

March 26, 2021

Secretary Xavier Becerra
U.S. Department of Health and Human Services
Xavier.Becerra@hhs.gov

Liz Richter
Acting Administrator
Centers for Medicare & Medicaid Services
Elizabeth.Richter@cms.hhs.gov

Re: HHS Notice of Benefit and Payment Parameters for 2022 – Docket CMS-9914-P

Dear Secretary Becerra and Acting Administrator Richter:

Patients Rising Now is a national nonprofit organization dedicated to advocating for the rights of patients with chronic and life-threatening illnesses. We support policies aimed at advancing patient access to and affordability of healthcare.

On January 20, the Biden administration issued a “regulatory freeze” memo asking agencies to consider postponing rules that have been published in the Federal Register but have not yet taken effect and open a 30-day comment period. This would allow President Biden’s appointees or designees to review and assess any new rules.

In light of the President’s memo, we ask the U.S. Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) to freeze “Docket CMS-9914-P, HHS Notice of Benefit and Payment Parameters for 2022” (NBPP 2022)” and open it up for comment.¹ Additionally, in your review of NBPP 2022, we ask that you reinstate NBPP 2020 protections governing the use of copay accumulator programs to limit potential harm to patients with serious, complex conditions who rely on financial assistance to afford their medications.

Background on Copay Accumulator Programs

Patients with rare, complex, and chronic conditions often need high-cost specialty medications for treatment. The cost of these specialty medicines can be thousands of dollars per month. As such, many individuals with these conditions who cannot afford their medications often rely on financial assistance from drug manufacturers to access their medically necessary treatments. Assistance can be crucial for these patients given that there are often no generic alternatives available for many of these conditions, such as HIV and hepatitis C, leaving patients with no other option than to use a prescribed brand name treatment.² In fact, research has found “that 87% of copay assistance

¹ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/>

² http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf

programs are for brand-name drugs that do not have a generic equivalent.”³ Individuals rely on this financial assistance to meet their annual deductible and maximum out-of-pocket limit. Without this assistance, if treatment becomes unaffordable, patients might ration their medications or stop treatment altogether.⁴ When patients cannot take their medications as prescribed, they can experience disease progression or other negative consequences that ultimately lead to increased use of costly healthcare resources and deterioration in patients’ quality of life.

Copay accumulator programs are an insurance practice that prevents the value of a drug manufacturer’s coupon from counting toward a patient’s deductible and maximum out-of-pocket limit.⁵ A report by the AIDS Institute found that copay accumulator programs for prescription medicines are becoming increasingly prevalent, raising costs for patients with HIV/AIDS and many chronic conditions at the pharmacy counter.⁶

The following example highlights not only how copay accumulator programs function, but also how insurers have used this practice to inappropriately benefit financially: A patient has a \$1,000 insurance deductible and receives \$500 in copay assistance. If there is no copayment accumulator program in place, the \$500 copay assistance counts towards the patient’s deductible, and the patient pays the remaining \$500 out of pocket to meet their annual deductible.⁷ If there is a copay accumulator program in place, the copay assistance will not count toward the patient’s deductible and the patient will still have to pay \$1,000 out of pocket to meet their deductible. At the same time, the insurer nonetheless collects the \$500 in copay assistance that was supposed to benefit the patient. Yet, the benefit is all but lost for the patient and absorbed entirely by the payer.

This is especially problematic as many individuals are now enrolled in high deductible health plans (HDHPs). Many employers only offer this option.⁸ In HDHPs, plan enrollees must incur high out-of-pocket costs until their deductibles are reached and their coverage kicks in. Given their high out-of-pocket costs, enrollees in HDHPs often rely on copay assistance programs to be able to afford their medications. Yet, financial assistance is only beneficial if its monetary value is counted toward the recipient’s deductible and maximum out-of-pocket limit. If not, once the assistance runs out, individuals go back to being unable to afford their medications.

CMS Should Reinstate NBPP 2020’s Limits on Copay Accumulator Programs to Protect Patients

³http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf

⁴ <https://www.healthaffairs.org/doi/10.1377/hblog20180824.55133/full/>

⁵ <https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more>

⁶ <https://www.businesswire.com/news/home/20200630005682/en/New-Report-Reveals-Prevalence-of-Hidden-Copay-Accumulator-Insurance-Programs-and-Higher-Costs-for-People-Living-with-HIVAIDS-and-Chronic-Diseases>

⁷ <https://www.businesswire.com/news/home/20200630005682/en/New-Report-Reveals-Prevalence-of-Hidden-Copay-Accumulator-Insurance-Programs-and-Higher-Costs-for-People-Living-with-HIVAIDS-and-Chronic-Diseases>

⁸ <https://buildcommonwealth.org/work/high-deductible-health-plans>

To reduce potential harm to patients from the growing use of copay accumulator programs, CMS should reinstate NBPP 2020's protections regarding the use of copay accumulator programs. NBPP 2020 limited the use of copay accumulator programs to instances in which both a brand and generic medication were available. It struck the right balance between patient protection and cost by encouraging the use of generic medications when available, but also recognizing that copay accumulator programs are inappropriate when there is no generic alternative. NBPP 2021 revoked those protections, and NBPP 2022 did not address this issue.

In NBPP 2021, CMS stated “we believe the impact of [increased out-of-pocket costs] may be limited if issuers that currently allow these amounts to be counted toward enrollees’ deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case.”⁹ However, that is *not* the case. If plans are allowed to implement copay accumulator programs indiscriminately, they will do so and they did. According to the Business Group on Health’s 2020 Health Care Strategy and Plan Design Survey, 39 percent of large U.S. employers adopted copay accumulator programs in 2020, and approximately 50 percent plan to implement a program in 2021.¹⁰ Another 14 percent said they are considering using copay accumulator programs in 2022 or 2023.¹¹ In other words, it is estimated that approximately two-thirds of employers will implement a copay accumulator program.

While NBPP 2021 does not prevent states from implementing their own laws limiting the use of copay accumulator programs, only five states and Puerto Rico have enacted such laws.¹² Additionally, state laws do not apply to employer-sponsored plans,¹³ which is how nearly 50 percent of insured individuals receive their health insurance.¹⁴ Therefore, establishing limits on copay accumulator programs at the federal level is vital.

Finally, copay accumulator programs are especially problematic during the COVID-19 pandemic. The pandemic has made it difficult for millions of people to afford their medications and other necessities, as the effects of record unemployment rates¹⁵ have been felt across the country. Additionally, copay accumulator programs often apply specifically to the types of underlying conditions that place individuals at increased risk for severe illness from COVID-19 (e.g., cancer, chronic kidney disease, liver disease, certain neurological conditions, cystic fibrosis). Yet, the Centers for Disease Control and Prevention (CDC) has stressed the importance of individuals with these conditions staying on their current treatment regimen.¹⁶ Therefore, it is crucial that they continue to have access to affordable medications at least during the remainder of the pandemic.

⁹ <https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf>

¹⁰ <https://pink.pharmaintelligence.informa.com/PS142755/Countering-Coupons-Large-Employers-Will-Boost-Copay-Accumulator-Programs-In-2021>

¹¹ <https://pink.pharmaintelligence.informa.com/PS142755/Countering-Coupons-Large-Employers-Will-Boost-Copay-Accumulator-Programs-In-2021>

¹² <https://aimedalliance.org/copay-accumulators-enacted-laws/>

¹³ <https://www.managedhealthcareexecutive.com/view/new-state-copay-accumulator-laws-complicate-the-coupon-compliance-landscape>

¹⁴ <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

¹⁵ <https://fas.org/sgp/crs/misc/R46554.pdf>

¹⁶ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

Given the considerations above, Patients Rising Now respectfully asks that CMS protect our nation's most vulnerable patients by freezing the enforcement of and opening a comment period for the NBPP 2022, and also reinstating the NBPP 2020 limitations on the use of copay accumulator programs. Thank you.