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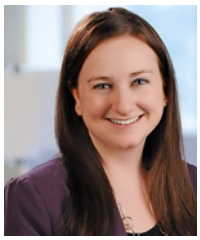
Patients, Payers, Prosecutors, and the Role of the Copay



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The uptick in enforcement activity related to manufacturer donations to independent charitable patient assistance organizations as violations of the False Claims Act (''FCA'') relies, in part, on the premise that copayment assistance is illegal remuneration under the federal Anti-Kickback Statute (''AKS'').

In several recent kickback-predicated FCA settlements, the government has taken the position that copayment assistance eliminates patients' price sensitivity, thereby illegally inducing patients to fill prescriptions they would not otherwise fill.

While cost-sharing obligations, including copayments, are often intended to steer patients toward more cost-efficient treatments, cost sharing may not always influence patient behavior—for example, a body of evidence suggests that this premise may not hold true for oncology and specialty tier drugs.

Where cost-sharing obligations do not steer patient behavior, one can argue that copayment assistance should not be considered illegal remuneration under the AKS.

The Purpose of the Anti-Kickback Statute Is to Protect Patients and Federal Health Care Programs From Fraud and Abuse

The AKS was enacted to protect patients and federal health care programs from fraud and abuse caused by the corrupting influence of money on health care decisions. *See, e.g.*, *Fact Sheet: Federal Anti-Kickback Law and Regulatory Safe Harbors*, Department of Health and Human Services Office of the Inspector General, November 1999, *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm.

Originally adopted as part of the 1972 amendments to the Social Security Act, the AKS was significantly strengthened five years later by the passage of the Medicare Anti-Fraud and Abuse Statute, which expanded the law's scope broadly to prohibit kickbacks, bribes, and rebates in return for patient referrals. *See* Pub. L. 92-603 (1972); Pub. L. 95-142 (1977).

At the time, Congressional leadership intended to target kickback schemes involving practitioners, administrators, and medical laboratories. *See* 132 Cong. Rec. H9,959 (daily ed. Sept. 23, 1977) (statement of Rep. William Cotter, Chairman of the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce); 123 Cong. Rec. H9,818 (daily ed. Sept. 22, 1977) (statement of Rep. Daniel Rostenkowski, House Democratic Chief Deputy Whip).

Consistent with this Congressional intent, AKS enforcement has largely focused on cases where a *doctor* received payment in exchange for referrals of Medicare and Medicaid patients. Recently, however, prosecutors have turned their focus to the *patient* as the recipient of the kickback.

In the current health care environment's increased focus on value and patient outcomes, one enforcement trend is especially worrisome: the uptick in enforcement of the AKS based on the theory that charitable grants to patients, which are funded by donations from pharmaceutical manufacturers to independent chari-

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table patient assistance organizations, can constitute illegal kickbacks.

DOJ Is Focused on Manufacturer Donations to Independent Charitable Patient Assistance Organizations as Illegal Remuneration to Patients

Independent charitable patient assistance organizations provide financial assistance to patients who meet certain financial eligibility requirements and cannot afford cost-sharing obligations associated with the drugs that their physicians have prescribed.

Many of these charitable organizations help relieve the financial burden on patients with cancer and other rare diseases, who rely on drugs that are often expensive and include significant patient cost-sharing obligations.

The U.S. Department of Health and Human Services Office of Inspector General (''OIG'') has long recognized that such organizations are not only lawful, but also beneficial as a method of providing financial relief to patients of limited means.

A 2005 OIG Special Advisory Bulletin concerning ''Patient Assistance Programs for Medicare Part D Enrollees'' stated, ''OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws.'' 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005).

OIG further acknowledged that ''cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, *even if the charities receive manufacturer contributions*.'' *Id.* (emphasis added).

Despite OIG's express approval, manufacturer contributions to independent charitable patient assistance organizations have become a focus of DOJ investigations in recent months.

For example, when DOJ settled with Celgene in July 2017, the covered conduct in the civil settlement agreement expressly included the allegation that ''Celgene, in violation of the [AKS], . . . induced purchases of Thalomid® and Revlimid® by defraying patients' copayment obligations for those drugs through its contribution to [an independent charitable patient assistance organization], which . . . *eliminated any price sensitivity* to physicians prescribing and patients taking'' the manufacturer's drugs. July 12, 2017 Settlement Agreement among the United States of America, Celgene Corporation, and Relator Beverly Brown, at F(3) (emphasis added).

Similarly, when DOJ announced its settlement agreement with Aegerion in September 2017, the covered conduct in the civil settlement agreement expressly included the allegation that ''Aegerion paid for patients' copayments through [an independent charitable patient assistance organization] to *eliminate any price sensitivity* to physicians prescribing and patients taking'' the company's cholesterol drug, Juxtapid. Sept. 22, 2017 Settlement Agreement among the United States of America, Aegerion Pharmaceuticals, Inc., and Relators Michele Clark, Tricia Mullins, and Kristi Winger Szudlo, at N(4) (emphasis added).

Most recently, when DOJ settled with United Therapeutics (''UT'') in late December 2017, the covered conduct in the civil settlement agreement expressly included the allegation that ''UT made donations to [an independent charitable patient assistance organization] and used it as a conduit to pay the copay obligations of thousands of Medicare patients taking [UT's drugs], to *eliminate price sensitivity* of patients purchasing or physicians prescribing [UT's drugs], and to induce those patients' purchases of [UT's drugs].'' Dec. 19, 2017 Settlement Agreement between the United States of America and United Therapeutics Corporation, at E (emphasis added).

Proving a Violation of the Anti-Kickback Statute Requires Evidence of Illegal Inducement

The AKS prohibits the offer or payment of ''any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind'' in exchange for referrals of federal health care program patients or purchasing items reimbursable by federal health care programs. 42 U.S.C. § 1320a-7b(1).

For purposes of the AKS, ''remuneration'' is defined broadly to include ''the transfer of *anything of value*, directly or indirectly, overtly or covertly, in cash or in kind.'' *See, e.g.*, OIG Advisory Opinion No. 15-12 (Aug. 6, 2015) (emphasis added).

Thus, in certain circumstances, copayment assistance could be considered ''remuneration'' under the AKS. However, the gravamen of an AKS violation is inducement: a violation is premised on the alleged wrongdoer's intent to execute a *quid pro quo* transaction. *See* Jury Instructions at 5, *United States v. Reichel*, No. 15-cr-10324-DPW (D. Mass. June 17, 2016), ECF. No. 244.

The government's position that donations to independent charitable patient assistance organizations are illegal kickbacks *to patients* has not yet been litigated. If it were, the government would need to prove that the manufacturer knowingly and willfully made the charitable donation with an intent to induce patients to fill prescriptions for medication reimbursable by a federal health care program.

The inducement requirement has been interpreted as requiring the ''intent to gain influence over the reason or judgment of a person making referral decisions.'' *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000). One open question is whether copayment assistance can be considered ''remuneration'' under the AKS in cases where the copayment obligation itself does not affect or otherwise influence patient behavior.

Cost Sharing May Not Steer Patient Behavior in the Cancer and Rare Disease Spaces

The basic premise that copayments can act as a control to steer patient behavior is not controversial. Cost-sharing provisions aim to encourage efficient utilization of health care resources.

Cost sharing in general—and cost sharing for Medicare recipients, in particular—is intended to cause pa-

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tients to evaluate the need for discretionary care, but—importantly—not to discourage necessary care. *See* U.S. Gov't Accountability Office, GAO-01-713T, Medicare Cost-Sharing Policies Problematic for Beneficiaries and Program 6 (2001) (Statement of William J. Scanlon, Director, Health Care Issues, Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives).

The impact of cost sharing on patients' treatment decisions has been the subject of much research over the years. Perhaps the most famous study attempting to measure the impact of cost sharing on patient behavior is the Rand Health Insurance Experiment (''HIE''), which ran from November 1974 through January 1982.

Although primarily concerned with health outcomes, the HIE answered the threshold question of health care utilization, finding that ''the more people had to pay for medical care, the less they used.'' Robert H. Brook et al., The Effect of Coinsurance on the Health of Adults: Results from the Rand Health Insurance Experiment 25 (1984).

The observation that an increase in the cost of medical care causes a decrease in the utilization of medical care is not surprising. However, there is a body of evidence suggesting that this basic principle of supply-and-demand may not hold true for patients with cancer or rare diseases.

For example, one study concluded that ''[i]ncreased cost sharing for specialty drug products will not reduce their use but will transfer a greater share of their costs to patients.'' Dana P. Goldman et al., *Benefit Design and Specialty Drug Use*, 25 Health Affairs 1319, 1330 (2006). Notably, the study found that even if a plan were to *double* the cost-sharing requirement for cancer patients, patient spending on cancer drugs would fall by *only one percent*. *Id*. at 1327.

The results of this study and others like it suggest that cost sharing may serve a purpose other than steering patients to the most cost-effective treatment, as the government's theory implies—for example, helping payers maintain a balance of healthy and unhealthy individuals within their plans.

For specialty and oncology drugs, where demand is relatively inelastic (*i.e.*, demand is not affected by a change in price), an increase in the patient's cost-sharing obligation will have little to no impact on the patient's decision to purchase the drug.

In such cases, the optimal scenario may be for payers to eliminate the cost-sharing burden entirely and distribute the cost equally among all plan participants. However, if any single payer moves to eliminate the cost-sharing burden for such treatments, that payer will become the least expensive provider in the space and attract all of the patients with cancer and other rare diseases.

In order to cover the increased cost of treatment, the payer would need to increase the annual premium for all patients in the plan. This increase would drive healthy patients to leave for less expensive plans, ultimately leaving only the sickest patients and an unsustainably high annual premium behind—a phenomenon known in the insurance industry as adverse selection.

Thus, the purpose of cost sharing in the rare disease and oncology space may be to maintain this necessary balance in our health care system—and not to steer patient behavior.

Furthermore, for cancer and rare diseases, the baseline assumption that a more cost-effective treatment exists is often incorrect. Such treatments are usually expensive and there are rarely more cost-effective treatments to which the patient can be steered—all options are expensive. For this type of patient, unfortunately, the only choice is to seek treatment or forego treatment altogether.

For example, a study of patients newly diagnosed with chronic myeloid leukemia found ''significantly lower fill rates and significantly longer time to initiation of [treatment] among beneficiaries . . . who were responsible for high out-of-pocket costs compared with their counterparts who faced minimal out-of-pocket costs due to receipt of [need-based financial assistance].'' Jalpa A. Doshi, Ph.D. et al., *High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia*, 24 (4 Suppl.) Am. J. of Managed Care S78, S82 (Mar. 2016).

Where there is no more cost-effective alternative treatment, requiring a patient to pay a hefty copayment without the benefit of charitable patient assistance may simply serve to delay or discourage necessary care—an outcome contrary to the purpose of copayments, generally.

Conclusion

While DOJ's enforcement priorities under the FCA and AKS may shift over time, this underlying principle remains constant—proving an AKS violation requires evidence of illegal inducement.

Since there exists a body of evidence suggesting that certain cost-sharing obligations may not affect patients' treatment decisions in the cancer and rare disease spaces, there is room to challenge the government's position that copayment assistance ''eliminates patients' price sensitivity'' or otherwise influences patient behavior in these spaces.

Although we do not know what 2018 will bring in terms of an opportunity to litigate the government's theory of AKS liability, a defense could involve expert testimony from economists, actuaries, health policy experts, insurance scholars, and doctors regarding the unique market dynamics and the true purpose of cost-sharing obligations in the oncology and rare disease spaces.

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