

HEALTH INDUSTRY ALERT

PHYSICIAN SELF-REFERRAL LAW: SIGNIFICANT REGULATORY AND CASE LAW DEVELOPMENTS



Recently, the Centers for Medicare and Medicaid Services (CMS) proposed significant new rules interpreting the Stark Law.¹ Monitoring these developments is especially important given last year's district court decision awarding the government more than \$64 million in a legal action alleging a violation of the Stark Law. Set forth below is a summary of CMS' latest proposed interpretation – and other legislative and regulatory developments involving the Stark Law – and a summary of the court's decision interpreting the Stark Law.

PROPOSED RULE: EXPANSION OF STARK LAW

Since the Stark Law was originally enacted in 1989, Congress has expanded it on several occasions. Similarly, CMS has promulgated multiple rounds of regulatory revisions as it seeks to obtain the golden mean between rooting out arrangements where financial incentives result in overutilization and corrupt medical judgment and leaving intact relationships that enhance patient care, reduce costs and lead to greater efficiency.

On July 12, CMS issued its latest proposed amendments to the Stark Law regulations in its Proposed Physician Fee Schedule (PFS). Specifically, the proposed amendments are intended to close perceived loopholes and to provide alternative methods for satisfying some Stark Law exceptions. If adopted, these amendments could create additional exposure to the extent they impact arrangements drafted to conform to the existing law. However, if the alternative methods for satisfying Stark Law exceptions are finalized, the result could ultimately provide some relief for persons or entities that may have inadvertently violated the Stark Law.

The proposed PFS rule contains a discussion of 11 different aspects of the Stark Law, some of which CMS is proposing to amend, and others for which CMS is seeking comments. Set forth below is a discussion of four of the more significant proposed amendments. CMS will be accepting comments on this proposed rule until August 31, and will publish a final rule this fall.² The final rule will be effective for cost reporting periods beginning on or after January 1, 2008.

¹ 72 Fed. Reg. 38,122, 38,179 (July 12, 2007).

² Because of an omission of an element to the Alternative Method for Compliance Section of the Proposed Rule, CMS has extended the comment period of that section to September 7, 2007.

“Set in Advance” and Percentage-Based Compensation Arrangements. To qualify for several of the Stark Law exceptions, CMS currently requires that arrangements have compensation that is set or fixed in advance. CMS considers this requirement satisfied if the “aggregate compensation, a time-based or per unit-of-service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation, is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid.”³ Over the years, CMS has vacillated regarding whether percentage-based compensation formulas could satisfy the law’s “set in advance” standard. At one point, CMS determined that payments based upon a percentage of an indeterminate sum, such as collections, did not satisfy the “set in advance” standard and then reversed its position.

In the PFS rule, CMS now proposes to revisit the issue. Specifically, it explained that its intent in permitting percentage compensation arrangements was so that entities could compensate physicians for the physician services they performed, but that it did not intend for physicians to receive percentage-based compensation related to the provision of other items and services, such as equipment and space rental. Thus, consistent with its expressed intent, CMS proposed “to clarify that percentage compensation arrangements: (1) May be used only for paying for personally performed physician services; and (2) must be based on the revenues directly resulting from the physician services rather than based on some other factor such as a percentage of the savings by a hospital department (which is not directly or indirectly related to the physician services provided).”⁴

Services Furnished Under Arrangement. In an “under arrangement” relationship, a hospital contracts with physicians to furnish services to the hospital’s patient, for which the hospital ultimately bills. In the PFS rule, CMS expressed concern that these arrangements “may be little more than a method to share hospital revenues with referring physicians in spite of unnecessary costs to the program and to beneficiaries.”⁵ Specifically, CMS noted that such improper revenue sharing may occur in questionable joint ventures between hospitals and physicians such as where the joint venture provides imaging services previously provided by the hospital directly.

CMS noted that the Medicare Payment Advisory Commission (MedPAC) had previously recommended that CMS prohibit physician ownership of any entity “that derives a substantial proportion of its revenue from a provider” such as a hospital. CMS is seeking comments regarding whether it should adopt MedPAC’s approach, and also is proposing to amend the definition of entity in the Stark Law so that it includes both the person or entity that performs the designated health service (DHS), which triggers the application of the Stark Law, as well as the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS.⁶

If adopted, CMS’ proposal would require that many existing relationships be restructured.

Stand in the Shoes. CMS also expressed concern about indirect financial relationships in the PFS rule — specifically, about parties who attempt to avoid triggering the Stark Law by inserting an entity or contract between the financial relationship that links a DHS entity and a referring physician. To prevent this practice, CMS is seeking comments on whether to amend current regulations to provide that “where a DHS entity owns or controls an entity to which a physician refers Medicare patients for DHS, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and on the same

³ 42 C.F.R. § 411.354(d).

⁴ 72 Fed. Reg. at 38,184.

⁵ 72 Fed. Reg. at 38,186.

⁶ 72 Fed. Reg. at 38,224.

terms as does the entity that it owns or controls.”⁷ CMS has already solicited comments on this issue with regard to collapsing agreements to treat physicians as standing in the shoes of their physician group and cautions commenters that it may already be addressing the issue in a separate upcoming final rule.

Alternative Methods for Satisfying Certain Exceptions. Although the majority of the PFS rule addresses expanding the reach of the Stark Law, it also contains some potential relief. CMS has apparently received numerous comments expressing concern that under the Stark Law even innocent or trivial violations have the potential to result in substantial penalties. To address this situation, CMS set forth an alternative method for compliance that it is currently considering. CMS explained that this alternative would not be available for all Stark Law exceptions, and also cautioned that “this alternative is intended to address only inadvertent violations in which an agreement fails to satisfy the procedural or ‘form’ requirements of an exception of the statute or regulations.”⁸ CMS describes as an example of an “innocent mistake” a situation where there is a failure to obtain a necessary signature on a written agreement.

Where applicable, CMS envisions that parties would meet the exception if: (1) the parties self-disclose the facts and circumstances of the arrangement, (2) CMS determines that the arrangement satisfied all but the procedural or “form” requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS, (3) the mistake was inadvertent, (4) the referral and the resulting claim for DHS were made without knowledge of the mistake, (5) the parties have brought (or will bring as soon as possible) the arrangement into complete compliance or have terminated the relationship, (6) the arrangement did not pose a risk of program or patient abuse, (7) no more than a set amount of time had passed since the time of the original noncompliance, and (8) the arrangement at issue is not the subject of an ongoing federal investigation or other proceeding.⁹

The ultimate decision as to whether an arrangement satisfies these elements will remain at the sole discretion of CMS and would not be subject to further administrative or judicial review. CMS is seeking comments on whether to adopt this alternative compliance method.

OTHER SIGNIFICANT DEVELOPMENTS REGARDING THE STARK LAW

There are two other recent Stark Law developments that are significant. First, the House recently passed a combined children’s health and Medicare bill, the Children’s Health and Medicare Protection Act of 2007. The bill includes a provision that would amend the Stark Law whole hospital exception by significantly restricting physician ownership of hospitals, and would ultimately require the restructuring of many existing entities. The Medicare provisions, including the Stark amendment, may ultimately be stripped from the bill, leaving the children’s health provisions intact and likely to be enacted. The Senate has yet to consider the Medicare provisions the House passed and, as such, the fate of the Medicare legislation is unclear.

Second, CMS is preparing to send a new, mandatory “Disclosure of Financial Relationships Report” (DFRR) to approximately 500 specialty and acute-care hospitals to elicit information regarding their physician investment, ownership and compensation relationships. The DFRR forms delve into details about all types of hospital-physician financial relationships, including space and equipment rentals, personal-services arrangements and physician recruitment. The hospital must also provide the National Provider Identifiers of all physicians who have a

⁷ 72 Fed. Reg. at 38,184.

⁸ 72 Fed. Reg. at 38,185.

⁹ *Id.*

compensation relationship with, or ownership or investment interest in, the hospital. The DFRR also inquires into under arrangement relationships.

STARK LAW ENFORCEMENT: U.S. v. ROGAN

Penalties for violating the Stark Law can include mandatory repayment of claims billed for prohibited referrals and civil monetary penalties. However, as close observers know, the Stark Law has been mainly enforced not by CMS or the OIG, but by the Department of Justice and private whistleblowers under the guise of the False Claims Act (FCA). In these FCA lawsuits, plaintiffs may receive treble damages and substantial civil penalties of \$5,500 to \$11,000 for each claim submitted under an unlawful arrangement. The underlying theory relied upon is that the hospital, physician and/or other entity knowingly submitted “false” claims to the government by billing for health care claims in violation of the Stark Law.

Recently, after a bench trial, a district court, in *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006), issued a sweeping decision, ruling that the government was entitled to \$64 million in damages and penalties, including the full amount it paid for services.¹⁰ The verdict was based on a finding that Rogan, the former owner and CEO of a Chicago teaching hospital, executed teaching, EKG, consulting and medical directorship contracts with physicians that the court found were “grossly above fair market value” for services or were for services that were never performed. The court ruled that each of the claims filed during the relevant time period were “false because they falsely certified that [the hospital] was in compliance with the Anti-Kickback and/or Stark Statutes.” In computing damages, the court found that the government could obtain the full amount it paid for the health care services because the court believed that the government would have paid nothing had it known about the underlying violations of law.

Historically, the government has settled several False Claims Act actions alleging a violation of the Stark Law. Now, with its recent court victory, it is likely that the government will redouble its enforcement efforts. This underscores the importance of closely monitoring CMS’ latest proposed revisions to and interpretations of the Stark Law.

CONTACT INFORMATION

If you have questions about this proposed rule or the Stark Law, or need assistance with preparing or revising agreements for DHS or drafting comments regarding this proposed rule, please contact:

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¹⁰ *United States v. Rogan*, 459 F. Supp. 2d 692 (N.D. Ill. 2006).