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The “Stark” Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?

*Paula Tironi**



The Beazley Institute for Health Law and Policy was created during a decade of intense debate as to whether “physician self-referral” was good or bad for the health care industry. The debate led to the 1989 adoption of the federal Ethics in Patient Referrals Act, commonly known as the “Stark Law,” after one of its chief sponsors, Rep. Fortney “Pete” Stark.¹ The Stark Law prohibits physicians from referring a Medicare or Medicaid patient for certain “designated health services” (DHS)² if the physician (or a member of the physician’s “immediate family”³) has a direct or indirect financial relationship with the DHS entity, unless certain exceptions apply. The twenty years that have passed since the Stark Law’s adoption have brought increasingly complex regulations and intensifying confusion among physicians and DHS entities, who find it difficult to develop and implement compliance programs, report discoveries of noncompliance, and structure business transactions without risk of inadvertently violating the Stark Law.

Physician self-referral occurs when a physician refers a patient to a

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1. See 42 U.S.C. § 1395nn (2000).

2. DHS currently includes clinical laboratory services, physical therapy, occupational therapy, and 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.

3. The Stark regulations define “immediate family member” as “husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.” 42 C.F.R. § 411.351 (2008).

provider of certain health care services and stands to benefit from the referral due to an otherwise legitimate financial relationship with the provider. The financial relationship may be an ownership interest. For example, a physician or his or her family member may be the owner, or part-owner, of a health service such as an imaging center, radiation therapy service, or home health care provider. The financial relationship may also be in the form of a compensation arrangement. These may include salaried or contract positions, such as a medical directorship at a hospital to whom the physician refers patients, or arrangements such as the lease of space or equipment to or from a physician or his or her family member to a health care provider to whom the physician refers patients.

During the 1970s, physician self-referral was unregulated and fairly common. The 1980s brought new cost containment initiatives (such as the Medicare prospective payment system) as well as new diagnostic and therapeutic technology, creating the incentive for physicians, hospitals, and other entities to develop new ways to deliver health care services efficiently and profitably. Physicians invested financially and contributed their expertise and professional skills to entities such as specialized outpatient centers, joint ventures, and limited partnerships.

A 1981 study of clinical laboratories found that Medicaid patients whose physicians had an ownership interest in clinical laboratory services and whose physicians referred them for such services received an average of forty percent more tests than patients whose physicians did not own such an interest.⁴ The study also found that physicians who owned an interest in clinical laboratory services referred more of their patients for tests than did physicians without such an interest. A subsequent study indicated that patients of physicians who had invested in clinical laboratories received 45 percent more clinical laboratory services.⁵ That same study concluded that physicians who owned and used independent laboratories that were related to their practices received more reimbursement than independent laboratories that were not practice-related, indicating that practice-related laboratories received both higher prices and more services per patient.⁶

These studies led critics to argue that self-referral generates additional fees for physicians, resulting in overutilization of services that increase the cost and decrease the quality of health care. They claimed that self-referral creates an inherent conflict of interest for physicians, whose patients rely on their physicians to refer them for services without regard to the physician's

4. OFFICE OF THE INSPECTOR GENERAL, OFFICE OF ANALYSIS AND INSPECTIONS, REPORT TO CONGRESS *Financial Arrangements Between Physicians and Health Care Businesses*, 3 (1989).

5. Theodore N. McDowell, Jr., *Physician self Referral Arrangements: Legitimate Business or Unethical 'Entrepreneurialism'*, 15 AM. J.L. & MED. 61, 66 (1989).

6. *Id.*

financial self-interest. This conflict of interest was said to exploit both patients and payors such as Medicare and could lead to a loss of trust in the medical profession. Self-referring physicians were accused of emphasizing entrepreneurialism over professionalism, allowing financial self-interest to influence their professional judgment, and making excessive and unnecessary referrals for financial gain. Since patients generally defer to their physicians' recommendations, critics argued that self-referral should be prohibited in order to maintain doctors' integrity and autonomy. Physicians who invested in health services were accused of controlling both the supply and demand. Their financial self-interest was also said to eliminate checks and balances inherent in the relationship between a referring physician and an independent provider of health services.

Defenders of physician self-referral responded that the studies did not prove that physician-owned services were over-utilized, merely that these services had experienced *increased* utilization: there was no evidence that the increased utilization was clinically inappropriate. Moreover, they reasoned, certain other common industry practices, such as fee-for-service reimbursement, could also be said to provide an incentive for overutilization. The Federal Trade Commission came down on the side of permitting self-referral, arguing that prohibition would eliminate an entire class of knowledgeable physician investors. The FTC argued that physicians' involvement in developing health care services helps identify community need and that physicians' expertise can help assure quality services. According to the FTC, a facility that earns a reputation for unnecessary services or poor quality will lose business, so physician-investors have an incentive to provide appropriate and high quality services. Moreover, the FTC maintained that physician involvement leads to better relationships between referring physicians and health service providers. The FTC took the position that self-referral leads to greater efficiency and increased competition, which tends to decrease costs and improve quality. Prohibiting self-referral could therefore decrease access to health care services and result in a market for medical services that is controlled by non-physicians.

The federal Ethics in Patient Referrals Act or "Stark Law," adopted in 1989, prohibited self-referral of Medicare patients for clinical laboratory services unless an exception applied. Over the succeeding twenty years, Congress and the U.S. Department of Health and Human Services have augmented the Stark Law with a confusing series of statutory and regulatory additions until it reached its present form. The Stark Law now applies to both Medicare and Medicaid patients, involves a number of "designated health services" (DHS) in addition to clinical laboratory services, and includes additional exceptions. If a physician makes a referral in violation of the Stark Law, the DHS entity may not bill for the item or

service (if payment has already been made the DHS entity must refund the payment). Individuals and entities that violate the Stark Law can be subject to civil monetary penalties and exclusion from federal health care programs. The Stark Law is a strict liability statute so it is immaterial whether one intended to violate the law; an inadvertent violation can trigger liability. Given the highly detailed and technical nature of the Stark Law exceptions, a seemingly minor oversight, such as neglecting to obtain a party's signature on an agreement, can trigger disproportionately severe consequences for a physician or DHS entity with no intention or awareness of the statute or the violation.

Since its inception, the Stark Law and regulations have developed a complex and frequently changing array of exceptions to the general prohibition against self-referral. The exceptions contain requirements that pertain to details such as the signatories to written agreements, the number of hours an office is open per week, the square footage of leased space and formulas for calculating rent, the duration of employment agreements, and the value of incidental medical staff benefits such as free parking. Certain exceptions apply only to ownership and investment interests, others apply to compensation arrangements, and some apply to both. The Stark Law features exceptions available only to group practices (as defined by the regulations), regulations that affect the distribution of compensation within a group practice, and a "stand in the shoes" provision that can be used to attribute one physician's financial relationships to a colleague. Given this complexity and the strict liability nature of the statute, inadvertent noncompliance seems inevitable. An internal self-referral compliance program can help a physician or DHS entity prove good faith and obtain leniency in the event of a violation; however, the Stark Law's complexity and frequent revisions make it difficult for physicians and entities to develop and implement such programs.

Adding to the confusion, a physician or DHS entity that discovers it has violated the Stark Law has no clear procedure to follow. Self-disclosure of a Stark Law violation, which had been permitted under the Provider Self-Disclosure Protocol introduced in 1998 by the U.S. Department of Health and Human Services Office of Inspector General, is no longer available unless a violation of the federal anti-kickback statute is also involved. Even if self-disclosure were possible, the Centers for Medicare and Medicaid Services (CMS) is not authorized to negotiate a DHS entity's liability for submitting claims in violation of the Stark Law. Thus, if a hospital were to discover that over the course of several years it submitted claims to Medicare for services to patients referred to the hospital by a physician who had (or whose family member had) a financial relationship with the hospital, and the referrals violated the Stark Law due to an inadvertent minor oversight such as omitting a signatory to a written agreement, the

hospital would be required to comply with the harsh sanction of refunding the entire amount of all such claims and CMS would not have the authority to compromise the sanction.

The Stark Law is often enforced through False Claims Act litigation alleging that a claim for Medicare reimbursement for DHS services provided in violation of the Stark Law amounts to a false claim in violation of the Act. False Claims Act litigation can be brought by a whistleblower under the Act’s *qui tam* provision, and can add additional exposure to the already harsh Stark Law penalties, including treble damages, penalties of up to \$11,000 for each violation, costs and attorneys’ fees. Recent amendments to the False Claims Act through the Fraud Enforcement and Recovery Act of 2009 (FERA) could increase health care providers’ Stark Law exposure significantly. FERA applies False Claims Act liability not only to claims that are presented to the government, but also to claims submitted to another recipient of federal funds. Under FERA, the retention of payments received for services provided pursuant to a prohibited referral is sufficient to state a claim under the False Claims Act. The combination of FERA’s increased exposure to False Claims Act liability, health care providers’ inability to self-disclose if they discover a Stark Law violation, and the difficulties inherent in implementing compliance programs and the structuring and restructuring of health care business transactions in the face of complex and frequently changing Stark Law regulations, make the Stark Law a quagmire for the health care industry and misdirects time, money, and energy into Stark Law compliance and defense that should be devoted to patient care and improving health care quality and efficiency.

As the Beazley Institute enters its twenty-fifth year, the Stark law is receiving intensified scrutiny and renewed criticism. Twenty-five years have seen enormous changes in the health care industry, and some argue that today’s market, dominated by managed care networks and preferred provider organizations, controls overutilization without the Stark Law’s complexity and propensity for inadvertent violations. Others contend that today’s constantly changing, competitive health care industry requires innovative business transactions to provide high quality health care that is efficient and cost-effective. The Stark Law should minimize the potential abuse inherent in certain physician self-referrals while promoting innovative business transactions that make efficient and cost-effective high-quality health care available in communities where it is needed. The Stark Law should provide clear, understandable prohibitions and exceptions to simplify compliance programs and business transactions, develop a protocol for self-disclosure, implement sanctions in proportion to the nature and severity of violations and authorize the compromise of liability, while protecting health care providers from the risk of disproportionately harsh Stark Law and False Claims Act liability. Physician self-referral law should

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be reformed to benefit patients, professionals, federal health care programs, and the health care industry as a whole.