

Is the Current Anti-Kickback Enforcement Environment Stifling Innovation in Health Care?



By Laura G. Hoey, Deborah L. Gersh, Timothy M. McCrystal, Joshua D. Asher, and Josef Weimholt

Laura Hoey is a partner in Ropes & Gray's Government Enforcement Group in Chicago. She can be reached at 312-845-1318 or Laura.Hoey@ropesgray.com. Deborah Gersh and Timothy McCrystal are partners in Ropes & Gray's Health Care Group in Boston and Chicago respectively. Timothy can be reached at 617-951-7278 or Timothy.Mccrystal@ropesgray.com; Deborah can be reached at 312-845-1307 or Deborah.Gersh@ropesgray.com. Joshua Asher is an associate in Ropes & Gray's Government Enforcement Group, and Josef Weimholt is an associate in the firm's Health Care Group. Matthew Colin also contributed to this article.

A fundamental shift is underway in the U.S. health-care system. Payers and providers are increasingly transitioning away from traditional "fee-for-service" models, in which reimbursement is based on the quantity of items or services provided to patients, toward value-based models designed to reward the quality and efficiency of care. See generally, e.g., Bruce Merlin Fried and Jeremy David Sherer, Value Based Reimbursement: The Rock Thrown into the Health Care Pond, Health Affairs Blog (July 8, 2016). As insurers, providers, drug and device manufacturers, and various partners and supporting organizations, such as health information technology companies, population health management experts, and other consultants, seek to collaborate on innovative delivery and supply models, they must navigate a regulatory environment that is poorly suited to value-based models of care. See Timothy M. McCrystal, Deborah L. Gersh, and Jennifer L. Romig, Brave New World: Compliance and the Transition to Value-Based Care (May 23, 2017). These challenges are compounded by novel and aggressive theories of liability under the Anti-Kickback Statute ("AKS") often advanced by creative whistleblower counsel and recently adopted by regulators, prosecutors, and courts. Such expansive interpretations of AKS liability may hinder the development of the innovative collaborations necessary to improve quality and reduce costs for payers (including the federal government) and patients alike.

The AKS Potentially Implicates a Broad Array of Arrangements in the Health-Care Space

The AKS, a criminal statute, prohibits the payment or receipt of "remuneration" in exchange for patient referrals or the ordering of products or services paid for by federal health-care programs. See 42 U.S.C. § 1320a-7b(b) (prohibiting the knowing and willful solicitation, receipt, offer, or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in

return for either referrals of federal health-care program patients or the arranging, recommending, leasing, or ordering of any item or service reimbursed by a federal health-care program). The statutory restriction is both nebulous and broad: remuneration includes anything of value, and the statute has been interpreted to cover any arrangement in which even one purpose of the remuneration is to induce referrals. See *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). The Affordable Care Act included amendments to the AKS that lessened the intent standard, 42 U.S.C. § 1320a-7b(h), and made it easier to bring a claim under the civil False Claims Act (“FCA”) for claims allegedly tainted by AKS violations, 42 U.S.C. § 1320a-7b(g), compounding the overall enforcement risk and scope of liability for health-care providers.

Recognizing the broad scope of arrangements potentially implicated by the AKS, Congress has provided for certain statutory exceptions and authorized the U.S. Department of Health and Human Services (“HHS”) Office of Inspector General (“OIG”) to promulgate additional safe harbors to protect innocuous, or even potentially beneficial, business and payment practices. See 42 U.S.C. § 1320a-7b(b)(3); Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100–93, § 14, 101 Stat. 697, 697–98. OIG has promulgated safe harbors protecting, for example, certain kinds of investment interests, rental of space and equipment, personal services and management contracts, sales of physician practices, warranties, discounts, bona fide employment relationships, and group purchasing organizations. See generally 42 C.F.R. § 1001.952. To qualify for protection, all elements of the applicable safe harbor must be satisfied. When a health-care arrangement exists outside of an exception or safe harbor, the government and courts must examine a number of factors to determine if the AKS is implicated.

Government Authorities Continue to Expand the Scope of AKS Enforcement Beyond Traditional Kickback Schemes

Consistent with the statute's underlying purposes—namely, protecting against the cost-, quality-, and competition-related effects of improper referral arrangements—early AKS enforcement cases centered on barely disguised bribes or kickback schemes in which hospitals, labs, drug companies, and other providers made cash payments to physicians in exchange for patient referrals. As health-care providers and their compliance programs have evolved, however, kickback cases have become more complex. Now, cases often involve one or more intermediaries and implicate payments or other forms of remuneration that arguably fall within a safe harbor.

One recent focus of OIG guidance and Department of Justice (“DOJ”) investigations and enforcement actions are patient assistance programs run by co-pay foundations. Co-pay foundations are 501(c)(3) charitable organizations—largely funded by donations from manufacturers—that provide financial assistance to patients who cannot afford the cost-sharing obligations of drugs prescribed by their physicians. These charities primarily assist Medicare Part D patients because Medicare often requires patients to pay significant out-of-pocket costs for life-saving drugs and federal law prohibits manufacturers from providing direct financial assistance to federal beneficiaries as they can for commercially insured patients. In contrast to more straightforward kickback schemes, which present clear risks of overutilization that would drive up costs for both beneficiaries and the government, the cost- and quality-related effects of industry-funded co-pay foundations are less apparent.

OIG has long acknowledged both the valuable safety net provided by co-pay foundations and the potential for abuse, establishing safeguards through a series of advisory opinions and special advisory bulletins. As summarized in OIG's 2005 Special Advisory Bulletin, “the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.” See OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (2005). The OIG guidance, therefore, prohibits manufacturers from exerting any direct or indirect influence or control over the charity or from receiving data from the charity that would enable the manufacturer to correlate the amount or frequency of its donations with the number of subsidized prescriptions for its products. See OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (2005); OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs (2014). Although manufacturers may earmark their contributions for specific disease funds supported by the charities, the disease funds must be defined “in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.”

Since 2015, co-pay foundations have been the focus of a number of ongoing DOJ investigations. Companies including Valeant Pharmaceuticals, Gilead Sciences Inc., and Celgene Corp., among others, have disclosed subpoenas requesting information related to their donations to co-pay foundations. See Benjamin Elgin & Robert Langreth, *Celgene Accused of Using Charities ‘Scheme’ to Gain Billions*, Bloomberg Businessweek (Aug. 1, 2016); Benjamin Elgin & Robert Langreth, *How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes*, Bloomberg Businessweek (May 19, 2016). News reports suggest that DOJ has advanced a theory that manufacturers have violated the AKS through their attempts to influence the charities in order to channel donations to patients who are prescribed the manufacturers’ own products, thereby inducing Medicare patients to purchase expensive drugs that they otherwise could not afford and shielding those patients from increases in drug prices. These investigations appear to mark a shift in DOJ's focus in AKS cases from pursuing alleged

kickbacks to physicians to induce prescription writing to kickback theories involving remuneration paid to the patient to induce the filling of prescriptions. To be sure, these investigations do not involve direct payments from manufacturers to patients; rather, they involve alleged payments made by the manufacturers indirectly to patients via a co-pay foundation with which the manufacturers have no formal affiliation.

While there is no case law that directly tests the government's theory, cases involving other indirect remuneration schemes may preview the arguments the government would make in cases against co-pay foundations and their donors. The United States recently filed an amicus brief in *U.S. ex rel. Greenfield v. Medco*, a case before the U.S. Court of Appeals for the Third Circuit. See Brief for the United States as Amicus Curiae in Support of Neither Party, United States of America, ex rel. Greenfield v. Medco Health Solutions, Inc. (3d Cir. Apr. 17, 2017). In *Medco*, a former vice president of Accredo Health Group, Inc., a provider of specialty pharmacy services to hemophilia patients, contends that his former company and related defendants paid kickbacks to two charities in order to induce the charities to refer hemophilia patients to Accredo and to recommend that the patients use Accredo's services. The district court, in granting defendants' summary judgment motion, held that, even assuming the relator had proven that Accredo violated the AKS, he had not established that the kickbacks caused the charities' referrals and recommendations, or that those referrals and recommendations caused the patients' decisions to use defendants' services. Without any evidence that particular patients chose Accredo because of its donations, the court concluded that the relator could not sustain a claim under the False Claims Act (noting that the FCA imposes civil liability on "any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval").

Even though the United States, in its amicus brief, agreed with the district court that, to establish a false claim, the claims Accredo submitted for federal beneficiaries must have resulted from the alleged kickbacks paid to the charities (i.e., those claims must be tainted by the kickbacks), the government argued that the district court erred by requiring a causal connection between the kickbacks and the false claims. According to the government, the FCA does not require "that the kickbacks in fact corrupted the charities' decision to refer patients to Accredo and recommend Accredo's services, and that those referrals and recommendations in fact corrupted the patients' decisions to use Accredo's services." The government's position is that, to establish a false claim, a plaintiff need only show that the claimed medical care was not provided in compliance with the AKS or that the underlying transaction did not comply with the AKS.

The United States' position in the *Medco* appeal may be a reaction not only to the lower court's decision, but also to a decision issued last year by a federal district court in California in *U.S. ex rel. Brown v. Celgene Corp.*, 226 F. Supp. 3d 1032, 2016 BL 437201 (C.D. Cal. Dec. 28, 2016). In *Celgene*, the relator alleged a number of claims under the FCA, including that the company violated the AKS by "directing money through co-pay foundations to induce patients to buy its [multiple myeloma] drugs." The court soundly rejected this argument on the grounds that there was no evidence that Celgene's donations were contingent on the foundation's agreement to purchase or recommend Celgene's drugs. In fact, the evidence suggested the opposite was true: the foundation supported a number of multiple myeloma drugs that were manufactured by companies other than Celgene.

While the United States did not intervene in *Celgene*, the government's position in *Medco* suggests that it would dispute any notion that either the AKS or FCA requires evidence that the co-pay foundations recommended a donor's products in exchange for donations or that the donations induced the patient's purchase of drugs reimbursable by Medicare.

Novel Interpretations of the AKS Have Also Been Adopted by Courts in Commercial Litigation

Expansive interpretations of the AKS have not been limited to the traditional criminal and civil false claims contexts. A recent decision involving an online auction arrangement, *MedPricer.com, Inc. v. Becton, Dickinson and Co.*, No. 3:13-cv-1545, 2017 BL 68209 (D. Conn. March 6, 2017) highlights the risk of nontraditional AKS scrutiny in the commercial litigation context and the increased risk that courts will invalidate innovative health-care arrangements. Online auction services provide a platform by which health-care providers and hospitals can negotiate with suppliers of medical equipment through an online system of requests and bids. This system gives purchasers of medical equipment the opportunity to seek competitive pricing and to award business to suppliers that can provide necessary products at lower prices. Operators of the online auction portals facilitate the bid process and receive a commission when bids are accepted. In *MedPricer*, a federal district court in Connecticut held that an online auction service contract violated the AKS. The contract, the court reasoned, would result in payment for "arranging" the purchase of goods for which reimbursement may be received from federal health-care programs.

The case originated as a contract dispute between *MedPricer.com, Inc.* ("MedPricer"), the operator of an online medical equipment auction portal, and *Becton, Dickinson and Company* ("Becton"), a supplier of medical equipment. Hospitals and other providers engage *MedPricer* to facilitate negotiations with suppliers of medical equipment through an online system of requests for quotes ("RFQs") and bids. *MedPricer* has no role in determining which suppliers are invited to participate in the

bidding and which are ultimately awarded the business. Those decisions are controlled entirely by the hospitals and other purchasers. Each supplier that is invited to participate in online bidding agrees, if selected, to pay MedPricer a fee of 1.5 percent of the value of the transaction based on the volume of business as detailed in required monthly sales reports. After successfully participating in three sourcing events, Becton refused to provide sales reports or pay MedPricer the fee. As a result, MedPricer filed an action against Becton alleging breach of contract, among other claims. In briefing on cross motions for summary judgment, Becton argued that the contract was unenforceable under Connecticut law because it violated the AKS.

The court agreed with Becton's argument that the contract "violates the AKS because it involves MedPricer's receiving 'remuneration' for 'arranging' the purchasing of goods for which payment may be made in whole or in part under a federal healthcare program." The court rejected MedPricer's contention that, to be liable for "arranging" a sale, a party must have intended to sell the products at issue. The court concluded that MedPricer, through the sourcing events, "arranges" for the purchase or selling of goods even though MedPricer plays no role in selecting the suppliers that are invited to bid or in selecting which supplier is awarded a contract. Instead, by providing services that buyers and suppliers may utilize in the bidding process and receiving a commission based on sales, the court found that MedPricer "arranges" for the purchase or selling of goods. The court further held that, because Becton sold the items to a hospital that provides services reimbursable under a federal health-care program, and the items themselves could be used in performing those services, the sales that MedPricer "arranges" consisted of items "for which payment may be made in whole or in part under a Federal healthcare program." Moreover, the court held that Becton was not required to establish that MedPricer "knowingly and willfully" solicited remuneration because the scienter requirement only applied to criminal enforcement actions and was not required to find that a contract violates the AKS.

The MedPricer decision is significant not only because of the expansive interpretation of the AKS adopted by the court, but also because it raises the possibility that disgruntled parties will increasingly seek to invalidate innovative health-care arrangements by arguing that the contract violates the AKS. Moreover, it is notable here that the court did not attempt to address how the arrangement in question would possibly increase federal health-care expenditures, which, as noted above, is one of the primary purposes of the AKS. Rather, by invalidating a valuable tool that had enabled hospitals and providers to entertain competitive bids from suppliers, the decision is likely to make procurement decisions more opaque and have the very effect that the AKS was intended to guard against.

Expansive Theories of AKS Liability May Impede Innovation and Collaboration in the Transition Toward Value-Based Care

Given the broad and nebulous scope of the AKS statutory prohibition, providers and other entities operating in the health-care space traditionally have sought to structure all arrangements involving potential remuneration to fit within one of the AKS safe harbors. This is often not possible with value-based care initiatives, because at least some portion of the fees under such arrangements are "at risk" based upon a combination of cost savings, improved clinical quality, or patient outcomes—in contrast to the relevant safe harbors, which generally require that the aggregate compensation, fee, or discount (as applicable) be set in advance. See generally 42 C.F.R. § 1001.952. Risk-sharing arrangements also complicate any fair market value analyses, making it even more difficult to satisfy the safe harbor requirements.

The Affordable Care Act authorized waivers of certain fraud and abuse laws, including the AKS, in connection with specific value-based care initiatives developed by the Centers for Medicare & Medicaid Services ("CMS"). OIG has promulgated model-specific waivers for the Medicare Shared Savings Program, the Bundled Payments for Care Improvement Initiative, the Comprehensive Care for Joint Replacement Model, and certain other value-based care initiatives. However, not all model-specific waivers are necessarily available to all participants in a given model, and a waiver will apply to a particular arrangement only if all conditions of the waiver are met. More importantly, such waivers are of no effect in the context of commercial value-based care initiatives, which account for a large and growing proportion of the value-based care market. See, e.g., *UnitedHealth, Aetna, Anthem Near 50% Value-Based Care Spending*, *Forbes* (Feb. 2, 2017) (noting that UnitedHealth, Aetna, and Anthem—three of the nation's largest health insurers—report paying out almost half of their reimbursements through value-based care initiatives).

In the absence of safe harbor protection or applicable waivers, companies typically seek to structure arrangements to meet as many of the elements of an applicable AKS safe harbor as possible. With respect to risk-sharing arrangements and other value-based care initiatives, companies also have looked to relevant sub-regulatory guidance from OIG, including advisory opinions highlighting certain safeguards that OIG has indicated may mitigate the risk of fraud and abuse. See, e.g., *Advisory Opinion 12-22* (Jan. 7, 2013).

Such one-off advisory opinions and special fraud alerts, however, provide limited guidance for health-care providers and other entities seeking to collaborate on value-based care initiatives, and there is a growing demand for OIG to adopt additional or

modified safe harbors to better facilitate such collaborations. For example, in response to a recent request for comments regarding the need to modify or expand existing AKS safe harbors, OIG received six comments—five of which requested additional or modified safe harbors to facilitate participation in value-based care initiatives. See Solicitation of New Safe Harbors and Special Fraud Alerts, 81 Fed. Reg. 95,551 (Dec. 28, 2016) (comments available here). While OIG has acknowledged that the transition to value-based care “requires new and changing business relationships among health care providers,” and has vowed to “monitor changes” and “seek stakeholder input,” no such additional safe harbors appear forthcoming, at least in the near term. See Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,370 (Dec. 7, 2016).

Conclusion

Companies operating outside of a safe harbor will always face some degree of enforcement risk. However, the rise in novel and expansive theories of AKS liability—not just in the criminal and civil false claims contexts but also in commercial litigation, as discussed above—heightens the legal and business uncertainty faced by payers and providers in every sector of the health-care industry. Such uncertainty will not reverse the inexorable shift to value-based care or prevent companies from participating in value-based initiatives that seek in good faith to adhere to limited, existing guidance and to mirror, to the extent possible, the government's own forays into value-based arrangements. However, the combination of the absence of clear guidance and aggressive enforcement will hamper the creativity and innovation that is critical to improving quality and reducing costs for payers and patients alike. Thus, even as DOJ and the courts continue to view AKS enforcement as a tool to address rising health-care costs, recent enforcement activity and litigation may have exactly the opposite effect.