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The Difficulty of Doing Business with Stark in an Ever-Changing and Overly Complex Regulatory Environment: After Twenty-Years, Where Are We Heading

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The Difficulty of Doing Business With Stark in an Ever-Changing and Overly Complex Regulatory Environment: After Twenty Years, Where Are We Heading?

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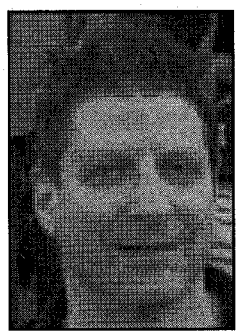
"What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law. The Ethics in Patient Referrals Act provides this bright line rule." Congressman Pete Stark, 1989[1]

I. INTRODUCTION



With all eyes on the Obama administration's push for an overhaul of the United States healthcare system, one milestone in connection with prior attempts at regulatory reform recently passed with little notice or celebration. Last year marked the twentieth anniversary of the enactment of "The Ethics in Patient Referrals Act of 1989,"[2] also known as "The Physician Self-Referral Prohibition Law" or simply, "Stark," named for its sponsor, Congressman Fortney "Pete" Stark of California. A critical look at Stark might serve as a warning to Congress should it wish to avoid the creation of another layer of healthcare regulation comprising wide-reaching

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1. 135 CONG. REC. H240-01 (daily ed. Feb. 9, 1989) (Statement of Rep. Stark).

2. Omnibus Budget Reconciliation Act of 1989 § 6204, Pub. L. No. 101-239, 103 Stat. 2106 (codified in scattered sections of 42 U.S.C.). This version of the statute is referred to as "Stark I" because it was replaced by the current version of the statute, which is sometimes referred to as "Stark II." Omnibus Budget Reconciliation Act of 1993 § 13562, Pub. L. No. 103-66, 107 Stat. 312 (1993) (codified in relevant part at Social Security Act § 1877, 42 U.S.C. § 1395nn (2008)).

and overly complex rules that are: (i) in need of continuous revision; (ii) understood by few; and (iii) chilling in their effect on the practice of medicine.

II. THE SELF-REFERRAL PROHIBITION: ITS CORE ELEMENTS

Reduced to its essence, Stark prohibits a physician from making a "referral" for a patient to an entity for the furnishing of an item or service that falls within one of eleven types of "designated health services" (DHS) covered by Medicare or Medicaid if the physician (or immediate family member) has a financial relationship with the entity furnishing the service, or unless a statutory or regulatory exception applies. Stark also prohibits the entity furnishing the DHS from submitting a claim for reimbursement, or otherwise billing Medicare, Medicaid, or any other person or entity for the prohibited referral.[3]

When Stark first became law in 1989 (Stark I),[4] the "self-referral" prohibition was limited to clinical laboratory services. Shortly after the statute took effect, its reach was dramatically expanded (Stark II)[5] to include the following eleven categories of DHS currently fall within the scope of the prohibition: clinical laboratory services, physical therapy services, occupational therapy services, radiology services including magnetic resonance imaging, computerized axial tomography scans, and ultrasound 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.[6] Considering that all inpatient and outpatient hospital services are included, the list is quite expansive.

Today, four categories of financial relationships implicate the prohibition: (i) a direct ownership or investment interest in the DHS entity; (ii) an indirect ownership or investment interest in the entity; (iii) a direct compensation arrangement with the entity; and (iv) an indirect compensation arrangement with the entity.[7] The definitions of these four types of relationships are not only complex, but they have also been subject to change over the past twenty years.

Generally, a physician's (or family member's) ownership or investment relationship with the DHS entity either through equity or debt triggers the prohibition; this also includes an interest in an entity that holds an

3. Social Security Act of 1935 § 1877(a), 42 U.S.C. § 1395nn (a) (2008).
4. *Supra* note 2.
5. *Id.*
6. § 1877(h)(6), § 1395nn (h)(6); 42 C.F.R. § 411.351 (2009).
7. § 1877 (a)(2), § 1395nn (a)(2); 42 C.F.R. § 411.354 (2008).

ownership or investment interest in any other DHS entity.[8] A compensation arrangement invokes Stark when most anything of value is exchanged between a physician (or family member) and the entity. In addition to financial remuneration, which may be paid as a salary, stipend or rental payment, anything of value such as a gift, meal, invitation to a picnic or party, or even a free continuing education class falls within the prohibition.

Presently, thirty-three Stark exceptions permit an otherwise prohibited referral—nine "general" exceptions involving ownership or investment and compensation relationships,[9] three ownership or investment exceptions,[10] and twenty-one compensation exceptions.[11] Fourteen of the exceptions were initially created by the statute,[12] while the others have been created by regulation.[13] The exceptions focus primarily on the terms of the financial relationship between the physician (or family member) and the entity to which the physician is making the referral. Since the general prohibition is so broad, the exceptions have become the rule; otherwise, almost no referrals would be permitted.

III. THE HISTORICAL CONTEXT FROM WHICH STARK EMERGED

Prior to the enactment of Stark, the Anti-Kickback Statute[14] had served as the government's main weapon against Medicare fraud and abuse. The Anti-Kickback Statute is an intent-based criminal statute that outlaws "kickbacks" or remuneration of any kind in exchange for patient referrals. Congressman Stark argued that although the Anti-Kickback Statute "reflect[ed] a firm resolve that patients should not be bought or sold. . .clever deal makers have found a loophole." "Referral schemes," according to him, "[were] being disguised as legitimate business arrangements, most commonly as partnerships involving referring physicians, but also as consulting or similar arrangements." The intent of the parties was "quite clear," he said, "to lock-in referrals by creating a web of financial relationships binding the referring physicians to the provider."[15] Mr. Stark complained that the Anti-Kickback Statute was ineffective at eliminating this form of fraud and abuse because of the difficulty in proving

8. This prohibition, however, does not apply in instances where publicly traded securities or bonds or ownership of shares in a large regulated investment company with assets exceed $75,000,000.

9. § 1877 (b), § 1395nn (b); 42 C.F.R. § 411.355 (2007).

10. § 1877 (c), § 1395nn (c); 42 C.F.R. § 411.356 (2007).

11. § 1877 (d), § 1395nn (d); 42 C.F.R. § 411.357 (2009).

12. § 1877 (b), (c) and (d); § 1395nn (b),(c) and (d) (2008).

13. 42 C.F.R. §§ 411.355 - .357.

14. Medicare and Medicaid Patient Protection Act ("The Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b).

15. *Supra* note 1.

a particular relationship was intentionally structured to induce referrals, and because the Government lacked sufficient resources to undertake prosecutions.[16]

He suggested to Congress that his bill would effectively target the three evils he believed arose out of self-referrals: compromised patient care, overutilization of services, and unfair competition. First, according to the Congressman, there was a risk that physician investors would not refer patients to the facility that provided the best care. Rather, the physician might refer patients to the facility with which the physician had financial relationships. Second, he stated patients might be referred for costly services that are unnecessary, and he cited government and academic studies which revealed higher utilization rates where physicians had financial ties with the providers. Third, he argued that "honest competition is undercut" by self-referrals, and he complained "suppliers are being forced to compete—not on price or quality—but on the cut they give physicians."[17]

Finally, he promoted his bill under the premise that it would provide regulation through clear bright line tests that would enable physicians to determine what exactly they may and may not do. Passage of his bill, according to Mr. Stark, would put an end to the "deal makers" and attorneys who put on seminars teaching people how to exploit new loopholes and since the proposed bill was to be a strict liability statute, the government would no longer need to prove violations were intentional.

IV. THE EVER-CHANGING NATURE OF STARK

The statute was enacted in 1989 (Stark I) and it was amended in 1993 (Stark II).[18] Since Stark II took effect, rules have been issued in ongoing phases in an attempt to fill in the many gaps left by the statute. Regulations were needed to clarify or expand the statutory definitions and exceptions as well as to create additional ones.

Proposed regulations implementing Stark II were first published in 1998, five years after the statute was enacted.[19] Many criticized the government for the length of time it took to propose regulations, and the Stark II Phase I Final Regulations were not released until 2001. The Phase I Regulations were not comprehensive, but were intended to be the first part of a bifurcated final rulemaking with additional regulations following. The Phase II Regulations were released and took effect in 2004.[20] Three years

16. *Supra* note 1.
17. *Id.*
18. *Supra* note 2.
19. Social Security Act, 63 Fed. Reg. 1659 (1998).
20. Social Security Act, 69 Fed. Reg. 16054, 16121 (Mar. 26, 2004).

later, in 2007, the Phase III Regulations were released and for the most part, they took effect later that year.[21] The Phase III Regulations were designed to respond to public comments from Phase II, and they address the entire regulatory scheme. These three phases of rulemaking were intended to be read as a whole; though they and their accompanying commentary are voluminous and confusing and have not served as the last word.

Rulemakings and revisions have also been included with the Medicare billing requirements on an ongoing basis. Each year CMS publishes the Physician Fee Schedule (PFS) Final Rule and the Hospital Inpatient Prospective Payment System (HIPPS) Final Rule which, amidst hundreds of pages, set forth the charges, codes and policies for Medicare billing during the following year. Important Stark issues are frequently raised in both the PFS and HIPPS rules. Most recently, in August of 2008 very significant changes to Stark were announced in the 2009 HIPPS Final Rule wherein portions of the Phase I, II and III regulations were reversed. [22]

After twenty years of trying to get Stark right, regulators continue to struggle with many aspects of this law, which they often find either in need of further tightening or loosening to redress the unintended consequences of a prior rulemaking. As a result, the Stark II rulemakings are scattered throughout various pronouncements. New regulations are often inconsistent with prior versions, and they have required the restructuring of many arrangements that were previously considered to be compliant with the law. In addition, disputes arising out of the interpretation of various provisions have begun to percolate into the nation's courthouses.

Also frustrating to the industry is CMS's habit of threatening changes it never finalizes. This habit leaves providers in a state of limbo, often for years, and it stifles investment in new technology. Yet, CMS makes no apologies. Rather, it describes its ad hoc approach as "measured and thoughtful," with the goal of "addressing program integrity concerns as they arise;" and the only thing it seems to indicate with certainty is that more change is to come. Indeed, the continuously changing character of this law is so widely recognized that it has become standard practice when drafting agreements that involve Stark issues to include clauses that permit the unwinding or restructuring of arrangements should the law change, yet again. When is enough enough?

V. THE DIFFICULTY OF DOING BUSINESS WITH STARK

Aside from the problem that the ever-changing character of this law makes compliance a challenge similar to shooting a moving target, Stark

21. Social Security Act, 72 Fed. Reg. 51012 (Sept. 5, 2007).
22. Social Security Act, 73 Fed. Reg. 48688 (Aug. 19, 2008).

roundly fails to fulfill its mission of providing easily understood bright line tests. While some components of the compensation exceptions are black and white and do include clear requirements such as the requirement that an agreement last for one year or be memorialized in a writing signed by the parties, other sections, which intend to offer greater flexibility, do not set out the bright line rules Mr. Stark envisioned. Consequently, the burden of proof to establish compliance, which falls on the provider, becomes more difficult to satisfy. Some exceptions, such as the "Fair Market Value Compensation Exception" require that the arrangement is "consistent with fair market value," "commercially reasonable," and that it "furthers the legitimate business purposes of the parties" in order to get around the prohibition.[23] Yet, these concepts, like beauty, may be in the eye of the beholder, and can easily lend themselves to different interpretations and, of course, to trouble. Simply ask the folks at Tenet.

In other sections, such as the In-Office Ancillary Services Exception[24] which addresses what referrals a physician may make within the office, the tests and definitions as to what constitutes "in the office" or within a physician "group" are enormously difficult to understand, and it should be asked whether this is fair and appropriate for a strict liability statute.

VI. CONCLUSION: A WARNING WITH RESPECT TO FUTURE EFFORTS AT REFORM

One hears that a growing number of physicians no longer wish to treat Medicare patients, and that our nation's seniors are having difficulty finding physicians.[25] Other physicians are enrolling in law school. This is, in part, the result of the increased regulation placed over them, and Stark deserves considerable blame for this. Physicians feel they are unduly constrained by a system that is too vast, too intrusive, and too complicated for them to understand. They are opposed to a strict regulatory framework that only addresses their financial relationships and leaves them no room to infuse professional judgment; and they are fearful of a regulatory environment where the failure to strictly comply with every aspect of the law—even inadvertently—can lead to disastrous consequences ranging from enormous fines to program exclusion.

Few clear trends have emerged from the rulemakings, and policy has shifted back and forth from accommodative to restrictive. It appears likely

23. 42 C.F.R. § 411.357(l) (2009).

24. Social Security Act § 1877 (b), 42 U.S.C. § 1395nn (b) (2008); 42 C.F.R. § 411.355(b) (2007).

25. Chris L. Jenkins, *The Doctor Is Out*,WASH. POST, Dec. 9, 2008, at HE01, *available at* http:www.washingtonpost.com/wp-dyn/content/article/2008/12/05/AR2008120503196.html.

this process will carry on ad infinitum, and at great expense to industry providers unless action is taken by Congress. Although some regulation of financial relationships between physicians and providers to whom they refer patients is necessary and appropriate, a more stable and limited approach is called for.

The difficulty of doing business with Stark these past two decades should serve as a warning with respect to current and future attempts at healthcare reform. Unnecessarily complex and overly restrictive regulatory intervention does not adapt well to evolving technologies, nor does it lead to efficiencies in the marketplace. Sadly, as our legislators embark on a new journey toward healthcare reform with the current political headwinds at their back, it appears likely Congress will cobble together more sweeping legislation that is filled with many holes. Bureaucrats will be left with another mess that will not only require decades to clean up, but will drive more physicians away from the practice of medicine.