

**Reasons for Disclosure in the
Physician-Patient Relationship:
How Physician Conduct and Reimbursement
Methodologies Lead to Fraud and Abuse in Medicare**

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Boca Raton

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Dissertation.com
Boca Raton, Florida
USA • 2010

ISBN-10: 1-59942-327-8
ISBN-13: 978-1-59942-327-2

ABSTRACT

The solvency of the Medicare Trust Fund has been debated for the past twenty-five years and despite various stop-gap measures, fraud and abuse continues. Public policy in the form of Stark legislation, anti-kickback laws and false claims act were enacted to reduce over-utilization of services, prohibit self-referral and inducements for patients and services.

Despite public policy and continued prosecution of fraud, Medicare reimbursement methods fail to control physician conduct of over-utilization and inducements for referrals.

Following the concept of the informed consent doctrine and the theory of fiduciary trust in the patient-physician relationship, it is the author's thesis that transparency and disclosure with respect to physician prescription and referral practices can mitigate the over-utilization problem.

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I. Introduction

In his January 20, 1961 Inauguration speech, President John F. Kennedy spoke these timeless words, “And so, my fellow Americans: ask not what your country can do for you—ask what you can do for your country.”¹

President Kennedy’s administration ushered in a new era of concern for the health and welfare of all citizens. Four years later in 1965, Medicare became law; its intent was to proffer a health plan for seniors and the disabled. Now forty-four years later, Medicare and health care are in trouble as costs spiral out of control, and reducing those costs require a new approach.

This dissertation examines the issue of the impact of fraud and abuse on the Medicare Trust Fund and its solvency. My primary focus will be on how previously enacted statutes designed to control physician behavior fails to achieve the goal of cost containment and fraud prevention. The second focus isolates the physician-patient relationship, including potential legal remedies available to patients harmed by physician conduct for failure to disclose conflicts of interests.

Accordingly, I raise the issue whether The Medicare Trust Fund (the “Trust Fund”), depended upon by so many individuals for health care coverage, is adequately protected from abuse. Types of abuse include but are not limited to financial fraud, kickbacks and False Claims. Other forms of Elder Abuse with respect to financial exploitation include referring patients for unnecessary medical services.

Since countless individuals rely on Medicare for health care insurance, the Federal Government must re-direct their efforts to combat fraud and over-utilization, both factors contributing to the cost of health care. There are many questions to examine in this puzzle of

fraud. It is an accepted fact that Medicare fraud has cost taxpayers some 60 billion dollars a year; the question is how to reduce the high cost of fraud and continue to protect the Trust Fund for current and future beneficiaries of Medicare.²

The Coalition Against Insurance Fraud reports that in 2007 both Medicare and Medicaid made an estimated 23.7 billion in improper payments.³ However combating Medicare fraud does save \$1.55 for every \$1 that the U.S. Government invests in the effort.⁴ In 1998, Donna E. Shalala, then Secretary of the Health and Human Services Department testified before the Senate Budget Committee regarding the Trust Fund.⁵ “As part of Secretary Shalala’s testimony she spoke of the legacy of Medicare, “today, virtually every American over the age of 65 and millions of Americans with disabilities, live with the security of knowing that Medicare is there for them if and when they need it.” She spoke in 1998 of the challenges of managing the Trust Fund and the Department of Health and Human Service’s “historic attack on waste, fraud and abuse and the remarkable results that occurred.” Secretary Shalala also addressed the "bipartisan Balanced Budget Act mandating a new payment system to help make Medicare a more prudent purchaser of health care services." Despite her positive outlook on the reduction of fraud and placing Medicare on solid financial ground, bureaucratic policies, fraud and abuse and the aging baby-boomer generation, have threatened the long-term solvency of Medicare.

Efforts by Congress to defeat fraud and abuse are evident in the framework of the False Claims Act, Anti-kickback Statute, Stark I, II, and III as well as the Medicare Integrity Program. Current measures by Congress to curb fraud and abuse in Medicare will require hospitals and pharmaceutical companies to disclose financial dealings with physicians these are perhaps the newest measures to potentially reduce fraud and abuse.

Furthermore, studies indicate that physicians are in part responsible for the fraud and abuse, from over-utilization, false claims and self-referral. Historically, physicians have not been held accountable given the reluctance of the American Medical Association (AMA), and physician groups to accept Medicare. However, as case law will indicate, physicians have reaped financial gain from questionable billing practices, over-utilization and self-referral. Physicians have been reluctant to disclose financial conflicts of interest including ownership in facilities to which they refer. Even though patients may have secondary, medigap coverage, the insulation from costs should not preclude patients from inquiring about costs of treatment.

Centers for Medicare and Medicaid (“CMS”) must require measures of accountability by health care providers to ensure that services are not being over-utilized. Mary Ann Bobinski in her 1994 Law Review Article stated it well, that “there is a new perception that patients can be injured by physician self-interest.”⁶

Whether self-interest leads to economic incentives prohibited by state and federal laws, the question is how to reduce or prohibit such behavior in the context of the impending health reform measures? In 2010, finding new solutions to this era of health care providers self-interest and abuse involves studying segments of the problem with new perceptiveness. The Attorney General’s office collaborating with Health and Human Services has announced new Medicare Fraud initiatives, an interagency effort known as Health Care Fraud Prevention and Enforcement Action Team (HEAT).⁷ This HEAT team combined with expanded efforts by “Medicare Strike Force Teams in Detroit and Houston, South Florida and Los Angeles will fight Medicare fraud on a targeted local level.”⁸ In addition to strike forces and enactment of stronger fraud laws, Medicare beneficiaries are advised to “Stop Medicare Fraud.” Patients should be proactive and

consistently review their Medicare statements for incorrect charges, to be cautious about who is using their Medicare number and report any inaccuracies to Medicare.

Regrettably, those same Medicare beneficiaries that Medicare was designated to protect are often the victims of fraud, often without their knowledge. One timely example of Medicare abuse involved medical suppliers using recipient Medicare numbers for billing for services not received by the beneficiaries. There are too many stories of Medical providers who see this government health care system as a method to increase their own wealth, who use self-referrals or false claims or kickbacks to add to the cost of care rather than be stewards of the system. The Medicare Health Care system must also undergo changes in relation to the health care reform plan. Specifically, health reform legislation must address issues to protect the beneficiaries of Medicare from fraud rather than using Medicare to pay for the program. We must adopt policies that affirm the fiduciary nature of the physician-patient relationship and extend disclosure requirements to physicians. Since the health reform measures currently contemplated by Congress appear to address the issue requiring hospitals and pharmaceutical companies to disclose financial conflicts to patients, physicians should be required to follow the same requirement. It should be noted however, that many of these approaches are complex and costly and may do little to save the Trust Fund.

Medicare regulations are complex and written in bureaucratic legalese that most Medicare patients would not understand or have little desire to comprehend. Rather, cost is the crucial concern for today's senior citizens. Trusting their physician's judgment is important and most will stay with their physician despite concerns about referrals or treatment issues. The cost factor for seniors is the breaking point for many; rising health care costs, pharmaceuticals and

insurance lead many seniors to avoid health care visits, which leads to medical problems being undetected and untreated.

Paul Starr commented in The Social Transformation of American Medicine, “Physicians long have had a history of sovereignty and authority in medicine.”⁹ It is from this point of strength that the physician in the 21st century must balance the welfare of the patient with his/her responsibility to monitor costs and utilization as a professional practitioner. Advocating for Medicare patients requires a discussion of why patients are at a disadvantage in the patient-physician relationship. It is a key element in this dilemma of self-referral, fiduciary duties, and informed consent and Medicare regulations.

While self-referral laws and anti-kickback statutes are enacted to protect the Trust Fund, those same laws have seemingly failed to stem the tide of fraud and abuse. Due to the complexity of the Medicare financing system, a new methodology needs to be developed that allows the Health Care Financing Administrator in combination with the Office of Inspector General (“OIG”) to review claims for fraud in a prompt manner.

A further concern for Medicare beneficiaries is the rising level of elder abuse, whether physical, emotional, or financial. Perhaps we need to explore whether a physician’s breach of the fiduciary duty rises to the level of financial elder abuse as addressed in the Older Americans Protection Act.¹⁰ The Older American Protections Act was designed to protect seniors from elder abuse, whether that abuse is physical, emotional or financial exploitation by another party, often a family member, caregiver or someone known to the senior. Thus, the act of fraud, costing a Medicare beneficiary more in out-of pocket costs for health care may be implicated as a form of financial exploitation.¹¹

Financial exploitation is explained by the Administration on Aging¹² as improper use of an elder's Trust Funds, property or assets, use of coercion or deceit in the provision of services not necessary and an elder's report of financial exploitation. It is the "provision of services not necessary" that may rise to the level of criminal prosecution.¹³

II: Identifying the Issues:

A. Background on Medicare Reimbursement

Medicare-related statutes¹⁴ continue to be amended in an ongoing effort to contain costs and protect the solvency of the Trust Fund. However, Medicare beneficiaries remain legitimately concerned with their out of pocket expenditures and access to care. The CMS website contains a wealth of information, but the average Medicare beneficiary does not easily comprehend the information. While cost containment is the goal to protect the Trust Fund, perhaps the focal point should be on promoting improving communications to patients from Medicare and the patients' physician. That very issue was addressed in a 2005 article titled, Medicare Agency Must be Fair, Accurate with Citizens.¹⁵ Mr. Deford addressed the "wanton conduct" of the CMS as failing to be honest and open to the very beneficiaries that Medicare serves. The article points out several instances of CMS "lying to appease the private health industry." This occurs in spite of legal challenges and consumer organizations that have forced CMS to comply with directives requiring disclosure of accurate information to beneficiaries. Yes, a new administration has taken over, but bureaucratic behavior often remains and change takes time.

Specifically, regarding communicating matters of costs, necessity of referrals, and fiduciary trust, and the physician-billing component of Medicare B have evolved from a

customary and reasonable fee schedule to a complicated Medicare fee schedule based on a “resource based relative value scale.”¹⁶

In establishing the need for disclosure, one must first understand the inherent problems with Medicare and the fiduciary relationship between physician and patients and the potential for abuse. Specifically, the Medicare handbook for beneficiaries has one chapter that discusses fraud and how to protect one’s Medicare benefits including phone numbers to the Medicare Hotline to report potential abuse. However, the handbook does not offer substantial information regarding physician referrals and the issue of self-referral. Furthermore, an August 2009 article in *Fitness & Wellness Week* reveals a survey that consumers are questioning the “longstanding practice of taking their doctor’s advice about where to go for health care.”¹⁷

While cost containment may permit the Trust Fund to continue, conceivably the cost containment issue should be part of the conversation between physician and patient. That conversation should specifically address matters of costs and fiduciary trust, how the physician can assist their patient in reducing out of pocket costs for health care. Physician reimbursement has dramatically been reduced in the past forty years from a prevailing reasonable charge to a complicated fee schedule. Physicians and the AMA have been reluctant to discuss fees with their patients. Perhaps it originates from the professional origins and the economic and social power bestowed on physicians implying that discussions with patients over treatment decisions and fee schedules are not acceptable conversations. Paul Starr writes in *The Social Transformation of American Medicine*, that the status of a physician arose from the 19th century growth of medical authority.¹⁸ It is from this medical authority that physicians gained the “rewards of privilege” and was “able to gain control over both the market for the physicians’ services and the organizations that governed medical practice.”¹⁹

While the economic realities of the 19th century do not resemble today's market, specifically the health care market, physicians were in a strategic position to set the market rate for reimbursement for their services. Thus, prior to health insurance and specifically consequently Medicare, physicians were able to use their authority to control the health care market.

Roger Feldman rationalizes that consumer demand is not “fully informed, voluntary or rational due to the special nature of medical care.”²⁰ As Feldman notes, health care as a commodity in the market is a supply v. demand equation, when the demand side of the equation lacks information. Feldman goes so far as to suggest that physicians may identify variations in patients' willingness to pay and “mark up” prices of health services. This may occur specifically with services where demand is inelastic, for example patients with deep insurance coverage or where consumers are the least informed. Finally, the “power to set high prices is especially pertinent for prices of services provided by specialist physicians. Feldman cites Lee and Ginsburg regarding the trend of increased expenditures for the services of a specialist. Even if volume did not increase due to over-utilization and referrals, Medicare reimbursement for surgeons in a seven-year period resulted in a 15 percent increase per year.²¹

Consequently, given the prior history of physicians and reimbursement, the physician-billing component of Medicare B has also experienced significant changes from a customary and reasonable reimbursement system that was a compromised solution to attract support from physicians for the Part B component of Medicare.²² The customary prevailing and reasonable reimbursement system grew from the customary and reasonable schedule. With this fee schedule, the physicians' actual charge goes through a dual screening process where the customary charge screen was what the physician charged for the same service during the

previous year and the prevailing charge screen is seventy-five percentile of the customary charges of other physicians in the same geographic region and specialty.²³ From 1972 to 1988, this system remained with increases in the fee schedule tied to the Medicare Economic Index; this MEI was the measurement of physician practice costs.²⁴

In 1988, the Physician Payment Review Commission (PPRC) recommended a new fee schedule for physicians based on a “relative value” defined as the relative value of work needed to produce each service. According to Roger Feldman of How to Fix Medicare, William Hsiao and his colleagues at Harvard created this conceptual framework of the relative value scale to be incorporated into the Physician Fee schedule.²⁵

This new framework, a complicated Medicare fee schedule, is based on a “resource based relative value scale.”²⁶ This new fee schedule was implemented as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA89)²⁷ The 1997 Balanced Budget Act established the “sustainable growth-rate system” (SGR)²⁸ which includes the payment structure for diagnostic testing reimbursement including the “technical component.”²⁹ With respect to radiology, for example, the “professional component is the interpretation of the image by a physician and is thus reimbursed under the fee schedule regardless of where the test is performed.”³⁰

This current physician fee schedule rewards physicians for performing an interpretation, a higher reimbursement level. “The fee schedule contains a flaw in the sustainable growth-rate system that does not control volume of services and thus avoids expenditure controls. Rather the physician in this scenario is responding to individual incentives to increase volume.”³¹ Through self-referral, the individual physician may be tempted to “game the system” to increase volume in order to receive a higher level of reimbursement for services that historically the physician had no control over.³²

Thus, evolved the Relative Value Scale and its application to the physician fee schedule for Medicare. The National Council on Aging recommends that seniors seek out information on the various types of services available to them. Furthermore it is suggested that while some arbitrary formula implies very little to the Medicare beneficiary, the real issue is making patients aware of reliable and accurate information that patients should have access to in order to make informed decisions. Overall, the actual fee schedule took over four years from concept to a working program as part of the OBRA89. The program underwent further changes from a volume performance standard to a sustainable growth-rate system. The changes were a response to the rising cost of health care. They amounted to an attempt to reduce costs through a complicated fee schedule to physicians that measures the actual charge of physicians and equates that charge to the relative value of the work needed to produce the charge, including costs such as overhead and risk of malpractice. However as fees are adjusted for the physicians, the Medicare beneficiary must pay an annual deductible plus twenty percent of the reasonable charges as determined by the Medicare Intermediary. Thus as physicians achieve a higher fee schedule, the patient or their supplemental insurance must pay 20% based on the new reimbursement rates. As physicians refer more patients for outpatient procedures and testing, those Part B charges require a twenty percent co-payment, and therefore the patient is paying more out of pocket on an annual basis to both physician and ancillary service providers.

As one reimbursement system changes to another, Congress initiated the SGR that has a negative impact on family or primary care physicians being able to “afford” to continue seeing Medicare patients. Their argument is that because of the low Medicare Reimbursement and other practice costs, there is a very thin margin to work with.

The SRG, which has been in place for most of this decade, has been threatening payment cuts to doctors. Congress has been preventing these cuts from taking place by enacting temporary fixes, which has resulted in SGR "debt" that is piled up over the years, into the billions.

Right now, the "accumulated SGR debt" is money that was removed from the Medicare Trust Trust Fund to pay physicians at the rate specified in a given year by Congress. Physicians in 2010 face a 21% cut to their Medicare payments unless Congress intervenes once again. On the regulatory side, the CMS has offered some relief in proposing to remove physician administered drugs from the formula used to calculate Medicare's physician fee schedule—something that doctors have wanted for years. Under the SGR formula, physician reimbursement is reduced when spending on all physician services—which includes Part B drugs—exceeds annual targets. The medical profession has argued that removing drugs from the formula would lessen the extent which spending would exceed targets and lead to payment cuts.

The AMA is vigorously advocating for the repeal of the Medicare SGR formula and is supporting the health care reform bills HR 3962 and HR3961 to improve access to health care for patients and regulatory relief for physicians and hospitals. Specifically, the AMA wants to “reduce costly and counterproductive administrative burdens and eliminate funded mandates which interfere with access to quality care for America’s seniors.”³³ Yet, the administrative burdens that the AMA is fighting against are the same burdens that protect the Trust Fund from fraud and abuse. Hospitals also counter that administrative burdens and inadequate payment methodologies place hospitals at risk for closure and thereby reduce patients’ access to health care.

In 2007, when Medicare lowered physician reimbursement rates, it seemed as though hospital based imaging services, specifically nuclear medicine scans, would see a shift in volume. According to Molchan, the Chief Financial Officer for Ultrascan, the Medicare reimbursement cuts may lead to abuse of services because if physicians do receive less per scan, they'll need to increase volume to make up for the difference. With that in mind, there will be even more competition with hospitals. According to Shay Pratt, a senior consultant with the Medicare Payment Advisory Commission."The diagnostic imaging arena will become even more competitive as free-standing centers look to capture more of the hospital share of the outpatient market,"

Glen Hackbarth, Medpac Chairman, cited research done by Dartmouth Medical School, Hanover, N.H., for MedPAC that "showed increasing imaging services was not associated with improved survival rates in any of the three patient groups-colon cancer, heart attack and hip fractures-it examined."³⁴ He also referenced a study by the National Committee for Quality Assurance that found nearly one-fourth of patients with lower-back pain in managed care plans received unnecessary imaging services, which included X-rays, magnetic resonance imaging and CT scans.³⁵

Mr. Hackbarth agrees that new standards could help stop the unnecessary services in physician offices and help ensure quality; on the contrary, Congress has taken no action. Perhaps due to recent Task Force Studies involving screening for cancer and the reactions thereof, legislators may fear the backlash combined with the health reform bill and the potential for health care rationing debate. The health reform debate has many individuals fearing that the new health reform measures will either reduce care or limit procedures. Proposed imaging

physician fee schedule cuts, which are aimed at aligning those payments with hospital outpatient payments may occur as needed but the enactment will be delayed.

Payment methodologies for hospital owned physician practices differ significantly from the SGRS because hospitals are allowed to include the operating costs of the provider-based physician practice on their Medicare cost reports and submit a separate claim for the physician's professional services reimbursed according to the aforementioned fee schedule. This allows hospitals to receive a higher level of reimbursement, one portion for the professional service and a second payment for overhead and operating costs.³⁶ The OIG in an attempt to compel compliance of hospitals is recommending the "elimination of the provider-based designation for physician practices." This OIG contends that this will reduce costs in co-insurance to Medicare beneficiaries.

In comparison, Hospital billing Medicare for Part A service has its own issues with the Medicare prospective payment system, initiated in 1982. The diagnosis related groups (DRG) was Congress's effort to reduce payments to hospitals in an attempt to rein in health care costs. The DRG prospective payment system is a method of categorizing patients based on principal (admitting) diagnoses, which are further categorized by body system into 23 systems or major diagnostic categories. (MDCS).³⁷ The MDC groups are further broken down to 511 separate DRGS considering both principal and secondary diagnoses and whether a surgical intervention was performed. Through this complex system of measuring the values of diagnoses, an actual payment is determined. The DRG system is not much different when compared to the relative value system employed for physician payment. The value of the service is weighed against a standardized formula of labor and costs and measured against facilities in similar regions.

Because the DRG formula considers the cost of labor, hospitals in a “high-cost labor market receive significantly higher Medicare payments compared to those in a lower cost labor market.”³⁸ However, the DRG is differentiated from the relative value scale for physicians in terms of adjustments for cases that are “outliers”, i.e. extraordinarily expensive cases. Hospitals that incur higher costs because of these expensive cases will have their payments adjusted upward to compensate for caring for such patients.

In the 1990’s hospitals and physicians witnessed a trend toward outpatient services from the traditional inpatient care; this trend was the beginning of the move by physicians to invest in various outpatient health entities from outpatient surgery and radiology to endoscopic suites and other specialized outpatient treatment facilities. Could this trend bring forth issues of the potential for over-utilization of health care services, the introduction of Stark laws and the need for financial disclosure? These issues have led writers such as Roger Feldman³⁹ to explore and discuss the supply and demand side of physician services. On the supply side, Mr. Feldman states that, “physicians have market power, the power to alter prices to their advantage.” On the demand side, the author notes that there is a lack of information to the consumer, primarily due to the “special nature of medical care and insurance coverage.” Mr. Feldman argues that despite changes in the payment structure of Medicare, patients with supplemental coverage seem insulated from the fact that the consumption of health care is reducing the Trust Fund.

B. Overview of Medicare Fraud and Abuse

E. Haavi Morreim, Ph.D., in her discussion of Physician Investment and Self-Referral⁴⁰ begins by defining self-referral, that it originates with a referral from the physician for a medical intervention, whether a laboratory test, imaging study or surgical intervention. By no means are legal scholars suggesting that the referred interventions are not in the patient’s best medical

interest, but rather that referrals to self-owned facilities lead to questions regarding overutilization. Prior to the growth of physician-owned facilities, physician referrals did not generate controversy; patients generally went to the hospital where the physician was on staff, and choices were limited. ⁴¹ However, in the late 1980s and early 1990s changes in reimbursement by Medicare and other insurers encouraged the growth of outpatient health facilities. Dr. Morreim citing a 1989 study by Dr. Kusserow that physicians were the first to invest in such facilities as they witnessed the need and the opportunity. “A 1989 report by the Department of Health and Human Services (DHHS), and OIG indicates that 12% of physicians who treat Medicare patients have a financial interest in outside laboratories or clinics.” Early on, these investments into ancillary services suggested a problem with overutilization of outpatient services, overpricing and reduced access⁴²and consequently, the introduction of the Stark II and III regulations ⁴³and accompanying exceptions⁴⁴. When these regulations were introduced, they generated substantial legal debate from law review articles, professional legal and medical journals and case law. Prior to the introduction of the Stark regulations self-referral abuses were prosecuted as kick-backs, “criminally prosecutable with penalties of fine or imprisonment.”⁴⁵ Yet, in 1987, there were second thoughts by Medicare and DHHS regarding the severity and vagueness of the law, leading to the issuance of safe harbor guidelines by OIG.⁴⁶ The 1991 regulations provided a “safe harbor” for a narrow range of physician investments, investment, wherein no more than 40% is held by physicians.”⁴⁷

C. Background on Stark regulations:

To counter the original issue of self-referral abuses, Rep. Fortney Pete Stark introduced legislation in 1983 herein known as “The Ethics in Patient Referrals Act” (commonly referred to as Stark I). was enacted to prohibit physician self-referrals for Medicare laboratory services.⁴⁸

The scope of Stark I and subsequently II involves financial relationships of an entity in which a physician and/or family member holds an interest and the prohibition to refer to those entities.⁴⁹ The financial relationship included compensation arrangements, ownership and investment interests and space and equipment rentals and recruitment.⁵⁰

In 1989 when the initial Stark law was enacted, the law applied only to clinical laboratories and did not include any of the exceptions that would be added in Stark II and III. The changes to the original Stark bill arose out of concern by hospitals and physician groups that there was too much uncertainty in the regulations and the regulations were seen as extremely wide in scope.

Consequently, Stark II and III broadened the list of applicable services and included numerous “exceptions” that permitted referrals by group practices and ownership interests through corporations at a specified limit.⁵¹ These exceptions are seen as a compromise to allow for physician investments for facilities that may not otherwise become available to improve access for patients. McDowell raises a valid point that self-referral bans may adversely affect access to care and its quality. In some cases investments by physicians with their knowledge of community health needs will enhance efficiency.⁵²

With respect to the Stark laws, most consumers have no understanding of the impact physician self-referrals and ownership of designated health services has on their health care services and the escalating cost of health care. It is not a surprising fact that physicians have a significant influence on their patients' access to medical service.⁵³ Thus, framing the physicians' argument that patients need their advice and counsel properly to select ancillary service providers given issues of quality and access, physicians argue that by establishing ownership interests in ancillary services, or providing those services within their own practices, they can be assured of their patients receiving quality care and immediate access to needed services. Physicians and the AMA counter that such joint ventures should be allowable under Stark and only a minority of physicians cross the line of abusive self-referral or kick-backs. However, there is no mention of the concern for creating demand and over-utilizing services in order to justify the costs of imaging equipment or laboratories within the practice.

One rather interesting issue was raised in an article by James Owens, in Topics in Health Care Financing How Stark laws influence the Trust Funding of new IT technologies such as Electronic Medical Records (EMR) to be shared between hospitals and physicians. Physicians want to incorporate the new EMR to facilitate patient care and immediate access to test results; but cost for this new technology is prohibitive for many physicians, and only 33 percent state that they could acquire or purchase the EMR system within the next year.⁵⁴ If the Stark laws permit hospitals to help finance this EMR system, 62 percent of the physicians can afford to acquire the technology.⁵⁵

Hospitals seem to argue that Stark laws serve to prohibit financial arrangements between hospitals and physicians that are part of a strategic plan to improve patient care and reduce costs. However, back in the 1990s prior to the introduction of the Stark laws, hospitals were seeking to

create integrated health care delivery systems that incorporated physician practices as part of that delivery system. Hospitals created integrated health systems based on the belief that they needed to compete for managed care dollars. There was very little concern addressed to issues such as disclosure of ownership or self-referrals and compliance. James Owens addressed some problematic issues, specifically self-referrals and integrated delivery systems (IDS) in a 1994 article in *Health Care Financing*.⁵⁶

In 1994, Mr. Owens specifically addressed whether the federal self-referral ban was relevant in the IDS scenario, “whether an IDS or Hospital foundation could legally provide designated health services to patients of physicians associated with the IDS.”⁵⁷ The conclusion from a literal reading of Stark was that a medical group that has entered into a financial relationship with an IDS or foundation would be prohibited under the Stark Law from referring patients to the foundation for health services. Mr. Owens expressed concern that even with the “group practice exceptions” to Stark, such an arrangement may not pass scrutiny. Whereas a group of “two or more physicians is contractually bound through a medical group to provide services to the IDS or foundation”, “the medical group is actually organized as a partnership or corporation, not as a foundation, which has other legal implications for the foundation.”

Many of these IDS arrangements are now the focus of one or more versions of the new health reform bill requiring disclosure of ownership by physicians of hospitals and requiring that hospitals disclose that potential conflict to patients. Physicians will further address this same issue in the discussion of the health reform measures and potential recommendations for disclosure.

D. Anti-kickback laws and other Fraud Statutes

While the primary focus in this dissertation involves the Stark statutes and its impact on the Trust Fund, I would be remiss not to briefly discuss relevant fraud and abuse statutes involving kick-backs, unjust enrichment and false claims. 42 U.S.C.A. § 1320A-7B provides the statutory language for both the issuance of false statements and illegal remunerations.

The legal framework of the anti-kickback statute includes prosecution for an (1) “individual(s) who knowingly and willfully solicits or receives remuneration (i.e., bribes, kickbacks or rebate) directly or indirectly, overtly or covertly in cash or in kind.”

(A) “In return for referring an individual to a person for the furnishing of an item or service for which payment may be made in whole or in part under a Federal Health Plan.”

While the accompanying False Claims Act predates Medicare, it has become a valuable tool to prosecute Medicare Fraud. The Medicare Fraud and Abuse statute clearly states that (1) “Making or causing to be made false statements or representations of a material fact in any application for payment under a Federal Health program.” (2) “At any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such payments.”

As in many of the fraud and abuse cases that arise, there are often multiple counts of fraud on different levels. For example some courts have held that inducing referrals does not have to be the “sole purpose of the scheme in order to fall within the anti-kickback law’s prohibition”.⁵⁸ While the Ninth Circuit in Hanlester Network v. Shalala, 51 F. 3d 1390 (1995) imposed a mens rea requirement, raising the question whether the defendant knew the transaction

was illegal, the court in Greber noted that a false motive was enough to taint an entire transaction that may otherwise have been lawful.

United States v. Starks, 157 F.3d 833 (1998) illustrates the issue of mens rea and its application in prosecuting an illegal kick-back scheme. Defendants argued that the anti-kickback statute was “unconstitutionally vague, people of ordinary intelligence could not ascertain from reading the safe harbor provisions that such conduct was illegal.” The court partially agreed with that argument, stating that a “criminal statute must define an offense with sufficient clarity such that an ordinary person could understand what conduct was prohibited.” Yet, given the facts of the case, the Ninth Circuit upheld the District Court’s ruling. The court noted that making payments surreptitiously was sufficient evidence of a guilty state of mind.

In U.S. v. Kats, 871 F.2d 105, the court applied the Greber court’s interpretation and convicted Kats of both conspiracy to commit “Medicare fraud and for the receipt of kickbacks in exchange for referral of Medicare payments.” The case arose out of an agreement between the owner of a diagnostic medical lab and Total Health Care to “kick-back 50 percent of the Medicare payments received by Tech-Lab as a consequence of referrals from Total Health Care.” An identical scheme compared to Kats involving “Medicare kick-backs arranged by Tech Lab and Community Medical Clinic where Kats began collecting payments under the alleged scheme.” Even though Kats was acquitted of the solicitation charge, as previously mentioned he was convicted on the conspiracy and receipt charges. The holding in Greber was correctly applied as the defendants in Kats did knowingly and willingly made and accepted payments for referring patients for federally Trust Funded medical services. As established by the Starks court, the “willful” provision “does not require knowledge that the arrangement for referrals violated the statute, but only requires knowledge that the conduct was unlawful.”

The False Claims Act⁵⁹ is used to enforce the anti-kickback statute as well as Stark violations. Yet, in cases such as Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997) the “Fifth Circuit rejected the prosecution’s argument that a violation of the anti-kickback statute can be prosecuted as a false claim under the False Claims Act”. While the court in *Thompson* did find the government incurred administrative costs because of the false claim, the court did not affirm the government suffered any harm from the kickback.

In the court’s reasoning, the claim failed to comply with the specific elements of the False Claims Act, 31 U.S.C.A. § 3729 to 3733. The plaintiff must prove each of the five elements; the “who, what, when, where and how” of the alleged fraud. Thus, “Thompson failed to meet the pleading requirements and submit a factual basis for his claim that the defendants submitted claims for medically unnecessary services.”⁶⁰

These arguments raised a significant issue as to whether the government should be permitted to use the False Claims Act in combination with the anti-kickback statute. Yet, if defendants commit one form of fraud such as inducing referrals or self-referral, should they receive reimbursement for claims arising from that inducement?

U.S. v. Aging Care Home Health raised the question of false claims in connection with a Stark Act violation. Aging Care, a home health services provider “compensated five physicians for performing advisory services.” 474 F. Supp. 2d 810. The compensation to the physicians for advisory services were billed by Aging Care Home Health and accordingly was “reimbursed for services furnished to patients of these physicians.”

The legal theory behind the Aging Care case includes two distinct regulatory schemes. In 1982, the Health and Human Services (“HHS”) issued 42 C.F.R. s 424.22(d) “restricting the