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Watching out for America's health

an interview with Mike Joyce

Vice President, Chief Auditor
& Compliance Officer
Blue Cross Blue Shield Association
Chicago

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by Gary W. Herschman, Esq., Victoria Vaskov Sheridan, Esq., and Paulina Grabczak, Esq.

Stark Law: What constitutes a "collection of documents?"

» Develop and implement a plan to audit physician arrangements for Stark compliance on a regular and on-going basis, and take corrective actions if any issues are identified.

» Avoid problems by not starting any physician arrangements and not paying or accruing compensation for services provided until a final agreement is signed by both parties.

» When relying on a "collection of documents," the documentation should include identifiable services, a timeframe, and a rate of compensation.

» At least one of the documents in the collection of documents should be signed by each of the parties.

» The documentation should contemporaneously reflect the course of conduct between the parties with respect to a particular arrangement.

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On March 15, 2017, the United States District Court for the Western District of Pennsylvania issued an opinion that sheds insight on how courts view the "writing" requirement of various exceptions under the federal physician self-referral law (Stark Law). The Court's detailed discussion of the Stark Law in its summary judgment opinion in *United States ex rel. Tullio Emanuele v. Medicor Assocs.*[1] provides guidance as to what may or may not constitute a "collection of documents" for purposes of satisfying a Stark Law exception.

The case was filed under the federal False Claims Act by whistleblower Tullio Emanuele, MD, against the Hamot Medical Center of the City of Erie, Pennsylvania (Hamot); Medicor Associates, Inc., a local cardiology practice (Medicor); and individually named physician defendants who were affiliated with Medicor. Dr. Emanuele is a cardiologist who previously worked for Medicor. Although the government declined to intervene in the case, it did submit a Statement of Interest in the case record.

The case involves a number of arrangements between Hamot and Medicor, beginning with a "paired leadership model," known as the Hamot Heart and Vascular Institute, and followed with a series of medical directorship arrangements. The particular arrangements at issue in the case included:

- a directorship position in connection with the Women's Heart Health Program (Women's Heart Program),
- a chairman position for Hamot's Department of Cardiovascular Medicine and Surgery (CV Chair), and

- six medical directorship arrangements that expired, but continued without formal renewals or extensions.

The parties did not dispute that services were actually performed under each of these arrangements. Nonetheless, Dr. Emanuele alleged that the arrangements failed to meet a relevant Stark Law exception, primarily because the arrangements were not set forth in a valid writing.

The Stark Law exceptions discussed in the case specifically require:

- **Personal service arrangements:** Each arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.[2]
- **Fair market value compensation:** The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.[3]

This opinion is of particular note because it marks the first time that a physician arrangement has been analyzed since the Stark Law was most recently amended in November 2015, at which time the Centers for Medicare & Medicaid Services (CMS) clarified and codified its longstanding interpretation of when the writing requirement is satisfied under various exceptions.

Specifically, the "collection of documents" language appeared in 80 Fed. Reg. 70886, 71314 when CMS discussed the rental of office space and the rental of equipment. CMS took the opportunity to clarify the writing requirement for several statutory exceptions under Stark, including the two noted above. CMS stated that:

> [d]epending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.[4]

Further, CMS noted that:

> [t]o satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.[5]

Arrangements established by a collection of documents

Due to the nature of the services provided under The Women's Heart Program and CV Chair directorships, both the professional services arrangement and fair market value exceptions were potentially applicable. Both exceptions contain a similar requirement that the arrangement be in writing and signed. However, neither arrangement was reduced to a formal written agreement. Thus, the defendants identified a collection of documents as evidence that the writing requirement was satisfied, including:

- Emails regarding a general initiative between Hamot and Medicor for cardiac services, but without any specific information regarding directorship positions, duties, or compensation;
- Letter correspondence between Hamot and Medicor discussing the potential establishment of a director position for the Women's Heart Program;

- Internal summary that identified a Medicor physician as the director of the Women's Heart Program;
- Unsigned draft agreement for medical supervision and direction of the Women's Heart Program; and
- A one-page letter appointing a Medicor physician as the CV Chair and identifying a three-year term that expired June 30, 2008.

The Court said that although "these kinds of documents may generally be considered in determining whether the writing requirement is satisfied, it is essential that the documents outline, at an absolute minimum, *identifiable services*, a *timeframe*, and a *rate of compensation*. (emphasis added)"[6] In addition, the Court noted that CMS requires that at least one of the documents in the collection be signed by each party. After confirming that these "critical" terms were missing from the documents described above, the Court concluded that no reasonable jury could find that either arrangement was set forth in writing in order to satisfy Stark's fair market value exception or personal service arrangement exception.

> "...it is essential that the documents outline, at an absolute minimum, *identifiable services*, a *timeframe*, and a *rate of compensation*."

The defendants also argued that certain payments made by Hamot to Medicor in connection with the Women's Heart Program and CV Chair directorships were protected from Stark Law liability under the "isolated transaction" exception. The payments were made by Hamot based on invoices submitted by Medicor for services provided under both directorships in December 2008. The Court, citing to existing case law, rejected this argument and explained that the exception is intended to only apply to singular transactions, such as the purchase of a medical practice. The Court further explained that the payment in this case can be "more accurately characterized as the first installment in a series of payments relating" to the directorships.[7] Therefore, the Court held that no reasonable jury could find that the arrangements satisfied the isolated transaction exception. For the reasons discussed, the plaintiff/relator's motion for summary judgment on its claims pertaining to the Women's Heart Program and CV Chair directorships was granted.

Expired arrangements

An additional six medical directorships between Hamot and Medicor were memorialized in formal written contracts, but they all terminated pursuant to their terms on December 31, 2006, and were not formally extended or renewed in writing on or prior to their termination. Nonetheless, following the termination date, Medicor continued to provide services and Hamot continued to make payments under the agreements. The parties eventually executed a series of "addendums" to extend the term of each arrangement through December 31, 2007. Although these addenda had an effective date of January 1, 2007, they were not executed until November 2007. Subsequently, in 2008 and 2009, the arrangements again expired and the parties again entered into a series of backdated addenda. During the timeframe between when the agreements expired and when the new addenda were executed, invoices were continuously submitted and paid.

Dr. Emanuele argued that the failure to execute timely written extensions resulted in a failure of all six

arrangements to meet the "writing" requirement under a relevant Stark Law exception. The Court disagreed, explaining that there is no requirement that the "writing" be a single formal agreement and CMS has provided guidance as to the type of collection of documents that could be considered when determining if the writing requirement is met at the time of the physician referral. In this case, the defendants specifically relied upon the invoices from Medicor to Hamot and the checks that were sent in payment thereof.

The Court further noted that the six directorships were originally governed by formal contracts that clearly outlined the services, the timeframe, and the compensation that would be provided under the arrangement—elements that were also addressed in the addenda. The Court further observed that CMS specifically pointed to check requests and invoices as types of documents that may collectively satisfy the writing requirement if such documents identify services provided, relevant dates, and/or rates of compensation. Thus, the Court determined that, "[w]hen viewed in conjunction with the original written agreements and the subsequent addenda" a reasonable jury could conclude that the invoices and payments represented "the necessary 'collection of documents, including contemporaneous documents evidencing the course of conduct between the parties'" to satisfy the signed writing requirement of a relevant Stark Law exception.[8]

In deciding that a reasonable jury could find that there was a sufficient collection of documents, the Court denied the plaintiff/relator's motion for summary judgment with respect to these six "expiring" directorships, and the case will proceed to trial on these claims.

Conclusion

Given the Court's interpretation of the Stark Law "writing" requirement, hospitals should consider this case both: (1) when entering into or renewing arrangements with physicians; and (2) when auditing Stark Law compliance of their physician arrangements.

1. United States ex rel. *Tullio Emanuele v. Medicor Associates (Emanuele).* No. 1:10-cv-245, 2017 U.S. Dist. LEXIS 36593 (W.D. Pa. Mar. 15, 2017). Discussion available at http://bit.ly/2rF9uXG
2. 42 C.F.R. § 411.357(d)(1)(i).
3. 42 C.F.R. § 411.357(l)(1).
4. 80 Fed. Reg. 70886, 71314.
5. 80 Fed. Reg. 70886, 71316.
6. Ibid, Ref. #1 at *31-32
7. Id. at *39-40.
8. Id. at *30 (citing 80 Fed. Reg. 70886, 71314-71315).

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