Health Industry Alert

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Co-Pay Assistance and Accumulators in the Legal Spotlight: A Changing Landscape

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Key Points:

- Patient outcomes studies suggest a clinical benefit of co-pay programs, and a negative impact of co-pay accumulator programs.
- Co-pay programs remain unavailable to participants in federal government-funded health care insurance, with one federal court upholding HHS' position that co-pay assistance for such patients is illegal.
- Another federal court has stricken down an HHS rule that would require manufacturers to "ensure" that patients get the benefits of co-pay assistance programs, or otherwise report such amounts as a discount in best price calculations.
- State legislatures are beginning to take action, banning co-pay "accumulator" programs; Congress may not be far behind.

Pharmaceutical patient assistance programs are intended to help patients afford expensive medications, often focusing on subsidizing patients' insurance co-pay obligations that themselves can be quite substantial. It is not surprising then, that a study published this May has found a potential link between the availability of co-pay programs and positive clinical outcomes for patients, due to improved treatment persistence and adherence, across several diseases.[1] In response to manufacturers' co-pay assistance programs, insurers have become concerned that these programs will disrupt their formulary design and inappropriately encourage patients to receive, and physicians to prescribe, expensive therapies. Thus, pharmacy benefit managers (PBMs)/payors have put in place co-pay "accumulator" programs whereby the amounts paid by manufacturers for co-pay assistance are **not** counted against the patient's deductibles and co-insurance amounts, thus driving up patient's health care costs overall. Another study previously found that co-pay accumulator programs are associated with a negative impact on patient medication adherence and increased discontinuation of therapy.[2] In addition, co-pay "maximizer" programs are also being implemented, where patient's medication is re-categorized, from an "essential health benefit" to a non-essential health benefit under the Affordable Care Act (ACA). Doing so permits the maximizer program to operate outside of the ACA's annual out-of-

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pocket maximum, with the patient's co-pay increased often up to the maximum amount that the pharmaceutical manufacturer is willing to reimburse patients for co-pay expenses. The elevated co-pay amount is paid for by the pharmaceutical co-pay assistance program, with the effect that the payor's costs are reduced. Groups such as the American Society of Clinical Oncology have formally opposed both accumulator and maximizer programs due to their negative financial impact on patients.[3]

To be sure, there are competing interests of pharmaceutical manufacturers, PBMs and the federal government as a payor. That said, as detailed below, several recent legal and legislative developments, may now be converging to change significantly the future co-pay landscape.

Development One: HHS' Prohibition of Manufacturer Co-Pay Assistance for Government-Insured Patients Was Upheld in the Southern District

Pfizer had unsuccessfully sought an advisory opinion from the Office of Inspector General (OIG) to clear proposed co-pay assistance programs relating to a very rare and debilitating heart disease that carries a life expectancy of 2 to 3.5 years after diagnosis, with the disease affecting mostly elderly and African American males. Pfizer has introduced two drugs, Vyndaqel and Vyndamax, which are the only Food and Drug Administration (FDA)-approved medications for the condition; the only other treatment option is a very expensive and risky heart and liver transplant procedure. The Pfizer medications cost $225,000 per year and Pfizer contends that many middle-income patients cannot pay the approximately $13,000 in cost sharing that would be required by the Medicare Part D program. Pfizer's proposed programs include a "Direct Copay Assistance Program" with financial assistance going directly to the patient from Pfizer for eligible Part D patients who were already prescribed the drug. Pfizer also proposed an independent charity program, funded by Pfizer, that would develop its own guidelines to help Part D patients pay for these drugs.[4]

Pfizer sued the United States Department of Health & Human Services (HHS) in federal court, and late last year, the U.S. District Court for the Southern District of New York granted a motion to dismiss Pfizer's complaint, and denied Pfizer's motion for summary judgment in its bid to seek a declaration that its programs would not violate the Anti-Kickback Statute (AKS) and the Beneficiary Inducement Statute (BIS).[5] The court dismissed Pfizer's causes of action on the charity program on the grounds that it did "not satisfy the standard for prudential ripeness" because HHS never made a decision that the charity program violated the AKS and BIS in its prior advisory opinions. As for the Direct Copay Assistance Program, the court ruled more substantively against Pfizer, stating that "**the AKS means what it says**. It prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services. While the statute is broad, that alone does not mandate that the Court must endorse a narrower reading." [emphasis added] Noting the expected impact on patients of not granting Pfizer's requested relief, the court stated, "While there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the Court."

Pfizer appealed the decision to the United States Court of Appeals for the 2nd Circuit. The appeal was filed only as to the District Court's decision on Pfizer's claim on the Direct CoPay Assistance Program, arguing that the District Court misconstrued the AKS. Pfizer argues that the "remuneration" criminalized by the AKS requires "an element of corruption." Similarly, Pfizer argues that a finding of "inducement" under the

statute cannot occur because something "merely influences a patient's ability to access necessary and appropriate medical care," without a quid pro quo, corrupt intent or improperly influencing or skewing independent decision-making by physicians or patients.[6] The hearing before the court was just held on May 25, 2022.

Development 2: HHS' Final Co-Pay Accumulator Rule Was Stricken Down by the D.C. District Court

Pharmaceutical Research and Manufacturers of America (PhRMA) just won this important suit addressing co-pay accumulator programs, convincing a federal court to strike down an HHS regulation that burdened manufacturers and threatened the very existence of co-pay programs. In *PhRMA v. Becerra, et al.*, PhRMA brought suit against HHS under the Administrative Procedure Act (APA) to invalidate HHS' Final "Accumulator Rule."[7] A specific provision of the Medicaid Best Price regulations provides that manufacturer co-pay program payments to patients do not count towards best price, as long as "the pharmacy, agent, or other entity does not receive any price concession." However, at the end of 2020, the Centers for Medicare & Medicaid Services (CMS) issued the Final Accumulator Rule that would require that manufacturers "ensure" that the full value of the program is passed on to the consumer (or otherwise be required to include such amounts in best price calculations as product discounts).[8] The trouble is that PBMs/payors have employed co-pay maximizer programs that arguably cause, in effect, the payments from the manufacturers to be diverted to themselves. This is the case because the amounts paid by manufacturers for co-pay assistance are not counted against patients' deductibles and co-insurance, effectively resulting in both higher costs to patients of other health care services under their plans, and similarly reducing PBM/payors' costs by keeping deductibles and co-pays elevated (as well as discouraging the use of the applicable medication itself).

The U.S. District Court for the District of Columbia decided that patients who receive manufacturer co-pay assistance do not, under the best price statute, qualify as 'best price eligible entities', and therefore HHS "lacks the statutory authority to adopt the accumulator adjustment rule." The court rejected HHS' argument that assistance to the patient acts as a price concession from the manufacturer to the commercial health plan. Therefore, the court held that the final Accumulator Rule violates the APA.

Development 3: States and Patient Groups Are Taking Action To Prohibit Co-Pay Accumulators. Is Congress far behind?

Several states are enacting legislation to prohibit co-pay accumulator programs by PBMs and payors. States with laws already on the books include Arizona, Arkansas, Connecticut, Georgia, Illinois, Kentucky, Louisiana, Maine, Nebraska, North Carolina, Oklahoma, Tennessee, Virginia, Washington and West Virginia, as well as Puerto Rico.[9] According to one recent report, this already represents about 11 percent of U.S. commercial patients.[10] Ohio's House passed a bipartisan bill, HB 135, which is now moving forward in the Senate for action.[11] New Jersey has not passed a bill, but is undertaking a study of the issue.[12]

Patients are weighing in as well. Groups such as the Primary Immune Deficiency Foundation and the National Hemophilia Foundation are advocating for legislation to end co-pay accumulators.

At least one bill has been introduced in the United States Congress, HR 5801, the Help Ensure Lower Patient Copays Act (HELP Copays Act),[13] which would amend the ACA and the Public Health Service Act (PHSA) with anti-accumulator provisions. The ACA would be amended specifically to include amounts "paid by, or on behalf of" patients in their deductibles, coinsurance, co-payments or similar charges. The PHSA would be amended specifically to state that "essential health benefits" are deemed to include "any item or service covered under the plan," thus effectively eliminating the opportunity for co-pay maximizer programs to avoid statutory co-pay maximums by re-categorizing benefits as "non-essential." The HELP Copays Act was introduced in November, 2021 and was referred to the Energy & Commerce Committee, Subcommittee on Health, where it awaits further consideration.

The Takeaway

HHS' Final Rule that would have potentially caused co-pay mitigation payments to count as discounts toward best price (and thus likely force manufacturers to limit or eliminate such programs because of the economic impact) has been invalidated. Meanwhile, HHS' refusal to allow co-pay programs for federal health care beneficiaries has been upheld, pending appeal. Congress has not yet acted to either codify or overturn HHS' position on either issue. PBMs are seeking to enforce the economics of their formulary design through co-pay "accumulator" and "maximizer" programs, in the face of significant co-pay mitigation programs offered by pharmaceutical manufacturers, but legislatures are pushing back to eliminate the accumulator mechanism, and patient and physician opposition to eliminate co-pay "maximizers" has also commenced.

The current state of affairs is that only commercially insured patients in states with anti-accumulator laws are getting the benefit of co-pay mitigation programs sponsored by industry; government pay patients and those residing in states that have been silent on the issue are not. The tension in the disparate treatment of these populations, which is not based on any singular policy concept, is being battled now in the courts and in the legislatures. The outcome of all of these interconnected dynamics may ultimately significantly alter which parties bear the financial burden of co-payments (and co-insurance, as well as deductibles) going forward.

[1] Parekh, Krupa, et. al., *Impact of Co-pay Assistance on Patient, Clinical and Economic Outcomes*, 28 AM. J. OF MANAGED CARE e189 (May 2022).

[2] Bruce W. Sherman, et. al., *Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence*, 25 AM. J. OF MANAGED CARE 335 (July 17, 2019).

[3] Am. Soc'y of Clinical Oncology, AMERICAN SOCIETY OF CLINICAL ONCOLOGY POSITION STATEMENT: COPAY ACCUMULATORS AND COPAY MAXIMIZERS (Jan. 21, 2021).

[4] Of note, just a few years before filing this suit, in 2018 Pfizer had settled allegations by the Department of Justice that it violated the False Claims Act by funding co-pay mitigation payments through a "purportedly independent" charitable foundation, with a payment of nearly $24 million. See Press Release, U.S. Atty's Off. Dist. of Mass., Pfizer Agrees to Pay $23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation (May 24, 2018), available at https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay.

[5] *Pfizer, Inc. v. U.S. Dept. of Health and Human Services, et.al.*, 1:20-cv-4920 (S.D.N.Y. Sept. 30, 2021). Pfizer also asserted Fifth Amendment Due Process claims on behalf of patients who need their drug. The court held that Pfizer had no standing to assert its Fifth Amendment Due Process claims, which broadly alleged that the OIG position "effectively bars middle-income Medicare recipients from accessing their federal health care insurance benefits based solely on their economic status."

[6] *Brief for Pfizer, Pfizer v. U.S. Dept. of Health & Human Services*, Case 21-2764 (Dec. 17, 2021).

[7] *Pharm. Rsch. & Mfrs. Of Am. v. Becerra*, No. 1:21-cv-1395, 2022 U.S. Dist. LEXIS 88736 (D.D.C. May 17, 2022).

[8] Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements, 85 Fed. Reg. 251 (Dec. 31, 2020) (to be codified at 42 C.F.R. pts. 433, 438, 447 and 456).

[9] Nat'l Conf. of State Legislatures, *Copayment Adjustment Programs* (Apr. 4, 2022), available at: https://www.ncsl.org/research/health/copayment-adjustment-programs.aspx#:~:text=As%20of%20spring%202022%2C%20laws,%2Dpocket%20cost%2Dsharing%20requirement.

[10] Avalere, *State Copay Accumulator Bans Impact 11% of US Commercial Lives* (May 13, 2022).

[11] H.R. 135, 134th Gen. Assemb., Reg. Sess. (Ohio 2021).

[12] Leg. Assemb. B. 1747, 220th Leg. (N.J. 2022).

[13] H.R. 5801, 117th Cong. (2021).

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