AIMED ALLIANCE

October 7, 2019

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SE
Washington, DC 20201

The Honorable Steven Terner Mnuchin
Secretary
U.S. Department of the Treasury
1500 Pennsylvania Ave., NW
Washington, DC 20220

The Honorable Eugene Scalia
Secretary
U.S. Department of Labor
200 Constitution Avenue, NW
C-2318
Washington DC, 20210

Re: Petition for Rulemaking to Revoke FAQs About Affordable Care Act Implementation Part 40 and to Issue a Guidance Clarifying Internal Revenue Services Notice 2004-50 Q&A-9

Dear Secretary Azar, Secretary Mnuchin, and Secretary Scalia:

Aimed Alliance respectfully submits this Petition for Rulemaking to the U.S. Department of Health and Human Services ("HHS"), U.S. Department of Labor ("DOL"), and U.S. Department of the Treasury ("Treasury") (collectively, "the Departments") pursuant to section 553(e) of the Administrative Procedure Act ("APA").[1] Petitioner requests that the following actions be taken:

1) The Departments rescind FAQs About Affordable Care Act Implementation Part 40 ("FAQ"); and
2) The Treasury issue guidance clarifying that individuals will not be disqualified from enrolling in a health savings account ("HSA") if an issuer or sponsor of a high deductible health plan ("HDHP") complies with the Notice of Benefit and Payment Parameters for 2020 ("NBPP").

With these changes, the Departments can then enforce the NBPP, specifically as it pertains to counting the value of drug manufacturers' coupons toward health plans' annual limitations on cost sharing.

[1] 5 U.S.C. § 553(e).

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## I. Introduction and Overview

### A. Copay Accumulator Programs

Historically, privately insured individuals who cannot afford their copayments or coinsurance have been able to obtain aid from copayment assistance programs – discount programs in which a pharmaceutical manufacturer may offer a coupon card or rebate to an individual to ease the burden of high out-of-pocket costs. The coupon card or rebate has not only contributed toward the patient's copayment but has also counted 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.

Health plans are increasingly implementing copay accumulator programs, which prevent copayment assistance from counting toward a plan enrollee's deductible.[2] Under such programs, once copayment assistance runs out, the plan enrollee is again faced with an inability to afford his or her medication. In some instances, there are no generic alternatives, and patients may be forced to ration their medications or abandon treatment altogether.[3] As a result, they can experience disease progression, relapse, and other adverse events, thereby increasing health care utilization.[4] These consequences will add stress and anxiety to the lives of people who are already vulnerable.[5]

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

On August 16, 2004, the Internal Revenue Services ("IRS") issued Notice 2004-50, which contained a set of questions and answers on HSAs.[6] 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.[7]

In other words, individuals who are enrolled in an HSA alongside an HDHP may only use copay assistance if that assistance does not count toward the annual deductible (i.e., a copay accumulator program).

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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://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[4] https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/
[5] https://www.apa.org/news/press/releases/stress/2017/uncertainty-health-care.pdf
[6] https://www.irs.gov/irb/2004-33_IRB
[7] https://www.irs.gov/irb/2004-33_IRB

### C. The NBPP

On April 25, 2019, HHS issued the final NBPP. In the NBPP, HHS declared that "plans and issuers are permitted to exclude the value of drug manufacturers' coupons from counting toward the annual limitation on cost sharing when a medically appropriate generic is available."[8] As the Departments note in the FAQ, 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.[9] Additionally, the NBPP states that an enrollee can use the appeals or drug exception process to obtain brand medication even if a generic equivalent is available in cases where the generic alternative would not be medically necessary.[10]

While there is still more work to be done to ensure that the terms of copay accumulator programs are transparent and adequately disclosed to plan participants, Aimed Alliance applauded HHS for taking reasonable steps to protect consumers from unfair copay accumulator practices. The NBPP does not prohibit copay accumulators altogether, but it does implement guardrails to align copay accumulator programs with their original intent—to steer consumers from pricier brand drugs to more affordable generics.

### D. The FAQ

On August 26, 2019, the Departments issued the FAQ, which noted that the Departments will not be enforcing key components of the 2020 NBPP.[11] In the FAQ, the Departments stated that an implied requirement in the NBPP to count copay assistance toward annual limitations on cost sharing creates a conflict with Q&A-9. As noted, Q&A-9 would require the value of drug manufacturers' coupons to be excluded from the deductible calculation for individuals with HDHPs and HSAs.[12] The Departments concluded that an issuer or sponsor of an HDHP may be unable to comply with both rules simultaneously, and, therefore, the NBPP should not be enforced against any plan.

## II. Petitioner Is an Interested Party

The Petitioner, Aimed Alliance, is 501(c)(3) nonprofit corporation registered to do business in the District of Columbia. The Petitioner's mission is to protect and enhance the rights of health care consumers and providers. Many of the Petitioner's efforts include ensuring that patients have access to medically necessary treatment and medical care. While copay accumulator programs limit consumers' access to such care, the NBPP created new regulatory protections for consumers so that they can access their treatments. As such, Aimed Alliance is interested in ensuring that the NBPP is enforced.

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[8] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf
[9] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf
[10] https://www.govinfo.gov/content/pkg/FR-2019-04-25/pdf/2019-08017.pdf
[11] https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf
[12] https://www.irs.gov/pub/irs-irbs/irb04-50.pdf; https://www.irs.gov/irb/2004-33_IRB

## III. The Proposed Withdrawal of the FAQ and Issue of Guidance

Aimed Alliance requests that 1) the Departments rescind the FAQ; and 2) the Treasury issue guidance to clarify that individuals will not be disqualified from enrolling in an HSA if an issuer or sponsor of an HDHP complies with the NBPP. These actions will allow the Departments to enforce the NBPP as written.

### A. The Departments Should Rescind the FAQ

The Departments should rescind the FAQ because the NBPP supersedes IRS Notice 2004-50. The FAQ is premised on the notion that the NBPP is in direct conflict with IRS Notice 2004-50 Q&A-9, and that an issuer or sponsor of an HDHP that is used in conjunction with an HSA could not simultaneously comply with both the NBPP and the Notice. However, this is flawed logic because the NBPP is a legally binding rule that supersedes a non-legally binding notice. Therefore, an issuer or sponsor of an HDHP need only comply with the NBPP to the extent that the two conflict.

The NBPP is an agency-issued rule. The APA defines a rule as ". . . an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy."[13] Legally binding rules must go through the official rulemaking process, including a notice and comment period.[14] Such a rule is "binding upon all persons and on the courts, to the same extent as a congressional statute."[15] Here, the NBPP went through the official rulemaking process, and therefore, carries the full force of law.

IRS Notice 2004-50, in contrast, 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 . . . ."[16] A guidance document is not legally binding.[17] Here, IRS Notice 2004-50 is explicitly described as "guidance on Heath Savings Accounts,"[18] and was issued without transparency, accountability, and an opportunity for the public to comment. Additionally, IRS Notice 2004-50 is contained in the Internal Revenue 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."[19] Therefore, IRS Notice 2004-50 is not legally binding, and the NBPP, a subsequent 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.

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[13] 5 U.S.C. § 551(4)
[14] 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.
[15] 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.
[16] https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf
[17] https://www.govinfo.gov/content/pkg/FR-2007-01-25/pdf/E7-1066.pdf
[18] https://www.irs.gov/irb/2004-33_IRB#ftn.idm139984853516144
[19] https://www.irs.gov/pub/irs-irbs/irb04-50.pdf

Moreover, the Department of Justice 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.[20] This appears to be what the FAQ is doing by giving so much weight to IRS Notice 2004-50 Q&A-9 and asserting that the NBPP should not be enforced because of it. Consequently, the FAQ should be rescinded.

**B. The Treasury Should Issue Guidance Clarifying Q&A-9**

While rescinding the FAQ is sufficient action by itself, we request that the Treasury also issue guidance that explicitly states that an HDHP issuer or sponsor is not in violation of IRS Notice 2004-50 Q&A-9 if it complies with NBPP. Such action would be consistent with the President's Executive Order on Improving Price and Quality Transparency in American Healthcare to Put Patient's First ("Executive Order").

On June 24, 2019, the President issued the Executive Order, which directed the Treasury to issue guidance "to expand the ability of patients to select high-deductible health plans that can be used alongside a health savings account, and that cover low-cost preventive care, before the deductible, for medical care that helps maintain health status for individuals with chronic conditions."[21] While the Treasury has issued guidance solely on preventive care,[22] it could go further to expand the ability of patients with chronic conditions to select HDHPs that can be used alongside HSAs to maintain their health status. One way to achieve this goal is to issue guidance that explicitly creates a safe harbor from Q&A-9 for plan issuers and sponsors who comply with the NBPP. Not only would this clear up any ambiguity or confusion between IRS Notice 2004-50 and the NBPP, but it would also expressly permit certain patients, including those with chronic conditions, to use copay assistance and still qualify for an HSA.

Notwithstanding the NBPP, Q&A-9 excludes individuals who seek to use copay assistance from qualifying for an HSA to be used alongside an HDHP. Many patients with chronic conditions may be enrolled in HDHPs with HSAs. They may have just as much difficulty affording their medications as patients in any other type of health plan. Additionally, many individuals with HSAs are not in a position to contribute to their HSAs.[23] Even when they are, they may need the funds in their HSAs to cover other treatments or medical services. Moreover, the contribution limits for HSAs ($3,550 for a self-only plan and $7,100 for a family plan in 2020) fall well below the annual out-of-pocket maximum limits for HDHPs ($6,900 for a self-only plan and $13,800 for a family plan in 2020). An individual could theoretically exhaust the value of manufacturers' coupon programs, use up all his or her HSA funds, and still owe a hefty amount toward the deductible.

Those who are still in the deductible phase of their plan but have not set aside, or who have run out of HSA funds, are far more likely to forego necessary care. According to the Kaiser Family Foundation, "high deductibles have actually forced people to delay care that could prevent health

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[20] https://www.justice.gov/file/1028756/download

[21] https://www.whitehouse.gov/presidential-actions/executive-order-improving-price-quality-transparency-american-healthcare-put-patients-first/

[22] https://www.irs.gov/pub/irs-drop/n-19-45.pdf

[23] https://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/health-savings-accounts/art-20044058

emergencies later or improve their quality of life."[24] A study conducted by UC-Berkeley and Harvard found that "people with high-deductible plans spent 42 percent less on health care before meeting their deductibles, primarily by reducing the amount of health care they received, not by shopping around for better price."[25] A carveout from Q&A-9 would allow the value of copay assistance to count toward the deductible only when a patient needs a medication for which no generic alternative is available. Allowing this assistance would help enrollees who fully leverage their HSAs to meet their deductible. Therefore, we respectfully request that the Treasury issue guidance explicitly stating that health plan sponsors and issuers would not violate IRS Bulletin 2004-50 Q&A-9 by complying with the NBPP.

## IV. Conclusion

For all of the foregoing reasons, Petitioner requests that the Departments rescind the FAQ and for the Treasury to issue guidance clarifying individuals will not be disqualified from enrolling in an HSA if an issuer or sponsor of an HDHP complies with the NBPP. These actions will help to reduce the risk that copay accumulator programs will adversely impact patients' ability to access their medications. Thank you for consideration. We look forward to your timely response.

Sincerely,

Stacey L. Worthy
Counsel for the Petitioner

[24] https://money.cnn.com/2017/08/05/news/economy/high-deductibles-insured-health-care/index.html
[25] https://academic.oup.com/qje/article/132/3/1261/3769421