May 10, 2019

Mr. Randy Pate
Director, Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201


Dear Mr. Pate:

On behalf of the undersigned patient advocacy organizations, we would like to thank CMS for the inclusion of language in the final 2020 Notice of Benefit and Payment Parameters preamble asserting drug manufacturer financial assistance must count towards a beneficiary’s annual cost-sharing limit for brand-name drugs where no generic equivalent exists, and when a patient gains access to a brand name drug with a generic equivalent through an issuer’s appeals or exception process. This clarification is very important to the millions of patients who depend on high cost prescription drugs and rely on financial assistance to afford them, particularly due to the predominance of high deductible health plans and escalating out of pocket costs.

We appreciate the meetings and conversations representatives of the Department of Health and Human Services have had with patient groups over the past year regarding the impact of copay accumulators on patient access to prescription drugs.

Although the preamble states that language has been added to the regulation text clarifying that drug manufacturer assistance must count towards a beneficiary’s annual limitation on cost-sharing in the aforementioned cases, the language is not explicit in the final rule. Without clarifying language, we are concerned that issuers will not adjust their contracts to abide by the policy. We respectfully request that CMS issue a correction to the Federal Register notice in order to provide the proper legal weight needed to enforce this position. As proposed below, at a minimum we believe it is important for CMS to issue further guidance or a FAQ to clearly state the policy.
We also look forward to working with CMS to ensure plans are aware of the policy and that it is properly reflected in 2020 plan submissions. In the past, plans have not been transparent regarding the use of copay accumulator programs and we believe they should specify in a patient’s summary of benefits and coverage when manufacturer financial assistance does not count towards cost-sharing limits. CMS should work with state Insurance Commissioners to ensure they are aware of the policy and review plans as they are filed to ensure compliance.

With any new regulation, there will undoubtedly be questions by issuers, employers, and beneficiaries regarding how this policy will be operationalized and enforced. In this case, because the provision applies to plans falling under ERISA, we propose the Department of Labor be involved in implementing and enforcing this provision alongside CMS. The development of a FAQ or further guidance is one approach. Among other questions, we hope the FAQ will clarify:

- Non-profit assistance and charitable contributions must also count towards a beneficiary’s annual cost-sharing limitations;
- Issuers are not required to implement copay accumulator policies for brand-name drugs that have a generic alternative;
- Whether issuers are required to count manufacturer copay assistance for high-cost generic drugs without a less expensive alternative; and
- Reiterate the final rule serves as a minimum standard and that state laws take priority in allowing copay assistance to count towards a beneficiary’s annual cost-sharing limitations.

We appreciate that CMS has put the interests of patients first in this policy decision and look forward to working with you to ensure it is properly implemented and enforced. Please contact Carl Schmid, Deputy Executive Director of The AIDS Institute, at cschmid@theaidsinstitute.org, with any questions or comments.

Sincerely,

All Copays Count Steering Committee

Kim Calder, Senior Director of Health Policy, National Multiple Sclerosis Society
Anna Hyde, Vice President of Advocacy and Access, Arthritis Foundation
Elizabeth Franklin, Executive Director, Cancer Policy Institute, Cancer Support Community
Kollet Koulianos, Senior Director Payor Relations, National Hemophilia Foundation
Carl Schmid, Deputy Executive Director, The AIDS Institute

cc: John O’Brien, Senior Advisor to the Secretary for Drug Pricing Reform, HHS