

Legal Update: Results and Impact of the Copay Accumulator Adjustment Programs Lawsuit

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Patient Groups File Suit to End Policy That Prohibits Copay Assistance from Counting Toward Patients' Out-of-Pocket Spending

Harmful Insurer & PBM Policy Increases Prescription Drug Costs for Patients

WASHINGTON (August 30, 2022) – Today, the [HIV+Hepatitis Policy Institute](#), the [Diabetes Leadership Council](#) (DLC), and the [Diabetes Patient Advocacy Coalition](#) (DPAC), representing 42 million people, [filed suit](#) in the U.S. District Court for the District of Columbia challenging a federal rule that allows health insurers to avoid counting the value of drug manufacturer copay assistance toward patients' out-of-pocket cost obligations.

ACA Violations

- ▶ **Insurers collect more than cost-sharing caps**
- ▶ **ACA Definition of cost-sharing:**
 - “deductibles, coinsurance, copayments, or similar charges; *and any other expenditure required of an insured individual* which is a qualified medical expense.”
 - Does not indicate where money comes from
- ▶ **ACA regulations for cost-sharing**
 - “any expenditure required by *or on behalf of an enrollee* with respect to essential health benefits,” including deductibles, coinsurance, copayments, or similar charges”

Arbitrary & Capricious

- ▶ **Allows insurers to decide if copay assistance can count or not**
 - They decide what constitutes cost-sharing
- ▶ **2020 Rule Abandoned w/o explanation**
 - Failed to present options
 - IRS Guidance on Discount Cards can't trump law
 - Further, not related to copay assistance
- ▶ **2021 Rule**
 - Assumed that use of copay accumulators would not increase

Administrative Procedures Act Complaint

▶ Requested Relief

- Set aside provision in 2021 NBPP rule allowing copay accumulators
- Declare that copay accumulators are illegal

Timeline of Key Events

- ▶ **Government Moves to Dismiss (Oct. 2022)**
- ▶ **Plaintiffs add 3 patients impacted by accumulators (Nov. 2022)**
- ▶ **Briefing Schedule Agreed to by all Parties) (Dec. 2023)**
 - Last brief due April 2023
- ▶ **Plaintiffs File Motion for Summary Judgment (Feb. 2023)**

Amicus Brief – Patient Community

- ▶ ADAP Advocacy Association
- ▶ Advocacy & Awareness for Immune Disorders Association
- ▶ Any Positive Chance
- ▶ The Association of Community Cancer Centers (ACCC)
- ▶ Autoimmune Association
- ▶ Chronic Care Policy Alliance (CCPA)
- ▶ Coalition of State Rheumatology Organizations
- ▶ Community Access National Network (CANN)
- ▶ Connecticut Oncology Association
- ▶ Community Oncology Alliance
- ▶ Equitas Health
- ▶ EveryLife Foundation for Rare Diseases
- ▶ Fabry Support & Information Group
- ▶ Gaucher Community Alliance
- ▶ Georgia AIDS Coalition

Amicus Brief – Patient Community

- ▶ Global Liver Institute
- ▶ Global Healthy Living Foundation
- ▶ Healthy Men Inc.
- ▶ Hemophilia Federation of America (HFA)
- ▶ International Cancer Advocacy Network (ICAN)
- ▶ Infusion Access Foundation
- ▶ International Foundation for Autoimmune & Autoinflammatory Arthritis
- ▶ National Health Law Program (NHeLP)
- ▶ National Infusion Center Association (NICA)
- ▶ National Consumers League (NCL)
- ▶ National Oncology State Network
- ▶ Rheumatology Nurses Society
- ▶ Triage Cancer

Amicus Brief - TrialCard

“the insurer pockets the full out-of-pocket maximum **plus** the amounts received through manufacturer assistance, resulting in a substantial windfall for the insurers while harming patients for whose benefit the assistance was intended.”

“TrialCard’s own internal data bear out these concerns. The data indicate that patients cease using drugs when accumulator programs are in effect.”

Amicus Brief - PhRMA

“This allows for the collection of the manufacturer’s cost-sharing assistance, *as well as* the full amount of the patient’s deductible or out-of-pocket maximum”

“The agencies appeared to misunderstand this basic feature of manufacturer cost-sharing assistance. According to HHS, this assistance might be viewed as “reducing the costs incurred by an enrollee under the health plan” because the assistance would “reduce the amount that the enrollee is required to pay in order to obtain coverage for the drug.”

...But these ...**programs do not reduce the total amount the patient owes to the pharmacy; they operate as an additional funding source to pay for a patient’s medication.**”

Government Brief

- ▶ Submitted after a 2-week extension (March 2023)
- ▶ No longer seeking dismissal of case

“it is **not accurate to say**, as Plaintiffs do throughout their brief, that **insurance companies “collect” the value of manufacturer coupons** through their accumulator adjustment programs...Rather, accumulator adjustment programs allow issuers and plans to **delay incurring coverage liability** until after the enrollee has satisfied the amount of the required cost sharing without including the amount of the manufacturer assistance”

Government Brief

- ▶ Plaintiffs' claims are **nonjusticiable** because the rule is not final agency action...the rule declines to set definite requirements in this area and provides complete flexibility to states
- ▶ HHS properly concluded that the relevant statute is ambiguous as to whether the value of manufacturer financial assistance counts as cost sharing, and **HHS's decision to permit flexibility in this area is not arbitrary or capricious.**
- ▶ If court rules HHS acted in an arbitrary and capricious manner, **should remand case back for further rulemaking**, and not make decision on definition of cost-sharing

Amicus Brief - AHIP

“Co-pay accumulator programs have been developed to mitigate the market distortion that coupons cause. Accumulators operate on a simple premise: when a manufacturer discounts its price through a co-pay coupon, the discount does not require the patient to incur any cost, so it does not count toward a patient’s cost-sharing. This preserves important cost-sharing incentives that help nudge patients toward lower cost, higher value choices.”

“Accumulators thus let patients benefit from the coupon discount—the patient’s out-of-pocket spending is still reduced or eliminated whenever a coupon is available, and the accumulator does not change that. Nor does the accumulator provide a windfall to health insurance providers, because the manufacturer pays the value of the co-pay coupon to the pharmacy (not the health insurance provider).”

Amicus Brief - AHIP

“Co-pay coupons are discounts. Copay accumulator programs do not stop patients from accessing those discounts, but simply ensure that such discounts actually reduce the total amount spent overall by the patient and health plan (and thus all consumers) on prescription drugs, rather than being used to inflate drug prices and drug spending. This is not a ‘windfall’ to health insurance providers. Instead, it lowers the cost of health care for everyone.”

Plaintiffs Response Brief

- ▶ **Filed after an 18-day extension (May 2023)**
- ▶ Ok, insurers may not technically collect the coupons but “government acknowledges that such programs seek to shift drug costs from insurers to patients and manufacturers” & “the net economic result is precisely the same”
- ▶ No merit in argument that despite copay rule “the agencies’ action is *actually* a “decision *not* to set definitive standards in this area.”

Government's Response Brief

- ▶ **Filed July 14th after 3 extensions, 53 days late**
- ▶ Rule issued because confusion with IRS guidelines
- ▶ Barring copay accumulators will lead to higher drug prices
- ▶ Copay assistance provides patients with a reduction in their costs offered by the drug manufacturers and therefore patient not responsible for it and it is not “cost-sharing”
- ▶ Government did not issue any legal requirements but let states decide



Court Strikes Down HHS Rule that Allowed Insurers to Not Count Copay Assistance

Copay Assistance for Drugs Must Now Count in Most Instances

WASHINGTON (October 2, 2023) – In a major victory for patients who depend on prescription drugs, Judge John D. Bates of the U.S. District Court for the District of Columbia [struck down](#) a Trump administration federal rule that allowed health insurers to not count drug manufacturer copay assistance towards a beneficiary’s out-of-pocket costs.

The [case](#) was brought against the U.S. Department of Health and Human Services by the [HIV+Hepatitis Policy Institute](#), [Diabetes Leadership Council](#), [Diabetes Patient Advocacy Coalition](#), and three patients who depend on copay assistance and whose insurers implemented “copay accumulator” policies.

Court Decision

- ▶ **VICTORY! Vacated 2021 Notice of Benefit and Payment Parameters Rule that allows copay accumulators**

“the Court will set aside the 2021 NBPP based on both its contradictory reading of the same statutory and regulatory language and the fact that the agencies have yet to offer a definitive interpretation of this language that would support their authorization of copay accumulators.”

- ▶ Agencies can't allow for the same meaning of a law and regulation to be chosen at the discretion of regulated parties. It is arbitrary and capricious.

Not a Complete Victory

- ▶ **ACA law** is not clear as to if manufacture assistance must count as cost-sharing
 - Therefore, vacate the rule & remand to permit the agencies to interpret the statutory definition
- ▶ **ACA regulation** that cost sharing is “any expenditure required by or on behalf of an enrollee” seems to conflict with 2021 NBPP.
 - Agrees, based on arguments presented by plaintiffs
 - While rejecting government’s arguments
 - But there could be another meaning: “required by” could mean the enrollee is requiring it & finds that odd
 - So asks agencies to grapple with this

Judge's Opinion

- ▶ **Fully understood and stated how copay assistance & accumulators work:**
 - Increase patient's costs
 - Increase manufacturer costs
 - Increase payments to insurers
 - Is not a discount from the cost of the drug
- ▶ **Didn't accept government argument that case was unjustifiable**
 - Rule was part of US Federal Code & had legal consequences

Judge's Opinion

- ▶ **Did not address that insurers collecting more money than permitted under ACA cost-sharing limits & double billing**
- ▶ **Did not address the IRS guidance issue with High Deductible HSA's**
- ▶ **Did not address other claims on why rule was arbitrary & capricious**
- ▶ **Did not declare copay accumulators illegal & didn't address copay maximizers**
 - Although it should ban maximizers for EHB drugs

Next Steps

- ▶ **2020 NBPP now in effect**

- Regulation: Accumulators may be allowed for brand name drugs w/ generic alternative, if permitted by state law
- Preamble: Copay assistance must count for brands w/o generic

- ▶ **Judge did not stay the decision so impact immediate**

- HHS can request stay and appeal

- ▶ **HHS can issue further clarifications**

- Perhaps issue a FAQ
- Future rulemaking (2025 NBPP Proposed Rule at OMB)
- Opportunities for all sides to weigh in
- May choose to do nothing

- ▶ **Federal legislation**

- ▶ **State laws & bills**

2020 Notice of Benefits & Payment Parameters Rule

“Notwithstanding any other provision of this section, and to the extent consistent with state law, **amounts paid toward cost sharing using any form of direct support offered by drug manufacturers** to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that **have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing** (as defined in paragraph (a) of this section).

Thank you!

<https://hivhep.org/copay-accumulator-litigation/>

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