July 20, 2020

Administrator Seema Verma
Centers for Medicare & Medicaid Services
US Department of Health & Human Services
P.O. Box 8016
Baltimore, MD 21244

Attention: CMS–2842-P

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-2842-P).

Dear Administrator Verma:

The AIDS Institute, a national non-profit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, viral hepatitis, and other chronic health conditions, is pleased to submit comments on the Centers for Medicare & Medicaid Services’ (CMS) proposed rule, “Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements.” These comments focus singularly on the provision that would revise the Medicaid Best Price determination criteria.

The AIDS Institute appreciates the Administration’s work to advance policies that will contain healthcare expenses, lower prescription drug prices, and reduce patients’ out-of-pocket costs. We also support the movement toward innovative value-based payment models that reward better health outcomes for patients. However, we are concerned CMS’ proposal will have unintended, detrimental consequences for patients with serious conditions, such as those living with HIV, who rely on specialty medications; therefore, we recommend CMS not finalize the provision as drafted leaving the best price determination criteria as is.

The current regulation for Medicaid best price, at 42 CFR §47.505(c)(8-12), states that manufacturer copay assistance programs, coupons, and rebates may be excluded from best
price if the full value of the discount is passed on to the patient or plan beneficiary. The proposal intends to revise the criteria to permit manufacturer copay assistance to be excluded from the calculation of best price only if the manufacturer can ensure that the full value of the assistance is applied to the consumer’s benefit, and is not withheld by the health plan as savings.

**Patients Bear the Burden of Changing Health Plan Designs**

The AIDS Institute has been a consistent advocate for patient access to prescription medications, because copay assistance is particularly essential for patients with chronic conditions who rely on specialty medications. Copay assistance has become even more crucial as health plan benefit designs have steadily shifted more cost-burden on patients over the last ten years, significantly raising deductibles across all health insurance markets. While deductibles in the commercial market have increased at a slower rate, growing 41% between 2014 and 2019, the average deductible for a silver-level, individual market plan jumped 87% in six years, from $2,425 in 2014 to $4,544 in 2020. And those are just the national averages: Based on a review of 2020 silver plans offered in Seminole County, Florida, The AIDS Institute noted that the average deductible in that market was $5,758, and several were as high as $7,700. When such high deductibles are coupled with 30-50% coinsurance for a specialty drug, patients are faced with the prospect of paying thousands of dollars at the outset of the plan year in order to fill their monthly prescriptions. As a result of these ever-rising costs, copay assistance has become a necessity for patients like ours to afford their medications.

Copay accumulator adjustment programs have been one more way in which health insurers and pharmacy benefit managers (PBMs) have changed plan benefit designs, placing undue financial burden on patients. As a result of CMS’ recent decision to allow health insurance plans and PBMs to determine whether or not that vital patient assistance may be counted toward the deductible and out-of-pocket costs in the 2021 Notice of Benefit and Payment Parameters, copay accumulator adjustment programs will undoubtedly become more widespread. While PBMs and payers pocket the money from copay assistance rather than apply it to the beneficiary’s deductible, patients will be left high and dry at the pharmacy counter when they

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are unable to pay thousands of dollars for their prescription, and their ability to access other medical care will be delayed.

This proposal, offered in the wake of CMS’ first approval of copay accumulator adjustment programs, would compound the affordability crisis for patients by dissuading manufacturers from offering patient copay assistance because of the burdensome and unrealistic requirement they will have to meet for best price.

The Black Box of Copay Accumulator Adjustment Programs

This proposal primarily operates under the assumption that manufacturers can control whether a health plan or PBM has implemented a copay accumulator adjustment program. While a manufacturer can establish guidelines that require the patient assistance it provides to be applied toward the patient’s cost-sharing responsibilities, and it can provide that assistance directly to the patient, it cannot force PBMs or insurance companies to honor the intent of that assistance. That is why, to address the problem of PBM’s and insurance companies not counting manufacturer copay assistance toward patients’ annual deductible and out-of-pocket limits, we recommend that CMS reverse the position it took allowing copay accumulator adjustment programs in the 2021 Notice of Benefit and Payment Parameters.

The AIDS Institute has spent a considerable amount of time investigating the practices of health insurance plans and their policies related to copay accumulator adjustment programs. One of the key takeaways from our research has been that health plans are not transparent about copay accumulators and the policies are difficult to find.7 We have found that these policies are sometimes in documents available exclusively to a member only after being enrolled in the plan. Other times the health insurer uses vague language, such as “we reserve the right” not to apply copay assistance toward a beneficiary’s deductible. Some health insurers have no language related to copay accumulators in any written documents, but customer service representatives for the plan have verbally relayed the insurer does have a copay accumulator adjustment program. Furthermore, an insurers’ implementation practices can vary by state. These tactics make it nearly impossible to know whether or not the plan is implementing a copay accumulator at all, uniformly, or perhaps on a case-by-case basis.

To have visibility into these health plans’ practices and to be able to comply with the revised requirement criteria that any copay assistance it offers exclusively benefits the patient, would require manufacturers have access to systems and data they currently do not have. A health plan or PBM would have to allow access to claims data, payment systems, or offer other methods for monitoring the application of copay accumulator adjustment programs at the patient level. Such a system is not feasible, and would, again, put medically and financially fragile patients at risk of not getting the medication they need.

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While copay accumulator policies are well hidden and their implementation is not transparent, the harmful effect on patients’ health is very clear. The risk this revision poses to manufacturers if they are unable to guarantee health plans and PBMs aren't keeping the copay assistance for their own benefit will likely deter them from offering patient assistance programs altogether. Patients will have absolutely no alternative to getting the medicines they need to survive.

**A Conundrum Avoided**

CMS could have helped to mitigate this issue by enforcing the final 2020 NBPP provision on manufacturer assistance. In the final rule, published in April 2019, CMS required issuers to count drug copayment assistance toward a patient’s annual limitation on cost sharing, in the absence of a generic equivalent.8 (The overwhelming majority -- 87% -- of copay assistance is offered for prescription drugs that have no generic equivalent.) This would ensure that, as has traditionally been the case, only the patient received the benefit.9,10

However, in a reversal of the 2020 final rule, the 2021 NBPP permits insurers and PBMs to benefit from the patient copay assistance by implementing copay accumulators, creating this conundrum.11

This may result in a lose-lose situation. If manufacturers see that they are unable to meet the best price exclusion criteria, and patients are clearly not getting the benefit of the assistance programs as intended, they will likely do away with copay assistance programs. That not only cuts the lifeline for patients, but without having to now claim this discount in the best price determination, CMS is also not benefiting from this policy by getting a better price for Medicaid.

**Benefits to the Medicaid Program Remain Unknown**

Health impact assessments and economic impact analyses are critical tools for policy making. This proposed revision will not only have harmful consequences for patients with serious illness, but without an economic impact analysis, it is unclear if there will be notable savings for Medicaid.

The AIDS Institute has serious concerns that this seemingly minor revision to the exclusion criteria for Medicaid best price will cause large-scale harm to millions of patients who rely on copay assistance to afford their medications, like those living with HIV, multiple sclerosis, hemophilia, and other rare diseases. The harm seems to outweigh the benefits for this

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10 IMS Institute for Healthcare Informatics. February 2014. Patient Savings Program Use Analysis
proposed change. We recommend that CMS explore other ways to drive better prices in Medicaid than risk patient access to life saving prescription drugs.

We appreciate your commitment to American patients and welcome your questions, should you have any. Feel free to reach out to Stephanie Hengst, shengst@taimail.org, or Rachel Klein, rklein@taimail.org.

Sincerely,

Stephanie Hengst
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The AIDS Institute