July 20, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

VIA Electronic Filing: http://www.regulations.gov

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:

Thank you for the opportunity to comment on behalf of the steering committee of the All Copays Count Coalition (ACCC). ACCC is an organization of over 80 chronic and rare disease member organizations representing millions of patients throughout the United States that suffer from at least one chronic disease. The steering committee respectfully submits these comments in response to the specific provision regarding the determination of best price in connection with manufacturer copay assistance (Proposed Rule). Moving forward, we respectfully urge CMS to provide greater than 30 days for stakeholders to provide meaningful comments.

For patients with serious chronic diseases, including life-threatening illnesses, access to medication is essential. Although 63% of Americans are unable to afford even a $500 emergency expense,[1] individual health care deductibles, which must be paid in their entirety before a plan pays one dollar toward a patient's care, now average $4,328 annually.[2] Escalating deductibles and out of pocket health costs jeopardize access to care for many patients. For millions of Americans living with complex chronic conditions, the only way to access their specialty medications (many without generic alternatives) is with copay coupons, discount cards, and charitable assistance.

The ACCC steering committee supports CMS' stated intent to ensure manufacturer assistance fully benefits the patient, a goal which is threatened with the growing prevalence of copay accumulator adjustment programs implemented by PBM's and payers. Currently, manufacturer assistance dollars are excluded from best price determination to the extent that the full value of the assistance or benefit is provided to the patient. PBM and payer copay accumulator programs reallocate the full value of the manufacturers' assistance intended to benefit the patient to the plan instead, leaving patients to meet the entire deductible before being able to access their treatments – a challenge which is insurmountable for many.

[1] Bankrate.com
[2] eHealth, 'How much does individual health insurance cost per month?', updated November 18, 2019, viewed online July 16, 2020 (https://www.ehealthinsurance.com/resources/individual-and-family/how-much-does-individual-health-insurance)

While short lived, the 2020 NBPP final rule prohibited these Copay Accumulator Adjustment Programs for medications that have no generic or biosimilar equivalent. However, the 2020 final rule was subsequently walked back in August 2019 and changed in the 2021 NBPP final rule to provide PBM's and payers the option to utilize these programs regardless of whether a generic or biosimilar equivalent is available.

The steering committee is disappointed to see that in this provision, CMS makes reference to a generic substitution as a cost saving option to demonstrate PBMs' contention that manufacturer copay assistance steers consumers toward more expensive medications. In fact, the 2021 NBPP specifically permits implementation of copay accumulator programs regardless of the availability of a generic. Similarly, by including an example of a PBM not allowing manufacturer copay assistance to be applied towards a patient's plan deductible for a brand name drug not on a plan's formulary, without also including an example of the financial burden confronting patients, CMS presents an imbalanced representation of the use and benefit of manufacturer assistance programs.

CMS is now proposing to revise the best price exclusions to provide expressly that they will "apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient." The steering committee does believe specific patient protections are needed to ensure that those who rely on manufacturer assistance to afford their medications are actually the ones benefiting. However, for the reasons discussed below, this goal cannot be achieved with copay accumulator programs in place.

CMS says it is their understanding that some manufacturers do not monitor or place parameters around how the benefits of their manufacturer sponsored assistance programs are applied when an individual has health plan coverage. To our knowledge, CMS's contention that "manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the patient" is unworkable. Just as PBM's or payers lack the ability to require manufacturers to provide assistance to patients, so, too, manufacturers lack the ability to ensure PBM's or payers exclusively apply the full value of that assistance to the patients. The structure of our health care system does not permit one independent entity to dictate the terms to another.

With the health and welfare of patients being our goal, the members of the steering committee pose the following questions to CMS in the hopes of gaining clarity and guidance:

1. What was the outcome CMS intended to achieve with this change?
2. What assumptions, if any, did CMS make regarding the implications of this Proposed Rule on patients and their ability to access/afford medications?
3. Based on the assumptions identified above, how will CMS ensure that patients who are impacted by accumulator adjustment programs will be able to afford their medications and maintain adherence to treatment?
4. What constitutes prominent disclosure of accumulator adjustment programs in health plans and how will it be enforced?
5. Will CMS require the right to a timely appeal or exception request to a treatment subject to a copay accumulator program?

We look forward to arranging a time to discuss the answers to these questions so that we may ensure patients are able to afford the medications they rely upon. In the meantime, we respectfully

urge CMS to withdraw this provision of the Proposed Rule and instead consider re-addressing the permissibility of copay accumulator programs in the NBPP guidance.

Respectfully,

Steering Committee
All Copays Count Coalition

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