FRAUD AND ABUSE UPDATE:

Stark, Anti-Kickback and False Claims Act Developments

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IT IS NO SECRET that fighting health care provider fraud and abuse, and recouping reimbursements as well as monetary penalties, is a primary (and well-rewarded) focus of the federal government as it seeks to protect the integrity of Medicare, Medicaid and other federal health care programs[1] and the well-being of beneficiaries by detecting and preventing fraud, waste and abuse. Recent developments continue to reflect health care fraud and abuse enforcement efforts, including increased penalties for violations of federal statutes making certain physician self-referrals, kickbacks, beneficiary inducements and other matters illegal. That said, recent developments offer some positive news for health care providers forced to defend against False Claims Act lawsuits.

The federal government is very well-rewarded for its investments in health care fraud and abuse enforcement efforts, a development which provides "internal funding" for ever-increasing enforcement efforts. Consider that the Department of Justice obtained more than $3.7 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2017. Recoveries since 1986, when Congress substantially strengthened the civil False Claims Act, now total more than $56 billion.[2] As a result, continued scrutiny of health care providers and their claims, transactions, relationships, etc. is certain.

Although there are a number of federal statutes underpinning federal fraud and abuse enforcement efforts, the primary statutes that physicians and other health care providers should be aware of are as follows:

Stark Law. The Ethics in Patient Referrals Act, 42 U.S.C. § 1395nn, is commonly referred to as the "Stark Law." It prohibits a physician from making referrals for certain "designated health services" (or "DHS") payable by Medicare or Medicaid to an entity with which he or she (or an immediate family member) has a financial relationship (direct or indirect ownership or compensation relationship), unless all such financial relationships are covered by one or more "exceptions." Further, Medicare may not be billed for DHS items or services provided to a patient based upon a tainted referral in violation of the Stark Law.

The Granston memorandum indicates a potential shift in DOJ policy and may provide defendants an opportunity to petition the U.S. Attorney to seek dismissal of a qui tam action when the government declines to intervene.

Anti-Kickback Statute. The Anti-Kickback Statute, 42 U.S.C. § 1320a-76(b), imposes both criminal and civil penalties on persons who knowingly and willfully solicit, offer, pay or receive remuneration, directly or indirectly, overtly or covertly, in cash or in kind, if "one purpose" is to induce or reward the referral of patients or business where the item or service may be paid for in whole or in part under any federal health care program (including Medicare or Medicaid).

False Claims Act. The False Claims Act, 31 U.S.C. § 3729(a)(1), imposes liability (among other grounds) on any person who "knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval." A Stark Law or Anti-Kickback Statute violation can form the basis for a False Claims Act lawsuit. The False Claim Act subjects violators to civil penalties of $11,181 to $22,363 **per claim,** in addition to **treble damages** (three (3) times the amount of damages which the government sustained).

Of course, both "outright fraud" (e.g., billing for services not provided or medically unnecessary services) and "technical fraud" (e.g., submitting claims that are "tainted" by technical Stark Law or Anti-Kickback Statute violations) can be enforced by the government or by "whistleblowers" in *qui tam* actions under the False Claims Act.[3]

The following summarizes recent developments relative to the health care provider fraud and abuse enforcement and liability landscape:

Increased Civil and Criminal Penalties. The Bipartisan Budget Act of 2018 ("BBA") increased the criminal and civil penalties that can be imposed for violating the Anti-Kickback Statute and other laws related to federal health care programs. The criminal fine for violating the Anti-Kickback Statute increased from $25,000 to $100,000, and a felony conviction now carries a maximum jail time of ten (10) years. The BBA also increased penalties under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, a catch-all statute that provides for civil money penalties for a variety of health care fraud and abuse violations involving the Medicare and Medicaid programs. The BBA doubled the maximum money penalties related to improper claims to $20,000, $30,000, or $100,000, depending on the type of violation. Similarly, the maximum money penalty related to payments to induce the reduction or limitation of services increased from $2,000 to $5,000.

Codification of Stark Law Exceptions. The BBA also codified certain existing Centers for Medicare & Medicaid Services ("CMS") regulations related to the Stark Law in ways which might make it easier (thankfully) for physicians to comply with the Stark Law's exceptions, as follows: (1) the writing requirement for the Stark Law exceptions that require a written agreement can now be "satisfied by such means as determined by the Secretary, which can consist of a collection of documents, including contemporaneous documents evidencing the course of conduct between parties involved"; (2) the signature requirement for certain Stark Law exceptions can now be met if the parties obtain the required signatures "not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant" as long as the other requirements of the exception are met; and (3) a holdover lease or personal service arrangement can now indefinitely meet the requirements for the applicable exception as long as: (a) the exception's requirements were met when the lease or arrangement ended; (b) the lease or arrangement continues on the same terms; and (c) the lease or arrangement continues to meet the requirements of the applicable exception. While these statutory updates merely codify existing CMS regulations, the benefit is that at least (2) and (3) above are now hard-wired in the statute and cannot be changed by CMS under its ever-evolving interpretations of the Stark Law.

Escobar. The recent Supreme Court decision in Universal Health Services Inc. v. United States ex rel. Escobar, 2016 BL 192168 (2016), raised the materiality requirements for False Claims Act claims. In Escobar, the Supreme Court held False Claims Act liability only arises from violation of a statutory, regulatory, or contractual requirement where the requirement *actually* matters to the government's decision to pay, and the defendant knew that it would. This decision stands for the proposition that mere technical violations of the Stark Law or the Anti-Kickback Statute are not actionable if the violation would not be material to the Government's decision to pay the claim.

DOJ's New Policy on Whistleblower Litigation. The DOJ, in a memorandum from Michael Granston, Director of the Commercial Litigation Branch of the DOJ's Fraud Section, suggests that government attorneys consider several factors in deciding whether to seek dismissal of "meritless" qui tam actions, pursuant to 31 U.S.C. § 3730(c)(2)(A) ("[t]he Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has

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provided the person with an opportunity for a hearing on the motion."). Historically, DOJ has either intervened in a whistleblower case (taking over prosecution of the matter) or declined to intervene (allowing the whistle blower plaintiff to continue prosecution of the matter). However, it has rarely sought dismissal of the action. The *Granston* memorandum indicates a potential shift in DOJ policy and may provide defendants an opportunity to petition the U.S. Attorney to seek dismissal of a qui tam action when the government declines to intervene.

In reported cases and opinions, anecdotally and within our health law regulatory and transactional practice, we see increased focus on fraud and abuse laws (e.g., Stark Law, Anti-Kickback Statute, etc.) in the context of contractual negotiations, joint venture negotiations, merger and acquisition transactions, etc. A qualified health lawyer with experience in fraud and abuse issues from a transactional perspective is in a unique position to identify and address the issues in a proactive fashion in order to minimize risks and downside loss potential. ■

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1 The law defines a federal health care program as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government other than the Federal Employee Health Benefit program." Federal health care programs include: Medicare, Medicaid, TRICARE, Veterans' Administration, Public Health Service, Indian Health Service, the Maternal and Child Health Service Block Grant Program, the Social Service Block Grant Program and children's health insurance programs under the Social Security Act.

2 See, Department of Justice, Office of Public Affairs, news release dated December 21, 2017.

3 "Qui tam is short for 'qui tam pro domino rege quam pro se ipso in hac parte sequitur,' which means 'who pursues this action on our Lord the King's behalf as well as his own.'" Rockwell Int'l Corp. v. United States, 549 U.S. 457, 463 n.2 (2007). The False Claims Act's qui tam provision allows "a private plaintiff, known as a relator, [to] bring[ ] suit on behalf of the [g]overnment to recover a remedy for a harm done to the [g]overnment." Woods v. Empire Health Choice, Inc., 574 F.3d 92, 97 (2d Cir. 2009); see 31 U.S.C. § 3730(b). As the "real party in interest" in a qui tam action, United States ex rel. Eisenstein v. City of New York, New York, 556 U.S. 928, 930 (2009) the government may intervene and take over prosecution of the lawsuit, 31 U.S.C. § 3730(b)(2), (4). In such cases, however, the relator is still entitled to a share of any recovery. 31 U.S.C. § 3730(d).