

July 28, 2021

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: Improving Patient Drug Affordability through Standardized Benefit Plans [CMS-9906-P]

Dear Secretary Becerra:

We, the undersigned 40 organizations, on behalf of millions of patients and American consumers who live with complex conditions such as HIV, autoimmune diseases, cancer, diabetes, lupus, hemophilia, and hepatitis, write in response to the request for comments on the proposed rule that would amend the 2022 payment and parameters rule. The patients we represent appreciate all you are doing to make healthcare more accessible and affordable for beneficiaries. There are many aspects of the proposed rule that we support; however, **one issue that we would like to focus on is your desire to offer standardized options for qualified health plans beginning in 2023.** Offering such plans can greatly assist the patients we represent better afford the prescription drugs and health services they rely on to treat their health conditions and prevent others.

Another way in which you can ensure beneficiaries can afford their prescription drugs is to ensure that copay assistance counts towards their deductible and out-of-pocket maximum. We also urge HHS to amend the *Notice of Payment Parameters Rule for 2022* to prohibit the practice of not allowing such copay assistance to count by insurers.

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 high patient cost-sharing often in the form of co-insurance. This negatively impacts patient adherence and leads to worse health outcomes and increased costs across the healthcare system. 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 across all metal levels, deductibles are increasing. For Bronze plans, the median deductible will be \$6,992 in 2021, an increase

of 11 percent from 2017; for Silver plans, it will be \$4,879, an increase of 31 percent since 2017.

- 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 study conducted by Ezra Golberstein examining National Health Expenditure Accounts data, in 2017 individuals were responsible for paying 14 percent of the total cost of prescription drugs. However, for hospital care, which accounts for nearly three and a half times more total spending, patients were responsible for paying only 3 percent.

While there are cost-sharing limits, they too are rising. For plan year 2022, CMS has set the maximum out-of-pocket responsibility at \$8,700 for an individual and \$17,400 for all others. Due to the proliferation of high deductible plans, depending on the drug, a patient may be required to pay that total amount of \$8,700 all at once for their medication at the beginning of the year.

Standard Plan Options

In order to limit patient cost-sharing and improve patient affordability and accessibility to prescription drugs, we urge HHS to require insurers to offer some plans that 1) establish nominal cost-sharing caps for prescription drugs and 2) include first dollar coverage of prescription drugs. This can be accomplished through the establishment of standard plan options.

The federal government can follow the lead of numerous states, including California, Delaware, Louisiana, and Maryland, along with the District of Columbia, that cap the amount a patient must pay out-of-pocket for a one-month supply of a single prescription medication.

Keeping prescription drug cost-sharing low will decrease prescription drug abandonment, keep patients healthy, and save money in other parts of the healthcare system, including emergency room visits and hospitalizations. Compounding the situation, many insurers utilize high co-insurance based on the list price of the drug, which is inflated by rebates negotiated by PBMs that do not get passed on to patients. According to the [Kaiser Family Foundation](#), the average payments towards coinsurance rose 67 percent from 2006 to 2016.

Establishing standard plan options must not only include nominal co-pays but also first dollar coverage of prescription drugs. This can be accomplished by requiring insurers to offer a certain percentage of these types of plans among those that they offer on the marketplace exchange. This has been done in Colorado, which has demonstrated that it can be accomplished without any meaningful impact on premiums, while helping beneficiaries afford their medications.

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. 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 particularly

be helpful to beneficiaries with chronic conditions who rely on prescription drugs from one year to the next.

[Many states](#) have requirements for plans to offer some degree of standardized plans. Some limit copays and exclude prescription drugs from the deductible for some metal levels or at least have a reduced deductible for prescription drugs. While guidelines for the previous federal standardized plan mostly relied on the use of reasonable copays, it still allowed plans to utilize 40 percent co-insurance for Silver plan specialty drugs. Beneficiaries also had to still contend with a high deductible.

Some states are reviewing their current guidelines for standard plans. The District of Columbia Health Benefit Exchange Authority Executive Board recently [recommended](#) to modify their standard plans based on the work of its Social Justice and Health Disparities Working Group, in an effort to stop racism in health care. The executive board recommends that standard plans eliminate cost-sharing, including deductibles, co-insurance, and co-payment, for medical care, prescription drugs, supplies, and related services that prevent and manage diseases and health conditions that disproportionately affect patients of color in the District. The Board is recommending this in order to eliminate health outcome disparities for communities of color and ensure equitable treatment for patients of color in health care settings and in the delivery of health care services.

We are pleased that HHS is considering offering standard plan options again in 2023, but in order to be meaningful to patients, some must include not only nominal copays but first dollar coverage of prescription drugs.

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

In order for patients to afford their prescription drugs, a growing number must 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 coupons 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 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."

We urge HHS to amend the *Notice of Benefit and Payment Parameters* rule to revert 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. Eleven states and Puerto Rico have passed laws that prohibit these harmful policies. 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 month 3 and 4 as they reach the cap in their annual benefits and terminate their therapies.

We thank you for the opportunity to share these recommendations and look forward to working with you and your department 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 Molly Murray, President and CEO of Autoimmune Related Diseases Association (AARDA) at mmurray@aarda.org.

Sincerely,

ADAP Advocacy Association
 Advocacy & Awareness for Immune Disorders Association
 AIDS Foundation Chicago
 Alliance for Patient Access
 American Autoimmune Related Diseases Association
 American Diabetes Association
 Beyond Type 1
 Bienestar Human Services
 Business Leaders for Health Care Transformation
 California Access Coalition
 Caring Ambassadors Program
 Center for Health and Democracy
 Coalition of Texans with Disabilities
 Color of Crohn's and Chronic Illness
 Community Access National Network (CANN)
 Consumers for Quality Care
 Dysautonomia International
 Fair Pricing Coalition
 Global Healthy Living Foundation

Good Days
 Hemophilia Federation of America
 HIV+Hepatitis Policy Institute
 ICAN, International Cancer Advocacy Network
 International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
 International Pain Foundation
 Lupus and Allied Diseases Association, Inc.
 Lupus Foundation of America
 Men's Health Network
 National Alliance on Mental Illness
 National Eczema Association
 National Viral Hepatitis Roundtable
 No Patient Left Behind
 Patient Services, Inc.
 Patients Rising
 SisterLove, Inc.
 Susan G. Komen
 The National Adrenal Diseases Foundation
 Treatment Action Group
 Triage Cancer
 United for Charitable Assistance

cc: Chiquita Brooks-LaSure, CMS Administrator