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# Pharma Copay Programs Raise Complex Economic Questions

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Law360 (September 22, 2025, 6:48 PM EDT)



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Copay accumulator and maximizer programs, which determine whether manufacturer copay assistance counts toward a patient's deductible or annual out-of-pocket maximum, have become increasingly prevalent over the past decade.

The design of these novel cost-sharing programs can substantially affect the share of drug costs paid by patients and insurers at the time the prescription is filled and over the course of the year.

Recently, these programs have been the focus of congressional action. In March 2025, Congress introduced the bipartisan HELP Copays Act, which requires that insurers and pharmacy benefit managers, or PBMs, count copay assistance from manufacturers toward patients' deductibles and out-of-pocket maximums. This bill is now under review in a [U.S. Senate](#) committee.<sup>1</sup>

Meanwhile, new state-level restrictions on copay accumulator programs took effect this year,<sup>2</sup> following similar protections enacted by more than 20 states since 2019.<sup>3</sup>

These legislative pushes follow the U.S. District Court for the District of Columbia's 2023 decision in *HIV and Hepatitis Policy Institute v. U.S. Department of Health and*

Human Services, requiring that such assistance count toward cost-sharing unless a generic equivalent is available.<sup>4</sup>

In parallel, pharmaceutical manufacturers and patients have filed lawsuits targeting insurers, PBMs and third-party administrators over accumulator and maximizer strategies.<sup>5</sup>

Proponents of copay accumulator and maximizer programs argue that these programs can lower drug costs to patients and align patient spending with the insurer's formulary design. Critics, however, assert that these programs shift the benefit of manufacturer discounts from patients to insurers and health plans.<sup>6</sup>

Some industry commentators have suggested that the rapid adoption of these programs could prompt manufacturers to increase prices to offset the additional discounts captured by insurers and health plans, or to limit patient discounts altogether.<sup>7</sup>

Given the growing adoption of copay accumulator and maximizer programs and the rapidly changing regulatory and litigation environment, a grasp of how these programs operate is important for practitioners involved in end-payor pharmaceutical litigation.

The assessment of economic harm and damages claims in these cases requires an understanding of how financial responsibility for payment for a prescription drug purchase is shared among parties. Copay accumulator and maximizer programs compound the existing economic complexities in such an assessment.

In this article, we discuss how these new cost-sharing programs have grown within the industry, their economic implications and how the landscape may continue to evolve.

## Overview

Drug manufacturers frequently offer financial assistance to patients in the form of coupons to help lower patient copay, coinsurance, deductible and other prescription drug costs.

Historically, the value of the coupon assistance from the manufacturer was counted as part of a patient's contribution in meeting their deductible and out-of-pocket maximum requirements.

As a result, the coupons simultaneously reduced both the patient's out-of-pocket payment at the time their prescription was filled and their total drug costs over the course of the plan year.

Beginning around 2018, however, some insurers and health plans began implementing copay accumulator programs, which prevent the manufacturer coupon value from being applied to a patient's deductible or out-of-pocket maximum.

The adoption of copay accumulators has increased steadily since their introduction in 2018, with the share of commercially insured plans that implement or offer copay accumulators as part of their plan design growing from 44% in 2018 to 89% in 2022.<sup>8</sup>

Copay maximizer programs similarly exclude manufacturer coupons from a patient's deductible or annual out-of-pocket limit, but they differ significantly from copay accumulator programs in their implementation.

Most importantly, copay maximizers often set the patient copay for a prescription fill of certain drugs equal to the maximum value of the manufacturer's coupon. Consequently, the patient copay is entirely — or almost entirely — covered by the coupon; however, none of the coupon's value is applied to the patient's cost-sharing obligation.

As a result, the lower patient payment at the time the prescription is filled may be offset by higher patient payments on other drugs and total payments over the course of the plan year.

Similar to accumulators, the adoption of copay maximizers has increased substantially since 2018. The share of commercial plans that implemented or made available copay maximizers grew from 14% in 2018 to 76% in 2022.<sup>9</sup>

The following table summarizes key differences in how copay accumulators and maximizers affect patient costs and manufacturer coupon use.

**Comparison of Copay Accumulator and Maximizer Program Effects on Patients and Manufacturers**

	No Copay Accumulator / Maximizer	Copay Accumulator	Copay Maximizer
Use of manufacturer coupons counts toward patients deductible and out-of-pocket max.	Yes	No	No
Full manufacturer patient assistance benefits may be exhausted.	No	No	Yes
Some costs of prescription drugs can be shifted from insurers to manufacturers and possibly patients.	No	Yes	Yes
Patients may face substantial out-of-pocket costs after exhausting all manufacturer coupons.	Yes	Yes	No. Patients' payments at the point of sales are often set to be covered largely by the manufacturer coupon benefit.
Patients may pay the full amount of their out-of-pocket maximum.	No	Yes	Yes

## Evolving Regulatory and Litigation Landscape

As these programs have become more widespread, they have drawn increasing scrutiny from patients, advocacy groups, lawmakers and courts. For example, in a federal lawsuit filed against the HHS, patient advocacy groups challenged a 2021 HHS rule that allowed insurers to exclude manufacturer coupons from counting toward patients' cost-sharing obligations.

In late 2023, the D.C. district court vacated this rule in the HIV and Hepatitis Policy Institute decision and reinstated a prior rule that allows insurers to exclude manufacturer support from cost-sharing limits only if a generic equivalent is available.<sup>10</sup>

Additionally, lawmakers at both the state and federal levels have pursued legislative changes. At least 21 states and Puerto Rico have outlawed copay accumulator programs.<sup>11</sup>

These laws primarily apply to fully insured plans regulated at the state level, leaving self-funded employer plans, which are governed by federal law under the Employee Retirement Income Security Act largely unaffected.

At the federal level, Congress introduced the HELP Copays Act in March. This proposed legislation would require all forms of copay assistance to count toward a patient's annual deductible and out-of-pocket maximum.<sup>12</sup>

Pharmaceutical manufacturers are also bringing legal challenges to copay maximizer programs.

In 2022, a lawsuit against a third-party administrator of copay maximizer programs in the U.S. District Court for the District of New Jersey alleged that it exploited a manufacturer's copay assistance program and engaged in practices to circumvent copay and annual out-of-pocket limits mandated by the Patient Protection and Affordable Care Act.

In the case, [Johnson & Johnson Healthcare Systems Inc. v. Save on SP LLC](#), the plaintiffs alleged that the copay assistance administrator coerced patients to enroll in the copay maximizer program.<sup>13</sup>

The legal dispute escalated in March 2024, when the complaint was expanded to include pharmacies and PBMs. In the amended complaint, the defendants were alleged to have employed a coordinated scheme to reclassify certain drugs as nonessential health benefits in order to bypass out-of-pocket maximums and improperly extract more than \$100 million from the patient assistance program.<sup>14</sup>

Parallel to litigation brought by manufacturers, patients have also begun to take legal action against entities administering copay accumulator and maximizer programs.

This new wave of litigation began in late 2024 with two federal class actions filed by patients, [Gluering v. Prudentrx LLC & Caremark RX LLC](#) in the [U.S. District Court for the District of Rhode Island](#) and [Gurwitch v. Save on SP LLC](#) in the [U.S. District Court for the Western District of New York](#).<sup>15</sup>

## Implications for Assessment of Injury and Damages in Litigation

Copay accumulator and maximizer programs can also have important implications for the assessment of injury and damages in litigation.

For example, in antitrust class action litigation involving pharmaceuticals, determining which entity paid an alleged overcharge on a product can be a threshold issue and may be particularly challenging for proposed classes involving end-payors.<sup>16</sup>

By shifting the distribution of financial responsibility for prescription drug purchases — both at the point of sale for an individual drug and throughout the plan year — these programs complicate the economic assessment of the cost borne by each entity in the pharmaceutical payment chain.

Even without these programs, manufacturer coupons can make brand-name drugs less expensive to patients than generics, weakening the financial incentive to switch.

Accumulator and maximizer programs further complicate this picture by changing how — and how much — assistance is applied. In maximizer programs, for instance, the patient's copay is set equal to the maximum value of the manufacturer's assistance, often making the branded drug appear less expensive than a generic at the point of sale.

However, because the assistance does not count toward the patient's deductible or out-of-pocket maximum, overall drug costs may be higher over the course of the year for a patient who remains on the branded drug.

These complexities can be particularly relevant in litigation. For example, in cases involving allegations of delayed generic entry, damages assessments often hinge on comparing the actual costs paid for branded drugs to the hypothetical costs that would have been incurred had a generic been available.

Accumulator and maximizer programs may affect not only whether a patient or plan would have switched to a generic but also whether doing so would have resulted in lower net costs.

Because these programs alter the flow and accounting of payments — particularly the division of payment for the prescription between manufacturers, insurers and patients — they make it more difficult to estimate what each party would have paid in a but-for scenario. As a result, they add a layer of complexity in assessing damages.

## Conclusion

While it remains to be seen how ongoing changes related to copay maximizer and accumulator programs will affect cost-sharing, the pharmaceutical distribution chain faces growing scrutiny of pricing practices and shifting policies across multiple fronts.

Ongoing litigation and regulatory activity across the pharmaceutical sector — from the evolution of copay accumulator and maximizer programs to broader initiatives, such as the Inflation Reduction Act and changes to Section 340B pricing — continue to reshape the pharmaceutical payment landscape.

This activity, along with the additional complexities introduced by such programs, underscores the need for more nuanced evaluations of how costs are distributed across the pharmaceutical supply chain.

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## Endnotes

- 1 "Kaine, Marshall Introduce Bipartisan Legislation to Protect Patients from High Drug Costs," March 7, 2025, available at <https://www.kaine.senate.gov/press-releases/kaine-marshall-introduce-bipartisan-legislation-to-protect-patients-from-high-drug-costs>. See also S.864 — Help Ensure Lower Patient Copays Act (HELP Copays Act), March 5, 2025, available at <https://www.congress.gov/bill/119th-congress/senate-bill/864>.
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- 4 Wetzel, Matt, and Heath R. Ingram, "Federal Court Strikes Down Copay Accumulator Programs," Goodwin, October 9, 2023, available at <https://www.goodwinlaw.com/en/insights/blogs/2023/10/federal-court-strikes-down-copay-accumulator-programs>. See also Memorandum Opinion, HIV and Hepatitis Policy Institute et al., v. [United States Department of Health and Human Services](#) et al., Civil Action No. 22-2604 (JDB), [United States District Court for the District of Columbia](#), September 29, 2023.

- 5 These cases include a lawsuit against SaveOnSP for alleged fraud and misuse of manufacturer assistance under its maximizer program, as well as a December 2024 class action in New York alleging ERISA and RICO violations tied to inflated copayments and the diversion of copay support. See Loftus, Peter, "J&J Accuses Big Health Insurer of Helping Drain Its Drug Copay Funds," *The Wall Street Journal*, December 13, 2024, available at <https://www.wsj.com/health/healthcare/j-j-accuses-big-health-insurer-of-helping-drain-its-drug-copay-funds-4b425811>. See also Long, Brandon, "Challenge to copay assistance strategy, another PBM ERISA preemption lawsuit, and other compliance issues for 2025," *McAfee Taft*, January 6, 2025, available at <https://www.mcafeetaft.com/challenge-to-copay-assistance-strategy-another-pbm-erisa-preemption-lawsuit-and-a-few-random-other-compliance-issues-for-2025>.
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- 14 Loftus, Peter, "J&J Accuses Big Health Insurer of Helping Drain Its Drug Copay Funds," *The Wall Street Journal*, December 13, 2024, available at <https://www.wsj.com/health/healthcare/j-j-accuses-big-health-insurer-of-helping-drain-its-drug-copay-funds-4b425811>.
- 15 See Long, Brandon, "Challenge to copay assistance strategy, another PBM ERISA preemption lawsuit, and other compliance issues for 2025," *McAfee Taft*, January 6, 2025, available at <https://www.mcafeetaft.com/challenge-to-copay-assistance-strategy-another-pbm-erisa-preemption-lawsuit-and-a-few-random-other-compliance-issues-for-2025>. See also, *Miller & Chevalier*, "The ERISA Edit: PBMs Face ERISA Fiduciary Breach Claims in Two New Lawsuits," January 9, 2025, available at <https://www.millerchevalier.com/publication/erisa-edit-pbms-face-erisa-fiduciary-breach-claims-two-new-lawsuits>.
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