

COMMENTARY

Collective Wisdom on The Stark Law

By Cynthia Y. Reisz, Esq.

In April health care attorneys from across the country gathered for the first day of what was designated the Stark Convener Session at Georgetown University's Public Policy Institute in Washington. The brainchild of the American Health Lawyers Association's Public Interest Committee, this meeting was attended by attorneys who represent hospitals, physicians, health plans, other providers and *qui tam* relators, some of whom were former government attorneys. Also in attendance were attorneys from the Centers for Medicare & Medicaid Services, the Office of Inspector General and the Department of Justice. However, they were merely observing, and would not participate in the discussions that ensued.

The purpose of the Stark Convener Session was to provide a forum for health care attorneys to pool their thoughts on and experiences with the Stark Law¹ and to develop a set of possible improvements to the law and its enforcement. Each attendee had prepared in advance a brief analysis, which was shared among the participants.² The analysis covered whether the Stark Law is working as intended, its practical impact (including some of the law's unintended consequences) and suggestions for improvement and in enforcement.

In its most simple form the Stark Law provides that if a physician (or immediate family member of the doctor) has a financial relationship with an entity that provides "designated health services³, the physician cannot make any referrals for DHS, and the entity cannot bill for them. What underlies that deceptively simple statute, however, are thousands of pages of regulations promulgated by CMS that define a myriad of exceptions to the prohibition.

All the participants agreed that a law designed to prevent physicians from over-utilizing services for financial gain is appropriate. Over the 20 years since the Stark Law was enacted, however, the regulations adopted

pursuant to the statute have taken on a life of their own and created a complex, confusing morass of fact-specific exceptions, often making compliance difficult without extensive research and legal guidance. It was an objective of the Convener Session to develop recommendations for Congress and CMS on how to simplify the means of achieving a worthwhile goal.

The session was aimed at providing a forum for health care attorneys to pool their thoughts and develop a set of possible improvements to the Stark Law and its enforcement.

The Stark Law's fundamental goal is to limit the influence of financial relationships on physician referrals. While the goal is certainly valid, the Stark Law imposes inflexibility in its implementation and enforcement methods. The intent of the parties is not an element of the Stark Law enforcement analysis, which means otherwise innocent parties that enter into a financial relationship that inadvertently violates the Stark Law are subject to the same consequences as parties who knowingly establish ownership or compensation relationships designed to reward physicians for referrals made for health care services that may not be appropriate for the patient.

Participants pointed to the in-office ancillary-services exception and its expansion over the years as an example of how the Stark Law has created more opportunities for potentially inappropriate financial relationships because it encouraged physicians to move ancillary services such as diagnostic imaging into their practices. As many industry observers have noted, the in-office ancillary-services exception is inconsistent with one of the Stark Law's legislative purposes because physicians have the greatest financial incentive to refer patients to their own practices.

The Stark Convener Session participants began their collective analysis with a robust discussion of positive and negative effects of the Stark Law. On the positive side, we generally agreed that compliance programs had become the rule and not the exception for health care providers as management put in place policies and procedures

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designed to educate personnel on the Stark Law and to encourage compliance. In addition, the Stark Law's prohibition of physician ownership in certain independent health care facilities likely caused a decrease in the number of physician-owned facilities. Finally, government prosecutors gained a weapon in their enforcement arsenal since Stark Law violations could serve as a basis for a False Claims Act action.

Some negative consequences of the Stark Law's enactment include the significant increase in legal and other expenses incurred by health care providers as they struggle to understand the complexity of the Stark Law regulations and to operate their services in compliance with all of them. Inevitably, providers violate the Stark Law, since even failure to obtain a signature on a timely basis for an agreement between a physician and a health care facility is prohibited, and currently no self-disclosure mechanism exists that might mitigate the punishment. In addition, the penalties for noncompliance are disproportionately staggering compared to the potential harm to the Medicare and Medicaid programs. Finally, the Stark Law imposes significant impediments to creative thinkers who are trying to develop programs to improve the delivery and quality of health care, since every financial relationship has to meet an exception. For example, some of the concepts currently being considered in federal health care reform bills such as bundled payments and accountable-care organizations may not comply with the Stark Law in its current form.

The structure of the Stark Law has created challenges for the health care industry and at the same time has made it easier for the government to bring FCA cases. Every financial relationship (as defined in the Stark Law) must meet an exception, and the government is not required to prove intent under a Stark Law enforcement action. Taking that a step further, the government then can bootstrap an FCA case onto a Stark Law violation.

The potential fines and penalties under an FCA case and a Stark Law enforcement action are both potentially very significant. For example, under an FCA case, violators may be assessed penalties of up to \$11,000 plus treble damages for each false claim, in addition to refund of the amounts paid. In a Stark Law enforcement action, violators may be liable for penalties of up to \$15,000 for each claim plus treble damages (in circumvention schemes, the penalties increase up to \$100,000 for each scheme) plus refund of the amounts paid for services rendered pursuant to prohibited referrals.

An additional challenge in the structure of the Stark Law is the extent to which a DHS entity's liability for a Stark Law violation can be disproportionate to the government's damages. In some instances, one Stark Law violation for

something as innocuous as an expired agreement conceivably could result in millions of dollars in recoupment for all payments made to the DHS entity as a result of referrals from one physician, plus fines, penalties and potential exclusion from the Medicare program.

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The Convener Session participants focused on suggestions for improvements in areas such as how the Stark Law could be more effectively enforced. First and foremost, participants recommended that Congress amend the Stark Law to give CMS flexibility to impose fines for technical noncompliance and discretion as to whether to require repayment from DHS entities for clinical services provided pursuant to a prohibited referrals. Historically, the Stark Law has been enforced through FCA proceedings in which the government and/or a *qui tam* relator have alleged that the provider that submitted the claim for reimbursement had made a false claim because the services had been provided pursuant to a referral made in violation of the Stark Law.

Recent changes to the FCA have increased the potential for Stark Law violations to trigger FCA exposure. Prior to these amendments, the retention of payments received for services provided pursuant to a prohibited referral created FCA liability if the claims were submitted in reckless disregard or deliberate ignorance of their truth or falsity. The Fraud Enforcement and Recovery Act of 2009⁴ expanded the reach of the FCA by including within the definition of claim the knowing and improper retention of an overpayment.⁵

Participant in the Stark Convener Session also posited the idea that the Stark Law's underlying premise be reversed so financial relationships between physicians and DHS entities would be permissible unless they contained one of a series of impermissible provisions. Other restructuring possibilities included adding the intent element already present in the anti-kickback statute⁶ or amending the statute to focus on ownership interests. Some participants were of the opinion that only compensation arrangements that varied with the volume or value of referrals made or other business generated between the parties, or were not fair market value, should be prohibited. Over the years, the anti-kickback statute became a more

powerful enforcement tool against improper compensation arrangements.

Unbalanced enforcement of the Stark Law was another topic of discussion during the Stark Convener Session. Although the Stark Law is directed at both the physician making the referrals and the entity providing the DHS and billing the government, in reality most of the settlements and FCA proceedings have involved only the DHS entities, the entities that bill the Medicare program for the prohibited referrals. Very few physicians and physician groups have been the targets of these investigations or the subject of settlements and corporate-integrity agreements. The Convener Session participants unanimously agreed that bilateral enforcement of the Stark Law is critical and might be easier to accomplish if CMS had more discretion and flexibility in its enforcement methods. Participants noted that if physicians were the targets of more enforcement actions, overall compliance with the Stark Law might increase.

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The Stark White Paper, as drafted by the Stark Convener Session participants, was finalized in June, and has since been circulated to congressional staffers, CMS, the OIG and other interested parties. It was the participants' hope that Congress would utilize the recommendations for change contained in the White Paper in passing legislation that empowers CMS to enforce the Stark Law directly, without basing it on an FCA action. Participants in the session believe a law giving CMS the ability to impose fines, penalties and sanctions based on its determination of the harm to the Medicare program would be more practical and serve as the basis for much stronger enforcement efforts against not only the DHS entities, but the physicians as well. In a positive move, Rep. Jim McDermott, D-Wash., (himself a physician) introduced a bill⁷ Sept. 14 that would require the secretary of the Department of Health and Human Services to adopt a new self-referral disclosure protocol for providers and suppliers who self-report violations of the Stark Law. Additionally, this bill would allow the Health and Human Services secretary to take into consideration factors such as the provider's cooperation and the nature and extent of the violations when determining the amount owed for the Stark Law violations.

The Senate Finance Committee's proposed health care reform bill⁸ also addresses Stark Law enforcement issues,

although in a more limited fashion. The proposed bill would authorize the OIG to create a new mechanism for providers to self-report actual or potential Stark Law violations. While the OIG could not alter the claim repayment obligations, it would have the discretion to impose penalties on the lower end of the range.

The FCA remains a critical enforcement tool in the government's arsenal of weapons to fight health care fraud and abuse. The modifications to the Stark Law suggested by the Stark Convener Session would provide the government with additional tools that will be critically necessary as the federal government considers legislation that would direct even more government funding into health care.

Notes

¹ 42 U.S.C. § 1395nn.

² The author of this article participated in the Stark Convener Session.

³ "Designated health services" means any of the following services (other than those provided as emergency physician services furnished outside the U.S.): clinical laboratory services; physical therapy, occupational therapy and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 C.F.R. § 411.351.

⁴ Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 (May 20, 2009).

⁵ 31 U.S.C. § 3729(b)(3).

⁶ 42 U.S.C. § 1320a-7b.

⁷ H.R. 3556.

⁸ S. 1796, America's Healthy Future Act of 2009.

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