges that have only worsened due to the cost of medications and 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 in affording 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 proposed changes to standardized plans, please consider the following:

- For qualified health plans, CMS reports the medium annual deductible for an individual on a Silver plan in 2023 is $5,388, an increase of 4 percent from 2022 and 21 percent from 2021. For Bronze plans, the median deductible for the plan year 2023 is $7,471, an increase of 8 percent from 2022 and 17 percent from 2021.[1]
- According to CMS' National Health Expenditures report, while overall healthcare spending grew at only 2.7 percent in 2021, out-of-pocket spending increased substantially higher by 10.4 percent. For prescription drugs, out-of-pocket spending totaled $49.8 billion, or 13.2 percent of the total spending on prescription drugs. However, for hospital care, which accounts for more than three and a half times more of the total spending than prescription drugs, patients were responsible for paying only 2.6 percent. Despite the smaller total amount of spending for prescription drugs, the out-of-pocket spending for prescription drugs ($49.8 billion) was higher than all the out-of-pocket spending for hospitals ($34.1 billion).[2]
- According to an IQVIA analysis, due in part to high costs, an estimated 81 million prescriptions were abandoned at the pharmacy in 2021, with the abandonment rate over one in three for prescriptions above $75 in out-of-pocket costs, especially for high-cost specialty medicines that treat cancer and immunology. In addition, of prescriptions with a final cost above $250, 61 percent are not picked up by patients, as compared with 7 percent of patients who do not fill when the cost is less than $10.[3]
- A recent comprehensive literature review by the National Pharmaceutical Council found that "when taken together, the included studies appear to suggest not only that increased cost-sharing is associated with decreased adherence but also that there is a 'dose-response' relationship, in which larger differences in cost-sharing were associated with worse adherence.

[1] "Plan Year 2023 Qualified Health Plan Choice and Premiums in HealthCare.gov Marketplaces," CMS, Dept. of Health and Human Services, October 26, 2022, https://www.cms.gov/cciio/resources/data-resources/downloads/2023qhppremiumschoicereport.pdf.

[2] "National Health Expenditure Data," CMS, last modified 12/15/22, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.

[3] "The Use of Medicines in the U.S. 2022: Usage and Spending Trends and Outlook to 2026," IQVIA Institute, April 2022, https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/the-use-of-medicines-in-the-us-2022/iqvia-institute-the-use-of-medicines-in-the-us-2022.pdf.

Similarly, increased cost-sharing was associated with more patients discontinuing treatment."[4]

- The Urban Institute, in its examination of 2018-2019 Medical Expenditure Panel Survey data, concluded that nearly 13 million adults delayed or did not get needed prescription drugs because of the cost, including 3.8 million nonelderly adults with private insurance.[5]

While after premiums are paid there are cost-sharing limits, they too are rising. For plan year 2024, CMS has set the maximum out-of-pocket responsibility at $9,400 for an individual and $18,800 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 $9,400 all at once for their medication at the beginning of the year.

Proposed Changes to Standardized Options: In order to limit patient cost-sharing and improve patient affordability and accessibility to prescription drugs, we are very pleased that CMS began requiring qualified health plans in 2023 on the federal and state exchanges to offer standardized plans. These plans utilize copays rather than co-insurance, and for many metal levels costs are pre-deductible. While we are very supportive of this action, in some areas they fall short, and we offer suggestions on how they can be improved.

First, for some of the metal levels, the maximum allowed copay for specialty-tier drugs is prohibitively high for patients. Co-pays of $250 to $500 will lead to beneficiaries abandoning their prescription drugs.

Secondly, for four metal levels, before beneficiaries can take advantage of copayments for drugs on the non-preferred and specialty drug tiers, they still must pay a high deductible.

It is extremely critical that prescription drugs for as many beneficiaries as possible be outside the deductible. Currently, beneficiaries must meet their annual deductible, which is based on the full cost of the list price of the drug and does not consider the substantial amount of rebates insurers and PBMs receive. 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 particularly helpful to beneficiaries with chronic conditions who rely on prescription drugs from one year to the next.

The proposed $7,500 deductible for the Expanded Bronze plans coupled with a $500 copay for Specialty Drugs and a $9,400 annual cost-sharing limit, or a $6,000 deductible in Standard Silver plans coupled with a $350 copay for Specialty Drugs and a $6,000 annual cost-sharing limit, would still make prescription drugs unaffordable for most patients, particularly those with

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[4] Nicole Fusco, Brian Sils, Jennifer S. Graff, Kristin Kistler, and Kimberly Ruiz, "Cost-Sharing and Adherence, Clinical Outcomes, Health Care Utilization, and Costs: A Systematic Literature Review," *Journal of Managed Care and Specialty Pharmacy*, 29, no. 1 (January 2022), https://www.jmcp.org/doi/full/10.18553/jmcp.2022.21270.

[5] Michael Karpan, Frederic Blavin, Stacy McMorrow, and Claire O'Brien, "In the Years Before the COVID-19 Pandemic, Nearly 13 Million Adults Delayed or Did Not Get Needed Prescription Drugs Because of Costs," Urban Institute, December, 2021, https://www.urban.org/research/publication/years-covid-19-pandemic-nearly-13-million-adults-delayed-or-did-not-get-needed-prescription-drugs-because-costs.

chronic conditions. **We strongly urge you to remove all drugs from the deductible and lower the copays for Specialty Drugs from a high of $500 to no more than $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.

For 2024, CMS has proposed to require generic drugs to be on the generic tier or on the specialty tier, if appropriate, and the tiering must be done in a non-discriminatory basis. Additionally, brand name drugs must be placed on either the standardized plan options' preferred brand or non-preferred brand tiers, or specialty drug tier if there is an appropriate clinical and non-discriminatory basis. We appreciate CMS' recognition that some plans place lower-cost generic drugs on higher tiers, which leads to higher patient cost-sharing. Generic drugs should, for the most part, be on the generic tier. We do not support the option that certain generics, such as those with a higher cost, be on the specialty tier. Reason would conclude that it should be on a lower tier than the brand, but other factors lead to drug tier placement.

Counting Copay Assistance Towards Patient's Out-Of-Pocket Maximums

While standardized plans can limit patient cost-sharing for prescription drugs in the exchange plans, they need to address affordability for all plans and certainly not for plans off the exchange. As described above, many beneficiaries are still 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 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 2024 failed to 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. There are no generics or low-cost alternative options for many patients with complex illnesses.

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.

Due to the inaction by CMS on this matter, the growth of both accumulators and maximizers has skyrocketed. According to IQVIA, in 2021, 43 percent of covered lives in commercial plans were in plans with accumulators, while 45 percent were in plans with maximizers. The growth of these plans "has led to [manufacturers] increased proportion in total assistance spend, costing manufacturers more than an estimated $5 billion dollars in copay budgets." In addition, the same study notes that across select specialty markets, exposure to or prevalence of accumulator and maximizer plans grew from 14 percent of commercially insured patients in 2019 to 33 percent in 2022.

One manufacturer of cystic fibrosis medications has taken the step to limit copay assistance to patients in plans with copay accumulators. Instead of receiving maximum copay assistance of $8,950 per month, people in plans with an accumulator or maximizer only receive copay assistance of $3,500 per monthly fill. Without action prohibiting copay accumulator programs, we are concerned that more manufacturers will take steps to limit copay assistance, which will further harm access and affordability of prescription medications.

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 they might be subject to. Additionally, insurers lack consistency in 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 & 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 intent of the ACA that further restrict access to

prescription medications that CMS must address. Some plans 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 should not be able to 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 require all cost-sharing associated with covered benefits and services count as patient 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 bypass 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.

One such company is very upfront in how it works. They clearly state that they are not insurance (thereby bypassing federal and state regulations) and describe that they access medications "through manufacturer free programs, grants/charities, our International Mail Order Pharmacy partner, domestic wholesale pharmacy and occasionally a copay card." It should be noted that importing medications is currently illegal in the United States. Further, the company asks patients for their income level so that they can utilize drug manufacturer-free drug programs. However, these free drug programs are only available to people who do not have insurance. People in these plans do have insurance, but their drug has been removed from the plan's formulary, and the company has forced them to enroll in an alternative "program," which is not insurance.

There are a growing number of other companies that are working with insurers, employers, and PBMs around the country. **CMS must investigate and prohibit these harmful schemes.**

Enforcement of Non-Discrimination Law & Regulations

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. We have repeatedly brought to your attention 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.

We were very supportive of CMS' amendments last year to the essential health benefits regulation (§ 156.125) that states "a non-discriminatory benefit design that provides EHB is one that is clinically based" and that it is presumptive discriminatory "to place all drugs for a particular condition on a high-cost tier to discourage enrollment by those with that condition."

It is important that the law, along with existing and new regulations, be enforced by both

federal and state regulators. We note that in the 2024 Draft Letter to Issuers, CMS states that it will begin conducting adverse tiering reviews in 2024 for the following medical conditions: the hepatitis C virus, HIV, multiple sclerosis, and rheumatoid arthritis. We are supportive of these reviews to ensure "enrollees have access to drugs or drug classes prescribed to treat chronic, and high-cost medical conditions at lower cost tiers, [and] to ensure that issuers are not placing drugs related to a specific condition on a high-cost prescription drug tier in order to actively discourage enrollment by individuals with that condition in the plan." However, we question why federal and state regulators did not conduct these reviews in the past and even this past year, when the new regulations became effective. We also question why more medical conditions are not included in the review.

CMS must ensure there are sufficient tools provided to state regulators to conduct annual and thorough plan reviews. States also must take the responsibility to fully review plans and take enforcement actions against issuers that are not in compliance.

Additionally, issuers must also follow Section 1557 ACA non-discrimination requirements, which remain in effect and whose regulations are currently being updated. Therefore, enforcement is needed to ensure compliance, and plans must begin to ensure compliance with the updated regulations, which are expected to be finalized in early 2024.

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

If you have any questions or comments please contact Carl Schmid, executive director of the HIV+Hepatitis Policy Institute at cschmid@hivhep.org, and Quardricos Driskell, vice president of public policy and government affairs of the Autoimmune Association at quardricos@autoimmune.org.

Sincerely,

ADAP Advocacy Association
Advocacy & Awareness for Immune Disorders Association (AAIDA)
Advocacy House Services Inc.
AIDS Action Baltimore
AIDS United
Allergy & Asthma Network
Alliance for Patient Access
American Behcet's Disease Association (ABDA)
Any Positive Change Inc.
APS Foundation of America, Inc.
Arthritis Foundation
Asthma and Allergy Foundation of America
Autoimmune Association
Bienestar Human Services, Inc.
California Chronic Care Coalition
California Hepatitis C Task Force
Cancer*Care*
Chronic Care Policy Alliance
Coalition for Headache and Migraine Patients (CHAMP)
Color of Crohn's and Chronic Illness
Community Access National Network
Community Oncology Alliance (COA)
COVID-19 Longhauler Advocacy Project
Depression and Bipolar Support Alliance
Derma Care Access Network

Dysautonomia International
Equitas Health
EveryLife Foundation for Rare Diseases
Gaucher Community Alliance
Georgia AIDS Coalition
Global Allergy & Airways Patient Platform
Global Healthy Living Foundation
Good Days
HBI-DC
Health and Medicine Counsel
Healthy Men Inc.
HealthyWomen
Hemophilia Association of the Capital Area
Hemophilia Council of California
Hepatitis B Foundation
Hereditary Angioedema Association
HIV+Hepatitis Policy Institute
Hope Charities, Inc.
ICAN, International Cancer Advocacy Network
Infusion Access Foundation (IAF)
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Pemphigus Pemphigoid Foundation
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
METAvivor
NASTAD
National Pancreas Foundation
National Psoriasis Foundation
National Viral Hepatitis Roundtable (NVHR)
Nevada Chronic Care Collaborative
No Patient Left Behind
Patient Access Network (PAN) Foundation
Patients Rising Now
PlusInc
Project Sleep
Pulmonary Hypertension Association
Solve M.E.
Spondylitis Association of America
The AIDS Institute
The Assistance Fund
The Hepatitis C Mentor and Support Group, Inc.—HCMSG
The Sumaira Foundation
Touro University of California
Treatment Action Group
Triage Cancer
U.S. Pain Foundation
US Hereditary Angioedema Association