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Stark Regulation: A Historical and Current Review of the Self-Referral Laws

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Introduction

Self-referrals to entities with which a practitioner has a financial relationship may encourage over utilization, and compromise the physicians' judgment as to whether the referral or service is medically necessary (DHHS, 2004).

H.R. 2264, The Omnibus Budget Reconciliation Act of 1993 (OBRA 93) contains provisions in section 13562 that address physician ownership and referral (Stark, 2000). OBRA 93, informally known as "Stark II", prohibits physician referrals for certain designated healthcare services (DHS) to entities in which the referring physician or an immediate family member has a financial interest (Stark, 2000; Siegal, 2004). The intended effect of this legislation is to prevent abusive referral patterns, and discourage physician ownership of various ancillary services to which Medicare and Medicaid patients are referred for DHS.

Physician ownership of healthcare businesses to which they refer patients has been debated in the literature (Hillman, Joseph, and Mabry et al., 1990; Mitchell and Scott, 1992a). These arrangements have attracted attention in the medical community, media, and from healthcare policymakers. Physician ownership and referral has also been the subject of government study and legislation (Hillman, Joseph, and Mabry et al., 1990; Mitchell and Scott, 1992a, 1992b). Evidence of overutilization leading to the current physician ownership laws was first reported in 1989 in an OIG report, that investigated physician owned laboratory ventures (Office of Inspector General, 1989). Following the OIG report the Florida legislator commissioned a study, which reported, increased utilization of physical therapy, diagnostic imaging, and clinical laboratory services (Joint Ventures Among Health Care Providers in Florida, 1991). In addition, the study found gross and net revenues were thirty to forty percent higher in physician owned facilities.

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The purported need for self-referral legislation is to ensure that physicians refer their patients to facilities that provide the best and most convenient care, to prevent costly services that are unnecessary, and to promote honest competition among healthcare professionals (Lindeke and Solomon, 1989). Physician self-referral and kickbacks has been an issue of debate as early as the 1890s (Margolis, 1993; Dean, 1995). The federal government had little interest in physician ownership, billing or referral patterns until the passage of Medicare and Medicaid in 1965. As originally enacted in 1965, the Medicare statutes did not include provisions related to fraud and abuse (AORN, 2004). In 1967 Health policy analysts Somers and Somers predicted that payments to providers would prove to be the "nerve center of the controversy" in the Medicare program (Gamble, 1989). Federal regulation relating to fraud and abuse began in 1972 with the Medicare Fraud and Abuse Statutes (AORN, 2004). These statutes contained anti-kickback provisions designed to combat the knowing and willful remuneration for inducing referrals (DHHS, 2004; Dean, 1995; AORN, 2004; Stout and Warner, 2003). In 1977 the Fraud and Abuse statute expanded the anti-kickback laws and upgraded violations from misdemeanor to felony offenses (AORN, 2004). Under the Medicare Fraud and Abuse statutes certain types of remunerations called "safe harbors" are allowed, however, critics contend that they may have the potential to induce improper referrals (Stout and Warner, 2003; APTA, 2004). In 1982 federal regulation was enacted that prevented physicians from referring patients to a Medicare certified home health agency if there was a direct or indirect financial interest (Flanagan, 1990). The Medicare and Medicaid Patient & Program Protection Act (MMPPPA) of 1987 combined both civil and criminal statutes (AORN, 2004). The MMPPPA contained prohibitions against false claims for reimbursement, failures to report forbidden business transactions, excessive charges, and remuneration for referrals (AORN, 2004).

On February 9, 1989, Fortney (Pete) Stark, democratic Congressman and then chairman of the House Ways and Means Subcommittee on Health, stated, "the integrity of our nations physicians is being threatened by seductive deals promoted by fast buck artists. Further proliferation of these ventures is bound to undercut public confidence in the medical profession" (Morse and Popovits, 1989).

State laws prohibiting self-referral arrangements have existed since 1983 with the first state law enacted in Delaware. State laws have varied in terms of regulations; in many states such as Florida, regulation may be of greater severity than federal laws. While it is recommended that healthcare practitioners become familiar with their state self-referral regulations a discussion of state laws is beyond the scope of this paper. This paper will

discuss the historical and legislative pathway leading to the current federal self-referral laws.

Statutory history of physician self-referral

The history of present day physician self-referral legislation dates back to August 10,1988 when Fortney (Pete) Stark introduced the Ethics in Patient Referrals Act (H.R. 5198) in an attempt to prohibit physician self-referral arrangements (Gamble, 1989), and reduce the costs of such arrangements to Medicare and its beneficiaries. Although Congress adjourned in 1988 without passing the bill (Gamble, 1989), Congressman Stark continued his legislative efforts to restrict self-referral. On February 9, 1989 Congressman Stark again introduced the Ethics in Patient Referrals Act (H.R. 939) (Lindeke and Solomon, 1989; Flanagan and Thiel; Morse, 1989). Similar to the 1988 bill, H.R. 939 prohibited physicians from referring Medicare patients to any healthcare entity in which they had an ownership or financial interest (Lindeke and Solomon, 1989; Flanagan and Thiel). The Ethics in Patient Referrals act was passed on December 19, 1989, in a diluted form, as part of H.R.3299-The Omnibus Budget and Reconciliation Act of 1989(OBRA 89) (DHHS, 2004; Stark, 2000). Section 6204 of OBRA 89, Public Law 101-239, informally known as "Stark I" prohibited the referral of Medicare patients to clinical laboratories by physicians who have or whose family members have a financial interest in those laboratories. Section 6204 of OBRA 89 added section 1877 to the Social Security Act (SSA)(DHHS, 2004; Stark, 2000; Centers for Menicare and Medicaid Services, 2004).

After passing OBRA 89, policy makers' monitored developments of joint ventures in areas other than laboratory services (Stout and Warner, 2003). On October 17, 1991; the Subcommittee on Health, the Subcommittee on Oversight and the Subcommittee on Ways and Means heard testimony from researchers on the status of physician ownership of healthcare facilities other than clinical laboratories. This hearing laid the groundwork for the expansion of the self-referral laws. On January 5, 1993, Congressman Stark introduced H.R. 345, the Comprehensive Physician Ownership and Referral Act of 1993. The purpose of this bill was to extend the Medicare ban on physician referrals to health care providers with which the physician has a financial relationship to all payers, expand the ban on self-referral to additional healthcare services, and to make changes in exceptions and other provisions under Medicare relating to compensation arrangements (Margolis, 1993). Although H.R. 345 was not passed, the language of this bill was adopted in a much-diluted form in section 13562 of OBRA 93 (Stark II). Stark II revised section 1877 of the SSA, and expanded the federal

self-referral ban to include ten additional DHS (1,19). The provisions of OBRA 93 also amended section 1903(s) to extend the self-referral prohibition to the Medicaid program.

Legislative history of H.R. 2264 and Stark II

Democratic Congressman Martin Olav Sabo introduced H.R 2264-OBRA 93' in the 103rd Congress on May 25, 1993. The proposed bill included Physician Ownership and Referral, which is currently referred to as Stark II. These provisions are cited in chapter 2, subchapter A, part 3, section 13562 of OBRA 93'. The bill passed the House by a recorded Democrat partisan vote of 219 yeas to 213 nays. The Senate passed the bill with an amendment on June 25, 1993, however, the vote was equally divided by forty-nine democratic yeas to 49 republican nays, with a leaning yea vote from democratic Vice President Al Gore. On august 10, 1993, Democratic President Clinton signed the bill, which became Public Law # 103-66. The provisions relating to physician ownership and referral may be found at Title XVIII (Stark, 2000) of the SSA "Health Insurance for the Aged and Disabled", part E - section 1877 "Limitation on Certain Physician Referrals". These provisions may also be found at Title 42 of the US code, chapter 7, subchapter 18, part D section 1395nn. A time-line for the legislative history is located in appendix B.

Regulatory history

Stark 1 legislation was enacted in 1989 and became effective January 1, 1992. The scope of Stark 1 was expanded in 1993 to include the new Stark II provisions as detailed in Section 13562 of OBRA 93. The Social Security Amendments of 1994 amended the list of DHS, changed reporting requirements, and modified some of the effective dates. The Health Care Financing Administration, now Centers for Medicare and Medicaid Services (CMS) published a proposed rule to implement the expanded law January 9, 1998 (Centers for Medicare and Medicaid Services, 2004; Physicians New Digest, 2004), which may be found in the Federal Register at 63 FR 1659. Public comments to the January 1998 proposed Stark II rule led to a 2-step rulemaking process titled Phase One and Phase Two (Centers for Medicare and Medicaid Services, 2004). Phase One primarily addressed the definitions applicable to the Stark law, general prohibitions, in-office ancillary exceptions, the impact on physician group practices, and financial relationships between physicians and entities that provide DHS. The Phase One final rules and regulations were issued Jan 4, 2001, and were effective

January 4, 2002 (Centers for Medicare and Medicaid Services, 2004). Phase One regulations may be found in the Federal Register at 42 CFR, parts 411 and 424. On March 26, 2004 CMS issued the Phase Two interim final rules with a comment period (Centers for Medicare and Medicaid Services, 2004; Wachler and Associates, 2004), which be found in the Federal Register at 69 FR 16054 (Centers for Medicare and Medicaid Services, 2004; Wachler and Associates, 2004). Phase Two addressed statutory exceptions related to ownership and investment interests, compensation arrangement exceptions, and reporting requirements (DHHS 42 CFR, parts 411,424). Phase Two also addressed public comments from Phase One and created new regulatory exceptions. Phase Two was effective July 26, 2004 (Centers for Medicare and Medicaid Services, 2004; DHHS 42 CFR, parts 411,424). A time-line for the regulatory history is located in appendix B.

Stark II regulations

CMS, in establishing the regulations for Stark II, has preserved the core statutory prohibitions of physician self-referral and has also made changes and clarifications in response to public comments. CMS stated that it "attempted to reduce the regulatory burden by broadening exceptions and creating new exceptions that pose no risk of fraud or abuse" in the Phase Two rules (DHHS 42 CFR, parts 411,424). The Stark II regulations prohibit a physician with a prohibited financial relationship from referring a Medicare patient to an entity that provides a DHS. In addition, the entity is prohibited from furnishing a Medicare claim or bill to any individual, third party payer or other entity for a service provided under a prohibited arrangement.

The current Stark II guidelines expanded the self referral prohibitions to include the following DHS in addition to the Stark I clinical laboratories ban: (a) physical therapy, (b) occupational therapy, (c) radiology services, (d) radiation therapy services and supplies, (e) durable medical equipment and supplies, (f) parenteral and enteral nutrients, equipment and supplies, (g) orthotics, prosthetics, and prosthetic devices and supplies, (h) home health services, (i) outpatient prescription drugs, and (j) inpatient and outpatient hospital services (Centers for Medicare and Medicaid Services, 2004; DHHS 42 CFR, parts 411,424; Guglielmo, 2004). Any service billed to Medicare in a hospital is considered a DHS, as hospital inpatient/outpatient services are part of the eleven listed DHS. Although inpatient and outpatient hospital services are designated services subject to prohibition under Stark II, a specific exception exists for "whole hospital" investment. As a result of this exception the number of physician owned specialty hospitals has tripled

since 1990 (Swartzmeyer and Killoran, 2004). As a result of this proliferation, a temporary eighteen-month ban on physician investments in new specialty hospitals was enacted as part of the Medicare Modernization Act of 2003 and is set to expire in June 2005.

The Phase Two final regulations describe specifically what services are included in each DHS subject to the laws in the March 26, 2004 Federal register (DHHS 42 CFR, parts 411,424; Guglielmo, 2004). CMS has created a list of specific CPT and HCPCS codes which will be updated annually.

Stark II highlights

The Stark II referral laws are subject to certain statutory exceptions. Without satisfying a statutory exception, a physician cannot make referrals of DHS to entities that they or their immediate family members have an ownership interest or a compensation arrangement with. An understanding of the definitions and exceptions are of particular importance in understanding the physician self-referral laws.

Generally, the exceptions of the Stark rules specify that compensation may not be based on the value or volume of referrals that the physician makes to the DHS entity. Fee for service arrangements do not violate the Stark laws provided that they are based on fair market value and that compensation does not vary based on referral volume or value (DHHS 42 CFR, parts 411,424). The agreements must be set out in writing and satisfy at least one exception that is listed in the Stark Phase Two regulations (DHHS 42 CFR). Fair market value may be established by any method that is reasonable and provides evidence of what is ordinarily paid for an item or service in the location at issue.

Percentage based compensation is permitted, provided the arrangement is established prospectively, is objectively verifiable, and is not changed over the course of the agreement based on the volume or value of referrals. CMS has defined the "set in advance" term to mean prior to the services being rendered. Compensation agreements established under Stark require a one-year agreement at minimum, however if the parties terminate such agreement within the year, both parties may not enter into a similar agreement for the original term of the terminated agreement. A "no cause" termination provision should be included in the agreement.

Remuneration is defined as any payment or other benefit made by a DHS entity directly or indirectly, overtly or covertly, in cash or in kind, to a referring physician or to an immediate family member of the physician. Remuneration includes a broad range of items and any such remuneration that does not satisfy one of the Phase Two exceptions such as the Medical

Staff Incidental Benefits or Professional Courtesy discounts is considered a violation. Medical Staff Incidental Benefits must be: (a) less than twenty-five dollars per occurrence, (b) offered to all staff members of the same specialty without regard to the value or volume of their referrals, (c) provided during time when the medical staff members are conducting related business activities, (d) used by the medical staff member on the hospital campus, (e) reasonably related to the delivery of services at the facility, and (f) not intended to induce referrals. Items such as pagers, computer access to facility records, free lunch and parking all meet the "on campus" exception provided they are less than twenty-five dollars per occurrence and offered to all members of the same specialty. This benefit may exceed the three hundred dollar exception.

Professional courtesy discounts may be provided to physicians on the entities medical staff, immediate family members, and to the office staff as long as the courtesy policy is set out in writing. The policy must be provided to all physicians without regard to volume or value of referrals to the DHS. This courtesy may not be offered to a federal health care program beneficiary unless a financial need is demonstrated. If the courtesy involves a co-payment or co-insurance reduction in part or in whole the insurance company must be advised in writing. Additional non-monetary compensation referred to as the "de minimus" exception permits compensation in the form of items or gifts (not cash or cash equivalents) that does not exceed three hundred dollars in any year (Siegal, 2004; DHHS 42 CFR; Wachler and Associates, 2004). This exception must not be dependent upon value or volume of referrals, therefore a hospital or facility may not give the physicians with higher volumes of referrals a gift unless all physicians received the same gift.

Under the 1998 proposed rule a referral included any request by a physician for a DHS. Due to responses during the comment period, services personally performed by a physician are no longer included in the definition of prohibited referrals (Siegal, 2004). Employer directed referrals have been addressed in both Phase One and Phase Two rules. A physician employee as part of his or her employment contract may have an agreement that they make referrals to a particular provider, practitioner or supplier. In these situations the compensation of the physician employee must be set in advance and in writing signed by both parties. Employers may as part of the conditions of employment require such referrals provided they do not violate fraud and abuse statutes and are not volume or value related. The exception does not apply, however, if the patient expresses a preference for a different provider, the patients' insurer determines that the referral should go to another entity, and if in the physician employee's judgment the referral is not

in the patients' best interest. This referral must also relate solely to the physician services covered by the scope of employment and be reasonably necessary to effectuate the legitimate interests of the compensation arrangement.

Group practice may comprise ownership by any number of entities. To constitute a group practice several key factors must be incorporated (Appendix A) (AAOS, 2004). These factors may be found in the Federal Register at 69FR 16054. A group practice has an advantageous benefit of referring patients to other members of the group and sharing profits generated by those referrals (AAOS, 2004). A group practice may also have a productivity bonus that is more liberal than a bona fide employment relationship. The group practice exceptions will not permit physicians to create a separate entity strictly for the purposes of splitting profits between them and the DHS. Bonuses allowed for group practice may include personal, incident to, and indirect structures as compared to a bona fide employment arrangement, which allows bonuses for personal services only. Compensation in group practice is not limited to fair market value and is not required to be set in advance. The volume and value restriction applies to both group practice and bona fide employment compensation. CMS has made it clear, for example, that group practices without walls and other pseudo-group arrangements will not be considered as true groups for purposes of the anti-self-referral laws (AAOS, 2004).

The "In-Office Ancillary" services exception has arguably been the single most important exception in the Stark law that has attracted the attention of the physical therapy profession. A physician may refer patients to a physical therapy center owned and operated by the same referring physician if these services are either performed in the same office suite in which at least one member of the physician group has a physician practice, or are performed in a location that is used for the centralized provision of the physical therapy services. In either of the two situations the physician, or a physician member of the group must provide direct supervision of the services (Siegal, 2004; Physical Therapy Services, 2004; Physical Therapists Applaud New Medicare Rule, 2004). The same building test has been revised in the phase two rules for clarification and is applicable to both group and solo practitioners (Siegal, 2004). The new phase two rules include three scenarios of which only one must be met to satisfy the same building requirement (Siegal, 2004). Under the first test the DHS is furnished in the same building if the building is one in which the referring physician or group practice has an office that is open at least thirty-five hours per week and that the referring physician or one or more members of the group regularly practices in that office at least thirty hours per week. Under the second test, the service is

furnished in the same building if the building is one in which the referring physician or his or her group practice has an office that is normally open to their patients at least eight hours per week, and that the physician personally practices non DHS services in at least six hours per week. Under the third new test the service is furnished in the same building if the building is one in which the referring physician or his or her group practice, has an office that is open at least eight hours per week, and the physician or members of his group regularly practice non DHS services in at least six hours per week (Siegal, 2004; DHHS 42 CFR).

Physicians are prohibited from leasing space in facilities providing DHS in an attempt to bill for services that the DHS provides. Phase Two regulations have also addressed the issue of a mobile entity as an in-office ancillary service (DHHS 42 CFR). The Phase two rules have stated that mobile equipment will qualify for the in-office ancillary exception if it is located inside the same building as the practice. A garage, trailer, or mobile vehicle is not considered acceptable under the exceptions, and constitutes a violation. CMS has not specified in the rules as to whether an ancillary service in the same building on a different floor qualifies under the in-office ancillary exception Lastly, the in-office exception applies to physicians that routinely provide ancillary services inside a patient's home as part of their principal medical practice. Long-term care and nursing home facilities will not qualify under this exception.

Rural Providers may be considered an exception, provided that the entity is not a specialty hospital and that at least seventy-five percent of the services must be provided to individuals residing in that rural area (DHHS 42 CFR; Guglielmo, 2004). CMS has also created an intra-family rural referral exception provided there is no other provider who may furnish the service in the patients home or within twenty five miles from their home (Siegal, 2004). Phase Two regulations have provided a ninety day grace period for noncompliance with the rural provider exception if the area is re-designated as a non-rural area (Siegal, 2004).

The Phase Two rules expanded the academic medical center exception in the hope of providing more guidance and latitude to academic medical centers. The exception exempts referrals from a physician who is a bona fide employee of the academic medical center as long as he or she provides substantial academic services or clinical teaching services (Siegal, 2004). Hospitals and health systems are allowed to qualify as an academic medical school provided certain conditions are met (Wachler and Associates, 2004).

Physician recruitment exceptions have been modified in Phase Two (Wachler and Associates, 2004). The physician recruitment exception applies to remuneration that is provided to a physician in order to induce the

physician to relocate to the area or to join a hospitals medical staff. The requirements state that a physician need not move their residence to qualify. However, they must relocate their practice location at least twenty-five miles or to a location such that at least seventy-five percent of the patients whom the recruit sees are not the same patients from their previous practice location (Siegal, 2004). Hospitals under this exception are permitted to provide recruitment benefits to a group practice that employs a recruit. Under this exception, physicians are not allowed to impose a practice restriction such as a restrictive covenant, and the arrangement may not be based upon value or volume of referrals. Employing physicians are legally prohibited from restricting the recruit from practicing in the area if the employment is terminated (Siegal, 20004). A medical student or physician who is in practice for less than one year is not subject to the relocation requirements (Siegal, 2004).

Physician retention exceptions are discussed in the Phase Two rules. The new retention payment exception applies to physicians in a health professional shortage area (HPSA) in any medical specialty. HPSA is an area designated as a HPSA under the Public Health Service Act, and is defined as an urban or rural area that has a health manpower shortage. The regulations also allow a hospital to provide malpractice coverage to obstetricians provided at least seventy-five percent of the patients who are treated by the physician resides in an HPSA, or underserved area. CMS has adopted standards that must apply to satisfy this exception. Parties entering into a retention compensation agreement should scrutinize their arrangements to avoid a Stark or anti-kickback violation.

The Phase Two regulations have addressed the "isolated transaction" definition, which now permits installations of payments when a practice is sold as opposed to full payment at closing (Siegal, 2004). This exception would apply, provided the installation amount is agreed upon prior to the first installation and that payments do not take into account referral value or volume (Siegal, 2004).

CMS has defined compliance training as encompassing the basic elements of a compliance program and federal health care issues (Siegal, 2004). Hospitals are allowed to provide compliance training to physicians who practice in the hospitals community and their staff. The exception does not include providing compliance services or continuing medical education (CME) training (Siegal, 2004). Compliance services or CME training must meet another exception or be provided to the physician at fair market value.

Leasing arrangements are permitted for space and equipment provided the lease: (a) is in writing, (b) specifies the exact space or equipment covered, (c) details equipment use, (d) is for a one year term at minimum, (e) is based

on fair market value, and (f) would be commercially reasonable for parties that may not have the potential to generate referrals (Siegal, 2004). Month to month holdover leases are allowed for a duration not to exceed six months, provided the terms are consistent with the original lease. The lease agreements may be terminated early, however, the providers may not enter into a similar agreement within the first year of the original lease (Siegal, 2004).

Entities that provide DHS are not required to report all financial arrangements with physicians. However, copies of the financial arrangements must be retained by each DHS entity and be produced within thirty days if requested by CMS or the Office of the Inspector General (OIG) (Centers for Medicare and Medicaid Services, 2004). Information that may be requested includes the name and unique physician identification number (UPIN) of each physician who has a financial relationship with the entity, the name and UPIN of each physician who has an immediate family member who has a financial relationship with the entity, and the covered services provided by the entity. Physicians must also upon request, disclose the nature of their financial relationship as evidenced in records that the entity knows about in the course of business (Centers for Medicare and Medicaid Services, 2004).

CMS, in response to comments created a temporary grace period for all exceptions that temporarily fall out of compliance, provided the arrangements have satisfied another exception for at least one hundred-eighty consecutive days prior (Siegal, 2004). The exception grace period is for ninety days and CMS has required parties to take steps to rectify non-compliance as expeditiously as possible. At the conclusion of the ninety-day exception parties must satisfy an exception or have terminated the prohibited arrangement. The three hundred dollar non-monetary compensation and Incidental Medical Staff benefit exceptions are not included (Siegal, 2004).

Stark regulations and the anti-kickback statutes

The Department of Health and Human Services (DHHS) has stated that the Stark regulations and the anti-kickback statutes are two totally independent laws (DHHS, 1999). The DHHS's Office of the Inspector General (OIG) has recognized the similarities in these laws and subsequently published an explanation of their differences and similarities in the Federal Register dated November 19, 1999 (DHHS, 1999). Stark and anti-kickback statutes are both federal laws directed at prohibiting the influence of financial incentives in medical decision-making. The anti-kickback laws apply to anyone whereas the Stark laws apply to physicians and their families. Stark laws are civil

matters while antikickback violations are both civil and criminal. Violations of either of the statutes may result in exclusion from the Medicare and Medicaid programs. Qui Tam (whistle blower) suits are permitted for violations of both the Stark and anti-kickback statutes. Stark laws are generally self-enforcing by the mere existence of a violation (Stark, 1999). An anti-kickback violation, however, requires proof of knowing and willful illegal remuneration such as bribes or rebates (AORN, 2004). The prosecutorial burden of proving unlawful intent limits the utility of the anti-kickback statute (DHHS, 2004). Stark laws create a powerful incentive to comply with the law since the simple existence of a violation may result in exclusion from Medicare payment and a civil fine. Unlike the Stark laws, which apply to DHS only, entities providing any service that is paid for in whole or in part by a federal payer may risk an antikickback violation (Gosfield, 2004). Meeting the safe harbor exceptions for the anti-kickback laws will not automatically indicate a legal exception to Stark (AAOS, 2004).

Influence on self referral: pros and cons

Influence has been based on anti-trust concerns, professional autonomy, fair competition, fraud and abuse concerns, financial costs, and ethics. Market-preserving regulatory policies in healthcare have been developed as a means to establish and enforce rules and conduct for providers in a truly anti-competitive market (Longest, 2002). Physicians may invest in ancillary services as a measure to reduce overhead costs and diversify their project risks (Mitchell and Scott, 1992a). Physicians contend that their ownership affords them the ability to coordinate treatment and monitor outcomes (Dean, 1995), however, evidence has shown that physician owners do not provide or supervise services at facilities of which they have ownership (Mitchell and Scott, 1992a).

Arguments against the current self-referral laws include issues relating to patient care, access to services, and continuity of care. Self-referral laws have been considered too restrictive; as a blanket ban on certain designated health services does not target the practitioners who are responsible for overutilization. Physicians cite the laws are too severe and decrease their ability to utilize clinical judgment, as treating a patient involves referral decisions. Proponents of self-referral arrangements have argued that the current laws are unnecessary, as the fraud and abuse statutes and managed care have had a direct impact on medical services already. Proponents also state that the anti-kickback laws sufficiently curb abuse making additional legislation unnecessary (Morse, 1989). Physicians involved in self-referral

arrangements have argued that they are necessary adjustments to decreased revenues that have occurred in the health care sector over the last few decades (Mitchell and Scott, 1992b). Some proponents argue that physicians are in the best financial position to bring new state of the art services to the communities (Dean, 1995) and in certain cases increase access to services in underserved areas (Mitchell and Scott, 1992a; Rosenfield, 1984). Purported benefits to physicians include increased ability to compete, improved access to capital financing, diversification of project risks, and improved quality control (Mitchell and Scott, 1992a; 1994b; Rosenfield, 1984).

Critics of self-referral contend that the current anti-kickback laws are ineffective and lead to the problem of improper self-referral arrangements. Critics of joint ventures maintain that physician owned joint ventures are direct conflicts of interest (Mitchell and Scott, 1992a; Relman, 1985) and that self-referral for profit may influence the physicians to place their needs ahead of the patient. Critics also propose that joint venture facilities have the ability to treat patients with only good insurance subsequently decreasing economic access (Mitchell and Scott, 1992a; 1992b). Evidence has shown that non-licensed workers are often substituted for licensed professionals in joint venture situations (Mitchell and Scott, 1992a; DHHS, 1994). Self-referral arrangements may reduce referrals to non-joint venture providers, which may adversely affect the patients' choice of services and options. Governmental and academic reports as well as public perception and special interest groups have influenced self-referral regulation.

The American College of Physicians (ACP) recognizes the conflict of interest when physicians refer to outside facilities of which they have ownership and do not provide care (ACP, 2004). It is their position that "physicians may, however, invest in or own health care facilities when capital funding and necessary services are provided that would otherwise not be made available (ACP, 2004)." The ACP in their ethics manual encourages disclosing these interests to patients, and establishing safeguards against abuse.

The American Medical Association (AMA) believes that the current self-referral laws are too restrictive and that patient benefit, convenience and access to healthcare facilities must remain the primary concern (Margolis, 1993; Dean, 1995). In 1986, prior to the proposed Stark regulations the AMA released conflict of interest guidelines, which included disclosure of ownership recommendations (Dean, 1995). The AMA was not in support of Stark 1 legislation in 1989. In 1991, however, the AMA declared self-referral inconsistent with best choice for patient (Dean, 1995). The AMA supports: (a) full disclosure of ownership interests to patients, and (b) allowing patients an informed choice of services. The official position of the

AMA is that "In general, physicians should not refer patients to a healthcare facility outside their office practice at which they do not directly provide services when they have an investment interest in the facility (Mitchell and Scott, 1992b). The AMA has also stated that the referral of patients to facilities in which physicians have an ownership interest is permissible provided that patients are apprised of this relation and have other choices, and provided that physicians always act to their patients best interests (Hillman et al., 1990).

The American Academy of Orthopaedic Surgeons (AAOS), in a position statement has stated that while self-referral for profit is unethical, physician ownership arrangements, per se do not necessarily result in inappropriate or excessive utilization (Dean, 1995). The AAOS has supported full disclosure of ownership (Dean, 1995). James W. Strickland M.D., in a statement before the House Ways and Means Subcommittee on Health in 1995, stated "while the Academy supports the intent of the so-called Stark II law to insure that Medicare patients are protected from fraud and abuse, there are some unintended consequences which neither protect patients nor encourage efficient and effective health care" (AAOS, 1995). Strickland (AAOS, 1995) cited situations where patients are sent elsewhere for services such as radiographs, which leads to delays in their diagnosis and inconvenience to the patient.

The American Physical Therapy Association (APTA) has strongly supported the prohibition on physician self-referral. The APTA has asserted that self-referral arrangements limit access to health care, eliminate free market values, and inhibit physical therapists development of professional autonomy (Dean, 1995; APTA, 2004). The APTA opposes arrangements that create incentives to underutilize or overutilize services for personal or institutional profit, or that are in any way based on the financial interest of the referral source (APTA, 2004). It is the position of the APTA that "Physician self-referral creates a potential conflict of interest and must be avoided to protect the health care consumer." It is the APTA 's position that physical therapists are the only professionals who provide physical therapy examinations, evaluations, diagnosis, prognosis, and interventions.

The American Clinical Laboratory Association (ACLA) has long supported legislation prohibiting lab ownership by physicians who are in a position to make referrals. The ACLA has stated that ownership by physicians who make referrals "creates a captive market of doctors who cease ordering of tests on the basis of price, quality and service; and instead order tests from the laboratory that they have an investment interest"(Angell, 1982). The General Counsel of the ACLA has supported the ban on self-referral, as they believed there should be an end to harmful arrangements

like self-referral, which distorts healthcare delivery (Dean, 1995).

Studies on joint-ventures and self-referral

Evidence suggests that physician ownership influences over utilization in a variety of services and increased costs healthcare services. While there are numerous anecdotal sources in the literature on the pros and cons of joint ventures, the specific problems leading to legislation have been well documented in the literature.

In 1989, the OIG reported that patients of referring physicians who own or invest in independent clinical laboratories received forty-five percent more services than Medicare patients in general. They reported costs of twenty eight million dollars to the federal government as a result of increased utilization of services provided by laboratories (OIG, 1989).

The Florida legislature commissioned a study (Joint Ventures Among Health Care Providers in Florida, 1991) under Chapter Law 89-345, designed to evaluate the effects of joint venture arrangements on access, costs, charges, utilization, and quality of care. The results of the study published in September 1991 indicated that problems existed in clinical laboratory services, diagnostic imaging, and physical therapy services. Using the information obtained in this legislative mandate the authors evaluated the effects of physician ownership of freestanding physical therapy and rehabilitation facilities on utilization, charges, profits, and service characteristics (Mitchell and Scott, 1992a). This study also found that licensed physical therapists in non joint venture facilities spend about sixty percent more time per visit treating physical therapy patients than joint venture facilities. In addition, joint venture facilities generate more of their revenues treating patients with well paying insurance (Mitchell and Scott, 1992a).

The OIG released a report in 1994 on physical therapy in physicians' offices (DHHS, 1994). The study used a stratified random sample of three hundred beneficiaries of which one hundred received physical therapy in an independent practice physical therapy office, and two hundred in a physician's office. The results indicated that most of the physical therapy records from physicians' offices had no treatment plans with goals, and no objective evaluations. Four out of five cases reimbursed did not represent true physical therapy services and were based on physicians coding of physical medicine procedures. The OIG estimated that in 1991, forty-seven million dollars was inappropriately paid for physical therapy services performed in physicians' offices (DHHS, 1994).

Mitchell and Scott (1992b) examined physician ownership of health care

businesses that provided diagnostic testing, or other ancillary services. This study was conducted in Florida based on data collected under a legislative mandate. The study found that at least forty percent of Florida physicians involved in direct patient care have an investment interest in a health care business to which they may refer their patients for services; over ninety-one percent of the physician owners are concentrated in specialties that may refer patients for services. About forty percent of the physician investors have a financial interest in diagnostic-imaging centers. These estimates indicate that the proportion of referring physicians involved in direct patient care who participate in joint ventures is much higher than previous estimates suggest.

Studies have found that financial incentives based on performance or referral patterns can lead physicians to alter their practice patterns. A before and after study of fifteen physicians found that when compensation changed from a flat salary to a system of monetary incentives laboratory tests increased twenty-three percent and radiographs sixteen percent (Hemenway et al., 1990).

A study comparing the frequency and cost of diagnostic imaging concluded that self-referring physicians used imaging at least four times more often than physicians who referred to a non-physician owned facility. The authors concluded that the differences could not be attributed to the physicians' specialty or the diagnostic classifications of the patients (Hillman et al., 1990).

Hillman et al. (1992) compared charges and utilization of diagnostic imaging in a broad range of clinical presentations and found that physicians who own imaging technology employ imaging significantly more often than do physicians who refer their imaging examinations to non-entity radiologists. The study also found charges to be 1.6 to 6.2 times higher in the physician owned groups (1992).

One study examined the effects of the ownership of freestanding radiation therapy centers by referring physicians who were not providers of the service. The study compared data in Florida where forty-four percent of such centers were joint venture to other areas where only seven percent of centers are joint ventures. The results found frequency and costs of radiation therapy to be forty to sixty percent higher in Florida than in the rest of the United States. The study also found that joint ventures in Florida provide less access to underserved areas (Mitchell and Sunshine, 1992).

Swedlow and Johnson analyzed the effects of physician self-referral on physical therapy, MRI, and psychiatric evaluation in the California workers compensation system. The results of the analysis revealed that physicians who self referred were likely to refer to physical therapy 2.3 times more often than the independent referral group. The mean cost of psychiatric

services was significantly higher in the self-referral group. The self-referral physicians were found to order MRI's that were medically inappropriate more often than the independent group (1999).

The U.S. General Accounting Office (GAO), issued a report based on imaging referrals from information obtained by researchers in Florida for the health care cost containment board and on Medicare claims for imaging in 1990. The GAO found that physician owners ordered fifty-four percent more MRI scans, twenty-seven percent more CT scans, and twenty-two percent more radiographs (1994). The report also indicated that physician owners had higher referral rates than non-owners of their same specialties.

The evidence has rejected criticism that these studies were biased by specialty or diagnostic category. Confounding issues to consider may include higher levels of use secondary to convenience, or because physicians who use such services or more likely to acquire their own (Hillman, et al., 1990).

Evaluation

Congressman Stark, in a statement to the House of Representatives in 1999, reported that the self-referral laws have prevented billions of dollars worth of business deals that would have abused laws through overutilization. On May 13, 1999 at a House Ways and Means Health Subcommittee hearing, HHS Inspector General D. McCarty Thornton testified that the many of the joint ventures of the 1980s have decreased significantly (Stark, 1999). The Department of Justice (DOJ), in a September 29, 2000 letter to Congressman Stark stated they had over fifty matters under investigation or in litigation as a result of qui tam allegations (DHHS, 2004; Stark, 2000). This letter also stated that several of the investigations were the subject of settlement negotiations in which millions of dollars would be recovered for the Medicare Trust Fund (Stark, 2000). Since 1995, physician payment arrangements involving payments that vary with referrals have largely disappeared from the health care industry. There has not been any disruption to the medical industry as a result. Fines and civil penalties recovered under the fraud and abuse law, as well as additional appropriations, are being transferred to the Medicare Trust Fund. Fiscally the government has benefited from legislation as it allows recovery of money that was claimed improperly from the Medicare Trust Fund (Stark, 2000). These statutes identify a clear role that the government will assume by not paying for items or services that are violations of the self-referral laws and for recovery of those funds. In 1997 the DOJ recovered twelve million dollars in a settlement from a national hospital chain secondary to allegations of

violations of the physician self-referral prohibitions (DHHS, 2004).

Stark laws have had a profound but not always well-directed effect on healthcare (Dechene and O'Neil, 1996). While the successes attributed to self-referral laws have included financial recovery and a decline in abusive situations, reports have not established the direct benefits for which patients have derived. Physicians are responsible for utilizing the most efficient means to care for their patients, however, self-referral restrictions may prevent the efficient integration of diagnosis and treatment that is afforded with physician owned entities. Continuity of care and inter-practitioner communication may be compromised when the physician is required to refer a patient to another facility. In addition to patient care effects, a decline in radiology fellowship and residency applications has been attributed to self-referral legislation (ARC, 2004). The potential negative impact on patient care arising from these restrictions has not been well discussed in the literature. Future research must examine both the positive and negative outcomes on self-referral laws.

Sanctions and penalties

The costs of non-compliance have influenced providers to scrutinize their arrangements. The penalties of violations may include claims denials, civil monetary penalties in excess of $10,000 per day for inadequate financial relationship reporting, $15,000 for each non-compliant service, penalties in excess of $100,000 for alleged circumvention schemes, Medicare and Medicaid program exclusions, and potentially even greater financial liability and exposure from government-initiated or whistleblower lawsuits under the False Claims Act (Lindeke and Solomon, 1989; Morse and Popovits, 1989; DHHS, 1999). The prevailing liability standards under the False Claims Act, Stark laws, and other legal authorities essentially dictate that every hospital, physician and provider of DHS should have in place a formalized process of reviewing business arrangements and financial relationships.

Conclusion

Self-referral legislation emerged in an effort to protect potentially abusive referral patterns, which allow economic incentives to take precedence over the medical interests of the patient (Mitchell and Scott, 1992b). The ability to effectively manage the care of a patient is dependent upon the ability of the physician to make decisions regarding referrals and to monitor quality of care. Physicians have the ethical obligation to ensure care that is in the best interest of his or her patient (Dean, 1995), and to remove financial incentives

from referral decisions. Evidence has shown that referrals to entities with which physicians have a financial relationship encourages overutilization and leads to increased costs (DHHS, 2004; Joint Ventures Among Health Care Providers of Florida, 1991). Physician ownership prevents fair competition as this type of arrangement holds a captive referral system. This captive referral system limits referrals to non-joint venture providers and may adversely affect the patients' choice of services and options. In addition Evidence shows that non-licensed workers are often substituted for licensed in joint venture situations (Mitchell and Solomon, 1992a).

Medical ethics evolved to protect the doctor-patient relationship, and to support the role of physicians as brokers or advocates for their patients within the health system. Ethically conducted medical treatment puts the healthcare needs of patients first, ahead of profit. Self-referral is an abrogation of the doctor's ethical responsibilities and a breach of the doctor-patient relationship (Fitzgerald, 2001). When costs are met by a third party, such as an insurer, the problem may be aggravated by the absence of a price signal. In an ideal market the consumer would be sufficiently informed to choose from a range of options and purchase the most suitable product, based on outcomes, preference and cost (Fitzgerald, 2001). However, the health system is not ideal. It is very complex, and there is considerable discrepancy between the information available to the consumer and that available to the provider. In fact, most people do not become sufficiently informed to make logical choices until well after they have become a consumer of health services (Fitzgerald, 2001). As a result of consumer and government concern about the effects of "for profit" delivery of healthcare in the United States, federal laws governing financial incentives and self-referral are necessary.

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Appendix A: Group practice definition

To qualify as a group practice under Stark, an entity must meet all of the following requirements:

- Presence of two or more physicians.
- The practice is legally organized as a partnership, professional corporation, foundation or faculty practice plan.
- The primary purpose of the company is physicians' practice (that is, the

company is not just formed to provide ancillary services).
- Each physician who is a member of the group must furnish substantially the full range of services that he or she routinely provides through the joint use of shared office space, facilities, equipment and personnel.
- Substantially all of the member physicians' services are furnished through the group and billed under the groups assigned billing number, and payments are treated as receipts of the group.
- The overhead expenses and income of the practice are distributed according to predetermined methods.
- There is a unified business with centralized decision making and consolidated billing, accounting and financial reporting.
- No member physician directly or indirectly receives compensation based on the volume or value of referrals generated by the individual except for permitted profit distributions and personal productivity bonuses.
- The member physicians personally conduct at least 75 percent of the physician-patient encounters of the practice.

Appendix B:

Legislative History of H.R. 2264 and Stark II

- May 25, 1993 Democratic Congressman Sabo introduces H.R.2264-OBRA 93'(2).
- June 10, 1993 Bill was placed on Senate Calendar.
- June 25, 1993 Bill passed by the Senate with an amendment. Leaning vote from then democratic Vice-President Al Gore.
- July 14, 1993 Congressman Sabo urges House to disagree with Senate amendment and proceed to conference.
- August 6, 1993 Senate and House agree to file a conference report.
- August 10, 1993 Democratic then President Bill Clinton signed the bill which became PUBLIC Law #103-66(20).

Regulatory History

- January 1, 1992 Stark I legislation became effective.
- August 10, 1993 Stark I is expanded to include the new Stark II provisions in Section 13562 of OBRA 93.
- January 1, 1995 Stark II law became effective (19).
- January 9, 1998 HFCA (now CMS) published proposed rule to implement Stark II, which led to a 2-step rulemaking process, titled

Phase One and Two (19).

- January 4, 2001 CMS issued Phase One rules and regulation.
- January 4, 2002 Phase One rules and regulations were effective.
- March 26, 2004 CMS Issued Phase Two final rules with comment period.
- July 26, 2004 Phase Two rules and regulations of Stark II became effective (19, 24).

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