

First federal court finds collection of documents meets Stark Law writing requirement

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On March 15, 2017, the United States District Court for the Western District of Pennsylvania issued the first federal court opinion on the writing requirement included in several commonly used Stark exceptions.

Background

United States ex rel Emanuele v Medicor Associates, Inc., involved multiple medical director agreements between Medicor Associates, Inc., a cardiology practice, and Hamot Medical Center, both located in Erie, Pennsylvania. The medical director agreements expired in December 31, 2006, and were not renewed in writing until nearly 11 months later on November 29, 2007, using addenda with a retroactive effective date of January 1, 2007. A whistleblower filed a qui tam complaint alleging that the medical director arrangements failed to comply with the Stark Law and the False Claims Act (FCA) because there was no written agreement in place during the 11-month period. Hamot argued that these medical director arrangements complied with the Stark personal services and fair market value exceptions, both of which require an arrangement to be in writing and signed by the parties.

As discussed in our previous [publication](#), in November 2015, the Centers for Medicare & Medicaid Services (CMS) clarified its prior guidance on the Stark writing requirement, stating that a collection of documents can satisfy the writing requirement in place of a formal written contract. Specifically, CMS identified a non-exhaustive list of documents that can be used to show the course of conduct between the parties to meet the writing requirement, including board meeting minutes or other documents authorizing payments for services; written communication between the parties in hard copy or electronic form; fee schedules for specific services; check requests, invoices or checks identifying services with dates and compensation; time sheets recording services; call coverage schedules with dates of services; and accounts payable or receivable records with dates and rates of services. All items used to demonstrate compliance with the writing requirement must be contemporaneous with the arrangement, however. Whether the collection of items meets the writing requirement depends on the facts and circumstances of the arrangement. Overall, the collection of items must permit a reasonable person to verify that the arrangement complied with an applicable Stark Law exception *at the time the referrals were made*.

The *Medicor* court's decision

In denying the plaintiff whistleblower's motion for summary judgment in part, the *Medicor* court held that six of the medical director arrangements complied with the writing requirement. The court found that checks and invoices exchanged throughout the duration of the agreements, and in between, applied to discrete periods of time and were commensurate with the rates of compensation specified in the written contracts and addenda. When coupled with the original written agreements and addenda, the court held that a reasonable jury could conclude that the defendants presented the necessary evidence to satisfy the writing requirement. As a result, the plaintiff's motion for summary judgment was denied and the case will move forward to trial with respect to the six medical director arrangements.

The court ruled the other way with respect to two other medical director arrangements, however. For these two arrangements,

the court found the records showed that the terms and conditions of those arrangements were never memorialized in any type of signed document. Although Hamot produced a handful of emails, memoranda, an unsigned draft agreement, meeting minutes and bylaws, it was unable to produce written contracts or sufficient contemporaneous writings evidencing these two arrangements. None of these items contained terms the court deemed “critical” — identifiable services, a timeframe and a rate of compensation — nor did they contain a signature. Citing CMS’s 2015 guidance, the court emphasized that the signature requirement is distinct, mandating that a signature appear on a contemporaneous writing to demonstrate the parties’ assent to the arrangement. As a result, the court held that none of these documents would permit a reasonable person to verify that the arrangements complied at the time the referrals were made under that compensation arrangement, and importantly, none of the documents were signed by the parties. The court also rejected Hamot’s attempt to use the Stark isolated transaction exception to protect the two medical director agreements, finding that the isolated transaction exception is available only to protect uniquely singular transactions, such as the purchase of an entire medical practice. By contrast, the medical director arrangements involved multiple installments in a series of payments. Thus, the court granted plaintiff’s motion for summary judgment in part for these two undocumented medical director agreements.

In addition, the court denied the defendants’ motion for summary judgment regarding the intent necessary to violate the FCA and whether any misrepresentation was material to the government’s payment under the FCA. Both Medicor and Hamot argued that they believed all the medical director arrangements complied with all legal requirements, including an applicable Stark exception, and as a result they did not “knowingly” submit false claims, as is required to violate the FCA. However, the evidence also suggested the parties knew some medical director agreements had expired but the physicians continued to provide and bill for their services. In addition, Hamot had received legal advice over a period of years cautioning about the need to structure its arrangements with Medicor to comply with Stark exceptions. Based on the record as a whole, the court found that a reasonable jury could conclude the parties knew the medical director arrangements may not have complied with the Stark Law after they expired, but nevertheless continued to submit claims for payment. Regarding materiality, the court applied the standard articulated in *United States ex rel. Escobar v Universal Health Services, Inc.*, and held, on balance, that a reasonable jury could find that the materiality standard under the FCA was met.

Conclusion

Although the *Medicor* court’s interpretation is merely one federal court’s view, and the case has not been ultimately decided, it is worth bearing in mind when attempting to rely on a collection of documents to demonstrate compliance with a Stark exceptions’ writing requirement. Parties should make every effort to enter into a written contract for any arrangement requiring a writing under an applicable Stark exception. However, in the absence of a single written agreement executed by both parties, parties may look to a collection of written documents to meet the Stark writing requirement if the collection includes contemporaneous signatures and the critical terms of identifiable services, the applicable time frame and the amount of the compensation.

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