

## FEDERAL DISTRICT COURT OPINES ON REVISED STARK LAW WRITING REQUIREMENT

On March 15, 2017, the U.S. District Court for the Western District of Pennsylvania provided the first federal court interpretation of the writing requirements affecting several regulatory exceptions in the federal physician self-referral statute ("Stark Law") and its implementing regulations since the Centers for Medicare & Medicaid Services ("CMS") provided sweeping revisions and clarifications to the Stark Law in 2016.<sup>1</sup> This court opinion provides an in-depth interpretation of the recently implemented changes to the Stark Law writing requirements and how they relate to cases brought pursuant to the False Claims Act ("FCA").

### BACKGROUND

Dating back to 1998, a private cardiology and internal medicine group practice ("Practice") provided exclusive cardiology services to an Ohio-based medical center ("Medical Center"). In the early 2000s, the two parties joined to form a heart institute, which involved entering into six agreements for the Practice physicians to provide medical director services ("Medical Director Agreements"). These Medical Director Agreements automatically terminated on December 31, 2006. However, the two parties continued their relationship with no change and did not formally renew the agreements until November 29, 2007 via addendums that were backdated to January 1, 2007. This scenario played out again in 2008 and in 2009, with the addenda expiring and the parties later entering into backdated addenda until the agreements were eliminated altogether in March 31, 2010 due to a restructuring plan. Further, in 2008, one of the Practice's physicians began performing administrative duties and receiving pay as a Chairman for the Medical Center's Department of Cardiovascular Medicine and Surgery ("CV Chair Arrangement"). However, this position was never documented in a formal arrangement.

A cardiologist who was formerly employed by the Practice ("Relator") filed a *qui tam* complaint against the Practice, the Medical Center and four individual physicians (collectively "defendants"). The Relator alleged that the defendants violated the FCA by submitting false claims for payment to the United States Government under the expired and missing agreements in violation of the Stark Law and the Anti-Kickback Statute. The defendants countered the allegations by arguing that the agreements were protected by three exceptions to the Stark Law: the personal services arrangements;<sup>2</sup> the fair market value;<sup>3</sup> and the isolated transaction<sup>4</sup> exceptions. Although the government declined to intervene, the Relator continued to pursue the action.

The opinion from March 15, 2017 deals with cross-motions for summary judgment and specifically addresses whether the Stark Law writing requirements were satisfied for the above discussed agreements during the periods of time when the agreements lapsed. The court evaluates these issues under the clarified and modified view of the requirements promulgated by CMS.

### CMS REVISIONS AND CLARIFICATION

In the CY 2016 Medicare Physician Fee Schedule **Final Rule** (for a summary of the Final Rule, click [here](#)), CMS clarified that the Stark Law writing requirement does not require an arrangement to be documented in a single, formal contract and that a collection of documents could satisfy the writing requirement as long as they are contemporaneous and one of those documents bears the signatures of the parties to the arrangement. CMS provided a non-exhaustive list of the types of documents that could on their own or together constitute satisfactory contemporaneous documents:

- Board meeting minutes;
- Hard copy and electronic communications;
- Fee schedules for services;
- Check requests or invoices containing details of items or services along with relevant dates and rates;
- Timesheets with details regarding services performed;
- Call coverage schedules;

- Accounts payable or receivable; and
- Checks issued.

## RELATOR'S MOTION - THE WRITING REQUIREMENT

As to the plaintiff's first claim that the Medical Director Agreements when lapsed did not meet the "in writing" requirement of the various Stark exceptions, the court began by outlining the requirements for the fair market value and personal service arrangement exceptions, stating the writing requirement is not a "mere technicality," but instead is essential to the transparency demanded by the Stark Law. The court then acknowledged that the writing requirement must be satisfied at all times by a "document or collection of documents that 'permit a reasonable person to verify that the arrangement complied with an applicable exception at the time a referral is made.'"<sup>5</sup> With these considerations in mind, the court determined the critical question of "whether sufficient documentation 'evidencing the course of conduct of the parties' exists for the periods of time in between the expiration of the agreements and the execution of the addenda."<sup>6</sup>

In applying the standards to the facts at hand, the court determined the Medical Director Agreements and addenda, when coupled with a collection of documents detailing the ongoing relationship, could persuade a reasonable jury that the necessary evidence was presented to show a course of conduct consistent with the writing requirement of the exceptions. The collection of documents the court found evidencing the Practice and the Medical Center's course of conduct included invoices and corresponding checks that coincided with the services, timeframe and compensation described in the Medical Director Agreements and subsequent addenda. Thus, with respect to the Medical Director Agreements, the Relator's motion for summary judgment was denied.

The court ruled differently in regards to the CV Chair Arrangement that was not formalized in any signed document. Instead, the defendants attempted to meet the collection of documents requirement with "undated, unsigned memoranda," a letter with a passing reference to the position, meeting minutes and bylaws, none of which described the positions in any specific details or contained the signatures of any involved parties. The court found that at minimum to satisfy the writing requirement, the document or collection of documents must describe identifiable services, a timeframe and a rate of compensation. The court also reiterated the signature requirement and made clear that regardless of the sufficiency of the "collection of documents," at least one contemporaneous document must contain the signatures of the parties. The defendants attempted to bring the CV Chair Arrangement under the isolated transaction exception, but the court found that exception typically only applies to "uniquely singular transactions" and does not apply in this instance where the payments were not singular, but instead the first in a series of payments. Thus, because the CV Chair Arrangement failed to meet each of the Stark exceptions, the Relator's motion for summary judgment was granted.

## DEFENDANTS' MOTION - FCA: SCIENTER AND MATERIALITY

The defendants' motion for summary judgment also argued that the Relator failed to establish the scienter and materiality requirements of the FCA. The court rejected both arguments and denied the defendants' motion.

*Scienter.* Under the FCA's scienter requirement, the Relator was required to show that the defendants: (i) had actual knowledge of the information; (ii) acted in deliberate ignorance of the truth or falsity of the information; or (iii) acted in reckless disregard of the truth or falsity of the information. In analyzing the scienter requirement, the court noted that there was ample evidence that the physicians of the Practice and the Medical Center believed all of the agreements to be in compliance with the Stark Law. However, the court opined that there was also ample evidence in the record to suggest that the Practice and the Medical Center may have knowingly violated the Stark Law in at least one manner by submitting claims for payment arising from medical directorships that were not covered by a written agreement. The court noted that a Senior VP and Medical Director of the Medical Center issued a memorandum expressly acknowledging that the parties continued to operate under expired contracts. There was also additional evidence, including solicited legal advice, engagement of a Stark consultant and retroactive addenda to cover the lapse of time that showed the Practice and the Medical Center were aware the documents relating to the agreements were not at all times in compliance with Stark and yet they continued to act upon those agreements. This evidence, the court determined, could lead a reasonable jury to conclude that the Practice and the Medical Center continued to submit claims for payment despite knowing that the underlying arrangements may not have been properly documented for purposes of Stark compliance.

*Materiality.* In order to be actionable, the FCA also requires a misrepresentation or false claim to be "material to the Government's payment decision," and the defendants argued that even if they were found to have violated the Stark Law, those violations would not hold up under

the materiality requirement of the FCA. Relying upon the 2016 standard outlined in *United States ex rel. Escobar v. Universal Health Services, Inc.*, the court considered the following factors: whether compliance with a statute is a condition of payment; whether the violation goes to "the essence of the bargain" or is "minor or insubstantial"; and whether the government consistently pays or refuses to pay claims when it has knowledge of similar violations.

In applying these factors, the court determined that the alleged violations at issue were material because the Stark Law "expressly prohibits Medicare from paying claims that do not satisfy each of its requirements, including every element of any applicable exception." Because compliance with each element is required, the writing requirement is not "minor or insubstantial." Rather, it is crucial to the transparency demanded by the Stark Law and goes to the very "essence of the bargain." The court also acknowledged that there was a lack of evidence suggesting the government refuses to pay or pays when they have actual knowledge of these violations but recognizes that providers who do violate these provisions are required to pay penalties when those violations are brought to light. Balancing all of these factors, the court determined summary judgment was not appropriate because the writing requirements contained in several Stark exceptions "are important, mandatory, and material to the government's payment decisions."

## PRACTICAL TAKEAWAYS

Even in light of the clarified Stark Law writing requirements, providers must exercise caution in documenting physician arrangements. As noted by the court in this case, any "collection of documents" relied upon must contain at least one contemporaneous writing, signed by the parties. The collection of documents must also describe: 1) identifiable services; 2) a timeframe; and 3) a rate of compensation. Therefore, mere checks alone will not be sufficient to satisfy the writing requirement. Providers should attempt to document all physician arrangements and obtain signatures wherever possible. This case also illustrates that a failure to satisfy the writing requirements may subject a provider to increased liability under the FCA. Further, the holding in this case demonstrates that awareness that some claims may not be covered by a written agreement may be enough to satisfy the scienter requirement under the FCA.

If you have any questions about this case, or related issues, please contact:

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<sup>1</sup> *U.S. ex rel. Tullio Emanuele v. Medicor Associates*

<sup>2</sup> 42 C.F.R. § 411.357(d)(1).

<sup>3</sup> 42 C.F.R. § 411.357(l).

<sup>4</sup> 42 C.F.R. § 411.357(f).

<sup>5</sup> *U.S. ex rel. Emanuele v. Medicor Associates* (citing 80 Fed. Reg. 70886, 71316).

<sup>6</sup> *Id.*

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