



December 30, 2020

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Secretary Azar and Administrator Verma:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for the opportunity to comment on “Docket CMS-9914-P, HHS Notice of Benefit and Payment Parameters for 2022” (NBPP 2022). We recommend that the Centers for Medicare and Medicaid Services (CMS) reinstate limitations on the use of copay accumulator programs as set forth in the NBPP 2020.

I. Background

Historically, privately insured individuals who cannot afford their copayments or coinsurance have been able to obtain aid from drug manufacturers in the form of copay assistance. This assistance not only contributes toward the patient’s copayment but also counts toward the patient’s annual deductible and maximum out-of-pocket limit. These programs have been especially helpful for individuals enrolled in high deductible health plans (HDHPs) in which the patient is required to pay significantly high out-of-pocket costs until the deductible is reached. In many instances, HDHP are patients’ only option; employers are increasingly offering only HDHPs.¹

Health plans are increasingly implementing copay accumulator programs, which prevent copayment assistance from counting toward a plan enrollee’s deductible.² Patients with complex health conditions often depend on patient assistance to access their medically necessary treatments. However, patient assistance is not a bottomless well. Patients receive a finite amount each year. Once copayment assistance runs out, many patients can no longer afford their medications.³ In many instances, there are no generic alternatives, placing patients at risk for medication adherence issues, including skipping refills, rationing medications, or abandoning treatment altogether.⁴ A recent survey by Truven Health Analytics revealed that cost is the biggest barrier to medication adherence.⁵ Nonadherent patients can face disease progression or relapse, and increased health care

¹ <https://buildcommonwealth.org/work/high-deductible-health-plans>

² <https://www.npr.org/sections/health-shots/2018/05/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more>

³ https://ajmc.s3.amazonaws.com/_media/pdf/AJMC_07_2019_Sherman%20final.pdf

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

⁵ <https://www.beckershospitalreview.com/opioids/truven-health-analytics-npr-health-poll-finds-cost-is-top-cause-of-unfilled-prescriptions.html>

utilization (e.g., more visits to the doctor and hospitalization).⁶ These adverse health consequences and increased financial strain add stress and anxiety to the lives of people who are already vulnerable.⁷

The NBPP 2020 limited the use of copay accumulator programs to instances in which both a brand and generic medication were available. It incentivized cost savings by steering patients to generic medications when available, but it also recognized that copay accumulator programs are inappropriate when there is no generic alternative. The NBPP 2021 revoked those protections, and the NBPP 2022 is silent on this issue.

II. CMS Should Reinstate NBPP 2020

Aimed Alliance respectfully requests that CMS reinstate NBPP 2020 to protect access to and affordability of medically necessary treatments. Such protections are especially important now during the COVID-19 pandemic and in light of the release of the final rule on Medicaid best price.

A. Lack of Federal Copay Accumulator Protections Will Harm Patients

NBPP 2020 was reasonably crafted to incentivize patients to select generic medications when available. NBPP 2021 did not achieve this same goal because it allowed health plans to implement copay accumulators regardless of whether a generic equivalent is available.

In the 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.”⁸ Yet, this year has proven that that is not the case. CMS gave plans free reign to adopt copay accumulator programs, and plans, in turn, have taken that liberty and run with it. According to the Business Group on Health’s 2020 Health Care Strategy and Plan Design Survey, 39 percent large U.S. employers adopted copay accumulator programs in 2020, and nearly 50 percent reported that they plan to implement a program in 2021.⁹ Another 14 percent said they are considering using copay accumulator programs in 2022 or 2023.¹⁰ While the NBPP 2021 allowed states to implement their own laws limiting copay accumulator programs, only five states and Puerto Rico have done so thus far.¹¹ Moreover, those laws do not apply to employer-sponsored plans,¹² and yet, according to the Kaiser Family Foundation, about 49 percent of Americans

⁶ <https://www.healthaffairs.org/doi/10.1377/hblog20180824.55133/full/>

⁷ <https://www.apa.org/news/press/releases/stress/2017/uncertainty-health-care.pdf>

⁸ <https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf>

⁹ <https://pink.pharmaintelligence.informa.com/PS142755/Countering-Coupons-Large-Employers-Will-Boost-Copay-Accumulator-Programs-In-2021>

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

¹¹ <https://aimedalliance.org/copay-accumulators-enacted-laws/>

¹² <https://www.managedhealthcareexecutive.com/view/new-state-copay-accumulator-laws-complicate-the-coupon-compliance-landscape>

receive their health insurance from their employer.¹³ Therefore, federal limitations on copay accumulator programs are necessary.

B. Medicaid Best Price Rule

Copay accumulator program limitations are also necessary because CMS recently finalized its Medicaid Value-Based Purchasing rule, which altered the method by which Medicaid best price is calculated.¹⁴ In particular, the rule requires the value of copay assistance to be subtracted from Medicaid best price calculations if a health plan implements a copay accumulator program. CMS's rationale for this change is that the full value of the financial assistance does not reach the patient. Yet, given the lack of transparency around copay accumulator programs, drug makers often do not know when a health plan has implemented such a program. As a result, the rule may disincentivize manufacturers from providing financial assistance to vulnerable patients. Even if drug manufacturers were able to determine if a health plan has imposed a copay accumulator program, manufacturers may be less likely to offer assistance to patients enrolled in such plans. There is no way for them to guarantee the assistance reaches only the patients, and they will be penalized by having the value of the assistance subtracted from Medicaid best price. Without this assistance, patients may not be able to afford medically necessary treatments. As such, CMS should reinstate protections from the NBPP 2020, which limited the use of copay accumulator programs when generic alternatives are unavailable. That way, CMS can ensure that patients receive the assistance as intended.

C. COVID-19 Pandemic

CMS should reinstate copay accumulator protections because although authorized vaccines are now available to some Americans, we are still in the midst of the COVID-19 pandemic. Unemployment rates remain high,¹⁵ and individuals are struggling more than ever to afford their medications. Many of these individuals may now rely on marketplace exchange plans with high out-of-pocket costs. Moreover, many of the underlying conditions that place patients at high risk for severe illness from COVID-19 are the same conditions requiring treatment for which copay accumulator programs are imposed. Yet, the Centers for Disease Control and Prevention (CDC) has stressed the importance of these patients staying on their current treatment regimen.¹⁶ Therefore, it is vital that they continue to have access to affordable medications at least during the remainder of the pandemic.

III. Conclusion

Based on the arguments herein, Aired Alliance requests that CMS reinstate NBPP 2020

¹³ <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

¹⁴ <https://www.federalregister.gov/public-inspection/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-and>

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>

protections as they pertain to copay accumulator programs. Thank you for considering our requests.

Sincerely,

Stacey L. Worthy
Counsel