

HEALTH INDUSTRY ALERT

PHYSICIAN SELF-REFERRAL LAW UPDATES – REVIEW OF 2007 EVENTS



In 2006 the healthcare community learned of the first substantial judgment the government obtained in a case alleging a violation of the Stark law, which prohibits physicians from referring Medicare and Medicaid patients for “designated health services” to an entity with which they have certain types of financial relationships. Specifically, in *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), the government alleged that a former owner of Chicago’s Edgewater Medical Center caused the Medical Center to submit false claims, in violation of the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, by violating the Stark law. The Court found that the Medical Center caused the submission of false claims by paying various physicians in excess of fair market value. The Court ordered the former owner to pay more than \$64 million for his part in engineering the scheme.

In 2007 the government instituted additional actions alleging a violation of the Stark law, obtained a substantial settlement alleging a violation of the Stark law, prevailed in another FCA action asserting a violation of the Stark law and promulgated significant amendments to the law. Because of the significant exposure to liability that the Stark law may create for any healthcare entity that furnishes healthcare services and contracts with physicians, these developments warrant close attention.

DEPARTMENT OF JUSTICE’S (DOJ) ENFORCEMENT ACTIVITY

DOJ instituted a significant lawsuit against a former compliance official and settled a lawsuit alleging a violation of the Stark law. These actions demonstrate the government’s intent to vigorously enforce the law.

United States v. Sulzbach. In September the government filed a complaint against former compliance officer and general counsel of Tenet Healthcare Corporation, Christi Sulzbach. The complaint alleges that Sulzbach learned in 1997 that a Tenet-owned hospital was violating the Stark Law. According to the complaint, twelve physician contracts resulted in those physicians being paid well in excess of fair market value.¹

¹ Complaint at 13, *United States v. Sulzbach*, No. 07-61329 (S.D. Fla. Sept. 18, 2007).

According to the complaint, Sulzbach stated in a compliance report prepared as part of Tenet's Corporate Integrity Program, that to the best of her knowledge and belief, Tenet was in material compliance with its Corporate Integrity Agreement (CIA) and federal program legal requirements in 1997 and 1998.² Sulzbach allegedly never notified the government that prior to certifying compliance Tenet's outside counsel had questioned whether Tenet was adhering to the Stark law.

The complaint alleges that Sulzbach's false certifications on the CIA allowed Tenet to bill Medicare for claims it was not legally entitled to receive and obstructed the government's discovery and recoupment of improper payments that Tenet had previously received.³ The government asserts that it has identified over 70,000 payments, totaling roughly \$18 million, that Tenet unlawfully obtained and for which Sulzbach is legally responsible.⁴ Under the FCA, the United States can recover treble damages and penalties of up to \$11,000 per violation. The defendant is entitled to an offset for the amounts previously collected on the claims at issue, but the government asserts, only after the damages have been trebled.⁵

HealthSouth. On December 14, HealthSouth Corporation and two physicians agreed to pay the United States \$14.9 million to settle allegations that the company submitted false claims and paid illegal kickbacks to physicians who referred patients for care.⁶ At issue were claims by HealthSouth to Medicare and Medicaid for services provided to patients referred by surgeons when HealthSouth had financial relationships with the physicians, their partnership, and their research and training foundation that violated the Stark Law and the Anti-Kickback Statute. HealthSouth had initially disclosed the compliance issue to the government. The government asserted that the doctors were given the title of "medical directors" and were paid above fair market value to guarantee that they would refer patients to HealthSouth.⁷ Under separate settlement agreements, HealthSouth will pay \$14.2 million and the physicians will pay a total of \$700,000.

CASE LAW DEVELOPMENTS

United States ex rel. Roberts v. Aging Care Home Health. In *United States ex rel. Roberts v. Aging Care Home Health*, 2007 U.S. Dist. LEXIS 92864 (W.D. La. Dec. 18, 2007), the government alleged that Aging Care Home Health Inc. (Aging Care) and its principal Janice Davis knowingly submitted false claims cost report certifications and claims for payment to the Medicare program and failed to refund payments that were issued based on false records or statements. Physician testimony in the case showed that Davis masked payments by creating contracts listing duties never performed by physicians.

In February, the defendants were found to have violated the Stark Law. In December, the government moved for partial summary judgment, stating that the defendants' violations of the Stark Law were made knowingly and thus also constituted violations of the FCA. Because the court had previously found that the defendants violated the Stark Law by presenting a false or fraudulent claim for payment, the court addressed only the scienter requirement of the FCA. The court found that the defendants had sufficient knowledge or reckless disregard of the truth to warrant their liability

² *Id.* at 31.

³ *Id.* at 37.

⁴ *Id.* at 37.

⁵ *Id.* at 37.

⁶ Press Release, Dept. of Justice, HealthSouth and Physicians Pay \$14.9 Million to Settle Health Care Fraud Claims (Dec. 14, 2007).

⁷ Jay Reeves, *HealthSouth, prominent doctors settle kickback claims*, The Ledger, Dec. 14, 2007.

under the FCA as a matter of law because they knew that the physicians were not performing their services under their contracts.

Under the FCA, the court awarded treble damages and on the amount previously determined as the government's damages for a total of approximately \$1.3 million. Additionally, the court imposed a civil penalty of \$5,500 for each false claim submitted, resulting in a total fine of \$3.41 million. The amount of the Court's judgment was thus approximately \$4.7 million.

REGULATORY DEVELOPMENTS

On the regulatory front, the Centers for Medicare and Medicaid Services (CMS) has issued important new survey information regarding the Stark Law and promulgated new, significant regulatory guidance.

DISCLOSURE OF FINANCIAL RELATIONSHIPS REPORT (DFRR)

In May, CMS solicited comments on a proposal to collect ownership, investment and compensation information through the "Disclosure of Financial Relationships Report" (DFRR).⁸ CMS stated in the notice that the DFRR would be used to obtain information necessary to analyze hospitals' compliance with the Stark Law, marking increased oversight of physician relationships by CMS. CMS has announced that it will electronically distribute the survey to 500 entities. Entities that fail to meet the reporting requirements are subject to civil monetary penalties of \$10,000 for each day for which reporting was required but not made.⁹

More specifically, the surveys require entities to submit information regarding the entity's "reportable financial relationships" including any ownership interest, investment interest or any compensation arrangement. Additionally, CMS can request: (1) the name and UPIN or NPI of each physician (or immediate family member of a physician) who has a reportable financial relationship with the entity, (2) the covered services the entity furnishes and (3) the "nature of the financial relationship that the entity knows or should know about in the course of prudently conducting business, including, but not limited to, records that the entity is already required to retain . . ." ¹⁰ The regulations require that an entity be furnished at least thirty days to respond to the request. CMS has indicated that where the agency determines that the nature or scope of the request is such that the information cannot be furnished within thirty days, the agency will extend the time for responding to the request.¹¹

PHASE III AND PHYSICIAN FEE SCHEDULE UPDATES TO THE STARK LAW

Since the enactment of the Stark Law, CMS has published various phases of regulations to clarify, update and change the application of the Stark Law. The summer and fall of 2007 brought another chapter of Stark regulations as revisions were proposed in the Physician Fee Schedule and the long-awaited third phase of Stark regulations (Phase III) were published in September. While Phase III was anticipated to mark the completion of the full set of regulations interpreting the Stark Law, CMS indicated its intent, in both Phase III and the Final Physician Fee Schedule, to continue to implement significant revisions to the Stark Law in the future.

⁸ Proposed Collection; Comment Request, 72 Fed. Reg. 28,056 (May 18, 2007).

⁹ Physicians' Referrals to Health Care Entities with which they have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,068 (Sept. 5, 2007).

¹⁰ *Id.* at 51,098.

¹¹ *Id.* at 51,069.

Specifically, in July CMS proposed various expansions of the Stark Law in the Proposed Physician Fee Schedule (PPFS).¹² The PPFS contained discussion of eleven different aspects of the Stark Law.¹³ However, in the Final Physician Fee Schedule, CMS finalized only one of its proposed amendments, an anti-markup provision for diagnostic tests.¹⁴ In the Final Physician Fee Schedule, CMS stated that given the number of proposals, the significance of the provisions, and the volume of public comments, the agency did not believe it was “prudent to finalize any of the proposals in this rule” with the exception of the anti-markup provision.¹⁵ However, CMS indicated its intent to publish a final rule addressing nine other proposals in the future, without the need for new proposals or additional public comment.¹⁶

Additionally, on September 5 CMS issued the third phase of regulations regarding the physician self-referral prohibition under the Stark Law, which became effective on December 4, 2007.¹⁷ Phase III makes some key updates and clarifications to the Stark Law. The following are some of the areas where Phase III clarified or updated the status of the Stark Law.

- **Academic Medical Centers (AMCs).** The AMC exception requires that the “total compensation” an AMC pays to referring physicians be set in advance, consistent with fair market value for the services provided, and not determined in a manner that takes into account the volume or value of referrals or other business generated between the parties. In Phase III, CMS clarifies that the dollar amount of a referring faculty physician’s compensation does not need to be set in advance.¹⁸ Rather, it is sufficient if each component of the AMC contributes to the aggregate compensation using a methodology that qualifies under the regulatory requirements for compensation.¹⁹ CMS also clarified that the aggregate compensation must satisfy the fair market value test, rather than each component satisfying the fair market value requirement.²⁰ CMS stated in Phase III that the definition of “indirect compensation agreement” and the corresponding exception are potentially applicable to AMCs and physicians.²¹
- **Stand in the Shoes.** Phase III adds a provision under which physicians are deemed to “stand in the shoes” of their “physician organization” in indirect compensation arrangements.²² CMS expressed concern that parties were improperly determining that arrangements involving financial incentives for physicians fell outside of the Stark Law due to narrow construction of the definition of “indirect compensation arrangement.” CMS stated that under the new provision “a physician is deemed to have a direct compensation arrangement with an entity furnishing DHS if the only intervening entity between the physician and the DHS entity is his or her physician organization.”²³ CMS intends that this new provision will treat compensation arrangements between DHS

¹² Proposed Physician Fee Schedule Updates, 72 Fed. Reg. 38,122, 38,179 (July 12, 2007).

¹³ For further discussion of these proposed changes, see Health Industry Alert, Physician Self-Referral Law: Significant Regulatory and Case Law Developments (Aug. 22, 2007), available at www.akingump.com.

¹⁴ Note that CMS has, for the most part, delayed the application of the anti-markup provision until January 1, 2009. Revisions to Payment Policies under the Physician Fee Schedule, 73 Fed. Reg. 404 (Jan. 3, 2008).

¹⁵ Final Physician Fee Schedule Updates, 72 Fed. Reg. 66,222, 66,306 (Nov. 27, 2007).

¹⁶ *Id.*

¹⁷ Phase III, 72 Fed. Reg. 51,012.

¹⁸ *Id.* at 51,037.

¹⁹ See 42 C.F.R. § 411.354(d).

²⁰ Phase III, 72 Fed. Reg. 51,012.

²¹ *Id.* at 51,038.

²² *Id.* at 51,087. The definition of “physician organization” was also changed in Phase III. Physician organization is now defined to include “a physician (including a professional corporation of which the physician is the sole owner), a physician practice or a group practice” *Id.* at 51083.

²³ *Id.* at 51,028.

entities and group practices “as if the arrangements are with the group’s referring physician.”²⁴ Thus, many arrangements that were previously analyzed under the indirect compensation exception now must be analyzed as direct compensation arrangements. Notably, CMS stated that pre-existing relationships entered into prior to the date of publication of Phase III “need not be amended during the original term of the arrangement or the current renewal term” to comply with the requirements.²⁵ CMS later issued a final rule stating that the “stand in the shoes” provision would not apply to specified compensation arrangements entered into by AMCs and 501(c)(3) organizations until December 4, 2008.²⁶

- **Fair Market Value Compensation.** Prior to Phase III, this exception applied only to payments made by an entity to a referring physician or group of physicians for items and services. Phase III expands the fair market value compensation exception to apply to payments from and to a physician.²⁷ CMS also clarified that the exception is not applicable to leases for office space.²⁸
- **Fair Market Value Safe Harbor.** In Phase II, CMS created a “safe harbor” provision consisting of two methodologies for calculating hourly rates that would be deemed “fair market value” (FMV): (1) hourly payments less than or equal to the average hourly rates for emergency room physician services in the relevant physician market and (2) hourly payments determined by averaging the fiftieth percentile national compensation level for physicians in the specialty as determined by salary surveys.²⁹ In response, commenters pointed to the impracticality of both of these survey methodologies. As a result, in Phase III, CMS ultimately abandoned these two methodologies, stating that appropriate FMV calculation “will depend on the nature of the transaction, its location, and other factors.”³⁰ Additionally, CMS stated that the parties to the arrangement are best situated to “ensure that the remuneration is at fair market value and to document it contemporaneously.”³¹
- **Compliance Training.** Phase III includes a compliance training exception to the referral prohibition related to compensation agreements.³² The exception includes compliance training provided by an entity to a physician who practices in the entity’s service area as long as compliance training is the primary purpose of the program.³³
- **Set in advance.** To qualify for certain Stark exceptions, CMS requires that compensation in an arrangement be “set in advance.” CMS stated in Phase III that percentage based compensation arrangements can be considered “set in advance” if the methodology is fixed, with sufficient specificity, at the outset of the contract

²⁴ *Id.*

²⁵ *Id.*

²⁶ Delay of the Date of Applicability for Certain Provisions of Physicians’ Referrals to Health Care Entities with which they have Financial Relationships, 72 Fed. Reg. 64,161, 64,162 (Nov. 15, 2007).

²⁷ *Id.* at 51,094-95.

²⁸ *Id.* at 51,095.

²⁹ *Id.* at 51,015.

³⁰ *Id.*

³¹ *Id.* at 51,060.

³² *Id.* at 51,095.

³³ *Id.*

and is not revised during the course of the agreement in a manner reflecting the volume of referrals.³⁴ CMS also confirmed that arrangements can be amended if the amendment is made for “bona fide reasons unrelated to volume or value of referrals or other business generated”³⁵ Notably, in the Proposed Physician Fee Schedule CMS proposed to further clarify when percentage compensation arrangements may qualify under the set in advance standard. Although this proposal was not finalized, as mentioned above, it is likely forthcoming.

CONCLUSION

DOJ’s recent enforcement activity sends a clear signal that DOJ will vigorously enforce the Stark law. Recent enforcement activities heighten the importance that all healthcare entities closely monitor CMS’ recent regulatory pronouncements and ensure that their practices are in compliance with those pronouncements.

CONTACT INFORMATION

If you have questions about the Stark law or about other health industry fraud and abuse issues, please contact:

Robert S. Salcido..... 202.887.4095rsalcido@akingump.com..... Washington, D.C.
 Jamie L. Anderson..... 202.887.4033jlanderson@akingump.com..... Washington, D.C.
 Mara B. McDermott 202.887.4337mmcdermott@akingump.com..... Washington, D.C.

Austin Beijing Dallas Houston London Los Angeles Moscow
 New York Philadelphia San Antonio San Francisco Silicon Valley Taipei Washington, D.C.

³⁴ *Id.* at 51,031.

³⁵ *Id.*