

Ensuring Copay Assistance Counts for Patients: Litigation Update







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*Copay, Reimbursement & Access Congress
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Federal Government Actions

▶ Annual Notice of Benefit and Payment Parameters Rule

- 2020: Copay assistance must count in most situations 
 - May limit for brand name Rx when generic exists
 - Suspended August 2019 
- 2021: Rule Allowed Copay Accumulators 
 - But allows states to decide
- 2022: No mention 
- 2023: No mention 
- 2024: 



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.

Administrative Procedures Act Complaint

- ▶ [APA Complaint](#) against HHS & CMS for 2021 NBPP Rule
- ▶ **Filed in U.S. District Court for D.C.**
 - Case 1:22-cv-02604
- ▶ **Major Claims**
 - Violates the ACA Law
 - Contrary to ACA Regulations
 - NBPP Rule is Arbitrary and Capricious

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

Patient groups sue HHS over copay assistance rule

They argue that the rule violates the 2010 health care law, which sets annual limits for how much patients have to spend out of pocket

Inside Drug Pricing

Patient Advocates Sue HHS Over Copay Accumulators

By Gabrielle Wanneh / August 30, 2022 at 1:43 PM



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POLITICOPRO



Patient advocates challenge HHS rule over copay aid

Patient groups sue feds to crack down on insurer, PBM copay adjustment programs

By Robert King · Aug 31, 2022 08:10am

Patient groups sue HHS over co-pay assistance program



Tina Reed, author of [Axios Vitals](#)



Paul W. Hughes

McDermott
Will & Emery

Paul Hughes co-chairs the Firm's practice groups focusing on **Supreme Court and Appellate Litigation** as well as **Government and Regulatory Litigation**. He briefs and argues complex appeals, and he develops legal strategy before trial courts, including strategic affirmative litigation.

An experienced appellate lawyer, Paul has argued nine times at the US Supreme Court, including in February, March, October and December 2019, March 2020 and January 2021. Having presented more than 60 arguments, Paul has appeared before *en banc* sittings of the Fourth, Fifth, Ninth and Tenth Circuits; panels of the First, Third, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth, Eleventh, DC and Federal Circuits; and several state appellate courts. Paul also frequently argues in state and federal trial courts across the country.

Senior Judge John D. Bates



Judge Bates was appointed United States District Judge in December 2001. He graduated from Wesleyan University in 1968 and received a J.D. from the University of Maryland School of Law in 1976. From 1968 to 1971, he served in the United States Army, including a tour in Vietnam. Judge Bates clerked for Judge Roszel C. Thomsen of the United States District Court for the District of Maryland from 1976 to 1977 and was an associate at Steptoe & Johnson from 1977 to 1980. He served as an Assistant United States Attorney for the District of Columbia from 1980 to 1997, and was Chief of the Civil Division of the U.S. Attorney's Office from 1987 to 1997. Judge Bates was on detail as Deputy Independent Counsel for the Whitewater investigation from 1995 to mid-1997. In 1998, he joined the Washington law firm of Miller & Chevalier, where he was Chair of the Government Contracts/Litigation Department and a member of the Executive Committee. Judge Bates has served on the Advisory Committee for Procedures of the D.C.

PAYERS

Judge strikes down association health plans, calls them 'magic trick' to avoid ACA

By Paige Minemyer · Mar 28, 2019 06:52pm

Next Steps

- ▶ **Government Response**
 - Motion to Dismiss?
 - Motion for Summary Judgement
- ▶ **Amicus Briefs**
- ▶ **Oral Arguments?**
- ▶ **Decision**
- ▶ **Potential Appeal**

Current Advocacy Actions

- ▶ **Section 1557 Nondiscrimination Proposed Rule**
 - Patient Group Sign-on letter
- ▶ **Notice of Benefits and Payment Parameters Rule**
 - Expected this Fall, Groups should weigh in now with HHS and White House
 - Use legal arguments & current economic hardships, inflation
- ▶ **Federal Legislation**
- ▶ **State Legislation**

Thank you!

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