July 16, 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: Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements – CMS-2482-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 "HHS Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements" (Proposed Medicaid Rule). If finalized, the Proposed Medicaid Rule would revise the Medicaid Best Price Rule to include copay assistance in the calculation of a prescription medication's best price if a health plan has implemented a copay accumulator program. This Proposed Rule could disincentivize drug manufacturers from providing copay assistance at all to vulnerable patients who may otherwise not be able to afford medically necessary treatments.

Patients with chronic conditions must be able to afford their medication, especially during the COVID-19 pandemic. These patients are at a high risk for severe illness, particularly if their underlying condition is not well maintained. Therefore, we ask the Department of Health and Human Services (HHS) to either 1) abandon this proposed rule as it pertains to the Medicaid Best Price Rule and copay accumulator programs; or 2) prohibit the use of copay accumulator programs if the patient is prescribed a brand medication and a generic alternative is not available.

I. Background

Historically, privately insured individuals who cannot afford their copayments or coinsurance have been able to obtain aid from copayment assistance programs – copay coupons offered by drug manufacturers. These copay coupons not only contribute toward the patient's copayment but also count toward the patient's annual deductible. 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

☎ 202-559-0380 policy@aimedalliance.org www.aimedalliance.org @aimedalliance
3000 K Street NW, Suite 270 · Washington, DC 20007

many instances, HDHPs are patients' only option; employers are increasingly offering only HDHPs.[1]

Yet, 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 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]

II. The Proposed Medicaid Rule May Harm Patients

The Proposed Medicaid Rule may have a chilling effect on copay assistance programs, thereby preventing patients from receiving the financial assistance they need to obtain medically necessary treatments. The Proposed Medicaid Rule simultaneously acknowledges that copay assistance is helpful to patients in obtaining needed medications, and conversely, that health insurers, rather than patients, benefit from copay accumulator programs.[8] However, rather than setting forth a regulation that would guarantee that patients receive the benefit of copay assistance or that would prohibit copay accumulator programs, the Rule sets up a system in which drug manufacturers may be discouraged from providing copay assistance to patients altogether.

The Rule states that if a health plan implements a copay accumulator program, then the value of any copay assistance received by the health plan will be counted toward the Medicaid best price calculation. The Medicaid Best Price Rule requires that drug makers give Medicaid programs the lowest price for their prescription drugs among nearly all purchasers, subject to certain exclusions.[9] The best price calculation is inclusive of applicable discounts, rebates, or other transactions to adjust prices.[10] However, currently, the Medicaid Best Price Rule excludes copay assistance based on the assumption that the patient, and not the health plan, is receiving the assistance.

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[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/do/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
[6] https://www.healthaffairs.org/do/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-2020-06-19/pdf/2020-12970.pdf
[9] 42 U.S.C. 1396r-8
[10] 42 U.S.C. 1396r-8

HHS acknowledges that manufacturers are unaware of which plans have implemented copay accumulator programs. HHS also acknowledges that drug manufacturers make reasonable assumptions that their assistance is passed on to patients and that their programs meet this best price exception. HHS further acknowledges that pharmacy benefit managers (PBMs), and not manufacturers, are the entities that identify when a copay card is used by a patient and decide whether or not to adjust the patient's deductible accordingly.

Nevertheless, the Proposed Medicaid Rule states that the value of the copay assistance will be taken into account when calculating the best price for that drug. The Proposed Rule puts the burden on the drug manufacturer to negotiate with the PBM to ensure that all the value from the patient assistance goes to the patient. This is a difficult feat because 1) as stated, drug manufacturers are typically not in a position to know whether PBMs have adopted copay accumulator programs; and 2) HHS recently released the Notice of Benefit and Payment Parameter for 2021 (NBPP 2021) final rule. NBPP 2021 explicitly states that health plans are expressly permitted to implement copay accumulator programs, regardless of whether generic medications are available. Therefore, in light of the newfound permission, more health plans are likely to adopt copay accumulator programs.

As the adoption of copay accumulator programs becomes more prevalent, more drugs will be impacted by the Proposed Medicaid Rule. Rather than being forced to provide discounts on medications, many drug manufacturers may simply choose to limit their copay assistance programs or exclude patients from receiving assistance.

While copay accumulator programs have created significant financial difficulty for many patients, if copay assistance is withheld altogether, then such patients may face dire situations in which they cannot afford their medications at all. Such a consequence is particularly troubling during the COVID-19 pandemic. First, many chronic patients are considered high risk for severe illness with COVID-19, especially if they are unable to manage their underlying condition. Therefore, it is vital that they be able to access their medications now more than ever. Additionally, the COVID-19 pandemic has resulted in an economic downturn that has left many American families with significantly less income. Therefore, copay assistance becomes even more necessary for them to afford their medications.

III. HHS Should Abandon This Rule or Outright Prohibit Copay Accumulator Programs

Aimed Alliance respectfully requests that HHS either 1) abandon the proposed changes to the Medicaid Best Price Rule pertaining to copay accumulators; or 2) ban copay accumulator programs altogether.

A. Abandon the Proposed Changes

The Proposed Medicaid Rule does not explain how drug manufacturers will be able to determine if a PBM or health plan has adopted a copay accumulator program for a particular medication. The Rule also does not explain how drug manufacturers can prevent any assistance from counting toward best price if a health plan or PBM insists on adopting an accumulator program. As noted, if health plans and PBMs refuse to abandon copay accumulator programs, drug makers are likely to simply abandon offering copay assistance, which would be harmful to patients.

As such, HHS should abandon this rule to avoid unnecessary health consequences for patients.

B. Revert Back to NBPP 2020

Alternatively, if HHS does finalize the Proposed Medicaid Rule, then HHS should revert back to the Notice of Benefit and Payment Parameter 2020 (NBPP 2020), which prohibited the use of copay accumulator programs when the patient was prescribed a brand medication for which a generic alternative was not available. Unlike in the NBPP 2021, HHS now expressly acknowledges the problematic nature of copay accumulator programs in the Proposed Medicaid Rule. However, if HHS's intention were to dissuade health plans and PBMs from adopting such programs, it is unclear how the Proposed Medicaid Rule will achieve that goal. As such, the simplest solution is to revert back to NBPP 2020.

NBPP 2020 was reasonably crafted to incentivize patients to select generic medications when available by allowing health plans to implement copay accumulator policies only when both a brand and generic are available. NBPP 2020 also allowed a patient to request an exception to the copay accumulator program if it was medically necessary for the patient to be on the brand medication. In other words, NBPP 2020 banned copay accumulator programs when patients had no alternative treatment options, but allow such programs if patients could safely use a less costly medication. NBPP 2021 does not achieve this same goal because it allows health plans to implement copay accumulators regardless of whether a generic equivalent is available. This policy limits patients' access to medically necessary treatments. If HHS were to both revert back to NBPP 2020 and implement the Proposed Medicaid Rule, then drug manufacturers may only be disincentivized from offering copay assistance in instances where it may not truly be necessarily (i.e., instances in which the patient can use a generic medication). This result would, once again, strike an appropriate balance between steering patients toward cost-savings and ensuring patients have access to medically necessary treatments.

Additionally, copay accumulator programs should be prohibited when generic alternatives are not available because not only are they harmful to patients, they are not necessary. Some argue that copay accumulators are needed to steer patients to lower cost medications. Accordingly, copay assistance enables patients to circumvent formulary tiers with higher cost-sharing requirements. However, health plans have many guardrails in place to ensure that patients are incentivized to use lower cost medications. These guardrails include prior authorization and step therapy. Patients typically are unable to access more expensive medications without first trying and failing on less costly alternatives or seeking advance approval based on their individualized needs. Once patients overcome these hurdles, a copay accumulator program presents an additional, unnecessary barrier to access.

Copay accumulator programs can also be deceptive and misleading. Given that many health plans either do not disclose the existence of copay accumulator programs or use confusing, dense language that the average American does not understand, these programs can come as a shock to patients.[11] Patients may be responsible for hundreds if not thousands of dollars in out-of-pocket costs that they did not account for, which is unfair. HHS acknowledges this lack of transparency, stating

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[11] https://aimedalliance.org/wp-content/uploads/2018/11/Employers-Beware.pdf

> [T]he manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefits to the patient to the detriment of the patient or consumer, thus generating savings for the plan.[12]

Therefore, to avoid these harmful effects, if HHS finalizes the Proposed Medicaid Rule, the agency should revert back to NBPP 2020 and ban copay accumulator programs in instances in which generic medications are not available.

IV. Conclusion

Based on the arguments herein, Aimed Alliance requests that HHS either 1) abandon the proposed changes to the Medicaid Best Price Rule pertaining to copay accumulators; or 2) ban copay accumulator programs in instances in which generic alternatives are not available. Thank you for considering our requests.

Sincerely,

Stacey L. Worthy
Counsel

[12] https://www.govinfo.gov/content/pkg/FR-2020-06-19/pdf/2020-12970.pdf