In late August 2017, a federal judge in Pennsylvania held that violations of the federal Stark Law and Anti-Kickback Statute that defendants characterized as merely “technical” were, in fact, material to the federal government’s decision to reimburse healthcare entities for goods and services. See U.S. ex rel. Emanuele v. Medicor Assocs., 2017 WL 3675921, No. 10-245 (W.D. Pa. Aug. 25, 2017). As such, these illegal healthcare referral practices violated the False Claims Act (“FCA”), a law designed to prevent federal contractors from defrauding the government.

The Emanuele decision is among the latest to apply the Supreme Court’s landmark FCA decision, Universal Health Services, Inc. v. United States ex rel. Escobar, which established standards for determining when a violation of a law, regulation, or contractual requirement is also a violation of the FCA.

The False Claims Act, Stark Law and Anti-Kickback Statute

The FCA applies in the healthcare context to individuals and entities that receive reimbursement through government healthcare programs, such as Medicare. Fraud in the healthcare context takes a variety of forms. For example, pharmaceutical companies may run afoul of the FCA by marketing a drug in a way inconsistent with the Food and Drug Administration’s approved indications. Hospitals and physicians, meanwhile, may violate the FCA by billing for services they did not provide, or by performing services that are not medically necessary but that result in greater reimbursement.

At issue in Emanuele were the Stark Law and the Anti-Kickback Statute, two laws that regulate the conduct of healthcare providers who receive reimbursement from the federal government. As the court noted in Emanuele, both laws generally prohibit a healthcare entity from receiving payments from the Centers for Medicare and Medicaid Services (“CMS”) based upon referrals from physicians who have a financial relationship with the healthcare entity. Both laws also contain safe harbor provisions that allow federal reimbursement if the referrals in question meet certain requirements. Among these safe harbor provisions is a requirement that any financial arrangement between the referring physician and the healthcare entity seeking federal reimbursement be in a writing that both parties have signed, and that the transactions and compensation reflect fair market value.

The Stark Law and Anti-Kickback Statute serve a number of important objectives. They allow for greater oversight and transparency in the provision of healthcare services, and they prevent abuses in the healthcare system that may increase costs to patients and taxpayers. The Stark Law in particular was designed to deter providers from engaging in such practices as referring patients for unnecessary tests and procedures from which a physician would benefit because of his or her financial stake in the entity conducting the tests. The Anti-Kickback Statute more broadly prohibits the exchange of something of value to induce referrals that lead to federal healthcare reimbursement.
Both the Stark Law and the Anti-Kickback Statute impose stiff penalties for violations, including the return of any funds received from CMS, potential exclusion from the federal healthcare reimbursement system, and potential criminal penalties. Violations of the laws may also subject an individual or entity to FCA liability.

The Emanuele Case

In Emanuele, the District Court for the Western District of Pennsylvania declined to reconsider an earlier ruling in which it had held that the underlying conduct that the relator – the individual bringing the FCA action on behalf of the federal government – alleged constituted a violation of the FCA. According to the relator, the Hamot Medical Center of the City of Erie (“Hamot”) and Medicor Associates, Inc. (“Medicor”), maintained financial and referral arrangements that violated the Stark Law and Anti-Kickback Statute. The undisputed facts of the case showed that Medicor was the exclusive third-party provider of cardiology services to Hamot, a tertiary care facility, and that Hamot and Medicor had established a joint leadership model of providing services. Pursuant to this arrangement, the defendants entered into a series of contracts, under which certain Medicor physicians received compensation as medical directors of the joint venture, known as Hamot Heart and Vascular Institute (“HHVI”). As a result, these medical directors had a financial stake in both defendant entities.

The medical directorship agreements were in writing and provided that the contracts would expire at the end of each calendar year unless renewed by the parties. Thus, they arguably fell within the safe harbor provisions of the Stark Law and Anti-Kickback Statute. On multiple occasions, however, the defendants allowed the contracts to lapse, but continued to refer patients and bill for services as before. The defendants attempted to correct these violations by entering into backdated contracts covering the periods for which no formal contracts existed. The relator argued that a violation of the FCA had occurred each time the defendants submitted a claim for federal reimbursement based on referrals that occurred when no written contracts existed – and thus when no safe harbor applied. In March 2017, the District Court denied the defendants’ motion for summary judgment and allowed the relator’s claims to proceed.

In reaching its March 2017 decision, the District Court applied Escobar and summarized the factors a court should consider in determining whether a violation of a condition for federal reimbursement was material. These factors were:

1. whether compliance with a statute is a condition of payment;
2. whether the violation goes to “the essence of the bargain” or is “minor or insubstantial;” and
3. whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations.

The court’s denial of summary judgment had concluded that each of these factors weighed in favor of materiality, noting that the Stark Law expressly prohibits Medicare from paying claims that do not meet each of its requirements, and that the writing requirement is central to the Stark Law’s purpose of promoting transparency and accountability in financial arrangements. The court also noted that the relator had pointed to evidence that healthcare providers repeatedly paid significant penalties for violations of the Stark Law, suggesting that the government often – if not consistently – refuses to pay claims based on noncompliance with the Stark Law.

After the District Court denied summary judgment, the defendants argued that a later case decided by the Court of Appeals for the Third Circuit had established a heightened standard for demonstrating materiality in the FCA context. According to the defendants, technical violations of the Stark Law and Anti-Kickback Statute were not material under this precedent, and therefore, the court should reconsider its previous decision and grant summary judgment against the relator. The court rejected
that position, holding that the case in question, *United States ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481 (3d Cir. 2017), did not represent a new precedent or a clarification of the law that required reconsideration of the prior decision.

In denying the defendants’ request for reconsideration, the District Court held that *Petratos* merely reinforced the materiality standards set forth in *Escobar*, something that the defendants’ briefs acknowledged. The *Emanuele* court also noted that the relevant facts in *Petratos* were fundamentally different from those in *Emanuele*. In *Petratos*, the relator failed to allege any violation of a regulation or statute and conceded that the federal government often paid claims with full knowledge of the violations at issue. In contrast, the relator in *Emanuele* clearly alleged violations of the Stark Law and Anti-Kickback Statute, and he pointed to evidence of the federal government’s refusal to pay claims based on those violations. The District Court therefore stood by its earlier decision and denied defendants a second chance to seek summary judgment.

**Conclusion**

The *Emanuele* case is emblematic of the ongoing battle among litigants to define the boundaries of materiality under the Supreme Court’s *Escobar* decision. While many decisions interpreting the *Escobar* materiality requirement have been favorable to defendants, the holdings in *Emanuele* suggest that courts will continue to undertake a fact-specific analysis in deciding what constitutes a false claim.

One lesson from the evolving case law, including *Emanuele*, is that in pleading an FCA claim, a relator should carefully consider the laws, regulations, or contractual provisions at issue and provide clear evidence of the government’s refusal to pay claims based on violations of those requirements. Failure to do so gives defendants an easy route to obtain dismissal of potentially viable FCA claims.