AIMED ALLIANCE

February 23, 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: HHS Notice of Benefit and Payment Parameters for 2021 – Docket CMS-9916-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 "Docket CMS-9916-P, HHS Notice of Benefit and Payment Parameters for 2021" (NBPP 2021). If finalized, NBPP 2021 would allow health plans to exclude the value of drug manufacturers' coupons from the calculation of patients' deductibles and annual out-of-pocket limits, even in instances in which a patient is taking a medication for which there is no generic alternative. This type of policy, commonly referred to as a "copay accumulator policy," can reduce patient access to medically necessary treatments. Aimed Alliance requests that the Centers for Medicare and Medicaid Services (CMS) refrain from implementing this rule, and instead, maintain and enforce the copay accumulator rule finalized in the Notice of Benefit and Payment Parameters for 2020 (NBPP 2020). Additionally, we request that CMS, in conjunction with the Internal Revenue Service (IRS), explicitly state that health plans will not violate laws and policies pertaining to high deductible health plans (HDHPs) and health savings accounts (HSAs) by choosing not to offer copay accumulator programs.

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 HDHPs in which the patient is required to pay significantly high out-of-pocket costs until the deductible is reached. In many instances, HDHP are patients' only option; employers are increasingly offering only HDHPs.[1]

[1] https://buildcommonwealth.org/work/high-deductible-health-plans

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]

A. Q&A-9 of IRS Notice 2004-50

On August 16, 2004, the IRS issued Notice 2004-50 in a bulletin (the "Bulletin"), which contained a set of questions and answers HSAs.[8] Q-9 asked "may an individual who is covered by an HDHP and also has a discount card that enables the user to obtain discounts for health care services or products, contribute to an HSA?" A-9 answers this question as follows:

> Yes. Discount cards that entitle holders to obtain discounts for health care services or products at managed care market rates will not disqualify an individual from being an eligible individual for HSA purposes if the individual is required to pay the costs of the health care (taking into account the discount) until the deductible of the HDHP is satisfied.[9]

Unlike copay assistance offered by drug manufacturers, a "discount card" typically refers to a discount program offered by a third party, such as a pharmacy benefit manager, as an alternative to traditional health insurance.[10] Patients without health insurance can use the discount card to obtain a lower price on their medications, and patients with insurance could use the discount card ***in lieu of*** their health insurance, depending upon the terms of the plan. Discount cards have an unlimited value whereas copay coupons have a finite annual value. Here, the IRS explained that individuals with HDHPs and accompanying HSAs could use these discount cards, but the value of the cards would not count toward the plan's deductible.

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[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.irs.gov/irb/2004-33_IRB
[9] https://www.irs.gov/irb/2004-33_IRB
[10] https://www.frierlevitt.com/articles/pharmacylaw/the-hidden-dark-side-of-prescription-discount-cards-what-your-pharmacy-needs-to-know/; https://news.wellrx.com/2017/09/06/prescription-savings-cards-vs-coupons/; https://www.modernhealthcare.com/article/20170321/NEWS/170329990/new-pbm-programs-bypass-insurers-to-offer-drug-discounts-directly-to-consumers; https://www.drugtopics.com/drug-costs/discount-drug-cards-are-flourishing

B. NBPP 2020

On April 25, 2019, the U.S. Department of Health and Human Services (HHS) issued NBPP 2020. In NBPP 2020, HHS declared that "amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to insured patients to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have a generic equivalent are not required to be counted toward the annual limitation on cost-sharing."[11] In other words, insurers could choose to exclude copay assistance from the calculation of a plan enrollee's deductible or annual out-of-pocket limit only for brand drugs for which generic equivalents are available. The agency noted that this copay accumulator rule was "intended to address the distortion in the market caused when consumers choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available."[12] To that end, NBPP 2020 also stated that an enrollee could use the appeals or drug exception process to obtain a brand medication, even if a generic equivalent was available, in cases where the generic alternative is not medically appropriate.[13] It explained that because the coupon would not disincentivize the less expensive choice in this scenario, it would not facilitate a market distortion.[14] Aimed Alliance applauded HHS for taking reasonable steps to protect consumers from unfair copay accumulator practices.

C. FAQ

On August 26, 2019, HHS, the U.S. Department of Labor (DOL), and the U.S. Department of Treasury issued an FAQ document, announcing that the agencies would not enforce the NBPP 2020 copay accumulator rule because of a perceived conflict with the Bulletin[15] that governs HDHPs with HSAs.[16] Conflating drug manufacturer coupons with third-party discount cards, the Departments noted in the FAQ that the 2020 NBPP could be interpreted to mean that "group health plans and issuers are required to count such coupon amounts toward the annual limitation on cost sharing" in all other circumstances, such as when an enrollee fills a prescription for a brand medication without a generic equivalent.[17] The FAQ document specified that the NBPP 2020 copay accumulator rule would be impossible for health plans to comply with because the Bulletin prohibits health plan enrollees of HDHPs with HSAs from utilizing financial assistance and coupons from pharmaceutical manufacturers. Conversely, the NBPP 2020 copay accumulator rule would have required health plans to count third-party financial assistance towards enrollees' deductibles when they fill a prescription for a brand medication without a generic equivalent.

II. CMS Should Reinstate NBPP 2020

Aimed Alliance respectfully requests that CMS maintain and enforce NBPP 2020.

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[11] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[12] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[13] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[14] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[15] https://www.irs.gov/pub/irs-drop/n-04-50.pdf
[16] https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40
[17] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf

A. NBPP 2020 and the Bulletin Do Not Conflict

CMS's rationale for choosing not to maintain and enforce the NBPP 2020 copay accumulator rule is based on a misinterpretation of the Bulletin. As noted, the Bulletin refers to a discount card, which is separate and distinct from a drug maker coupon. Discount cards traditionally are used in lieu of health insurance, so it would naturally follow that such cards were excluded from the calculation of an annual deductible when the Bulletin was released in 2004. However, copay assistance from a drug maker has traditionally counted toward annual deductibles and out-of-pocket limits, up until very recently when plans began to adopt copay accumulator programs. Therefore, it is highly unlikely that the IRS was referring to drug manufacturers' coupons when it issued the Bulletin in 2004. As such, the perceived conflict between NBPP 2020 and the Bulletin does not exist.

B. NBPP 2020 and the Bulletin Cannot Conflict

NBPP 2020 cannot conflict with the Bulletin because the Bulletin is not a legally binding document. NBPP 2020 was a legally binding rule that went through the formal notice and comment rulemaking process. As such, it supersedes the Bulletin, which is a non-legally binding guidance document. An issuer or sponsor of an HDHP, therefore, need only comply with NBPP 2020.

NBPP 2020 was an agency-issued rule. The Administrative Procedure Act defines a rule as ". . . an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."[18] Legally binding rules must go through the official rulemaking process, including a notice and comment period.[19] Such a rule is "binding upon all persons and on the courts, to the same extent as a congressional statute."[20] Here, NBPP 2020 went through the official rulemaking process, and therefore, carries the full force of law.

In contrast, the Bulletin is a guidance document and does not carry the force of law. According to the Office of Management and Budget's Final Notice for Agency Good Guidance Practices, a "guidance document" is defined as "an agency statement of general applicability and future effect, other than a regulatory action . . . ."[21] A guidance document is not legally binding.[22] Here, IRS Notice 2004-50 is explicitly described as "guidance on Health Savings Accounts,"[23] and was issued without transparency, accountability, and an opportunity for the public to comment. Additionally, IRS Notice 2004-50 is contained in the IRS Bulletin, which explicitly states that "[r]ulings and procedures reported in the Notice do not have the force and effect of Treasury Department Regulations . . . . In applying published rulings and procedures [described in the Bulletin], the effect of subsequent legislation, regulations, court decisions, rulings, and procedures must be considered."[24] Therefore, the Bulletin is not legally binding, and NBPP 2020, a subsequent

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[18] 5 U.S.C. § 551(4)
[19] National Latino Media Coalition v. Federal Communications Commission, 816 F.2d 785, 788 (D.C. Cir. 1987); https://fas.org/sgp/crs/misc/IF10003.pdf
[20] National Latino Media Coalition v. Federal Communications Commission, 816 F.2d 785, 788 (D.C. Cir. 1987); https://fas.org/sgp/crs/misc/IF10003.pdf
[21] https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf
[22] https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf
[23] https://www.irs.gov/irb/2004-33_IRB#ftn.idm139984853516144
[24] https://www.irs.gov/pub/irs-irbs/irb04-50.pdf

regulation, supersedes it. As such, an issuer or sponsor of an HDHP does not need to comply with Q&A-9 to the extent that it conflicts with NBPP 2020.

Additionally, the Department of Justice (DOJ) has warned against using guidance to coerce policy, impose substantive obligations, or otherwise create rights despite the technically not legally binding nature of guidance documents.[25] This appears to be what the FAQ is doing by giving so much weight to the Bulletin and asserting that NBPP 2020 should not be enforced because of it. CMS should rescind the proposed NBPP 2021 and allow NBPP 2020 copay accumulator rule to carry the force of law. If there is any confusion about how these rules interact, the Treasury should issue a new bulletin explaining that plans will not violate the Bulletin by complying with NBPP 2020 copay accumulator rule.

C. The Definition of "Cost-Sharing" Should Include Coupons

NBPP 2021 proposes to interpret the definition of "cost-sharing" in section 1302(c)(3)(A) of the Patient Protection and Affordable Care Act (ACA) to "exclude expenditures covered by drug manufacturer coupons."[26] Section 1302(c)(1) of the ACA defines "cost-sharing" as "(i) deductibles, coinsurance, copayments, or similar charges; and (ii) any other expenditure required of an insured individual which is a qualified medical expense (within the meaning of section 223(d)(2) of Title 26) with respect to essential health benefits covered under the plan."[27] In explaining its rationale for excluding manufacturer coupons from the definition of cost-sharing, CMS argues that the "value of the coupon is not a cost incurred by or charged to the enrollee." However, this appears to be a misunderstanding of the current definition of cost-sharing. The current cost-sharing definition refers to deductibles, coinsurance, copayments, and similar charges required of the plan enrollee by the health plan. Plan enrollees are responsible for those expenditures whether or not they receive financial assistance from any third party. The fact that a plan enrollee receives a coupon to assist in paying for the cost of a health care product or service does not relieve him or her of that responsibility, nor does it reduce the amount that the health plan will be paid. The plan enrollee is simply receiving assistance in meeting that responsibility, as the enrollee would if he or she accepted assistance from a friend or family member.

Moreover, CMS's new interpretation of "cost-sharing" is inconsistent with the definition of "cost-sharing" for exchange plans. The definition of "cost-sharing" in section 1302(c)(3)(A) applies to essential health benefits and qualified health plans. "Cost-sharing" is also defined in 45 C.F.R. § 155.20.[28] This regulation, which pertains to qualified health plans offered in exchanges, defines cost sharing as "any expenditure required by ***or on behalf of*** an enrollee with respect to essential health benefits; such term includes deductibles, coinsurance, copayments, or similar charges . . ." (emphasis added).[29] Given that the regulation explicitly includes financial assistance from third parties in its definition, drug manufacturer coupons offered on behalf of plan enrollees are classified as cost-sharing. As such, CMS's new interpretation of cost-sharing creates a conflict for qualified health plans offered in marketplace exchanges.

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[25] https://www.justice.gov/file/1028756/download
[26] https://www.govinfo.gov/content/pkg/FR-2020-02-06/pdf/2020-02021.pdf
[27] 42 U.S.C. § 18022(c)(3)
[28] 45 CFR § 155.20
[29] 45 CFR § 155.20

D. NBPP 2021 Copay Accumulator Rule Will Harm Patients

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. While CMS still urges plans to incentivize generic drug use, NBPP 2021 will not achieve this same goal because it allows health plans to implement copay accumulators regardless of whether a generic equivalent is available. This policy will limit patients' access to medically necessary treatments. As noted above, copay coupons are limited in value. If the value is expended, the patient may be unable to afford his or her medication. This can lead to disease progression, relapse, or other adverse events; additional health care utilization; and greater overall health care costs for the patient and their health plan.[30]

E. Copay Accumulator Programs Are Unnecessary in Light of Other Utilization Management Strategies

Some argue that copay accumulators are necessary to steer patients to lower cost medications. They claim that 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.

F. Copay Accumulator Programs Can Be Unfair and Deceptive

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.[31] Patients may be responsible for hundreds if not thousands of dollars out-of-pocket that they did not account for, which is unfair. While CMS acknowledges this lack of transparency, it does not require health plans to implement standards that would result in increased clarity. Instead, the agency recommends that plans "prominently include [information on accumulators] on their websites and in brochures, plan summary documents, and other collateral materials that consumers may use to select, plan, and understand their benefits." To the extent that a plan is allowed to implement a copay accumulator program, such disclosures should be required.

G. Payers Have Adequate Notice to Implement NBPP 2020 Rule

In response to NBPP 2020, some stakeholders voiced opposition to the rule because they argued that they did not have enough time to implement it. However, stakeholders have now been on notice of the rule for over a year. As such, they have had ample time to consider how an implementation strategy. Moreover, some states have codified laws similar to NBPP 2020. Plans can look to issuers in those states as models when determining how to implement NBPP 2020.

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[30] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/

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

H. NBPP 2021 Undermines States' Efforts to Regulate Copay Accumulator Programs

NBPP 2021 undermines efforts from states to enact and enforce legislation governing copay accumulator programs. Over the past two years, four states – Arizona, Illinois, Virginia, and West Virginia – have enacted legislation that restricts health plans' use of copay accumulator programs.[32] Some of these laws ban copay accumulator programs altogether, and others ban the programs only in instances in which generic medications are available. Additionally, several states have introduced copay accumulator legislation.[33] While NBPP 2021 explicitly states that it is not intended to preempt state law, NBPP 2021 also includes language that creates confusion for health plans in states with copay accumulator laws. As discussed above, CMS states that the IRS Bulletin essentially requires HDHPs to implement copay accumulator programs. Health plans may feel that they cannot comply with both the Bulletin and state law without further guidance from CMS and IRS. Therefore, CMS, in conjunction with IRS, should clarify that plans will not violate the Bulletin if they choose not to implement copay accumulator programs.

III. Conclusion

Based on the arguments herein, Aimed Alliance requests that CMS abandon changes proposed in NBPP 2021 and instead maintain and enforce NBPP 2020 as it pertains to copay accumulators. Additionally, we ask that CMS, in conjunction with IRS, explicitly state that plans will not violate the Bulletin if they choose not to offer copay accumulator programs. Thank you for considering our requests.

Sincerely,

Stacey L. Worthy
Counsel

[32] https://aimedalliance.org/copay-accumulators-enacted-laws/
[33] https://aimedalliance.org/copay-accumulators-enacted-laws/