THE
NATIONAL LAW REVIEW

Is Stark Law's "Signed Writing" Requirement Material to Payment: One Federal Court Says Yes

McDermott Will & Emery

Article By
Joshua T. Buchman
Tony Maida
Daniel H. Melvin
Joan Polacheck
Rebecca Waltuch
McDermott Will & Emery
FCA Update Blog

- Health Law & Managed Care
- Criminal Law / Business Crimes

- All Federal
- 3rd Circuit (incl. bankruptcy)

Thursday, May 11, 2017

In a case of first impression, a federal court found that the federal ***physician self-referral law's (Stark Law)*** requirement that financial arrangements with physicians be memorialized in a signed writing could be material to the government's payment decision. This case raises troubling questions about applying the ***False Claims Act (FCA)*** to what many in the industry consider "technical" Stark issues, especially given the Supreme Court's description of the materiality test as "demanding" and not satisfied by "minor or insubstantial" regulatory noncompliance.

***United States ex rel. Tullio Emanuele v. Medicor Associates* (*Emanuele*)**, in the US District Court for the Western District of Pennsylvania, involves Medicor Associates, Inc., a private medical group practice (Medicor), and Hamot Medical Center's (Hamot) exclusive provider of cardiology coverage. Tullio Emanuele, a *qui tam* relator and former physician member of Medicor, alleged that Hamot, Medicor, and four of Medicor's shareholder-employee cardiologists (the Physicians) violated the FCA and Stark Law because Hamot's multiple medical director compensation

arrangements with Medicor failed to satisfy the signed writing requirement in the Stark Law's personal services or fair market value exceptions during various periods of time. The US Department of Justice declined to intervene in the case, but filed a statement of interest in the summary judgment stage supporting the relator's position.

In ruling on the summary judgment motions, the court agreed with defendants that six of the eight arrangements met the signed writing requirement, but agreed with relator that a jury could find that two arrangements did not satisfy the signed writing requirement. The court also denied Hamot and Medicor's motions for summary judgment on the FCA scienter and materiality issues.

The court's opinion is the first to consider the crucial question of whether and when a false certification of compliance with the signed writing requirements of the applicable Stark Law exception(s) is material to the Medicare program's payment decision for FCA purposes. First, the court noted that the Stark Law contains an express payment prohibition for claims that originate from referrals by physicians with financial relationships that do not meet an exception, and the relevant exceptions in this case contained a signed writing requirement. Second, the court found that a violation of the signed writing requirement was not "minor or insubstantial" because the requirement creates "transparency and verifiability" and "plays a role in preventing fraud and abuse." Finally, the court referenced *Centers for Medicare and Medicaid Services (CMS) Self-Referral Disclosure Protocol (SRDP) settlements*, where disclosures of noncompliance with the Stark Law's signed writing requirements are common, as an indication that CMS views the writing requirement as material to payment.

While the signed writing requirement helps assure "transparency and verifiability" and plays a role in preventing fraud and abuse, this rationale confuses the materiality of the signed writing to compliance with the Stark Law with the materiality of the signed writing to CMS' payment decision under the FCA. In the SRDP, CMS consistently allows disclosing parties that have not complied with the signed writing requirement to keep, and not refund, most of the Medicare payments at issue when the violations are discovered and disclosed. This has meant retention of tens, perhaps hundreds, of millions of dollars in Medicare payments by hospitals that did not comply with the signed writing requirement, and, in and of itself, demonstrates that even CMS appears to consider such violations to be garden-variety and relatively minor. Further, the outcome in *Emanuele* seems inconsistent with the Supreme Court's direction to interpret the materiality standard as "demanding" and caution that the FCA is not an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract or regulatory violations.

The argument for treating a failure to satisfy the signed writing requirement as "minor or insubstantial" is not an argument that the requirement is not meaningful and important to the prevention of fraud and abuse or to compliance with the Stark Law. It goes without saying that, if Congress included a signed writing requirement in the law, the requirement is important, and noncompliance with the requirement is noncompliance with the Stark Law. However, the fact that the signed writing requirement is meaningful and important to both the prevention of fraud and abuse, and to compliance with the Stark Law, does not end the examination of whether such

noncompliance is necessarily material to Medicare's payment decision for purposes of the FCA.

Many hospitals and health systems today have contract management and accounts payable protocols in place that reduce the risk of noncompliance with the Stark Law's signed writing requirements and, importantly, help establish that any particular failure was not deliberate or due to reckless disregard for compliance with the requirement. *Emanuele* is a discouraging reminder that even an innocent failure to discover and disclose signed writing or other technical Stark violations could result in the harsh choice between a high-risk trial or an expensive settlement under the FCA.