DOJ Kickback Concerns Extend Beyond Federal Funds

By **Jaime Jones and Brenna Jenny** (April 13, 2022)

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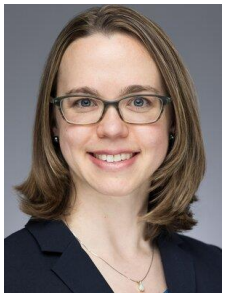

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The federal government has expressed growing interest in pursuing enforcement actions focused on alleged kickbacks in the health care industry that it cannot reach with its tried-and-true lever, the Anti-Kickback Statute.

Specifically, where alleged kickback arrangements do not implicate federal funds, the U.S. Department of Justice increasingly is turning to the Travel Act and the Eliminating Kickbacks in Recovery Act, or EKRA.

The Anti-Kickback Statute has historically imposed rigid and unique standards of practice for those serving federal health care programs, and this government enforcement trend suggests that health care companies may need to reassess referral-based arrangements even where they do not directly bill in the federal health care programs and thus historically have not been subject to the AKS.

The Travel Act, Title 18 of the U.S. Code, Section 1952, criminalizes using the facilities of interstate commerce with the intent to promote or facilitate any unlawful activity, which includes bribery as defined by state law.

Thus, the Travel Act's broad reach means that depositing checks or using the mail in connection with conduct that could be construed as a kickback or bribe can provoke a federal criminal action prosecuted by the DOJ. The Travel Act is not limited to bribes that implicate the federal health care programs, and instead is restrained only by the contours of the underlying laws that define the predicate violations.

Critically, while the AKS has a number of important statutory and regulatory safe harbors that protect common forms of arrangements, state bribery laws that may be used as the unlawful activity often lack similar safeguards.[1]

The Travel Act has been used with relatively more frequency in the health care industry over the past few years. One notable example that made headlines was the DOJ's use of the Travel Act in U.S. v. Beauchamp in the U.S. District Court for the Northern District of Texas in 2019.

In that case, the government alleged that defendants affiliated with Forest Park Medical Center executed a scheme whereby they avoided in-network contracts, demanded heightened out-of-network rates and then offered kickbacks to physicians to steer their commercially insured patients to the center.[2]

Prosecutors involved with the case acknowledged that as they began investigating, they realized that most of the funds at issue related to commercial insurance, and so they researched causes of action that would not require federal health care funds.[3] The case is currently up on appeal before the U.S. Court of Appeals for the Fifth Circuit.[4]

A set of related cases in the U.S. District Court for the District of Massachusetts demonstrates how a traditional government investigation into potential violations of the AKS, implicating reimbursement of claims by the federal health care

programs, can expand under the Travel Act and capture conduct unrelated to federal funds.

Although this is not the first time the DOJ has used both the AKS and the Travel Act in coordination,[5] these cases highlight how a qui tam complaint addressing one arrangement can pull unrelated arrangements under the DOJ's microscope.

In 2015, a whistleblower filed a sealed qui tam complaint under the federal False Claims Act against SpineFrontier Inc., a manufacturer and distributor of spine surgery devices, its related entities and the physician who allegedly controlled those companies, Kingsley Chin.[6]

The whistleblower, a former employee of one of the defendant entities, alleged that the defendants paid kickbacks to surgeons, in the form of payments for product evaluations, to induce those surgeons to use SpineFrontier products in their surgeries.

The federal government investigated and then intervened in 2020.[7] A year and a half later, the DOJ initiated a parallel criminal case, filing an indictment against Chin, a second physician and SpineFrontier, principally based on alleged violations of the AKS.[8]

In a separate but related criminal enforcement matter, the DOJ is investigating whether SpineFrontier engaged in a separate scheme with a personal injury attorney, in which the attorney agreed to refer his clients needing spine surgery to specific physicians using SpineFrontier devices, in exchange for receiving a percentage of the patient's payment for surgery.

A recently unsealed affidavit in support of a search warrant in that criminal case asserts that the referral fee was largely funded by SpineFrontier charging full list price for the devices, when it otherwise charged about 60% of list price.[9]

The referred patients were all uninsured or self-paying, and there is no federal health care program reimbursement alleged. However, the government appears to be investigating claims that these payments were bribes, in violation of Texas and Massachusetts anti-bribery laws,[10] and thus triggered liability under the Travel Act.

The DOJ's interest in using the Travel Act to target commercial transactions outside the scope of the AKS reflects a wider government enforcement priority to address the concern that offering something of value in exchange for referrals in the health care context may compromise patient safety, result in overutilization and otherwise diminish confidence in the system.

In response to this same set of concerns, in 2018 Congress passed EKRA, Title 18 of the U.S. Code, Section 220, which prohibits paying or receiving any remuneration for referrals of patients to a recovery home, clinical treatment facility or laboratory.

Although EKRA was passed as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act and is focused on kickbacks relating to substance abuse testing and treatment, the scope broadly covers all clinical laboratory tests and all payors, whether government or commercial.

While EKRA does include seven statutory exceptions largely mirroring some of the AKS statutory exceptions, important distinctions exist; for example, EKRA's exception for employee compensation does not cover payments that vary with the number of tests or referrals. Furthermore, the U.S. Department of Health and Human Services has yet to

exercise its authority to promulgate any regulatory safe harbors.

So far, the government's use of EKRA has been relatively limited and primarily focused on schemes involving brokers who pay kickbacks to patients to recruit them to sober living homes, where they are subjected to medically unnecessary drug testing.[11]

But the DOJ has begun to explore broader uses, including relating to COVID-19 testing.[12] EKRA enforcement can be expected to pick up in the coming years as a means to target lab testing arrangements that do not implicate federal health care programs, and alongside it, the DOJ may similarly turn to the Travel Act to target arrangements outside the lab testing sphere that are also distinct from federal health care programs.

Historically, health care providers and life sciences companies that offer services and items largely covered by commercial insurance or cash-paying customers, and not reimbursed by the federal health care programs, have felt insulated from the effects of the AKS and FCA — statutes the DOJ has leveraged to extract tens of billions of dollars from the industry over the last 20 years.

By adding the Travel Act and EKRA to its arsenal, the DOJ can now reach arrangements that historically have been immune from this enforcement scrutiny. Providers and life sciences companies are well advised to consider risk mitigation steps including:

- Engaging in risk assessments around commercial arrangements involving exchanges of value that vary based on referrals.
    - Arrangements should be gauged against the standard factors that drive government enforcement decisions in the realm of federal health care programs, including potential for increased health care costs (here, particularly to patients), overutilization or interference with clinical decision making.
    - Aspects of arrangements that prosecutors are accustomed to targeting on the federal health care program side may be more attractive candidates for enforcement. For example, one of the factual allegations highlighted by the Forest Park Medical Center prosecutors was the use of payments per lead generated.[13] While these payments were made in the context of Medicare referrals, thereby implicating the AKS, the Travel Act could cover certain lead generation payments outside of federal health care programs.

- Understanding state laws in major areas of operations that could serve as a predicate for a Travel Act violation, keeping in mind that a historical absence of state-level enforcement does not protect from future Travel Act enforcement. Indeed, as the Forest Park Medical Center defendants pointed out, the state of Texas had never prosecuted a health care provider under the Texas Commercial Bribery Statute prior to the DOJ using this law as the predicate for its Travel Act theory of liability.[14]

- Exploring other safeguards to reduce the risk that financial arrangements may be alleged to involve inducements to refer or recommend health care items or services, such as:
    - Conducting fair market value assessments for services arrangements. While the DOJ has taken the position that fair market value does not necessarily protect service arrangements, it can be helpful in demonstrating the company's good faith efforts to avoid unlawful remuneration.
    - Ensuring employees receive appropriate training and education on the company's lawful intentions with respect to arrangements that vary based on referrals, and that internal and external-facing communications accurately reflect those intentions.
    - Deploying targeted data analytics to understand any outliers (e.g., on sales compensation payments) that may warrant further review.

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[1] See, e.g., Tex. Penal Code §32.43.

[2] Superseding Indictment, United States v. Beauchamp, 16-cr-516 (N.D. Tex. Aug. 30, 2017).

[3] Rachel Rose, Lessons from the Forest Park Case and the revitalization of the Travel Act (Apr. 15, 2021), https://www.physicianspractice.com/view/lessons-from-the-forest-park-case-and-the-revitalization-of-the-travel-act.

[4] United States v. Shah, No. 21-10292 (5th Cir.).

[5] See, e.g., Press Release, DOJ, New Jersey Clinical Lab At Center Of Largest Physician Bribery Case Ever Prosecuted Pleads Guilty (June 28, 2016), https://www.justice.gov/usao-nj/pr/new-jersey-clinical-lab-center-largest-physician-bribery-case-ever-prosecuted-pleads.

[6] Complaint, United States ex rel. Birchall v. SpineFrontier, Inc., 15-cv-12877 (D. Mass. July 20, 2015).

[7] Complaint-in-Intervention, United States ex rel. Birchall v. SpineFrontier, Inc., 15-cv-12877 (D. Mass. March 5, 2020).

[8] Indictment, United States v. Chin et al., 21-cr-10256 (D. Mass.).

[9] Affidavit of Special Agent Meaghan Fleury in Support of an Application for a Search Warrant, 19-mj-2330 (D. Mass. Aug. 14, 2019).

[10] Tex. Occ. Code. §102.001(a); Tex. Penal Code §32.43; Mass. Gen. Laws ch. 271, §39(a).

[11] See, e.g., Press Release, DOJ, Justice Department Announces Series of Cases to Combat Addiction Treatment Kickback Schemes in Orange County (Dec. 16, 2021), https://www.justice.gov/usao-cdca/pr/justice-department-announces-series-cases-combat-addiction-treatment-kickback-schemes.

[12] See, e.g., Indictment, United States v. Lepetich, 21-cv-32 (M.D. La. May 20, 2021).

[13] First Superseding Indictment at 28–29, United States v. Beauchamp, 15-cr-516 (N.D. Tex. Aug. 30, 2017)

[14] Memorandum Opinion and Order at 36, United States v. Beauchamp, 15-cr-516 (N.D. Tex. Sept. 20, 2017).