

State Copay Accumulator Program Reform In Light of The Notice of Benefit and Payment Parameters 2021

BACKGROUND

As health care costs in the U.S. continue to rise, an increasing amount of out-of-pocket costs are shifted onto patients. Yet, many patients have less available income due to the economic impact of the COVID-19 public health emergency. One way that states can help is by enacting patient-focused legislation to limit the use of copay accumulator programs. This fact sheet explains states' authority to do so.

WHAT ARE COPAY ACCUMULATOR PROGRAMS?

When patients cannot afford their medications, they may rely on copay assistance (i.e., coupon cards from drug manufacturers). These coupon cards not only contribute toward the patient's copay but also count toward the patient's annual deductible. Copay assistance programs have been especially helpful for individuals enrolled in high deductible health plans (HDHPs) in which patients are required to pay significantly high out-of-pocket costs until their deductibles are reached. Increasingly, HDHPs are patients' only options; many employers and marketplace exchanges only offer HDHPs.¹

However, health plans are increasingly implementing copay accumulator programs, which are policies that prevent the value of the coupon from counting toward a patient's deductible.²

HOW DO COPAY ACCUMULATORS IMPACT PATIENTS?

Patients with complex health conditions often depend on using patient assistance to access their medically necessary treatments. However, patient assistance is not a bottomless well. Patients can receive a finite amount each year. Once copayment assistance runs out, many patients can no longer afford their medications. 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.³ A recent survey by Truven Health Analytics revealed that cost

is the biggest barrier to medication adherence. Nonadherent patients can face disease progression or relapse, and increased health care utilization (e.g., more visits to the doctor and hospitalization).⁴ These adverse health consequences and increased financial strain add stress and anxiety to the lives of people who are already vulnerable.

WHY ARE COPAY ACCUMULATORS USED?

Insurers use copay accumulators to collect the value of the financial assistance and extend the time that patients are in the deductible phase of their health plan. The longer patients remain in the deductible phase of the health plan, the more money that the health plan makes.

Health plans argue that they use copay accumulators to steer patients to lower cost, generic medications. However, health plans already use other benefit utilization management policies to achieve this goal. Insurers typically require patients to first try and fail on less costly alternatives (i.e., step therapy) or seek the insurer's advance approval based on their individualized needs (i.e., prior authorization) before they can access more costly medications. Once patients overcome these hurdles, a copay accumulator program presents an additional, unnecessary barrier to access.

Additionally, many medications for which copay assistance is available do not have generic equivalents. In these instances, if a patient cannot access a brand medication, he or she generally has no other treatment option. Therefore, a more practical solution would be to only allow copay accumulator programs in instances where generic alternatives are available.

WHAT IS THE NOTICE OF BENEFIT AND PAYMENT PARAMETERS AND WHAT DID IT DO?

A. Notice of Benefit and Payment Parameters

Each year, the U.S. Department of Health and Humans Services (HHS) issues the Notice of Benefit and Payment Parameter (NBPP), which governs how health insurers implement health plans, including both marketplace exchange plans and Employee Retirement Income Security Act (ERISA) plans.

B. NBPP 2020

On April 25, 2019, HHS finalized the NBPP 2020. NBPP 2020 would have only allowed health plans to implement copay accumulators when both a brand and generic medication were available. The rule was intended to steer patients to less costly,

generic medications when possible. This rule was a major win for patients with chronic, rare, and debilitating diseases who do not have access to alternative, less costly medications. While it created appropriate cost-saving incentives, it also inherently prohibited copay accumulators in instances in which generic alternatives were not available.

C. FAQ & IRS Bulletin No. 2004-50, Q&A-9

On August 26, 2019, HHS, Department of Labor (DOL), and Department of Treasury issued an FAQ document, announcing that they would not enforce NBPP 2020 because of a perceived conflict with an Internal Revenue Service (IRS) Bulletin from 2004 that governs HDHPs with accompanying health savings accounts (HSAs). In actuality:

- NBPP 2020 and the Bulletin <u>do not conflict because the agencies</u>

 <u>misinterpreted the Bulletin</u> (the agencies conflated third-party discount cards with pharmaceutical manufacturers' copay coupons; see the attached comment for more details); and
- NBPP 2020 and the Bulletin <u>cannot conflict because the NBPP is legally</u> <u>binding, whereas the Bulletin is not</u>. (NBPP 2020 went through the formal notice-and-comment rulemaking process whereas the Bulletin is a guidance document that did not.)

D. NBPP 2021

On May 17, 2020, HHS finalized the <u>NBPP 2021</u>. In the <u>NBPP 2021</u>, HHS revoked NBPP 2020's copay accumulator protections. Instead, NBPP 2021 explicitly allows health plans to implement copay accumulators in all instances, regardless of whether a generic equivalent is available. HHS used the faulty FAQ as support for this proposed change.

MAY STATES ENACT THEIR OWN LEGISLATION ADDRESSING COPAY ACCUMULATORS?

Yes. States may enact their own laws governing copay accumulators, including laws that offer strong patient protections. NBPP 2021 does not preempt state laws that govern the use of copay accumulator programs in state-regulated health plans. Specifically, HHS stated in the Federal Register notice accompanying the NBPP 2021 that states may:

[R]equire direct drug manufacturer support amounts to be counted by health insurance issuers towards the annual limitation on cost sharing. To the extent states want to require health insurance issuers to count direct drug manufacturer support amounts towards the annual limitation on cost sharing, they can do so when such action would be consistent with other applicable laws and rules (for example, federal non-discrimination requirements).⁵

State laws also will not conflict with the IRS Bulletin. As noted, the Bulletin is not legally binding and does not implicate pharmaceutical copay assistance programs.

SHOULD STATES ENACT THEIR OWN LEGISLATION LIMITING THE USE OF COPAY ACCUMULATOR PROGRAMS?

Yes. State legislation is a vital patient protection given the lack of federal protections. Last year's rule, NBPP 2020, was crafted to incentivize patients to use lower cost medications only when such medications were available. It was developed to strike a balance between the interests of health plans and pharmaceutical manufacturers without unreasonably penalizing patients for relying on financial assistance. In contrast, NBPP 2021 limits patients' access to medications even when there are no cheaper alternatives available, putting their health at risk and potentially increasing costs to the health system.

Millions of American across the country rely on cost-sharing assistance to afford their medications. Such assistance is only helpful if it can be counted toward patients' deductibles or maximum out-out-pockets limits. This is especially problematic during the COVID-19 pandemic when unemployment rates are dramatically increasing every week, and individuals are struggling more than ever to afford their medications. According to data from May 2020, the national unemployment rate has increased to 14.7 percent, the highest it has been since the Great Depression,⁶ and a large majority of states are experiencing their own historically high rates.⁷ Many of these individuals may now rely on marketplace exchange plans with high out-of-pocket costs. Without protections, such as legislation to restrict the use of copay accumulator programs, many patients will be unable to afford their medications.

HOW CAN YOU HELP?

You can call on your state legislators and ask them to introduce or pass state legislation that limits the use of copay accumulator programs. For a list of states that have already enacted such laws, click here. For a list of states that have introduced legislation, click here.

WHERE CAN YOU GET MORE INFORMATION?

For more information, contact Aimed Alliance:

Aimed Alliance 3000 K Street NW, Suite 270 Washington, DC 20007 (202) 559-0380 policy@aimedalliance.org

¹ https://www.goodrx.com/blog/the-pros-and-cons-of-high-deductible-health-plans

 $^{^2\} https://www.npr.org/sections/health-shots/2018/o5/30/615156632/why-some-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-drugmakers-help-are-paying-more-patients-getting-getti$

 $^{^{\}rm 3}$ https://www.healthaffairs.org/do/10.1377/hblog20180824.55133/full/

 $^{^{4} \} https://ajmc.s3.amazonaws.com/_media/_pdf/AJMC_o7_2019_Sherman\%20 final.pdf$

 $^{^{5}\} https://www.govinfo.gov/content/pkg/FR-2020-05-14/pdf/2020-10045.pdf$

 $^{^{6}\} https://www.washingtonpost.com/business/2020/05/08/april-2020-jobs-report/$

⁷ https://www.bls.gov/web/laus/lauhsthl.htm