AIMEDALLIANCE

July 23, 2021

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

Martin J. Walsh
Secretary
U.S. Department of Labor
200 Constitution Ave NW
Washington, DC 20210

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Janet Yellen
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Ave NW
Washington, DC 20220

Re: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)

Dear Secretaries Becerra, Walsh, and Yellen and Administrator Brooks-LaSure:

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 the "Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)" ("RFI").[1] The RFI seeks to implement certain reporting requirements for group health plans to promote greater price transparency in health care, improve competition, and bring down overall costs. We support these goals. We also recommend that the Departments **1) exclude copay assistance from the definition of "rebates, fees, and other remuneration"; 2) reinstate patient protections regarding copay accumulator programs; and 3) in the alternative, require insurers to report on copay accumulator programs in efforts to measure harm to patients and identify bad actors.**

I. Copay Assistance Is Not a Rebate, Fee, or Other Renumeration

The U.S. Departments of the Treasury, Labor, and Health and Human Services (collectively "Departments") have proposed that plans report rebates, fees, and any other remuneration paid by drug manufacturers to plans. In determining how to define "rebates, fees, and other remunerations," the Departments asked how to account for manufacturer copay assistance programs, coupon cards, and copay accumulator programs. The value and benefit of copay assistance is intended to convey solely to patients who cannot afford their medications rather than to health plans. Patients with complex health conditions often depend on patient assistance to access and afford their medically necessary treatments. Given that health plans are not the intended recipient of copay assistance, the assistance is not a rebate, fee, or other renumeration to a health plan.

[1] https://www.federalregister.gov/documents/2021/06/23/2021-13138/request-for-information-regarding-reporting-on-pharmacy-benefits-and-prescription-drug-costs

II. NBBP 2020 Protections Should Be Reinstated

The Departments asked how to account for copay accumulator programs. Rather than monitoring and reporting on copay accumulator programs, we strongly urge the Departments to reinstate protections originally adopted in the Notice of Benefit and Payment Parameters 2020 ("NBPP 2020"). The NBPP 2020 prohibited the use of copay accumulator programs in instances where a patient is prescribed a brand medication for which there is no generic equivalent.[2] The NBPP 2020 was reasonably crafted to allow for appropriate patient access to medically necessary therapies but also incentivize patients to select generic medications when available. The rule, therefore, would have achieved the Departments' goal of the RFI to improve competition and bring down overall costs. Yet, the NBPP 2021 revoked these protections.

In most instances in which copay assistance is offered for brand medications, there are no generic alternatives, placing patients at risk for medication adherence issues, including skipping refills, rationing medications, or abandoning treatment altogether.[3] A recent survey by Truven Health Analytics revealed that cost is the biggest barrier to medication adherence.[4] Nonadherent patients can face disease progression or relapse, and increased health care utilization (e.g., more visits to the doctor and hospitalization).[5] These adverse health consequences and increased financial strain add stress and anxiety to the lives of people who are already vulnerable.[6]

Moreover, 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."[7] Yet, this year has proven that that is not the case. According to the Business Group on Health's 2020 Health Care Strategy and Plan Design Survey, 39 percent of large U.S. employers adopted copay accumulator programs in 2020, and nearly 50 percent reported that they plan to implement a program in 2021.[8] Another 14 percent said they are considering using copay accumulator programs in 2022 or 2023.[9] While 10 states and Puerto Rico have chosen to limit copay accumulator programs, those laws do not apply to employer-sponsored plans.[10] Yet, according to the Kaiser Family Foundation, about 49 percent of Americans receive their health insurance from their employer.[11] Therefore, federal limitations on copay accumulator programs are necessary.

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[2] https://www.federalregister.gov/documents/2019/04/25/2019-08017/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2020
[3] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[4] https://www.beckershospitalreview.com/opioids/truven-health-analytics-npr-health-poll-finds-cost-is-top-cause-of-unfilled-prescriptions.html
[5] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[6] https://www.apa.org/news/press/releases/stress/2017/uncertainty-health-care.pdf
[7] https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf
[8] https://pink.pharmaintelligence.informa.com/PS142755/Countering-Coupons-Large-Employers-Will-Boost-Copay-Accumulator-Programs-In-2021
[9] *Id.*
[10] https://www.managedhealthcareexecutive.com/view/new-state-copay-accumulator-laws-complicate-the-coupon-compliance-landscape
[11] https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

III. Insurers Should Be Required to Report on Copay Accumulator Programs

Alternatively, if the Departments choose not to reinstate the NBPP 2020 protections, then the Departments should require insurers to report on copay accumulator programs to measure harm to patients and identify bad actors. As noted, copay accumulator programs wrongfully divert copay assistance from patients to insurers. Without the full benefit of copay assistance counting toward their deductible, many patients cannot afford their medications.

As states have begun to implement protections against copay accumulator programs, the mechanisms in which health plans are implementing such programs continue to evolve in egregious manners. For example, companies like SaveonSp and PrudentRx have adopted a new model in which they claim they have found a "loophole" to the Patient Protection and Affordable Care Act ("ACA").[12] They claim that many of plans' covered prescription drugs are not essential health benefits ("EHBs"), and therefore, do not count toward the ACA's annual out-of-pocket limit.[13] They argue that only the same ***number*** of drugs within a class or category of drugs that a benchmark plan covers needs to be considered EHBs.[14] If a plan covers any number of drugs above and beyond the number of drugs covered by the benchmark plans, they argue that those drugs can be categorized as "non-essential drugs."[15] While these non-essential drugs are still covered by the plan, SaveonSP claims that these drugs are not subject to ACA requirements, such as the annual out-of-pocket limit.[16] Plan enrollees are then charged significantly high out-of-pocket costs for such drugs unless they opt into SaveonSp's or PrudentRx's copay maximizer program.[17] The copay maximizer program extracts the maximum value of copay assistance from the drug manufacturer, provides it to the insurer, and does not count that value toward the patient's deductible.[18]

This type of policy harms patients by forcing them to either pay significantly high out-of-pocket costs or convey the value of copay assistance to the health plan. Even if patients opt into the copay maximizer program, the value of the assistance still does not count toward their deductible. Moreover, this type of policy may also violate the ACA. HHS has previously stated that if an individual plan or small group plan "is covering drugs beyond the number of drugs covered by the EHB-benchmark plan, all of these drugs are EHB and cost sharing paid for the drugs must count toward the annual limitation on cost sharing."[19] HHS has also stated that large group plans only have discretion to define an EHB only to the extent that HHS has authorized a particular

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[12] https://www.bcbswny.com/content/dam/BCBSWNY/broker-group/public/pdf/group/computer-task-group/Saveon-Member-Flyer.pdf; https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html

[13] https://www.bcbswny.com/content/dam/BCBSWNY/broker-group/public/pdf/group/computer-task-group/Saveon-Member-Flyer.pdf; http://medicine.buffalo.edu/content/dam/medicine/d/gme/residents/CL-0001-POS-298-SBC-2020%20--2021%20.pdf https://www.drugchannels.net/2020/11/saveonsps-copay-maximizer-failed-me.html; https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html; https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html

[14] https://www.drugchannels.net/2020/11/saveonsps-copay-maximizer-failed-me.html; https://www.drugchannels.net/2020/05/why-do-cvs-and-express-scripts-rely-on.html; https://www.drugchannels.net/2020/02/latest-express-scripts-data-slow-drug.html

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf

definition.[20] Yet, HHS has not authorized the definition being used by these companies. Therefore, SaveonSP's and PrudentRx's interpretation is inconsistent with the ACA and its implementing regulations and guidance. We ask the Departments to monitor for this type of egregious activity and take enforcement action against it. In collecting this data, we hope that the Departments will be persuaded to prohibit copay accumulator programs, following the lead of 10 states and counting who have done just that.

Thank you for considering our requests.

Sincerely,

Stacey L. Worthy
Counsel

[20] 2011 FAQ