



LETTER OF REQUEST

"The world as we have created it is a process of our thinking. It cannot be changed without changing our thinking."

– Albert Einstein

July 23, 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: Comments in Response to Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (Docket EBSA-2021-0005)

Dear Secretary Becerra:

Color of Crohn's and Chronic Illness ("COCCI") on behalf of patients and American consumers, primarily those of color, who live with IBD and associated chronic illnesses, write in response to the *Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs*.

COCCI is a national patient advocacy organization whose mission is to improve the quality of life for BIPOC who are affected by IBD, digestive disorders, and associated chronic illnesses, through community engagement, research, education and advocacy.

The patients represented by COCCI rely on prescription drugs to treat their health conditions and prevent others. We are pleased that the Biden administration is moving forward with the requirement that insurance plans must report on various data points associated with prescription drug spending. We believe with this greater understanding and transparency of prescription drug costs, the administration can better implement policies and measures that increase competition, improve prescription drug affordability and access for the American people.

Our comments are focused on issues related to pharmaceutical manufacturer cost-sharing assistance programs and the copay accumulator policies being implemented by health insurers and pharmacy benefit managers (PBMs).

Millions of vulnerable Americans across the country, including many IBD patients of color represented by COCCI, rely on pharmaceutical manufacturer cost-sharing assistance programs, also known as copay assistance or copay coupons, to afford the medicines they need. Pharmaceutical companies often provide financial assistance (such as a copay card) to help patients afford expensive medications. This means that the person paying for the drug could end up saving money, sometimes thousands of dollars. These cards are particularly important to underinsured individuals and those with chronic conditions, such as IBD, that rely on multiple medications to manage their illness.

Patients in the private health insurance market have increasingly relied on this assistance due to rising out of pocket costs for drugs.

Historically, when a patient has used cost-sharing assistance at the pharmacy counter, the amount of the assistance has counted towards a patient's deductible and maximum out-of-pocket limit depending on the insurance plan.

However, with increasing frequency, health insurers and PBMs are implementing policies that don't count the value of copay assistance towards a patient's annual deductible or out-of-pocket cost sharing responsibility. These copay accumulator adjustment policies allow PBMs and health insurers to keep available copay assistance, received on behalf of a patient, then "double-dip" by making the patient pay it again.

Today, these copay accumulator or accumulator adjustment programs unfortunately are more prevalent in commercial health insurance plans than ever before. According to a 2021 report from the AIDS Institute, 90 percent of all U.S. states have implemented these policies in at least one Affordable Care Act insurance plan offering. The same report found that in 32 states, at least two thirds of plans include a copay accumulator policy. In 14 states, every plan includes a copay accumulator policy.

As the AIDS Institute report states,

"... the trend in health insurance benefit design is to shift more of the cost of health care to patients through high deductibles and coinsurance rates [...] In order to afford the medicine that they need, patients increasingly rely on manufacturer copay assistance."

In short, a primary concern is that these copay accumulators create massive adherence problems. Patients are simply stopping filling their drug prescriptions. Most of these drugs are single source therapies with no equivalent generic version or therapeutic alternative.

For many this creates an untenable burden and results in treatment abandonment, which can certainly lead to poorer health outcomes and increase the overall healthcare burden; by accelerating the disease progression, increasing ER visits and hospitalizations, and in many cases affect their ability to work and function.

Amid the health and economic challenges of COVID-19, rising insurance premiums, and the expansion of high-deductible health plans, patients are more frequently bearing the burden of higher out-of-pocket costs for their healthcare to the benefit of insurers.

With copay accumulators, the individuals who need assistance the most will be unable to benefit from it fully and can end up paying more out-of-pocket for their treatments.

An analysis from IQVIA demonstrates the magnitude of this phenomenon. More than one in four specialty brand prescriptions are abandoned during the deductible phase which is three times the rate of prescription abandonment when there is no deductible.

Health insurance should offer protection to people who are unfortunate enough to require treatments for serious IBD conditions. We regard copay accumulators as blatant discrimination against patients undergoing intensive therapies for IBD and other chronic illnesses.

Moreover, these accumulator adjustment programs are contrary to the requirements of the Affordable Care Act (ACA) which requires all non-grandfathered group health plans and health insurance issuers to count cost sharing for essential health benefits including manufacturing assistance- toward the annual limitation on cost-sharing.

COCCI also would like to highlight and emphasize the important findings of a new national online survey of patients and caregivers, sponsored by such leading patient advocacy organizations as the National Hemophilia Foundation (NHF), the American Kidney Fund, the Arthritis Foundation, and others, that illustrates the alarming challenges that many patients across the country – including those in vulnerable and underserved communities that COCCI represents– are experiencing in affording and accessing necessary prescription

medications during the COVID-19 pandemic. According to the NHF, The national survey, Patients & Family Caregivers: Prescription Drug Affordability Challenges During COVID-19,” was conducted to better understand patient and caregiver experiences with copay assistance programs and found that nearly half of respondents (46%) say they or someone in their immediate household has not been able to afford their out-of-pocket costs in the past year. Of those who reported being unable to afford their medications or treatments because their copay assistance ran out, one in three (33%) was a person of color and more than four in ten (43%) reported difficulty affording their prescription(s) due to COVID-19. More than nine out of 10 patients and caregivers surveyed (93%) said the federal government should require health plans and pharmacies to count the value of copay assistance programs towards patient out-of-pocket costs.

The COVID-19 pandemic has exposed deep health inequities and treatment affordability challenges that exist within our healthcare system and made clear how much patient communities rely on copay assistance to afford, access, and adhere to their medications to manage their health.

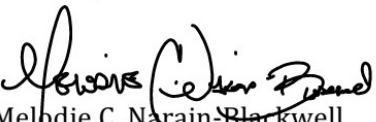
A number of key findings in the survey illustrate how the COVID-19 pandemic has exacerbated health disparities and treatment affordability challenges for vulnerable and underserved populations, and that broad support exists for policy that ensures health plans count the value of copay assistance towards patient out-of-pocket costs.”

Therefore, COCCI asserts its strong opposition to the use of copay accumulator adjustment programs for patients with IBD and related chronic illnesses and makes the following recommendations:

1. The Centers for Medicare and Medicaid Services should prohibit the use of copay accumulator adjustments in the programs it administers and regulates and instead, should adopt policies which require health plans in the commercial market to count the value of copay assistance toward a patient’s annual deductible or out-of-pocket maximum, a simple solution that would protect already vulnerable patients and help them afford their prescriptions.
2. HHS, along with the Departments of Labor and Treasury, should implement the ACA’s annual limit on cost-sharing provision as Congress intended, and ban the practice of accumulator adjustment programs.
3. Commercial insurers and PBMs should immediately discontinue the use of copay accumulator adjustment and copay maximizer programs.
4. At a minimum, while copay accumulator adjustment programs remain in place, public and commercial insurers and PBMs should ensure transparency by clearly describing its design for beneficiaries, as required by the Centers for Medicare and Medicaid Services Summary of Benefits and Coverage Instruction Guide.
5. Public and commercial insurers and PBMs should be required to report on the treatment and accounting of copay assistance.

COCCI thanks you the opportunity to share our views and our recommendations.

Sincerely,


Melodie C. Narain-Blackwell
President, *Color of Crohn's & Chronic Illness*