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Anti-Kickback

New Year, Not So New Anti-Kickback Statute Enforcement Trends at the DOJ

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If 2023's criminal investigations and civil actions under the federal Anti-Kickback Statute (AKS) and the False Claims Act (FCA) are any indication of what is to come from the DOJ in 2024, professionals and business owners occupying the medical space should buckle up and tread lightly.

Over the last several years, the DOJ has steadily upheld its commitment to pursue AKS and FCA violations and rid corruption from the healthcare industry. The activity throughout 2023 certainly has grown the DOJ's brag list – and the momentum does not seem to be letting up any time soon.

The AKS is a criminal statute, but the DOJ can pursue civil remedies for AKS violations through the FCA, as the AKS provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." The FCA is a civil statute providing for payment of damages and penalties for the knowing submission of false or fraudulent claims to the government for payment. Civil monetary penalties range between $12,537 to $25,076 per claim, plus three times the amount of damages the government sustains.

What we saw throughout 2023 is consistent with what was seen in previous years. That is, the DOJ's biggest enforcement priority, at least measured by quantity and scope, is the healthcare industry. With good reason, the DOJ remains unrelenting in its efforts to extinguish commercial healthcare corruption (*i.e.*, the use of kickbacks and other illicit inducements), evidenced by the multitude of criminal and civil AKS enforcement actions.

See, for example, the 2022 Order in United States ex rel. Chao v. Medtronic PLC, denying a medical device manufacturer's motion to dismiss an FCA action, alleging that it paid kickbacks to doctors to induce their use of medical device manufacturers' devices for patients' surgeries.

Also see the DOJ's press release from July 1, 2022, in which Principal Deputy Assistant Attorney General Brian M. Boynton, head of the DOJ's Civil Division, reaffirms that the DOJ "is committed to redressing the corrupting influence of kickbacks" on federal healthcare programs.

Following are snippets of DOJ settlements – either criminal, under the FCA or both – obtained in the past 12 months, resulting from alleged AKS violations.

See "Implications of the Updates to the Pharmaceutical Research and Manufacturers of America Code" (Sep. 29, 2021).

Litany of Settlements

- On January 10, 2024, the owner and CEO of RDx Bioscience Inc., a New Jersey clinical laboratory, agreed to pay the U.S. $10.32 million and will pay an additional $2.93 million to the State of New Jersey. RDx allegedly paid commissions to marketers for healthcare providers' orders of RDx laboratory testing; paid providers, both directly and through disguised fees of its marketers, to induce them to order RDx laboratory tests; paid substance abuse recovery centers to induce providers to order RDx laboratory testing; and paid specimen collection fees to the staff members of referring providers to induce those providers to order RDx laboratory testing. The settlement resolves the FCA allegations concerning five types of kickbacks paid to induce referrals to RDx for laboratory testing illegal kickbacks and medically unnecessary laboratory testing.
- On December 22, 2023, Philips Respironics Inc., a manufacturer of durable medical equipment (DME) based in Pennsylvania, agreed to pay nearly $2.5 million to resolve allegations that it violated the FCA by giving free masks to sleep laboratories to treat and diagnose sleep-related respiratory disorders to induce the laboratory physicians to write referrals or prescriptions for Respironics-brand masks that suppliers would fill and bill to federal healthcare programs.
- On December 21, 2023, a Massachusetts pharmaceutical company, Ultragenyx Pharmaceutical Inc., agreed to pay $6 million to resolve allegations that the company paid kickbacks to induce prescriptions for its drugs. Specifically, Ultragenyx allegedly paid a genetic testing laboratory for free genetic tests, with no charge to the patients or healthcare providers, as well as a separate fee to receive test result information for marketing purposes, enabling Ultragenyx to induce healthcare providers to prescribe its drug, Crysvita.
- On November 2, 2023, a Florida laboratory, Genesis Reference Laboratories LLC, agreed to pay nearly $1.2 million to resolve FCA allegations that it violated the AKS, as Genesis marketers paid illegal kickbacks to healthcare providers, disguised as investment returns distributed by managed services organizations, to induce laboratory testing referrals.
- On November 2, 2023, the owner of a marketing company located in India pled guilty in the District of New Jersey and agreed to pay $11.5 million for his role in conspiracies to commit healthcare fraud and to pay and receive illegal kickbacks. The owner participated in a kickback and bribery scheme with DME companies, telemedicine companies and genetic testing laboratories, which led to the submission of false and fraudulent claims to Medicare.
- On October 4, 2023, Genomic Health paid $32.5 million to settle FCA allegations that Genomic conspired with healthcare providers to evade Medicare's 14-Day Rule, including the allegation

that Genomic failed to send timely invoices to hospitals for laboratory services that fell under the 14-Day Rule and instead wrote off the unpaid fees for laboratory services, thereby violating the AKS.

- On October 2, 2023, a Delaware pharmacy, BioTek reMEDys Inc., and its CEO reached a $20-million settlement in light of allegations of illegal kickbacks to patients and physicians. BioTek allegedly waived Medicare and Tricare patients' copayments to induce them to purchase BioTek's prescription drugs and services without the determination of financial need.
- On July 14, 2023, electronic health record (EHR) vendor NextGen Healthcare Inc. agreed to pay $31 million to settle allegations that the company violated the FCA by misrepresenting capabilities of its software and providing unlawful remuneration to its users to induce them to recommend NextGen's software. Moreover, NextGen violated the AKS by giving sporting tickets and other entertainment to induce referrals, as well as providing large monetary credits to customers whose recommendation of NextGen's EHR software led to a new sale.
- On June 21, 2023, a California nursing facility, Alta Vista Healthcare & Wellness Centre, LLC, and its management company, Rockport Healthcare Service, settled with the federal and state government for a total of approximately $3.8 million to resolve civil claims that it violated the federal FCA, California FCA and the AKS by providing unlawful remuneration in exchange for referrals, causing the submission of false claims to Medicare and Medicaid. Specifically, the government alleged that the defendants gave referring physicians extravagant gifts, such as expensive dinners, golf trips, limousine rides, massages, e-reader tablets and gift cards, as well as monthly stipends of $2,500 to $4,000 for their supposed services as medical directors.

See "Lessons on Compliant Speaker Programs From the OIG's Life Sciences Fraud Alert" (May 12, 2021).

Healthcare in Focus

The above settlements highlight a mere fraction of the FCA and AKS violations that the DOJ has resolved over the course of the last year. For example, at the end of fiscal year 2022, DOJ settlements and judgments under the FCA alone exceeded $2.2 billion. Over $1.7 billion of the settlements and judgments involved the healthcare industry, including hospitals, pharmacies, medical device and drug manufacturers, home health and managed care providers, DME suppliers, hospice organizations and physicians. While the total amount of recoveries for 2023 remains to be seen, it is expected to surpass the 2022 number.

Additionally, the trend of relators' obtaining substantial awards in cases where the DOJ declined to intervene continues. For example, the DOJ declined to intervene in a recently settled FCA case where a former CCO pursued claims against a hospital system for alleged AKS violations, asserting that the hospital provided support services, such as nurse practitioners, hospitalists and physician assistants, to physicians at no cost or below fair market value, and that the physicians then referred

patients to the hospital. Notwithstanding the government's declination, the whistleblower and relator's counsel brought home a $7.6-million settlement for Delaware Medicaid.

Historically, the overwhelming majority of the government's recovered funds through the FCA has come from cases brought by the DOJ or in which the DOJ intervened, with typically less than 1% of this money coming from declined qui tam cases. (See the file attachment to the DOJ press release, "Justice Department Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015.") That is a natural result of the FCA's qui tam provisions and incentives for the DOJ to pursue cases with the best evidence and largest recoveries.

However, in recent years, recoveries in declined qui tam cases have bucked this trend. In 2022, recoveries from declined cases amounted to $1.18 billion, more than 53% of total recoveries. (See the file attachment to the DOJ press release, "False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022.") While this was largely owing to a single outlier case, 2021's recoveries from declined qui tam cases were roughly 8.4% of a record total of $5.71 billion, and 2020's were approximately 8.4% of that year's total of $2.26 billion. In 2019, declined qui tam cases yielded roughly 10% of the year's total recoveries of $3.07 billion.

If 2023 foreshadows what is to come from the DOJ in 2024, then the aggressive AKS and FCA enforcement trends are here to stay. The DOJ has demonstrated that those failing to toe the line will find themselves head-to-head with the DOJ answering for suspected wrongdoing. To reiterate the warning noted above, life science and healthcare companies and professionals should familiarize themselves with the federal and state AKS laws and the FCA – the DOJ will continue its crackdown on healthcare fraud and corruption.

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