KICKBACKS AS FALSE CLAIMS: THE USE OF THE CIVIL FALSE CLAIMS ACT TO PROSECUTE VIOLATIONS OF THE FEDERAL HEALTH CARE PROGRAM'S ANTI-KICKBACK STATUTE

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INTRODUCTION

The investigation and prosecution of health care fraud has been a top priority of the federal government in recent years.[1] A variety of weapons are in

1. Fiscal year 1999 netted 396 criminal convictions for health care fraud. For fiscal year 1999, the federal government claims to have recovered over $524 million in judgments, settlements and administrative fines from health care fraud enforcement activities. *See Why Have a Compliance Program?*, HEALTH CARE AND FRAUD ABUSE NEWSLETTER (Leader Publ'ns, New York, N.Y.), Aug. 2000, at 5. At least one health care fraud specialist has been established in every local U.S. attorney's office in the country. *See id.* In 1997 alone, 167 new federal jobs were added to the health care fraud fighting force, with an additional 77 FBI agents dedicated to health care

the federal government's arsenal for combating health care fraud. Two of the most significant weapons are the Federal Health Care Program's Anti-Kickback Statute[2] (Anti-Kickback Statute) and the civil False Claims Act[3] (False Claims Act or FCA). The Anti-Kickback Statute generally prohibits the payment and receipt of kickbacks and other remuneration in return for the referral of business reimbursed by a Federal Health Care Program,[4] e.g., Medicare and Medicaid, while the False Claims Act generally prohibits the submission of false reimbursement claims to the federal government.[5] Historically, these two statutes have been used to address seemingly separate and distinct conduct. However, attempts have been made in recent years to use the False Claims Act to prosecute alleged violations of the Anti-Kickback Statute.

A number of well-publicized lawsuits have been filed under the False Claims Act alleging that the defendants submitted false claims to the federal government because the claims were for items or services furnished in violation of the Anti-Kickback Statute. One of the most significant issues raised by this line of cases is whether a violation of the False Claims Act can be predicated on a violation of a Medicare or Medicaid requirement, such as the Anti-Kickback Statute. Unlike a traditional False Claims Act case, in which the submitted claim contains false or fraudulent information, cases brought under the False Claims Act pursuant to this theory oftentimes may not contain false information on the face of the claim, nor involve services that were not rendered as indicated. Rather, the claims are deemed false because they have been "tainted" by the defendant's improper conduct in paying or accepting kickbacks.

As described below, the federal government has endorsed the theory that violations of the Anti-Kickback Statute can constitute violations of the False Claims Act.[6] In fact, the government has filed suit in its own right, and supported lawsuits filed by private parties, based upon this legal theory. For example, in two cases, the government formally intervened on behalf of a private party bringing suit. In another case, the government filed amicus briefs in support of the private party who brought the suit.

Generally, the complaints filed in these cases contain fairly common allegations: (1) The defendants violated the Anti-Kickback Statute by paying remuneration to persons or entities in a position to refer or direct Medicare and/or Medicaid beneficiaries to the defendants for health care items and/or

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issues. *See id*. The Department of Health and Human Services' (HHS) fraud and abuse-related budget for 2001 will increase 29% over fiscal year 2000 levels. *See id*. The HHS Office of the Inspector General (OIG) is implementing a plan to hire 243 new investigators.

2. *See* 42 U.S.C. § 1320a-7b(b) (1994).
3. *See* 31 U.S.C. §§ 3729-3733 (1994).
4. *See* 42 U.S.C. § 1320a-7b(b).
5. *See* 31 U.S.C. § 3729.
6. *See infra* Part III (for a discussion of the specific cases addressed here).

services; (2) The persons or entities referred Medicare and/or Medicaid beneficiaries to the defendants; (3) The defendants submitted claims for reimbursement to the Medicare and/or Medicaid programs for health care items or services furnished to the beneficiaries referred to the defendants; and (4) The claims submitted by the defendants were false or fraudulent under the False Claims Act since the claims arose from referrals made in violation of the Anti-Kickback Statute. In many of these cases, the defendants have filed motions to dismiss the complaints for failing to state a claim upon which relief can be granted.[7] The defendants have typically argued that a violation of the Anti-Kickback Statute cannot form the basis for a violation of the False Claims Act since a claim is false or fraudulent under the False Claims Act only if it contains false information on its face, not if it is for an item or service that may have been furnished in violation of other federal laws.

The legal theory set forth in these cases concludes that FCA liability may be based solely upon a violation of the Anti-Kickback Statute. Specifically, the pleadings and/or the decisions in these cases all suggest that FCA liability may exist simply based upon a violation of the Anti-Kickback Statute. However, as discussed below, this conclusion greatly expands the application and scope of the False Claims Act. Furthermore, the theory that a violation of the Anti-Kickback Statute is grounds for imposing FCA liability is based upon a number of underlying assumptions. Among other things, the theory assumes that: (1) FCA liability can be based on "implied certifications" of compliance with the Anti-Kickback Statute where claim forms do not require express certifications of compliance; (2) FCA liability can be imposed for regulatory violations that are not material to the government's payment decision; (3) FCA liability can be based upon a failure by the claimant to disclose regulatory violations to the government; (4) FCA liability may exist for regulatory violations which do not cause injury to the public fisc; and (5) A private right of action to enforce the Anti-Kickback Statute may be created. However, as discussed below, the legal basis for each of these assumptions is questionable.

I. FEDERAL HEALTH CARE PROGRAM'S ANTI-KICKBACK STATUTE

A. The Statutory Provision

The Anti-Kickback Statute prohibits, among other things, the payment or receipt of any type of benefit in return for the referral of business that is reimbursable under a "Federal Health Care Program."[8] Specifically, the statute

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7. *See* FED. R. CIV. P. 12(b)(6) (motion to dismiss for failure to state a claim upon which relief can be granted).

8. 42 U.S.C. § 1320a-7b(b). The term "Federal Health Care Program" is defined as: (1)

makes it unlawful for a person or entity to "knowingly and willfully" offer, pay, solicit, or receive any "remuneration," including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for, or to induce: (1) The referral of an individual for the furnishing of, or the arranging for the furnishing of, any item or service for which payment may be made in whole or in part under a Federal Health Care Program; or (2) The purchase, lease, or order of, or arranging for or recommending the purchase, lease, or order of, any item, good, service or facility for which payment may be made in whole or in part under a Federal Health Care Program.[9]

Violations of the Anti-Kickback Statute can result in severe criminal and civil penalties. The United States Department of Justice (DOJ) is responsible

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any plan or program, other than the Federal Employees Health Benefits Program, that provides health benefits either directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government (e.g., Medicare, the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), Department of Veterans Affairs health programs); and (2) any "State Health Care Program," defined as a state program funded under United States Code Title 42, Chapter 7, Subchapter XIX (i.e., Medicaid), Subchapter V (i.e., Maternal and Child Health), or Subchapter XX (Social Services Block Grants). *See also* 42 U.S.C. § 1320a-7b(f)(1) (definition of Federal Health Care Program); 42 U.S.C. § 1320a-7(h) (definition of State Health Care Program).

9. *See* 42 U.S.C. § 1320a-7b(b). The Anti-Kickback Statute has been subject to numerous amendments over the years. As originally enacted in 1972, the Anti-Kickback Statute made it a misdemeanor to solicit, offer, or receive a "kickback," "bribe," or "rebate" in connection with the referral of a Medicare or Medicaid beneficiary, or for the furnishing of items or services reimbursable by Medicare or Medicaid. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1419. The legislative history indicates that the 1972 statute was enacted in order to prohibit "certain practices which have long been regarded by professional organizations as unethical, . . . and which contribute appreciably to the cost of the [M]edicare and [M]edicaid programs." H.R. REP. NO. 92-231, at 107 (1971), *reprinted in* 1972 U.S.C.C.A.N. 5093. In 1977, the Anti-Kickback Statute was significantly amended. Perhaps most importantly, the scope of the statutory prohibition was expanded from kickbacks, bribes, and rebates to also encompass "any remuneration," whether direct or indirect, overt or covert, or in cash or in kind. *See* Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, § 4, 91 Stat. 1175. In 1980, the statute's scienter requirement was modified to require that conduct constituting an offense be committed "knowingly and willfully." Omnibus Budget Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599. This amendment was prompted by a concern that "criminal penalties [would] be imposed under [the then] current law to an individual whose conduct, while improper, was inadvertent." H.R. REP. NO. 96-1167, at 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572. In 1996, Congress again expanded the scope of the Anti-Kickback Statute to cover all "Federal Health Care Programs." Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 204, 110 Stat. 1936. Numerous proposals have been made over the years to amend the statute to make it applicable to items and services reimbursable by private commercial insurers. *See, e.g.*, Medicare and Medicaid Fraud, Abuse, and Waste Prevention Amendments of 1997, H.R. REP. NO. 105-1770, at § 111(a) (introduced June 3, 1997) (proposing to expand the scope of the Anti-Kickback Statute to cover private health care programs).

for criminal enforcement of the statute. Each violation of the statute is a felony punishable upon conviction by up to five years imprisonment and/or fines of up to $25,000.[10] The HHS OIG is responsible for civil enforcement of the statute. The OIG has the authority to exclude an individual or entity from participation in Federal Health Care Programs if the OIG determines that the individual or entity has violated the statute. The exclusion remedy may be imposed by the OIG pursuant to an administrative proceeding and absent a criminal conviction or investigation.[11] Finally, a violation of the Anti-Kickback Statute constitutes grounds for imposition of a civil monetary penalty (CMP) and other civil monetary assessments.[12]

The Anti-Kickback Statute contains a number of exceptions that describe certain practices which are immune from either criminal or civil prosecution. Statutory exceptions exist for: (1) a discount or other reduction in price obtained by a provider of services or other entity under a Federal Health Care Program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity to a Federal Health Care Program;[13] (2) any amount paid by an employer to a bona fide employee for employment in the provision of items or services reimbursable under a Federal Health Care Program;[14] (3) any amount paid by a vendor of goods or services to a purchasing agent acting for a group of individuals or entities who furnish services reimbursed under a Federal Health Care Program;[15] (4) a waiver of any coinsurance amount owed under Medicare if the waiver is provided by a federally-qualified health care center (FQHC) with respect to an individual who qualifies for subsidized services

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10. *See* 42 U.S.C. § 1320a-7b(b)(1)-(2).

11. *See id*. § 1320a-7(b)(7); 42 C.F.R. § 1001.951.

12. *See* 42 U.S.C. § 1320a-7a(a). Specifically, for each violation of the Anti-Kickback Statute, a party is subject to a $50,000 CMP, plus an assessment of up to three times the total amount of remuneration offered, paid, solicited, or received in violation of the Anti-Kickback Statute. *See id*.

13. *See id*. § 1320a-7b(b)(3)(A).

14. *See id*. § 1320a-7b(b)(3)(B).

15. *See id*. § 1320a-7b(b)(3)(C). Under this exception, the purchasing agent must have a written contract with each such individual or entity that specifies the amount to be paid to the agent and, if the entity is a "provider of services" (i.e., hospital, rural primary care hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility, home health agency, or hospice) the agent discloses to the entity, and upon request to HHS, the amount received by the agent from each vendor with respect to purchases made by or on behalf of the entity. *See id*. § 1395x(u) (definition of "provider of services").

under a provision of the Public Health Service Act (PHSA);[16] and (5) any payment practice specified in regulations issued by the HHS Secretary.[17]

B. Safe Harbor Regulations

Congress recognized that the Anti-Kickback Statute's broad language had the potential for creating confusion in the health care industry regarding the legality of many commonplace business arrangements. Consequently, in 1987, Congress expressly directed HHS to promulgate regulations defining certain payment practices that would not violate the law.[18] These regulations have become popularly known as "safe harbors," since parties who structure their business arrangements to satisfy all the criteria of an applicable safe harbor are sheltered from liability under the Anti-Kickback Statute.[19]

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16. *See* 42 U.S.C. § 1320a-7b(b)(3)(D). The Medicare coinsurance amount is the portion of the cost or charge of an item or service which a Medicare beneficiary must pay. Currently, the Medicare Part B coinsurance amount is generally 20% of the reasonable charge for the item or service. *See id*. § 1395l(a)(1). A FQHC is an entity that receives a grant under the PHSA, a non-grant receiving entity that is determined by the Secretary of HHS to meet the PHSA requirements for receiving such a grant, and certain facilities that were classified as federally-funded health centers (e.g., community health centers and migrant health centers) eligible for PHSA grants as of January 1, 1990. *See also* 42 U.S.C. § 1395x(aa) (providing a Medicare benefit for outpatient services furnished by an FQHC); 42 U.S.C. § 201.

17. *See* 42 U.S.C. § 1320a-7b(b)(3)(E).

18. *See* Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (directing the Secretary of HHS, in consultation with the Attorney General, to promulgate regulations "specifying payment practices that shall not be treated as a criminal offense . . . and shall not serve as the basis for an exclusion").

19. The OIG published an initial set of final safe harbors in July 1991. *See* Medicare and Medicaid Patient and Program Protection Act, 56 Fed. Reg. 35,952 (July 29, 1991) (codified at 42 C.F.R. § 1001.952(a)-(k)). These final safe harbors were based upon proposed regulations published in January 1989. *See* Medicare and Medicaid Patient and Program Protection Act, 54 Fed. Reg. 3088 (proposed Jan. 23, 1989). A second set of final safe harbors was issued in January 1996. *See* Medicare and State Health Programs, 61 Fed. Reg. 2122 (Jan. 25, 1996) (codified at 42 C.F.R. pt. 1001). These final safe harbors were based upon interim final regulations published in November 1992. *See* Medicare and Medicaid Patient and Program Protection Act, 57 Fed. Reg. 52,723 (Nov. 5, 1992). In November 1999, the OIG released a third set of final safe harbors, as well as clarifications to the original safe harbors. *See* Medicare and State Health Programs, 64 Fed. Reg. 63,518 (Nov. 19, 1999) (codified at 42 C.F.R. pt. 1001). These final safe harbors were based upon proposed safe harbors published in 1993. *See* Medicare and Medicaid Patient and Program Protection Act, 58 Fed. Reg. 49,008 (proposed Sept. 21, 1993). The clarifications to the existing safe harbors were based upon a proposed rule issued in 1994. *See* Medicare and Medicaid Patient and Program Protection Act, 59 Fed. Reg. 37,202 (proposed July 21, 1994).

There are currently twenty-one safe harbor regulations. A number of safe harbors implement statutory exceptions.[20] Safe harbors exist for: (1) certain types of investment interests;[21] (2) space rental arrangements;[22]

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20. The OIG has taken the position that its authority to interpret the statute encompasses the authority to place restrictions on the availability of the statutory exceptions. Consequently, in order to meet a statutory exception, all elements of the corresponding safe harbor must be satisfied. *See* 56 Fed. Reg. 35,956 (July 29, 1991).

21. *See* 42 C.F.R. § 1001.952(a) (2000). Prohibited "remuneration" does not include any return on an investment interest held in entities receiving referrals as long as certain standards are met. The safe harbor specifies three types of investment relationships. First, if the entity in which the investment interest is held possesses more than $50,000,000 in undepreciated net tangible assets related to the furnishing of health care items and services within the previous fiscal year or previous twelve-month period, all of the following requirements must be met: (1) Where the investment interest is an equity security, the security must be registered with the Securities and Exchange Commission; (2) The investment interest of an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms and at a price equally available to the public through trading on a registered national securities exchange; (3) The entity must not market or furnish its items or services to investors differently than to non-investors; (4) The entity must not lend funds to, or guarantee a loan for, an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity, if the investor uses any part of such loan to obtain the investment interest; and (5) The return on investment interest must be directly proportional to the amount of the capital investment of that investor. *See* 42 C.F.R. § 1001.952(a)(1).

Second, if the entity does not have more than $50,000,000 in undepreciated net tangible assets, and the investment interests are held by either active investors, i.e., general partners, corporate officers, or passive investors, i.e., limited partners, shareholders, all of the following standards must be met: (1) No more than 40% of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous twelve-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity; (2) No more than 40% of the gross revenues of the entity related to the furnishing of health care items and services in the previous fiscal year or previous twelve-month period may come from referrals or business otherwise generated from investors; (3) The terms on which an investment interest is offered to a passive investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors; (4) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity; (5) There must be no requirement that a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor; (6) The entity must not market or furnish the entity's items or services to investors differently than to non-investors; (7) The entity must not lend funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity if the investor uses any part of such loan to obtain the investment interest; and (8) The return to an investor for the investment interest must be directly proportional to the amount of the capital investment. *See* 42 C.F.R. § 1001.952(a)(2).

(3) equipment rental arrangements;[23] (4) personal service arrangements;[24]

Third, if the entity does not have more than $50,000,000 in undepreciated net tangible assets, the investment interests are held by either active or passive investors, and the entity is located in an underserved area, all of the following eight standards must be met: (1) No more than 50% of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity; (2) The terms on which an investment interest is offered to a passive investor, if any, who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different from the terms offered to other passive investors; (3) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity; (4) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor; (5) The entity or any investor must not market or furnish the entity's items or services (or those of another entity as part of a cross-referral agreement) to passive investors differently than to non-investors; (6) At least 75% of the dollar volume of the entity's business in the previous fiscal year or previous 12-month period must be derived from services furnished to persons who reside in an underserved area or are members of medically underserved populations; (7) The entity . . . must not loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest; and (8) The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment. *See* 42 C.F.R. § 1001.952(a)(3)(i).

22. *See* 42 C.F.R. § 1001.952(b) (2000). Prohibited "remuneration" does not include any payment made by a lessee of space to a lessor for the use of premises, as long as all of the following standards are met: (1) The lease agreement is set out in writing and signed by the parties; (2) The lease specifies the premises covered by the lease; (3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals; (4) The term of the lease is for at least one year; (5) The aggregate rental charge is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State Health Care Program; and (6) The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. *See id*. The term "fair market value" means the value of the rental property for general commercial purposes, unadjusted to reflect the additional value that one party, either the prospective lessee or lessor, would attribute to the property as a result of its proximity or convenience to sources of referrals or business. *See id*.

23. *See* 42 C.F.R. § 1001.952(c) (2000). Prohibited "remuneration" does not include any payment made by a lessee of equipment to the lessor for the use of the equipment, if all of the following standards are met: (1) The lease agreement is set out in writing and signed by the parties; (2) The lease specifies the equipment that is covered; (3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-

(5) sale of a professional practice;[25] (6) referral service arrangements;[26]

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time basis, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval; (4) The term of the lease is for at least one year; (5) The aggregate rental charge is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; and (6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental. *See id*. The term "fair market value" means the value of the equipment when obtained from a manufacturer or professional distributor, unadjusted to reflect the additional value one party would attribute to the equipment as a result of its proximity or convenience to sources of referrals or business. *See id*.

24. *See* 42 C.F.R. § 1001.952(d) (2000). Prohibited "remuneration" does not include any payment made by a principal to an agent (i.e., a non-employee) as compensation for the services of the agent under a personal service arrangement or management contract, if all of the following standards are met: (1) The agreement is set out in writing and signed by the parties; (2) The agreement specifies the services to be provided by the agent; (3) If the agreement is intended to provide for the services of the agent on a periodic, sporadic, or part-time basis, rather than on a full-time basis, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals; (4) The term of the agreement is for at least one year; (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and (7) The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services. *See id*.

25. *See* 42 C.F.R. § 1001.952(e) (2000). Prohibited "remuneration" does not include payments made for the purchase of a practitioner's practice. *See id*. The safe harbor specifies two types of transactions. First, prohibited remuneration does not include any payment made by a practitioner to another practitioner in order to purchase the latter practitioner's practice if two criteria are met: (1) The time from the date of the first agreement pertaining to the sale of the practice to the completion of the sale is no more than one year; and (2) The selling practitioner will not be in a position to make referrals to, or otherwise generate business for, the purchasing practitioner after one year from the date of the first agreement pertaining to the sale. *See* 42 C.F.R. § 1001.952(e)(1). Second, prohibited remuneration does not include any payment made to a practitioner by a hospital or other entity where the practitioner is selling his or her practice to the hospital or other entity, so long as the following standards are met: (1) The period from the date of the first agreement pertaining to the sale to the completion date of the sale is not more than three years; (i2) The practitioner who is selling his or her practice will not be in a professional position after completion of the sale to make or influence referrals to, or otherwise generate business for, the purchasing hospital or entity for which payment may be made in whole or in part under Medicare or a State Health Care Program; (3) The practice being acquired must be located in a Health Professional Shortage Area (HPSA) . . . for the practitioner's specialty area; and (4) Commencing at the time of the first agreement pertaining to the sale, the purchasing hospital or entity must diligently and in good faith engage in commercially reasonable recruitment activities that [may] reasonably be expected to result in the recruitment of a new practitioner to take over the acquired practice within a one year period,

(7) warranties;[27] (8) discounts on goods or services;[28] (9) payments to bona

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and [that] will satisfy the conditions of the practitioner recruitment safe harbor in accordance with 42 C.F.R. § 1001.952(n). *See* 42 C.F.R. § 1001.952(e)(2).

26. *See* 42 C.F.R. § 1001.952(f) (2000). Prohibited "remuneration" does not include any payment or exchange of anything of value between an entity serving as a referral service and an entity or individual participating in that service if the following requirements are met: (1) The referral service does not exclude from participation any individual or entity who meets specified requirements for participation; (2) Any participation fee charged by the referral service is assessed equally against all participants, and is calculated based on the cost of operating the referral service, and not the volume or value of any referrals or business generated by the participants; (3) The referral service imposes no requirements on the manner in which the participant provides services to a person referred to the participant, except that the referral service may require that the participant charge the person at the same rate as it charges other persons not referred by the referral service, or that the services be furnished free or at a reduced rate; and (4) The referral service makes the following five disclosures to each person seeking a referral, and maintains a written record, certifying that the disclosures have been made, which is signed by either the individual seeking the referral or the disclosing individual: (i) the manner in which the referral service selects participants in the referral service to which it could make a referral (e.g., all members of a hospital's medical staff); (ii) whether the participant has paid a fee to the referral service; (iii) the manner in which the referral service selects a particular participant (e.g., alphabetical); (iv) the nature of the relationship between the referral service and the participants to whom it could make the referral; and (v) the nature of any restrictions that would exclude an individual or entity from continuing as a participant in the referral service. *See id*.

27. *See* 42 C.F.R. § 1001.952(g) (2000). Prohibited "remuneration" does not include payments or exchanges made pursuant to a warranty agreement whereby a seller offers to replace a defective item, provided both the seller and buyer meet certain requirements. *See id*. The buyer must: (1) fully and accurately report, on the appropriate cost report or claim form, any price reductions or free items obtained as part of the warranty; and (2) upon the request of HHS or a state Medicaid agency, provide any information regarding the warranty that is received from the seller. *See id*. The seller must: (1) fully and accurately report, on the invoice or statement submitted to the buyer, any price reductions or free items obtained as part of the warranty, and inform the buyer of its reporting obligations or, where the amount of the price reduction is not known at the time of sale, report the existence of the warranty on the invoice or statement, inform the buyer of its reporting obligations and, when the price reduction becomes known, provide the buyer with documentation of the calculation of the price reduction resulting from the warranty; and (2) not pay any remuneration to any individual or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than the cost of the item itself. *See id*.

28. *See* 42 C.F.R. § 1001.952(h) (2000). Prohibited "remuneration" does not include certain "discounts" on a good or service received by a buyer from a seller. This safe harbor implements a statutory exception that applies to "a discount or other reduction in price obtained by a provider of services . . . if the reduction in price is properly reported and appropriately reflected in the costs claimed or charges made by the provider or entity." 42 U.S.C. § 1320a-7b(b)(3)(a). The safe harbor applies to any "reduction in the amount a buyer . . . is charged for an item or service based on an arm's-length transaction." 42 C.F.R. § 1001.952(h)(5). Not within the coverage of the safe harbor, however, are cash payments, price reductions applicable to one payer but not to Medicare or a State Health Care Program, and free or reduced-charge goods or services provided in exchange for an agreement to purchase a different good or service, unless the goods or services are reimbursed by the same Federal

fide employees;[29] (10) arrangements involving group purchasing

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Health Care Program using the same methodology and the reduced charge is fully disclosed and accurately reported. *See* 42 C.F.R. § 1001.952(h)(5).

In order to qualify for the discount safe harbor, the buyer, seller and, if applicable, "offeror" (i.e., an individual or entity that is not a seller, but who offers a discount by promoting the purchase of an item or service on behalf of the seller) must meet certain requirements which vary based upon the status of the buyer. The safe harbor identifies three types of buyers. If the buyer is an entity that reports its costs on a cost report (e.g., hospital, nursing facility) the buyer must meet the following conditions: (1) The discount must be earned by the buyer based upon purchases of that same good or service bought within a single fiscal year; (2) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year; (3) The buyer must fully and accurately report the discount in the applicable cost report; and (4) Upon request by HHS or a state Medicaid agency, the buyer must provide information regarding the discount that is furnished to the buyer by the seller or offeror. *See* 42 C.F.R. § 1001.952(h)(1)(ii). No requirements are imposed on the buyer if the buyer is a health maintenance organization (HMO) or a competitive medical plan that has entered into a contract with HHS or a state Medicaid agency. *See* 42 C.F.R. § 1001.952(h)(1)(i). Finally, any other type of buyer (e.g., physician) must ensure that the following requirements are met: (1) The discount must be made at the time of the sale of the good or service, or the terms of the discount must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service; and (2) Upon request by HHS or a state Medicaid agency, the buyer must provide information regarding the discount that is furnished to the buyer by the seller or offeror. *See* 42 C.F.R. § 1001.952(h)(1)(iii).

Sellers also have to comply with certain requirements based upon the status of the buyer. No requirements are imposed if the buyer is an HMO or competitive medical plan that has entered into a contract with HHS or a state Medicaid agency. *See* 42 C.F.R. § 1001.952(h)(2)(i). However, for all other buyers, the seller is required to fully and accurately report the discount on the invoice or statement submitted to the buyer and inform the buyer of the buyer's obligations to report the discount. *See* 42 C.F.R. § 1001.952(h)(2) (ii),(iii). When the value of the discount is not known at the time of sale (e.g., year-end discounts to cost report buyers) the seller must fully and accurately report the existence of the discount program on the invoice or statement submitted to the buyer, inform the buyer of its reporting obligations and, when the value of the discount becomes known, provide the buyer with documentation of the discount calculation. *See id*.

Offerors also have to comply with certain requirements based upon the status of the buyer. No requirements are imposed if the buyer is an HMO or competitive medical plan that has entered into a contract with HHS or a state Medicaid agency. *See* 42 C.F.R. § 1001.952(h)(3)(i). However, for all other buyers, the offeror is required to inform the buyer of the buyer's obligations to report the discount, and refrain from doing anything that would impede the buyer's ability to meet its obligations. *See* 42 C.F.R. § 1001.952(h)(3)(ii), (iii).

29. *See* 42 C.F.R. § 1001.952(i) (2000). Prohibited "remuneration" does not include any amount paid by an employer to an employee who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State Health Care Program. *See id*. This safe harbor implements a statutory exception for payments made to employees. *See* 42 U.S.C. § 1320a-7b(b)(3)(b).

organizations;[30] (11) certain waivers of beneficiary coinsurance and deductible obligations;[31] (12) increased coverage or reduced cost sharing obligations offered by certain types of health plans;[32] (13) price reductions offered to

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30. *See* 42 C.F.R. § 1001.952(j) (2000). Prohibited "remuneration" does not include any payment by a vendor of goods or services to a group purchasing organization (GPO) acting on behalf of individuals or entities. This safe harbor implements a statutory exception. *See* 42 U.S.C. § 1320a-7b(b)(3)(C). A GPO is "an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare or a State Health Care Program." 42 C.F.R. § 1001.952(j)(2). In order to meet the safe harbor, two requirements must be met. First, the GPO must have a written agreement with each individual or entity on whose behalf the GPO will purchase items or services which specifies that: (1) participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3% or less of the purchase price of the goods or services; or (2) if the fee paid to the GPO is not fixed at 3% or less, the agreement specifies the maximum amount the GPO will be paid by each vendor. *See* 42 C.F.R. § 1001.952(j)(l)(i)(ii). Second, if the entity for which goods or services are being purchased is a health care provider, the GPO must annually disclose to the entity, and to HHS upon request, the fee received from each vendor. *See* 42 C.F.R. § 1001.952(j)(2). Third, the members of the GPO may not be wholly owned by the GPO, nor subsidiaries of a parent corporation that wholly owns the GPO. *See id*. Thus, the GPO safe harbor could not be met if the GPO and the providers for which the GPO served as a purchasing agent were subsidiaries of a common parent corporation.

31. *See* 42 C.F.R. § 1001.952(k) (2000). Prohibited "remuneration" does not include a reduction or waiver of a Medicare beneficiary's obligation to pay certain coinsurance or deductible amounts. *See id*. The safe harbor identifies two types of protected arrangements. For coinsurance or deductible amounts owed to a hospital for inpatient hospital services reimbursed under the Medicare prospective payment system, the following criteria must be met: (1) the hospital must not claim the amount reduced or waived as a bad debt for Medicare payment purposes, or otherwise shift the burden of the reduction or waiver onto other payers; (2) the hospital must offer the reduction or waiver without regard to the reason for admission, length of the beneficiary's stay, or diagnosis-related group into which the patient is classified; and (3) the hospital's reduction or waiver must not be made as part of a price reduction agreement between a hospital and a third party payer. *See* 42 C.F.R. § 1001.952(k)(1). Prohibited "remuneration" also does not include a FQHC or other health care facility, operating under any PHSA grant program or under Title V of the Social Security Act, from reducing or waiving coinsurance or deductible amounts owed by an individual qualified to receive subsidized services under the PHSA or Titles V or XIX of the Social Security Act. *See* 42 C.F.R. § 1001.952(k)(2). This portion of the safe harbor implements a statutory exception. *See* 42 U.S.C. § 1320a-7b(b)(3)(D).

32. *See* 42 C.F.R. § 1001.952(l) (2000). Prohibited "remuneration" does not include certain benefits offered to enrollees by health plans, defined to include HMOs and competitive medical plans that provide health insurance coverage or health care services in exchange for a premium payment, such as increased coverage of items or services and/or reduced premiums or enrollee cost-sharing obligations (e.g., coinsurance, deductible, or copayment amounts). *See id*. In order to qualify for the safe harbor, the health plan must have a contract with either HHS or a state Medicaid program, or have its premium structure regulated by state law, and meet certain other requirements that vary based upon the structure of the health plan. *See id*. If the health plan is a risk-based HMO, competitive medical plan, or other plan operating under a risk contract, the health plan must offer the same increased coverage or reduced cost-sharing

certain types of health plans by contract health providers;[33] (14) payments for practitioner recruitment;[34] (15) subsidies for obstetrical malpractice insurance

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obligations to all enrollees, unless otherwise approved by HHS or a state Medicaid program. *See* 42 C.F.R. § 1001.952(l)(i). If the health plan is an HMO, competitive medical plan, or other plan operating under a contract pursuant to which it is reimbursed on a cost basis, the health plan must: (1) offer the same increased coverage or reduced cost-sharing obligations to all enrollees, unless otherwise approved by HHS or a state Medicaid program; and (2) not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to other payers. *See* 42 C.F.R. § 1001.952(l)(ii).

33. *See* 42 C.F.R. § 1001.952(m) (2000). Prohibited "remuneration" does not include reduced fees offered to a health plan by a contract health care provider for the purpose of furnishing items or services to health plan enrollees. *See id*. In order to qualify for safe harbor protection, however, the arrangement must meet certain criteria. *See id*. For all arrangements, the following requirements must be met: (1) The provider must reduce the total charges (i.e., reduction or waiver of coinsurance and deductible amounts only is unprotected); (2) There must be a written agreement; and (3) The agreement must be for the sole purpose of providing health care to plan enrollees (i.e., agreements to obtain peer review or utilization review services are not protected). *See id*. In addition to these requirements, other requirements must be satisfied depending upon the type of arrangement. Agreements with health plans having risk-based contracts must also satisfy the following criteria: (1) The provider may not separately bill any program for items or services furnished under the contract; and (2) The provider may not shift the cost of the discounts or reduced fees to Medicare or other payers or individuals. *See* 42 C.F.R. § 1001.952(m)(l). Plans with cost contracts must meet the following requirements: (1) The agreement must be for at least one year; (2) The agreement must specify the items to be furnished and the payment methodology; (3) The health plan must report to Medicare or the State Health Care Program amounts paid to the provider under its agreement; and (4) The provider must seek payment only from the health plan, unless specific authorization to bill others is given by Medicare or a State Health Care Program. *See* 42 C.F.R. § 1001.952(m)(i). Finally, plans without contracts with Medicare or a State Health Care Program must meet the following requirements: (1) The agreement must be for at least one year; (2) The contract must specify the items to be furnished, the fee schedule, and who will submit claims to Medicare or the State Health Care Program; (3) The fee schedule cannot change during the contract term without specific authorization from Medicare or a State Health Care Program; (4) Parties submitting claims under the agreement may not seek more than the fee schedule amount; (5) Full and accurate reporting of amounts paid to providers must be made on any Medicare or State Health Care Program cost report; and (6) The party who is not contractually authorized to submit claims for payment to Medicare or a State Health Care Program may not do so, nor otherwise shift the burden of the arrangement to other payers or individuals. *See* 42 C.F.R. § 1001.952(m)(ii).

34. *See* 42 C.F.R. § 1001.952(n) (2000). Prohibited "remuneration" does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA for his or her specialty area, that is served by the entity, as long as all of the following nine standards are met: (1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party; (2) If a practitioner is leaving an established practice, at least 75% of

premiums;[35] (16) investment interests by practitioners in group practices;[36]

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the revenues of the new practice must be generated from new patients not previously seen by the practitioner at his or her former practice; (3) The benefits provided to the practitioner by the entity are for a period of not more than three years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; (4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; (5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for, any other entity of his or her choosing; (6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State Health Care Program; (7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal Health Care Program in a nondiscriminatory manner; (8) At least 75% of the revenues of the new practice must be generated from patients residing in a HPSA or a medically underserved area (MUA) or who are part of a medically underserved population (MUP); and (9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments. *See id*.

35. *See* 42 C.F.R. § 1001.952(o) (2000). Prohibited "remuneration" does not include any payment made by a hospital or other entity to another entity that is providing malpractice insurance, where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner, including a certified nurse-midwife, who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as all of the following seven standards are met: (1) The payment is made in accordance with a written agreement between the entity paying the premiums and the practitioner that sets out the payments to be made by the entity and the terms under which the payments are to be provided; (2) The practitioner must certify that for the initial coverage period, not to exceed one year, the practitioner has a reasonable basis for believing that at least 75% of the practitioner's obstetrical patients treated under the coverage of the malpractice insurance will either reside in a HPSA or medically underserved area, or be part of a medically underserved population, and that thereafter, for each additional coverage period, not to exceed one year, at least 75% of the practitioner's obstetrical patients treated under the prior coverage period, not to exceed one year, must have resided in a HPSA or medically underserved area, or been part of a medically underserved population; (3) There is no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition for receiving the benefits; (4) The practitioner is not restricted from establishing staff privileges at, referring any patient to, or otherwise generating any business for, any other entity of his or her choosing; (5) The amount of payment may not vary based on the volume or value of any previous or expected referrals to, or business otherwise generated for, the entity by the practitioner for which payment may be made in whole or in part under Medicare or a State Health Care Program; (6) The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal Health Care Program in a nondiscriminatory manner; and (7) The insurance is a bona fide malpractice insurance policy or program, and the premium is calculated based on a bona fide assessment of the liability risk covered under the insurance.

36. *See* 42 C.F.R. § 1001.952(p) (2000). Prohibited "remuneration" does not include any payment that is a return on an investment interest to a solo or group practitioner investing in his

(17) arrangements involving cooperative hospital service organizations;[37] (18) investment interests in ambulatory surgical centers;[38] (19) referral

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or her own practice or group practice if the following four standards are met: (1) The equity interests in the practice or group must be held by licensed health care professionals who practice in the practice or group; (2) The equity interests must be in the practice or group itself, and not some subdivision of the practice or group; (3) In the case of group practices, the practice must meet the definition of "group practice" in § 1877(h)(4) of the Social Security Act, and be a unified business with centralized decision making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers; and (4) Revenues from ancillary services, if any, must be derived from "in-office ancillary services" that meet the definition of such services in § 1877(b)(2) of the Social Security Act.

37. *See* 42 C.F.R. § 1001.952(q) (2000). Prohibited "remuneration" does not include any payment made between a cooperative hospital service organization (CHSO) and its patron-hospital, both of which are described in § 501(e) of the Internal Revenue Code and which are tax-exempt under § 501(c)(3) of the Internal Revenue Code, where the CHSO is wholly owned by two or more patron-hospitals, as long as one of the following standards is met: (1) If the patron-hospital makes a payment to the CHSO, the payment must be for the purpose of paying for the bona fide operating expenses of the CHSO; or (2) If the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under § 501(e)(2) of the Internal Revenue Code. *See id.*

38. *See* 42 C.F.R. § 1001.952(r) (2000). Prohibited "remuneration" does not include any payment that is a return on an investment interest made to an investor as long as the investment entity is a Medicare-certified ambulatory surgical center (ASC) whose operating and recovery room space is dedicated exclusively to the ASC, patients referred to the entity by an investor are fully informed of the investor's investment interest, and certain other criteria are met based upon the type of ASC in which the interest is held. The safe harbor identifies four types of ASCs: (1) surgeon-owned ASCs (where all of the investors are surgeons who are in a position to refer patients directly to the entity and perform surgery on such referred patients, surgical group practices composed of such surgeons, or investors not in a position to make or influence referrals); (2) single-specialty ASCs (where all of the investors are physicians engaged in the same medical practice specialty who are in a position to refer patients directly to the entity and perform procedures on such referred patients, group practices composed of such physicians, or investors not in a position to make or influence referrals); (3) multi-specialty ASCs (where all of the investors are physicians who are in a position to refer patients directly to the entity and perform procedures on such referred patients, group practices composed of such physicians, or investors not in a position to make or influence referrals); and (4) hospital/physician ASCs (where at least one investor is a hospital, and all of the remaining investors are physicians, group practices, surgical group practices, or investors not in a position to make or influence referrals). *See id*. The requirements of the safe harbor are the same for surgeon-owned ASCs and single-specialty ASCs: (1) The terms on which an investment interest is offered to an investor must not be related to the previous or expected volume of referrals, services furnished, or the amount of business otherwise generated from that investor to the entity; (2) At least one-third of each surgeon/physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures; (3) The entity or any investor must not loan funds to or guarantee a loan for an investor if the investor uses any part of such loan to obtain the investment interest; (4) The amount of payment to an investor in return for the investment must be directly

agreements for specialty services;[39] (20) price reductions offered to managed care organizations;[40] and (21) price reductions to managed care organizations

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proportional to the amount of the capital investment of that investor; (5) All ancillary services for Federal Health Care Program beneficiaries performed at the entity must be directly and integrally related to primary procedures performed at the entity, and none may be separately billed to Medicare or other Federal Health Care Programs; and (6) The entity and any surgeon/physician investors must treat patients receiving medical benefits or assistance under any Federal Health Care Program in a nondiscriminatory manner. *See id*. Multi-specialty ASCs are subject to the same requirements for surgeon-owned ASCs and single-specialty ASCs, as well as an additional requirement that at least one-third of the procedures performed by each physician investor for the previous fiscal year or previous 12-month period be performed at the ASC. *See id*. Physician/hospital ASCs are subject to the same requirements for surgeon-owned ASCs and single-specialty ASCs, except for the requirement that at least one-third of each physician investor's medical practice income from all sources for the previous fiscal year or previous 12-month period must be derived from the surgeon's performance of procedures. *See id*. Furthermore, physician/ hospital ASCs are subject to three additional requirements: (1) The entity may not use space, equipment or services owned or provided by any hospital investor unless the provision of such space, equipment or services meet applicable safe harbors; (2) The hospital may not include on its cost report or any claim for payment from a Federal Health Care Program any costs associated with the ASC (unless such costs are required to be included); and (3) The hospital may not be in a position to make or influence referrals directly or indirectly to any investor or the entity. *See id*.

39. *See* 42 C.F.R. § 1001.952(s) (2000). Prohibited "remuneration" does not include any exchange of value among individuals and entities where one party agrees to refer a patient to the other party for the provision of a specialty service payable in whole or in part under Medicare or a State Health Care Program in return for an agreement on the part of the other party to refer that patient back at a mutually agreed upon time or circumstance as long as the following four standards are met: (1) The mutually agreed upon time or circumstance for referring the patient back to the originating individual or entity is clinically appropriate; (2) The service for which the referral is made is not within the medical expertise of the referring individual or entity, but is within the special expertise of the other party receiving the referral; (3) The parties receive no payment from each other for the referral and do not share or split a global fee from any Federal Health Care Program in connection with the referred patient; and (4) Unless both parties belong to the same group practice, the only exchange of value between the parties is the remuneration the parties receive directly from third-party payers or the patient compensating the parties for the services they each have furnished to the patient. *See id*.

40. *See* 42 C.F.R. § 1001.952(t) (2000). Prohibited "remuneration" does not include certain payment arrangements involving eligible managed care organizations. Such organizations are: (1) HMOs or competitive medical plans with risk or cost-based contracts under § 1876 of the Social Security Act; (2) Medicare Part C health plans that receive capitated payments from Medicare and that have Medicare beneficiary cost-sharing arrangements approved by HCFA under § 1854 of the Social Security Act; (3) Medicaid managed care organizations, as defined in § 1903(m)(1)(A) of the Social Security Act, that provide or arrange for items or services for Medicaid enrollees under a contract in accordance with § 1903(m) of the Social Security Act (except for fee-for-service plans or medical savings accounts); (4) Any other health plans that provide or arrange for items and services for Medicaid enrollees in

offered by contractors with substantial financial risk.[41]

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accordance with a risk-based contract with a state Medicaid agency; (5) Programs For All-Inclusive Care For The Elderly (PACE) under §§ 1894 and 1934 of the Social Security Act; and (6) Federally qualified HMOs. *See id*.

The safe harbor extends protection to two types of arrangements involving eligible managed care organizations. Prohibited "remuneration" does not include any payment between an eligible managed care organization and any first-tier contractor (i.e., an individual or entity that has a contract directly with an eligible managed care organization to provide or arrange for items or services). *See id*. In order for such a payment to be protected, three standards must be met. First, the eligible managed care organization and the first-tier contractor have an agreement that: (1) is set out in writing and signed by both parties; (2) specifies the items and services covered by the agreement; (3) is for a period of at least one year; and (4) specifies that, except in limited circumstances, the first-tier contractor cannot claim payment in any form from a Federal Health Care Program for items or services covered under the agreement. *See id*. Second, in establishing the terms of the agreement, neither party gives or receives remuneration in return for or to induce the provision of business, other than business covered by the agreement, for which payment may be made in whole or in part by a Federal Health Care Program on a fee-for-service or cost basis. *See id*. Third, neither party to the agreement shifts the financial burden of the agreement. *See id*.

Prohibited "remuneration" also does not include any payment between a first-tier contractor and a downstream contractor (i.e., an individual or entity that has a subcontract with a first-tier contractor for the provision of items or services that are covered by an agreement between an eligible managed care organization and the first-tier contractor) or between two downstream contractors, to provide or arrange for items or services. *See id*. In order for such a payment to be protected, the same three requirements noted above must be met. In addition, the agreement between the eligible managed care organization and first-tier contractor covering the items or services that are addressed by the agreement between the parties must not involve: (1) a federally-qualified health center receiving supplemental payments; (2) an HMO or competitive medical plan with a cost-based contract under § 1876 of the Social Security Act; or (3) a federally qualified HMO, unless the items or services are covered by a risk based contract under §§ 1854 or 1876 of the Social Security Act. *See id*.

41. *See* 42 C.F.R. § 1001.952(u) (2000). This safe harbor implements a statutory exception. *See* 42 U.S.C. § 1320a-7b(b)(3(F). Prohibited "remuneration" does not include any payment between a qualified eligible managed care plan (i.e., a health plan providing a comprehensive range of health services that meets certain other requirements) and a first-tier contractor (i.e., an individual or entity that has a contract directly with a qualified managed care plan to provide or arrange for items or services) for providing or arranging for items or services. *See* 42 C.F.R. § 1001.952(u)(i). In order for such a payment to be protected, the following five standards must be met. First, the agreement between the plan and first-tier contractor must be in writing and signed by the parties, specify the items and services covered by the agreement, be for a period of a least one year, require participation in a quality assurance program, and specify a methodology for determining payment that is commercially reasonable and consistent with fair market value established in an arm's-length transaction. *See id*. Second, if a first-tier contractor has an investment interest in a qualified managed care plan, the investment interest must meet the criteria of the investment interests safe harbor at 42 C.F.R. § 1001.952(a)(1). *See id*. Third, the first-tier contractor must have "substantial financial risk" for the cost or utilization of services it is obligated to provide through one of the following four payment methodologies: (1) a periodic fixed payment per patient that does not take into account the dates services are provided, the frequency of

It is important to note that the safe harbor regulations do not purport to represent the only types of arrangements that are permissible under the Anti-Kickback Statute. In other words, the failure of an arrangement to meet all of the criteria of an applicable safe harbor does not necessarily mean that the arrangement violates the statute. In the preamble to the final safe harbor regulations issued in 1991, the OIG states that the failure of an arrangement to qualify for a safe harbor can mean one of three things:

> First . . . it may mean that the arrangement does not fall within the ambit of the statute. In other words, the arrangement is not intended to induce the referral of business reimbursable under [a Federal Health Care Program]; so there is no reason to comply with the safe harbor standards, and no risk of prosecution. Second, at the other end of the spectrum, the arrangement could be a clear statutory violation and

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services, or the extent or kind of services provided; (2) a percentage of premium; (3) inpatient diagnosis-related groups (DRGs); or (4) bonus and withhold arrangements meeting specified criteria. *See id*. Fourth, payments for items and services reimbursable by a Federal Health Care Program must comply with the following two standards: (1) The qualified managed care plan must generally submit the claims directly to the Federal Health Care Program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal Health Care Program; and (2) Payments to first-tier contractors and any downstream contractors (i.e., an individual or entity that has a subcontract directly or indirectly with a first-tier contractor for the provision or arrangement of items or services that are covered by an agreement between a qualified managed care plan and the first-tier contractor) for providing or arranging for items or services reimbursed by a Federal Health Care Program must be identical to payment arrangements between such parties for the same items or services provided to other beneficiaries with similar health status. *See id*. Fifth, in establishing the terms of an arrangement, neither party must give or receive remuneration in return for or to induce the provision or acceptance of business for which payment may be made in whole or in part by a Federal Health Care Program, and neither party must shift the financial burden of the arrangement to the extent that increased payments are claimed from a Federal Health Care Program. *See id*.

Prohibited "remuneration" also does not include any payment between a first-tier contractor and a downstream contractor, or between downstream contractors, to provide or arrange for items or services, as long as the following three standards are met, First, both parties are paid for the provision or arrangement of items or services in accordance with one of the payment methodologies set forth above. *See* 42 C.F.R. § 1001.952(u)(ii). Second, payment arrangements for items and services reimbursable by a Federal Health Care Program must comply with the following two standards: (1) The qualified managed care plan must generally submit the claims directly to the Federal Health Care Program, in accordance with a valid reassignment agreement, for items or services reimbursed by the Federal Health Care Program; and (2) Payments to first-tier contractors and any downstream contractors for providing or arranging for items or services reimbursed by a Federal Health Care Program must generally be identical to payment arrangements between such parties for the same items or services provided to other beneficiaries with similar health status. *See id*. Third, in establishing the terms of an arrangement, neither party must give or receive remuneration in return for or to induce the provision or acceptance of business for which payment may be made in whole or in part by a Federal Health Care Program on a fee-for-service or cost basis, and neither party to the arrangement must shift the financial burden of the arrangement to the extent that increased payments are claimed from a Federal Health Care Program. *See id*.

> also not qualify for safe harbor protection. In that case, assuming the arrangement is obviously abusive, prosecution would be very likely. Third, the arrangement may violate the statute in a less serious manner, although not be in compliance with a safe harbor provision. Here there is no way to predict the degree of risk. Rather, the degree of the risk depends on an evaluation of the many factors which are part of the decision-making process regarding case selection for investigation and prosecution.[42]

Where a particular practice "falls within the ambit of the statute"[43] and does not qualify for a safe harbor, the OIG and DOJ will consider a variety of factors in determining whether the arrangement is abusive and a candidate for investigation and prosecution. Specifically, consideration is given to: (1) the potential for increased charges or reported costs to a Federal Health Care Program; (2) the possible encouragement of overutilization; (3) the potential for adversely affecting competition by freezing competing suppliers out of the marketplace; and (4) the intent of the parties.[44] No one factor is dispositive, and the OIG and DOJ have considerable discretion in bringing enforcement actions.[45]

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42. 56 Fed. Reg. 35,954 (July 29, 1991).

43. *See id*.

44. *See id*. at 35,954, 35,956, 35,978; *see also* United States v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

45. The OIG's position regarding the analysis of an arrangement that fails to qualify for a safe harbor may be clarified through the use of an example involving a diagnostic imaging supplier that leases space for operating an outpatient imaging center. The first scenario identified by the OIG in the preamble to the 1991 safe harbor regulations would arise if the supplier leased space from a commercial real estate developer that is not a health care provider. *See* Fed. Reg. 35,954, 35,956, 35,978. The Anti-Kickback Statute would not be implicated by this arrangement since the lessor is not in a position to refer patients to the supplier or order services from the supplier. Consequently, there is no need to assess whether the terms of the lease arrangement comply with the space rental safe harbor.

The second scenario identified by the OIG would arise if the supplier leased space from a physician who referred patients to the supplier for imaging services and the methodology for calculating the lease payments to the physician-lessor was based upon a percentage of the supplier's gross revenues. *See id*. The Anti-Kickback Statute would be implicated by this arrangement since the lessor is in a position to refer patients to the supplier. The space rental safe harbor would not be met since the aggregate lease payments to the physician would not be set in advance; rather, these payments would be dependent upon the gross revenues of the supplier. Moreover, the arrangement would also pose the threat of overutilization since the physician-lessor would be able to increase the amount of lease payments made by the lessee simply by increasing the volume of patients referred to the supplier for imaging services.

Finally, the third scenario might arise if the supplier leased space from a referring physician pursuant to an oral agreement under which the supplier agreed to pay the physician a set dollar amount per month for the space subject to renegotiation at six-month intervals. *See id*. The Anti-Kickback Statute would be implicated by this arrangement since the lessor is in a position to refer patients to the supplier. The space rental safe harbor would not be met since the arrangement is not in writing and is not at least one year in duration since the lease amount is subject to renegotiation after six months. However, the arrangement is not a clear violation of the Anti-Kickback Statute since the lease amount is set in advance and does not directly vary

C. OIG Special Fraud Alerts

The OIG has issued a number of "Special Fraud Alerts" to identify certain practices that may violate the Anti-Kickback Statute. Although Special Fraud Alerts are not regulations having the force of law, they are significant since they offer insight into the OIG's enforcement priorities and provide the OIG's interpretation of the Anti-Kickback Statute as applied to various factual situations.[46] Moreover, at least one federal court has expressly relied upon a Special Fraud Alert in finding a violation of the Anti-Kickback Statute.[47] Special Fraud Alerts have been issued to address the application of the Anti-Kickback Statute in the following general areas: (1) joint venture arrangements;[48] (2) routine waivers of beneficiary copayment and deductible

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based upon the volume of referrals by the physician. Consequently, in determining whether to prosecute, enforcement officials would likely assess: (1) whether the intent of the parties was to compensate the physician for referrals by determining if the lease amount paid by the supplier was greater than fair market value; and (2) whether the arrangement has the potential for leading to overutilization by determining if the criteria used in renegotiating the lease amount was based upon the volume or value of business referred to the supplier by the physician.

46. *See* 59 Fed. Reg. 65,372 (Dec. 19, 1994); 60 Fed. Reg. 40,847 (Aug. 10, 1995); 61 Fed. Reg. 30,623 (June 17, 1996); 63 Fed. Reg. 20,415 (April 24, 1998); 64 Fed. Reg. 1813 (Jan. 12, 1999) (setting forth previously issued Special Fraud Alerts).

47. *See* Polk County v. Peters, 800 F. Supp. 1451 (E.D. Tex. 1992) (in refusing to enforce a recruitment agreement between a hospital and a physician, on grounds that the agreement violated the Anti-Kickback Statute, the court cites the May 1992 OIG Special Fraud Alert on "Hospital Incentives to Physicians").

48. *See* Special Fraud Alert: Joint Venture Arrangements (Aug. 1989), *reprinted in* 59 Fed. Reg. 65,373 (Dec. 19, 1994). The Special Fraud Alert states that the OIG has become aware of the proliferation of "joint venture" arrangements between ongoing businesses that furnish health care items or services and physicians who refer patients to those businesses. *See id*. Such arrangements may take a variety of forms, ranging from a contractual arrangement between two or more parties to cooperate in providing services, to the creation of a new legal entity by the parties (such as a limited partnership or a closely-held corporation) to provide services. According to the Special Fraud Alert, these joint ventures may be intended not so much to start a legitimate business, but to indirectly compensate physician-investors for their referrals, in violation of the Anti-Kickback Statute. The questionable features of these suspect joint ventures may be reflected in three areas: (1) the manner in which investors are selected and retained; (2) the nature of the business structure of the joint venture; and (3) the financing and profit distributions of the venture. *See id*. The Special Fraud Alert offers examples of "questionable features" in each of these three general areas, which features separately or taken together may result in an arrangement that violates the Anti-Kickback Statute. The following examples of questionable features pertain to the manner in which investors are selected: (1) Investors are chosen because they are in a position to make referrals to the venture; (2) Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals; (3) Physician-investors may be actively encouraged to make referrals to the joint venture (and may be encouraged to divest their ownership interest if they fail to sustain an "acceptable" level of

obligations under Part B of the Medicare program;[49] (3) hospital incentives to

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referrals); (4) The joint venture may track its sources of referrals, and distribute this information to the investors; (5) Investors may be required to divest their ownership interests if they cease to practice in the service area; and (6) Investment interests may be nontransferable. *See id*. In discussing the business structure of a suspect joint venture, the Special Fraud Alert notes that the joint venture may be no more than a "shell." Specifically, one of the parties to the venture may be an ongoing entity, already engaged in a particular line of business, which acts as the supplier and manager for the joint venture. *See id*. For example, in the case of a "shell" medical equipment joint venture established between a group of physicians and an ongoing medical equipment supplier, the supplier may own all of the medical equipment and assume full responsibility for the day-to-day operations of the joint venture (e.g., equipment delivery, customer assistance, billing). Finally, the following examples of questionable features pertain to the financing and profit distributions of the venture: (1) The amount of capital invested by the physicians may be disproportionately small and the returns on investment disproportionately large when compared to a typical investment in a new business enterprise; (2) Physician-investors may invest only a nominal amount, such as $500 to $1,500; (3) Physician investors may be permitted to borrow the amount of the investment interest from the entity; and (4) Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50% to 100% per year. *See id*.

49. *See* Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B (May 1991), *reprinted in* 59 Fed. Reg. 65,374 (Dec. 19, 1994). Briefly, Part B of the Medicare program provides reimbursement for, among other things, physician services, diagnostic testing, and rehabilitation therapy services. *See id*. A Medicare beneficiary's participation in Part B is optional. In order to participate, the beneficiary agrees to pay a monthly premium of $45.50, a $100 yearly deductible, and a 20% copayment based upon the Medicare allowable cost or charge for the item or service furnished to the beneficiary. *See id*. The Special Fraud Alert addresses situations where providers, practitioners, and suppliers routinely waive collection of the deductible and copayment amounts from beneficiaries. According to the Special Fraud Alert, "[w]hen providers, practitioners or suppliers forgive [patients'] financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them" in violation of the Anti-Kickback Statute. *See* 59 Fed. Reg. at 65,375. Thus, a good faith effort should be made to collect deductibles and copayments in most cases; however, it is permissible to forgive a particular patient's copayment and deductible obligations based upon a showing of financial hardship. *See id*. The Special Fraud Alert identifies certain practices which indicate that providers, practitioners, or suppliers are routinely waiving Medicare deductibles and copayments: (1) advertisements which state "Medicare accepted as payment in full," "insurance accepted as payment in full," or "no out-of-pocket expense;" (2) routine use of "financial hardship" forms which state that the beneficiary is unable to pay the coinsurance/deductible amounts (i.e., there is no good faith attempt to determine the beneficiary's actual financial condition); (3) collection of copayments and deductibles only where the beneficiary has Medicare supplemental insurance coverage that pays the copayments and deductibles; (4) higher charges to Medicare beneficiaries than those made to other persons in order to offset the waiver of coinsurance; (5) failure to collect copayments or deductibles for a specific group of Medicare patients for reasons unrelated to indigency (e.g., a supplier waives coinsurance or deductible obligations for all patients from a particular hospital); and (6) sham insurance programs which cover copayments or deductibles only for items and services provided by the entity offering the insurance, where the premium is insignificant (e.g., $1/month, and not based on actuarial risks). *See* 59 Fed. Reg. at 65,374.

physicians;[50] (4) prescription drug marketing practices;[51] (5) clinical laboratory

50. *See* Special Fraud Alert: Hospital Incentives to Physicians (May 1992), *reprinted in* 59 Fed. Reg. 65,375 (Dec. 19, 1994). According to the Special Fraud Alert, a variety of incentive programs, or "practice enhancements," are often used by hospitals to recruit and retain physicians. *See id*. Certain incentive programs may violate the Anti-Kickback Statute because the incentives are offered to induce the referral of Medicare and Medicaid beneficiaries to the hospital. *See id*. The Special Fraud Alert indicates that incentive packages which incorporate the following "questionable" features may be subject to enforcement action: (1) payment of any sort of incentive by the hospital each time a physician refers a patient to the hospital; (2) the use of free or significantly discounted office space or equipment; (3) provision of free or significantly discounted billing, nursing, or other staff services; (4) free training for a physician's office staff in such areas as management techniques, coding, and laboratory techniques; (5) income guarantees; (6) low-interest or interest-free loans, or loans which may be "forgiven" if a physician refers patients to the hospital; (7) payment of the cost of a physician's travel and expenses for attending conferences; (8) payment for a physician's continuing medical education courses; (9) coverage of the physician on the hospital's group health insurance plans at an inappropriately low cost to the physician; and (10) payment for services which require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of the services rendered. *See id*.

51. *See* Special Fraud Alert: Prescription Drug Marketing Schemes (Aug. 1994), *reprinted in* 59 Fed. Reg. 65,376 (Dec. 19, 1994). According to the Special Fraud Alert, "[m]any prescription drug marketing activities go far beyond traditional advertising and educational contacts. Physicians, suppliers and, increasingly, patients are being offered valuable, non-medical benefits in exchange for selecting specific prescription drug brands." *Id*. The Special Fraud Alert identifies specific activities that are potentially violative of the Anti-Kickback Statute: (1) a "product conversion" program pursuant to which a drug company offers a cash award to pharmacies for each time a drug prescription is changed from another drug company's product; (2) a "frequent-flier" campaign in which physicians are given credit toward airline frequent flier mileage each time the physician completes a questionnaire for a new patient placed on the company's product; and (3) a "research grant" program in which physicians are given substantial payments for de minimus record-keeping tasks (e.g., making brief notes about the treatment outcome). *See id*. In addition, the Special Fraud Alert identifies several more general marketing practices that may warrant OIG investigation: (1) any prize, gift or cash payment, coupon or bonus offered to physicians and/or suppliers, including pharmacies, mail order prescription drug companies, and managed care organizations in exchange for, or based on, prescribing or providing specific prescription products, particularly if provision of these benefits is based on the value or volume of business generated for the drug company; (2) materials which offer cash or other benefits to pharmacists, or others in a position to recommend prescription drug products, in exchange for performing marketing tasks in the course of pharmacy practice, e.g., sales-oriented "educational" or "counseling" contacts, or physician and/or patient outreach; (3) grants to physicians and clinicians for studies of prescription products when the studies are of questionable scientific value and require little or no actual scientific pursuit; and (4) any payment, including cash or other benefit, given to a patient, provider, or supplier for changing a prescription, or recommending or requesting such a change, from one product to another, unless the payment is fully consistent with a safe harbor regulation or other federal law governing the reporting of prescription drug prices. *See id*.

arrangements;[52] (6) home health care fraud;[53] (7) the provision of medical supplies to nursing facilities;[54] (8) nursing home arrangements with hospices;[55]

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52. *See* Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services (Oct. 1994), *reprinted in* 59 Fed. Reg. 65,377 (1994). The Special Fraud Alert states that "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business[,]" such as the referral of specimens for testing. *Id.* The Special Fraud Alert provides the following examples of practices of clinical laboratories that may violate the Anti-Kickback Statute: (1) provision of a phlebotomist to a physician's office to collect specimens for testing as well as to perform certain tasks that are normally the responsibility of the physician's office staff and not directly related to the collection or processing of the specimens (e.g., clerical services, nursing functions); (2) offering a kidney dialysis facility reduced rates on composite rate laboratory tests – which the facility is required to furnish to each Medicare beneficiary treated at the facility and for which the facility is reimbursed directly by Medicare – in return for the facility agreeing to refer non-composite rate testing to the laboratory, which is billed directly to Medicare by the laboratory; (3) agreeing with a physician to perform laboratory services free of charge for patients of the physician who are enrollees of managed care plans that pay the physician a bonus if the utilization or cost of ancillary services, such as laboratory testing, is kept below a particular level, in return for the physician referring other patients to the laboratory; (4) free pick-up and disposal of bio-hazardous waste products unrelated to the collection of specimens; (5) provision of free computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the laboratory's work; and (6) provision of free laboratory testing for health care providers, as well as their families and employees. *See id.*

53. *See* Special Fraud Alert: Home Health Fraud (June 1995), *reprinted in* 60 Fed. Reg. 40,847 (Aug. 10, 1995). Briefly, Medicare pays for home health care services if a Medicare beneficiary's physician certifies that the beneficiary is homebound and requires one or more of the following services: physical therapy, speech-language pathology, or intermittent skilled nursing. *See* 42 U.S.C. § 1395n(a)(2)(A). According to the Special Fraud Alert, the OIG is aware of home health agencies furnishing remuneration to physicians, beneficiaries, and hospitals in return for the referral of business to the agency. Such remuneration has taken the following forms: (1) payment of a fee to a physician for each plan of care certified by the physician on behalf of the home health agency; (2) disguising referral fees as salaries by paying referring physicians for services not rendered, or in excess of the fair market value for services rendered; (3) offering free services to beneficiaries, including transportation and meals, if the beneficiaries agree to switch home health providers; (4) providing hospitals with discharge planners, home care coordinators, or home care liaisons in order to induce referrals; (5) providing free services, such as twenty-four-hour nursing coverage, to retirement homes or adult congregate living facilities in return for referrals; and (6) subcontracting with retirement homes or adult congregate living facilities for the provision of home health services in order to induce the facility to make referrals to the agency. *See* 60 Fed. Reg. at 40,847.

54. *See* Special Fraud Alert: Medical Supplies to Nursing Facilities (Aug. 1995), *reprinted in* 60 Fed. Reg. 40,849 (Aug. 10, 1995). According to the Special Fraud Alert, the OIG is aware of cases where a supplier furnishes a nursing facility with free medical supplies in return for the facility assisting in the procurement of products which the supplier bills directly to the Medicare or Medicaid programs. The OIG gives the example of a supplier furnishing incontinence kits to a facility. *See id.* These kits may consist of supplies reimbursable by Medicare, as well as non-reimbursable items, such as disposable underpads or adult diapers.

and (9) physician certifications for medical equipment, supplies, and services.[56]

D. Advisory Opinions

The OIG is required to issue written advisory opinions to private parties in response to requests regarding whether existing or proposed transactions violate

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The supplier bills Medicare Part B directly for the Medicare-covered supplies contained in the kits. The supplier does not, however, bill the facility for the other items contained in the kits which are not covered by Medicare (e.g., adult diapers). Thus, furnishing these items to the facility at no charge can be viewed as a form of remuneration given to the facility to induce it to order more kits from the supplier, in violation of the Anti-Kickback Statute.

55. *See* Special Fraud Alert: Fraud and Abuse in Nursing Home Arrangements with Hospices, *reprinted in* 63 Fed. Reg. 20,415 (Apr. 24, 1998). Briefly, Medicare's hospice benefit provides palliative care to individuals who are terminally ill. *See id*. In order to elect the hospice benefit, a Medicare beneficiary must be certified as terminally ill, which is defined as a medical prognosis of a life expectancy of six months or less if the illness runs its normal course. Palliative care focuses on pain control, symptom management, and counseling for both the patient and family. *See* 42 U.S.C. § 1395x(dd). According to the Special Fraud Alert, arrangements between nursing homes and hospices are vulnerable to fraud because nursing home operators have control over the hospices they will permit to provide hospice services to their residents. Some nursing home operators and/or hospices may request or offer illegal remuneration to influence a nursing home's decision to do business with a particular hospice. According to the OIG, specific practices which are potential kickback arrangements between nursing homes and hospices include: (1) a hospice offering free goods, or goods at below fair market value, to induce a nursing home to refer patients to the hospice; (2) a hospice making "room and board" payments to the nursing home in amounts exceeding what the nursing home would have received directly from Medicare had the patient not been enrolled with the hospice; (3) a hospice paying amounts to the nursing home for "additional" services that Medicare considers to be included in its room and board payment to the hospice; (4) a hospice paying above fair market value for "additional" non-core services which Medicaid does not consider to be included in its room and board payment to the nursing home; (5) a hospice referring its patients to a nursing home to induce the nursing home to refer its patients to the hospice; (6) a hospice providing care that is free or below fair market value to nursing home patients, for whom the nursing home is receiving Medicare payment under the skilled nursing facility benefit, with the expectation that after the patient exhausts the Medicare skilled nursing facility benefit the patient will continue to receive hospice services from that hospice, for which the hospice will be reimbursed; and (7) a hospice providing staff at its own expense to the nursing home to perform duties that otherwise would be performed by the nursing home. *See* 63 Fed. Reg. 20,415.

56. *See* Special Fraud Alert: Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services, *reprinted in* 64 Fed. Reg. 1813 (Jan. 12, 1999). Briefly, the Medicare program only pays for items or services that are medically necessary, and Medicare payment for many items and services is conditioned upon a certification signed by the beneficiary's treating physician that the items and services are medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A). According to the Special Fraud Alert, "a physician may receive compensation [from an individual or entity providing items and services] in exchange for his or her signature. Compensation can take the form of cash payments, free goods, or any other thing of value. Such cases may trigger additional criminal and civil penalties under the [A]nti-[K]ickback [S]tatute." 64 Fed. Reg. at 1815.

the Anti-Kickback Statute.[57] Advisory opinions will address, among other things, what constitutes "remuneration" under the Anti-Kickback Statute and whether an arrangement satisfies the criteria for a statutory exception or a regulatory safe harbor. However, advisory opinions will not address questions involving the intent of parties to an arrangement, the fair market value of goods, services, or property, or whether an individual is a bona fide employee.[58] Advisory opinions are only binding upon the parties requesting the opinion.[59]

E. Case Law

Federal case law has provided broad interpretations of the Anti-Kickback Statute. The statute has been held applicable to a wide variety of relationships that are quite different from an obvious kickback for a patient referral or a bribe to recommend the purchase of specific items or services. Federal courts and administrative bodies considering the statute in the context of actual enforcement proceedings have established several important interpretive principles: (1) The statute may be violated if even one purpose, as opposed to a primary or sole purpose, of a payment arrangement is in exchange for, or to induce, the referral of patients or the ordering, purchasing, leasing or recommending of items or services;[60] (2) Giving a potential referral source the

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57. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 205, 110 Stat. 1936 (adding 42 U.S.C. § 1320a-7d(b), which requires the issuance of advisory opinions by the OIG). The OIG has issued a rule specifying the process for seeking an advisory opinion. *See* 63 Fed. Reg. 38,324 (July 16, 1998) (adding 42 C.F.R. Part 1008).

58. *See* 42 C.F.R. § 1008.5 (1999).

59. *See* 42 C.F.R. § 1008.53 (1999).

60. *See, e.g.*, United States v. Greber, 760 F.2d 68, 72 (3d Cir. 1985) (in upholding the criminal conviction of the owner of a mobile diagnostic imaging service company that paid "consultation fees" to referring physicians which were in excess of the value of any services actually performed by the physicians, the court stated that "[i]f the payments were intended to induce the physician to use[the defendant's] services, the [Anti-Kickback] [S]tatute was violated, even if the payments were also intended to compensate for professional services"); United States v. Kats, 871 F.2d 105, 108 n.1 (9th Cir. 1989) (in upholding the criminal conviction of the owner of a community medical clinic for entering into an arrangement with a clinical laboratory under which the laboratory agreed to return to the clinic 50% of the receipts from all tests referred to it by the clinic, the court approved a jury instruction which stated, in part, that "[t]he government must prove beyond a reasonable doubt that one of the purposes for the solicitation of the remuneration was to obtain money for the referral of services which may be paid in whole or in part out of Medicare funds."); United States v. Bay State Ambulance and Hosp. Rental Serv., Inc., 874 F.2d 20, 30 (1st Cir. 1989) (in upholding the criminal conviction of the president of an ambulance company, as well as a hospital employee who made recommendations to the hospital on the award of ambulance contracts while also being paid by the ambulance company to serve as a "training consultant," the court noted that an expansive reading of the Anti-Kickback Statute "implies that the issue of the sole versus primary reason for payments is irrelevant since *any* amount of inducement is illegal.").

opportunity to earn a fee, particularly a fee that exceeds the reasonable value of any services provided or return on investment made, is evidence that the payment is unlawful;[61] (3) The mere potential for increased costs to Medicare or Medicaid may be enough to violate the law, meaning that no actual payout by Medicare or Medicaid is necessary if the challenged remuneration pertains to an item or service that could be paid for by Medicare or Medicaid;[62] (4) The fact that a particular arrangement is common in the health care industry is not a defense to a violation of the statute;[63] and (5) An illegal intent may be inferred from the circumstances of the case, absent an explicit agreement to refer business.[64]

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61. *See Bay State Ambulance*, 874 F.2d at 29 (stating that "[g]iving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient").

62. *See Ruttenberg*, 625 F.2d at 174, 177 (in upholding criminal convictions against a pharmacist who paid "fees for consulting services" to a skilled nursing facility in return for "the opportunity to provide drugs and pharmaceutical services" to the facility, the court noted that the mere "*potential* for increased costs" to the Medicare or Medicaid programs is sufficient to violate the Anti-Kickback Statute); *Greber*, 760 F.2d at 71 (stating that "[e]ven if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains").

63. *See Polk County*, 800 F. Supp. at 1455 (in refusing to enforce a physician recruitment agreement entered into by a hospital, the court noted that "[a]s many hospitals have become more aggressive in their attempts to recruit and retain physicians and increase patient referrals, . . . 'practice enhancements' . . . are becoming increasingly common. . . . [although] [i]ncentive programs directly or indirectly aimed at inducing doctors to refer patients to a hospital violate the [A]nti-[K]ickback [S]tatute").

64. In a 1992 administrative exclusion action brought by the OIG challenging an arrangement under which physicians received limited partnership interests in a clinical laboratory joint venture, the HHS Departmental Appeals Board concluded that "a violation [of the Anti-Kickback Statute] occurs whenever an individual or entity knowingly and willfully offers or pays anything of value, in any manner or form, with the intent of exercising influence over a physician's reason or judgment in an effort to cause the referral of [Medicare or Medicaid] program-related business. Nothing in the statutory language [of the Anti-Kickback Statute] explicitly or implicitly requires an agreement." Inspector v. Hanlester Network, Dec. No. 1275 (HHS Departmental Appeals Board, Appellate Division, Sept. 18, 1991) Medicare & Medicaid Guide (CCH) ¶ 39,566, *aff'd in part* and *rev'd in part*, Dec. No. 1347 (HHS Departmental Appeals Board, Appellate Division, July 24, 1992), Medicare & Medicaid Guide (CCH) ¶ 40,406B, *aff'd sub nom*. Hanlester Network v. Sullivan, No. CV 92-4552-LHM, 1993 WL 78299 (C.D. Cal. 1993), *aff'd in part* and *rev'd in part sub nom*. Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

The U.S. Court of Appeals for the Ninth Circuit agreed with the conclusion of the HHS Departmental Appeals Board that an explicit agreement to refer business is not required in order for there to be a violation of the Anti-Kickback Statute. *See Hanlester*, 51 F.3d at 1397. However, the court concluded that in order to act "knowingly and willfully" under the Anti-Kickback Statute there must nevertheless be evidence that the defendant: (1) actually knew that the law prohibited giving or receiving remuneration for referrals or the ordering, purchasing,

II. FALSE CLAIMS ACT

A. The Statutory Provision

1. *Prohibited Conduct*

The False Claims Act prohibits the submission of false or fraudulent claims to the United States.[65] The False Claims Act was enacted in 1863 to prosecute defense contractors who were defrauding the United States during the U.S. Civil War.[66] The statute has been subject to numerous amendments over the years which have expanded its scope.[67]

Currently, the False Claims Act specifies seven types of prohibited conduct. Specifically, the statute imposes liability on any person or entity who:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid; (4) has possession, custody, or control of property or money used . . . by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt; (5) . . . intending to defraud the Government, makes or delivers the receipt [of a document certifying receipt of property used, or to be used, by the United States

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or recommending of items or services; and (2) acted with a specific intent to violate the law. *Id*. at 1397, 1400. The OIG has announced that it will "aggressively contest" in other judicial circuits the Ninth Circuit's ruling that a violation of the Anti-Kickback Statute requires an intentional violation of a known legal duty. *See Fraud and Abuse: DOJ Refuses to Ask for Supreme Court Review of Hanlester Anti-Kickback Case*, 7 BNA Medicare Report 6, d22 (Feb. 9, 1996). In fact, several courts in other jurisdictions have expressly declined to follow the Ninth Circuit's conclusion on this issue. *See, e.g.*, United States v. Jain, 93 F.3d 436, 440-41 (8th Cir. 1996) (the "*mens rea* standard [of the Anti-Kickback Statute] should only require proof that [the defendant] knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty'"). *Accord* United States v. Starks, 157 F.3d 833, 838 (11th Cir. 1998); United States v. Neufeld, 908 F. Supp. 491, 497 (S.D. Ohio 1995).

65. *See* 31 U.S.C. § 3729 (1994).

66. *See* Act of Mar. 2, 1863, ch. 67, 12 Stat. 696 (1863). *See* S. REP. NO. 99-345, at 2d Sess. 8-10 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5273-75. *See* United States v. McNinch, 356 U.S. 595, 599-600 (1958) (noting that the False Claims Act was enacted because of widespread fraud against the Union government, including billing for non-existent or worthless goods, charging exorbitant prices, and generally robbing the government).

67. *See* Pub. L. No. 213, ch. 377, 57 Stat. 608 (1943); Pub. L. No. 99-562, 100 Stat. 3153 (1986); Pub. L. No. 103-272, 108 Stat. 1362 (1994). There are several articles that discuss in depth the history of the False Claims Act. *See, e.g.*, JOHN T. BOESE, CIVIL FALSE CLAIMS AND *QUI TAM* ACTIONS (1993); John Robertson, Comment, *The False Claims Act*, 26 ARIZ. ST. L.J. 899 (1994).

> government] without completely knowing that the information on the receipt is true; (6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.[68]

2. *Damages and Civil Penalties*

A person or entity convicted of violating the False Claims Act is liable to the United States Government for both damages and civil penalties. Specifically, for each violation of the False Claims Act, a defendant will be liable for a civil penalty of between $5,000 and $10,000, plus three times the amount of actual damages sustained by the Government as a result of the prohibited conduct.[69] In addition to being liable for damages and civil penalties, a person or entity violating the False Claims Act is subject to exclusion from participation in Federal Health Care Programs,[70] and liable to the United States Government for the costs of any civil action brought by the Government to recover any damages or penalties.[71] Significantly, since each claim submitted to the Government can constitute a separate violation of the False Claims Act, the potential liability for civil penalties can be enormous and oftentimes seemingly disproportionate to the amounts actually sought by the claimant from the Government.[72] A claimant's potential exposure under the False Claims Act

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68. 31 U.S.C. § 3729(a)(1)-(7) (1994).

69. *See* 31 U.S.C. § 3729(a) (1994). Generally, "damages" reflect the difference between what the government actually paid pursuant to the claims and what the government should have paid absent the fraud. Civil penalties are calculated on a per claim basis separately from damages. *See id*.

70. *See* 42 U.S.C. § 1320a-7 (1994); 42 C.F.R. § 1001.901 (1998).

71. *See* 31 U.S.C. § 3729(a) (1994).

72. In other words, if a large number of claims are submitted, even if each false claim is only for a small amount, the manner in which damages and civil penalties are calculated under the False Claims Act means that a claimant's potential exposure can be much greater than the amount of damages sustained by the government. The case of *United States v. Lorenzo*, 768 F. Supp. 1127 (E.D. Pa. 1991), illustrates this fact. In *Lorenzo*, the claimant was found to have violated the False Claims Act for knowingly filing 3,683 false Medicare claims, resulting in the defendant receiving $130,719.10 in excessive Medicare reimbursement. *See Lorenzo*, 768 F. Supp. at 1129. However, since the court assessed damages at three times the government's loss and ordered that the statutory minimum penalty of $5,000 per false claim be imposed, the defendant's actual liability was $18,807,157.30. Significantly, the defendant's liability could have been over $37 million if the court had chosen to impose the statutory maximum penalty of $10,000 per false claim. *See id*. at 1133; *see also, e.g.*, United States v. Diamond, 657 F. Supp. 1204 (S.D.N.Y. 1987) (physician convicted under the False Claims Act for filing thirty-nine false Medicare claims, resulting in $549 in improper reimbursement, was liable to the government for $79,098).

can be limited in two ways. First, the False Claims Act allows a court to limit a claimant's liability for damages to twice the government's actual damages if the claimant cooperates with the government's investigation.[73] Second, since the Eighth Amendment to the United States Constitution prohibits the federal government from imposing "excessive fines," the civil penalties imposed under the False Claims Act in a particular case can be reduced below the statute's minimum statutory assessment if such penalties are deemed to be excessive.[74]

3. *Meaning of Key Terms*

Most cases brought pursuant to the False Claims Act have been filed under Subsections (a)(1) and (a)(2) of the statute.[75] Certain common elements must be proven in order to establish that conduct violates the prohibitions in these subsections: (1) A "claim" for payment or approval must be presented to the United States; (2) The claim, or a record or statement made or used in support of the claim, must be "false or fraudulent"; and (3) The claimant(s) must act "knowingly" when presenting the claim, or in making or using the record or statement in support of the claim. In fact, a number of courts have expressly required that each of these three elements be proven in order to state a cause of action under these provisions of the False Claims Act.[76] Some courts also have required that, in addition to proving these three elements, it

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73. In order to limit damages in this manner, the court must find that: (1) the person or entity committing the violations furnished government officials responsible for investigating the violations with all information known about the violations within thirty days after the date on which the person or entity first obtained the information; (2) such person or entity fully cooperated with any government investigation of the violations; and (3) at the time such person or entity furnished the information about the violations, no criminal prosecution, civil action, or administrative action had commenced with respect to such violations, and the person or entity did not have actual knowledge about the existence of any investigation into the violations. *See* 31 U.S.C. § 3729(a)(A)-(C) (1994).

74. *See* U.S. CONST. amend. VIII; s*ee, e.g.*, United States v. Halper, 490 U.S. 435 (1989), *overruled by* Hudson v. United States 522 U.S. 93 (1997) (civil penalty of $130,000 was excessive when government damages were only $585); *see also* United States *ex rel*. Smith v. Gilbert Realty, 840 F. Supp. 71 (E.D. Mich. 1993).

75. *See* JOHN T. BOESE, QUI TAM: BEYOND GOVERNMENT CONTRACTS 21 (PLI Litig. & Admin. Practice Course Handbook Series No. H-450, 1993) ("Virtually all FCA cases are filed under subsections (a)(1) and (2) of section 3729(a).").

76. *See, e.g.*, United States *ex rel*. Pentagen Tech. Int'l Ltd. v. CACI Int'l, Inc., No. 96-CIV-7827, 1997 WL 473549 (S.D.N.Y. 1997); Wilkens *ex rel*. United States v. Ohio, 885 F. Supp. 1055 (S.D. Ohio 1995); United States v. Truong, 860 F. Supp. 1137 (E.D. La. 1994); United States v. Shaw, 725 F. Supp. 896 (S.D. Miss. 1989); Blusal Meats, Inc. v. United States, 638 F. Supp. 824 (S.D.N.Y. 1986), *aff'd*, 817 F.2d 1007 (2d Cir. 1987).

must be shown that the government suffered financial injury as a result of the claim, record, or statement.[77]

The False Claims Act defines the term "claim" as including

> [A]ny request or demand . . . for money or property which is made to a contractor, grantee or other recipient if the United States [g]overnment provides any portion of the money or property which is requested or demanded, or if the [United States] [g]overnment will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.[78]

Thus, a claim comes within the scope of the False Claims Act if it is either submitted directly to the United States government or if it is submitted to a non-governmental third party and federal funds will be used to reimburse any portion of the claim.[79] For example, Medicare reimbursement claims submitted directly to private insurance companies that contract with HHS to administer the Medicare program as fiscal intermediaries and carriers are "claims" under the False Claims Act.[80] Likewise, Medicaid reimbursement claims submitted to state Medicaid agencies are also "claims" under the False Claims Act.[81] A "claim" also includes so-called "reverse false claims," which encompass situations where an individual or entity does not submit a claim for payment to the government, but instead makes misrepresentations to avoid paying money owed to the government. For example, a "reverse false claim" might arise where a person obligated to pay the government a percentage of net revenue falsely understates income or overstates expenses in calculating the amount owed to the government. Prior to the 1986 amendments to the False Claims Act, courts were divided on whether "reverse false claims" came within the purview

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77. *See, e.g.*, Young-Montenay, Inc. v. United States, 15 F.3d 1040 (Fed. Cir. 1994); United States v. Azzarelli, 647 F.2d 757 (7th Cir. 1981); Wilkens *ex rel*. United States v. Ohio, 885 F. Supp. 1055 (S.D. Ohio 1995). Correspondingly, other courts have expressly rejected the need to prove actual financial injury by the government in order to recover the per claim civil penalty. *See, e.g.*, United States *ex rel*. Schwedt v. Planning Research Corp., 59 F.3d 196 (D.C. Cir. 1995); United States v. Rohleder, 157 F.2d 126 (3d Cir. 1946); United States *ex rel*. Hagood v. Sonoma County Water Agency, 929 F.2d 1416 (9th Cir. 1991); United States v. Kensington Hosp., 760 F. Supp. 1120 (E.D. Pa. 1991).

78. 31 U.S.C. § 3729(c).

79. *See, e.g.*, United States *ex rel*. Luther v. Consol. Indus., Inc., 720 F. Supp. 919 (N.D. Ala. 1989); United States *ex rel*. Simmons v. Smith, 629 F. Supp. 124 (S.D. Ala. 1985).

80. *See, e.g.*, United States *ex rel*. Woodard v. Country View Care Ctr., Inc., 797 F.2d 888 (10th Cir. 1986); Peterson v. Weinberger, 508 F.2d 45 (5th Cir. 1978); United States v. Krizek, 859 F. Supp. 5 (D.C. Cir. 1994).

81. *See, e.g.*, United States *ex rel*. Aranda v. Comty. Psychiatric Ctrs. of Okla., Inc., 945 F. Supp. 1485 (W.D. Okla. 1996); United States *ex rel*. Fahner v. Alaska, 591 F. Supp. 794 (N.D. Ill. 1984); United States *ex rel*. Davis v. Long's Drugs, Inc., 411 F. Supp. 1144 (S.D. Cal. 1976).

of the False Claims Act.[82] However, the 1986 amendments expressly made "reverse false claims" actionable under the False Claims Act.[83]

Prior to 1986, the False Claims Act did not define the term "knowingly." As a result, courts differed on whether a violation of the False Claims Act required the claimant(s) to have a specific intent to defraud the government or simply knowledge that information contained in a claim was incorrect.[84] Due in part to this variance in judicial opinion, as well as a desire to lessen the burden for proving liability under the False Claims Act, Congress amended the statute in 1986 to expressly define "knowingly" to mean that a person or entity: (1) has actual knowledge of the truth or falsity of the information in the claim, record, or statement; (2) acts in deliberate ignorance of the truth or falsity of the information in the claim, record, or statement; or (3) acts in reckless disregard of the truth or falsity of the information in the claim, record, or statement.[85] Consequently, as a result of the 1986 amendments, a violation of certain provisions of the False Claims Act does not require a specific intent to defraud or proof that the defendants have actual knowledge

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82. A number of courts held that "reverse false claims" were actionable under the pre-1986 False Claims Act. *See, e.g.*, Smith v. United States, 287 F.2d 299 (5th Cir. 1961); United States v. Douglas, 626 F. Supp. 621 (E.D. Va. 1985); United States v. Gardner, 73 F. Supp. 644 (N.D. Ala. 1947); United States *ex rel*. Rodriguez v. Weekly Publ'ns, Inc., 68 F. Supp. 767 (S.D.N.Y. 1946). Correspondingly, a number of courts held that "reverse false claims" were not actionable under the pre-1986 False Claims Act. *See, e.g.*, United States v. American Heart Research Found., Inc., 996 F.2d 7 (1st Cir. 1993); United States v. Howell, 318 F.2d 162 (9th Cir. 1963); United States *ex rel*. Kessler v. Mercur Corp., 83 F.2d 178 (2d Cir. 1936); United States v. Lawson, 522 F. Supp. 746 (D.N.J. 1981); United States v. Marple Cmty. Record, Inc., 335 F. Supp. 95 (E.D. Pa. 1971).

83. *See* 31 U.S.C. § 3729(a)(7) (1994) (making "reverse false claims" actionable by establishing liability for "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government"). *See* Pub. L. No. 99-562, 100 Stat. 3153 (1986).

84. For example, a number of courts interpreted the term "knowingly" to require proof that the claimant(s) had an intent to defraud the government. *See, e.g.*, United States v. Davis, 809 F.2d 1509 (11th Cir. 1987); United States v. Ekelman & Assocs., Inc., 532 F.2d 545 (6th Cir. 1976); United States v. Aerodex, Inc., 469 F.2d 1003 (5th Cir. 1972); United States v. Mead, 426 F.2d 118 (9th Cir. 1970); United States v. Ueber, 299 F.2d 310 (6th Cir. 1962). Correspondingly, other courts interpreted the term "knowingly" to not require proof that the defendant(s) acted with an intent to defraud the government. *See, e.g.*, United States v. Hughes, 585 F.2d 284 (7th Cir. 1978); United States v. Coop. Grain and Supply Comp., 476 F.2d 47 (8th Cir. 1973); Fleming v. United States, 336 F.2d 475 (10th Cir. 1964).

85. *See* 31 U.S.C. § 3729(b) (1994); Pub. L. No. 99-562, 100 Stat. 3153 (1986); S. REP. NO. 99-345, at 6-7 (1996), *reprinted in* 1986 U.S.C.C.A.N. 5266 (noting that 1986 amendments defining the meaning of "knowingly" were intended "not only to adopt a more uniform standard [for imposing liability], but a more appropriate standard for remedial actions").

that information is false.[86] As a result, liability may extend to "corporate officers who insulate themselves from [actual] knowledge of false claims submitted by lower-level subordinates."[87] Furthermore, liability may also extend to situations where the information is false because the claim, record, or statement was prepared in a reckless, unsupervised, or grossly negligent manner.[88] Liability does not extend, however, to instances where false information results from an honest mistake or mere negligence.[89]

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86. *See* 31 U.S.C. § 3729(b) (stating that the term "knowingly" does not require proof of a specific intent to defraud). *See, e.g.*, United States v. Oakwood Downriver Med. Ctr., 687 F. Supp. 302 (E.D. Mich. 1988); United States v. Children's Shelter, Inc., 604 F. Supp. 865 (W.D. Okla. 1985).

87. S. REP. NO. 99-345, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272. In this regard, the legislative history of the 1986 amendments states that:

> By adopting this definition of knowledge, the [Congress] intends not only to cover those individuals who file a claim with actual knowledge that the information is false, but also to confer liability upon those individuals who deliberately ignore or act in reckless disregard of the falsity of the information contained in the claim. It is intended that persons who ignore "red flags" that the information may not be accurate or those persons who deliberately choose to remain ignorant of the process through which their company handles a claim should be held liable under the [False Claims] Act. This definition, therefore, enables the Government not only to effectively prosecute those persons who have actual knowledge, but also those who play "ostrich."

H.R. REP. NO. 99-660, at 20-21 (1986). *See, e.g.*, United States v. Entin, 750 F. Supp. 512, 518 (S.D. Fla. 1990) (Pursuant to the 1986 amendments, the "scienter standard was eased in order to preclude 'ostrich' type situations, where an individual has 'buried his head in the sand' and failed to make any inquiry which would have revealed the false claim.").

88. *See* 132 CONG. REC. H9389 (daily ed. Oct. 7, 1986) (statement of Rep. Berman) (noting that "the [False Claims] Act . . . is intended to apply in situations that could be considered gross negligence where the submitted claims to the Government are prepared in such a sloppy or unsupervised fashion that resulted in overcharges to the Government"); *see, e.g.*, United States v. Krizek, 859 F. Supp. 5, 13-14 (D.D.C. 1994) (finding a physician liable for violating the False Claims Act where the physician "failed utterly in supervising [his staff] in their submissions of claims on his behalf [and,] [a]s a result of his failure to supervise, [the physician] received reimbursement for services which he did not provide"); United States v. Lorenzo, 768 F. Supp. 1127, 1131-32 (E.D. Pa. 1991) (finding a dentist liable for violating the False Claims Act where the dentist disregarded information received from his Medicare carrier that should have put him on notice that certain types of claims which he submitted were improper).

89. *See* S. REP. NO. 99-345, at 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5272 ("[Congress] is firm in its intention that the [False Claims] [A]ct not punish honest mistakes or incorrect claims submitted through mere negligence"); *see also* 132 CONG. REC. H9389 (daily ed. Oct. 7, 1986) (statement of Rep. Berman) (noting that "the [False Claims] Act was not intended to apply to mere negligence"); *see, e.g.*, Wang v. FMC Corp., 975 F.2d 1412, 1420-21 (9th Cir. 1992) ("Bad math is no fraud [and] . . . [p]roof of one's mistakes or inabilities is not evidence that one is [liable under the False Claims Act]."); United States *ex rel*. Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) ("Innocent mistake is a defense to the criminal charge or civil complaint [under the False Claims Act]. So is mere negligence."); Ali v. United States, 904 F. Supp. 915, 922 (E.D. Wis. 1995) (negligence is not actionable under the False Claims Act).

4. *Enforcement*

The DOJ is responsible for investigating alleged violations of the False Claims Act and filing civil actions in federal district court to enforce the statute.[90] In fact, the False Claims Act is "the primary vehicle by which the [federal] government prosecutes civil fraud."[91] The attractiveness of the False Claims Act to prosecutors is due, in part, to the fact that the burden of proof required for a conviction is based upon the less demanding preponderance of the evidence standard.[92] A civil action must be brought within the later of: (1) six years after the date of the violation; or (2) three years after the date that the government learns, or should have learned, that a fraud has been committed.[93] However, in no event may a civil action be commenced more than ten years after the violation.[94]

The False Claims Act also contains a qui tam provision which allows a private party, known as a "relator," to enforce the statute by bringing a civil action in the name of the federal government.[95] Consequently, the False Claims Act permits private citizens to supplement the government's efforts in enforcing the statute.[96] The specific procedures for filing a qui tam complaint are set forth in the statute. Briefly, a relator is required to prepare a complaint and serve it on the government along with written disclosure of substantially all material evidence and information the relator possesses regarding the allegations contained in the complaint.[97] The complaint is not served on the defendant, but

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90. *See* 31 U.S.C. §§ 3730(a), 3732(a) (1994).

91. 132 CONG. REC. 22,335 (1986) (statement of Rep. Glickman).

92. *See* 31 U.S.C. § 3731(b) (1994). *See, e.g.*, Brooks v. United States, 64 F.3d 251 (7th Cir. 1995) (a violation of the False Claims Act requires proof of all the essential elements by a preponderance of the evidence). *See also* M. Cheh, *Constitutional Limits on Using Civil Remedies to Achieve Criminal Law Objectives: Understanding and Transcending the Criminal-Civil Law Distinction*, 42 HASTINGS L.J. 1325 (1991) (noting that "prosectors have embraced [the False Claims Act] . . . because officials believe that civil remedies offer speedy solutions that are unencumbered by the rigorous constitutional protections associated with criminal trials, such as proof beyond a reasonable doubt").

93. *See* 31 U.S.C. § 3731(b) (1994).

94. *See* § 3731(b).

95. *See* § 3730(b)(1) . The term "qui tam" is taken from the Latin expression "*qui tam pro domino rege, . . . quam pro se ipso in hac parte sequitur*," which means "he who brings the action for the king as well as for himself." 3 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAW OF ENGLAND, 160 (1884).

96. *See* S. REP. NO. 99-345, at 6-7 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5267 (noting that "[i]n the face of sophisticated and widespread fraud, the [Congress] believes only a coordinated effort of both the Government and the citizenry will decrease this wave of defrauding public funds").

97. *See* 31 U.S.C. § 3730(b)(2).

is filed in camera and remains under seal for at least sixty days.[98] During the period the complaint is under seal, the government investigates the allegations before deciding whether to formally intervene.[99] The government may petition the court to extend the sixty-day period.[100]

If the government intervenes, it assumes primary responsibility for prosecuting the case.[101] Although the relator may continue as a party in the case, the relator's role may be minimized. Specifically, upon motion of the government, the case may be settled or dismissed over the objections of the relator,[102] or restrictions may be placed on the relator's participation in prosecuting the case.[103] If the government declines to intervene, it notifies the court and the relator may proceed with the case, although the government may request to be served with copies of pleadings and deposition transcripts, as well as petition the court to intervene at a later date.[104]

A relator is entitled to a portion of the proceeds resulting from a successful prosecution or settlement of a qui tam action. The amount of the award will depend, in part, on whether the government intervened in the case. If the government intervenes in the case, the relator is entitled to an award equal to between 15% to 25% of the proceeds of the judgment or settlement, as determined by the court based upon the extent of the relator's contribution to the prosecution.[105] However, if the court determines that the action is based primarily on the disclosure of specific information by sources other than the relator, the court may limit the award to an amount which it deems appropriate, but in no case more than 10% of the proceeds.[106] If the government does not intervene in the case, the relator is entitled to an award equal to between 25% and 30% of the proceeds of the judgment or settlement, as determined by the court.[107] In addition to the above awards, relators are also entitled to reasonable expenses, costs, and attorneys' fees incurred as a result of a successful prosecution or a settlement.[108] Correspondingly, reasonable attorneys' fees and expenses may be awarded against the relator

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98. *See id*.

99. *See id*. § 3730(b)(4).

100. *See id*. § 3730(b)(3).

101. *See id*. § 3730(c)(1).

102. *See id*. § 3730(c)(2)(A)-(B).

103. *See id*. § 3730(c)(2)(C). Such restrictions may include: (1) limiting the number of witnesses the relator may call during trial; (2) limiting the length of testimony of such witnesses; and (3) limiting the relator's cross-examination of witnesses. *See id*.

104. *See id*. § 3730(c)(3).

105. *See id*. § 3730(d)(1).

106. *See id*.

107. *See id*. § 3730(d)(2).

108. *See id*. § 3730(d)(1)-(2).

if the government does not intervene, the defendant prevails, and the court determines that the relator brought the action frivolously, vexatiously, or primarily for the purposes of harassment.[109] If the court finds that a relator participated in the fraud, the court may reduce the share of the proceeds the relator would otherwise receive.[110] Furthermore, if the relator is convicted of a crime relating to the conduct violating the False Claims Act, the relator will not be entitled to any portion of the proceeds of the action or settlement and the court may dismiss the relator from the action.[111]

The False Claims Act provides protection for relators who bring actions against their employers. Specifically, "[a]ny employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of [the filing of a qui tam action] shall be entitled to all relief necessary to make the employee whole."[112] Such relief may include reinstatement with full restoration of seniority, double the amount of back pay with interest, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees.[113]

The False Claims Act identifies several types of qui tam actions over which courts do not have subject matter jurisdiction. Specifically, the FCA bars relators from filing so-called "parasitic" suits. For example, once a qui tam action has been initiated with the filing of a sealed complaint, no one other than the government or the original relator can bring any case based on the facts of the sealed complaint.[114] Furthermore, no one may file a qui tam action which is based upon allegations or transactions that are the subject of a civil or administrative proceeding to which the government is already a party.[115] Finally, a qui tam action is barred if it is based upon information that has already been "publicly disclosed," unless the relator is the "original source" of the information.[116] Public disclosure of information can result

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109. *See id*. § 3730(d)(2).
110. *See id*. § 3730(d)(3).
111. *See id*.
112. 31 U.S.C. § 3730(h).
113. *See id*.
114. *See id*. § 3730(b)(5).
115. *See id*. § 3730(e)(3).
116. *Id*. § 3730(e)(4)(A). As originally enacted in 1863, the False Claims Act did not bar relators from bringing suits based upon publicly disclosed information. *See* Act of March 2, 1863, Ch. 67, 12 Stat. 696; *see, e.g.*, United States *ex rel*. Marcus v. Hess, 317 U.S. 537 (1943) (qui tam action brought against a government contractor was allowed where the relator merely copied the government's criminal indictment of the contractor and offered no additional information). The statute was amended in 1943 to make it more difficult to bring a qui tam action in such cases. Specifically, pursuant to the 1943 amendments, a relator could not bring a qui tam action if it was "based on evidence or information the government had when the action was brought," even if the

from, among other things, criminal, civil, or administrative proceedings or hearings, congressional, administrative, or Government Accounting Office reports, government audits or investigations, and the news media.[117] An "original source" is defined as one who has direct and independent knowledge of the information on which the allegations are based and who has voluntarily provided the information to the government before filing a qui tam action.[118]

B. Application of the False Claims Act to the Health Care Context

Although the original purpose of the False Claims Act was to combat defense fraud, the statute has increasingly been used to combat fraud in other areas of government spending. For example, the statute has been used against

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relator was the original source of the information. *See* Act of Dec. 23, 1943, ch. 377, 57 Stat. 608. *See, e.g.*, United States *ex rel*. Wisconsin v. Dean, 729 F.2d 1100 (7th Cir. 1984) (qui tam action brought by the state of Wisconsin dismissed on the grounds that the federal government had prior knowledge of the information underlying the action, even though the state was solely responsible for uncovering the information and reporting it to the federal government). The statute was amended again in 1986 to establish the current provision which precludes jurisdiction over actions based on publicly disclosed information, unless the relator is the "original source" of the information. *See* False Claims Act Amendments of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (Oct. 27, 1986); United States *ex rel*. Stinson v. Prudential Ins. Co., 944 F.2d 1149, 1154 (3d Cir. 1991) (1986 amendments to the False Claims Act were intended to "have the qui tam suit provision operate somewhere between the almost unrestrained permissiveness represented by the *Marcus* decision, and the restrictiveness of the [*Dean* case], which precluded suit even by original sources" (citations omitted)).

117. *See* 31 U.S.C. § 3730(e)(4)(A). The meaning of "public disclosure" has been interpreted broadly by most courts. *See, e.g.*, United States *ex rel*. Stinson v. Prudential Ins. Co., 944 F.2d 1149 (3d Cir. 1991) (information disclosed during discovery in a private civil lawsuit is publicly disclosed); United States *ex rel*. Doe v. John Doe Corp., 960 F.2d 318 (2d Cir. 1992) (information disclosed during interviews by federal agents in the course of a search is publicly disclosed); United States *ex rel*. Fine v. MK-Ferguson Co., 861 F. Supp. 1544 (D. N.M. 1994) (information disclosed in a Department of Energy audit report issued to the state of Oregon was publicly disclosed); Hindo v. Univ. of Health Sciences, 65 F.3d 608 (7th Cir. 1995) (information disclosed in correspondence between two private parties is not publicly disclosed).

118. *See* 31 U.S.C. § 3730(e)(4)(B); *see, e.g.*, Gold v. Morrison-Knudsen Co., 68 F.3d 1475 (2d Cir. 1995) (contractor was not an original source of information regarding cost overruns on government housing construction projects where contractor obtained information from the media, administrative reports prepared for the Army Corps of Engineers, and arbitration hearings concerning such overruns); United States *ex rel*. Barth v. Ridgedale Elec., Inc., 44 F.3d 699 (8th Cir. 1995) (union's business representative was not an original source of information regarding electrical contractor's alleged fraud against the government since the representative did not have direct knowledge of the fraud but derived the information from copies of publicly-filed payroll records); Cooper v. Blue Cross Blue Shield Ass'n, 19 F.3d 562 (11th Cir. 1994) (relator was original source of information regarding insurer's Medicare secondary payer fraud where relator conducted a thorough investigation of the insurer's practices and made repeated complaints to government agencies prior to public disclosure of the fraud).

defendants for making false claims or statements to obtain: (1) federal agricultural subsidies;[119] (2) federal housing subsidies;[120] (3) federal loan guarantees;[121] (4) federal monies for flood loss;[122] (5) federal food stamp benefits;[123] and (6) federal research grants.[124] Tax fraud is expressly excluded from the scope of the False Claims Act.[125]

In recent years, the False Claims Act has been increasingly used to combat fraud in the health care industry, including the submission of allegedly false or fraudulent claims for Medicare and Medicaid reimbursement. Recent applications of the False Claims Act to the health care context include: (1) claiming Medicare reimbursement for medically unnecessary items or services;[126] (2) claiming Medicare reimbursement for procedures that use

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119. *See, e.g.*, United States v. Thomas, 709 F.2d 968 (5th Cir. 1983); United States *ex rel.* LaValley v. First Nat'l Bank of Boston, 707 F. Supp. 1351 (D. Mass. 1988); United States v. Ettrick Wood Products, Inc., 916 F.2d 1211 (7th Cir. 1990); Federal Crop Ins. Corp. v. Hester, 765 F.2d 723 (8th Cir. 1995); Kelsoe v. Federal Crop Ins. Corp., 724 F. Supp. 448 (E.D. Tex. 1988); United States *ex rel.* Sequoia v. Sunland Packing House Co., 912 F. Supp. 1325 (E.D. Cal. 1995).

120. *See, e.g.*, United States v. Intervest Corp., 67 F. Supp. 2d 637 (S.D. Miss. 1999); United States *ex rel.* Floyd Phillips Co. v. Seivers, No. 95-C-4246 (N.D. Ill. 1996); United States v. Inc. Vill. of Island Park, 888 F. Supp. 419 (E.D.N.Y. 1995); United States v. Ehrlich, 643 F.2d 634 (9th Cir. 1981), *cert. denied*, 454 U.S. 940 (1981).

121. *See, e.g.*, United States *ex rel.* S. Prawer & Co. v. Fleet Bank of Maine, 24 F.3d 320 (1st Cir. 1994); United States v. First Nat'l Bank of Cicero, 957 F.2d 1362 (7th Cir. 1992).

122. *See, e.g.*, Thevenot v. Nat'l Flood Ins. Program, 620 F. Supp. 391 (W.D. La. 1985); Plywood Prop. Ass'n v. Nat'l Flood Ins. Program, 928 F. Supp. 500 (D.N.J. 1996).

123. *See, e.g.*, United States v. Truong, 860 F. Supp. 1137 (E.D. La. 1994).

124. *See, e.g.*, United States *ex rel.* Milam v. Regents of the Univ. of California, 912 F. Supp. 868 (D. Md. 1996).

125. *See* 31 U.S.C. § 3729(e).

126. Briefly, items or services furnished to Medicare beneficiaries are only reimbursable by the Medicare program if the items or services are deemed "reasonable and necessary" to the diagnosis or treatment of illness or injury or to improving the performance of a malformed body part. 42 U.S.C. § 1395y(a)(1)(A) (1994). In other words, Medicare reimbursement is not available if the items or services are deemed medically unnecessary. *See* Medicare Intermediary Manual, § 3439; Hospital Manual, § 295; Skilled Nursing Facility Manual, § 356. Consequently, violations of the False Claims Act may occur where Medicare claims are submitted for medically unnecessary items or services. *See, e.g.*, United States v. Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991) (dentist violated the False Claims Act by submitting Medicare claims for oral cancer screenings, which are considered medically unnecessary unless specifically requested by the patient's treating physician); United States v. Kensington Hosp., 760 F. Supp. 1120 (E.D. Pa. 1991); United States v. Mahar, 801 F.2d 1477 (6th Cir. 1986); United States *ex rel.* Dowden v. Metpath, Inc., No. 91-1843, *available at* 1993 WL 397770, at *1 (C.D. Cal. Sept. 13, 1993); United States *ex rel.* Mikes v. Straus, 931 F. Supp. 248 (S.D.N.Y. 1996); United States *ex rel.* Pub. Integrity v. Therapeutic Tech., Inc., 895 F. Supp. 294 (S.D. Ala. 1995); United States v. Geri-Care, Inc., No. CIV. A.895720, *available at* 1990 WL 9463, at *1 (E.D. Pa. Feb. 1, 1990).

A recent national enforcement initiative by the DOJ illustrates the application of the False Claims Act to claims for medically unnecessary items or services. Over the last several

experimental or investigational devices that have not received marketing approval by the U.S. Food and Drug Administration (FDA);[127] (3) billing for

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years, the DOJ has investigated a number of clinical laboratories for allegedly violating the False Claims Act by performing medically unnecessary tests and submitting reimbursement claims to the Medicare program for such tests. At issue in these investigations has been order forms used by the laboratories for a series of laboratory tests conducted on a "sequential multiple analysis computer" (SMAC). Generally, Medicare reimburses laboratories a flat fee for the series of SMAC tests, even if the ordering physician only needs the results of a few tests comprising the SMAC panel. *See* Medicare Intermediary Manual, § 3628.J (Clinical Diagnostic Laboratory Services Other Than to Inpatients, Laboratory Tests Utilizing Automated Equipment) (stating that "in the case of multi-channel automated and/or batch automated laboratory determinations, . . . there is normally only one charge for the battery of tests"). In 1991, the DOJ commenced an investigation of National Health Laboratories (NHL). At issue was the fact that NHL had revised its SMAC order forms and compendium of services so that high density lipoprotein cholesterol and ferritin tests, which were not SMAC tests and which are billed separately to Medicare, were combined with the SMAC tests. As a result, physicians who wanted to order only the SMAC tests also had to order the cholesterol and ferritin tests, even if such tests were not medically indicated for the patients. NHL billed Medicare separately for the cholesterol and ferritin tests. The DOJ investigation led to a settlement agreement under which NHL agreed to pay $110 million to the federal government. *See* "Terms of Proposed Settlement in Laboratory Fraud Case," Press Release, U.S. Attorney, San Diego, CA (Dec. 18, 1992), *reprinted in* [1993-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 40,975, at 34,089. The DOJ has conducted similar investigations against other clinical laboratories, including Bioran Laboratories, Corning Clinical Laboratories and Allied Clinical Laboratories. *See* DEPARTMENT OF JUSTICE HEALTH CARE FRAUD REPORT FISCAL YEARS 1995-96.

127. Generally, Medicare coverage is not available for procedures involving experimental or investigational devices that have not received some form of marketing approval by the FDA. *See* 42 U.S.C. § 1395y(a)(1)(A) (1994 & Supp. 2000); 42 C.F.R. § 405.201 (2001); 60 Fed. Reg. 48,417 (Sept. 19, 1995); Medicare Carriers Manual, § 2303.1. Consequently, violations of the False Claims Act may occur where Medicare claims are submitted for the implantation or use of experimental or investigational devices. For example, in March 1994, a False Claims Act suit was filed alleging that 132 hospitals submitted false claims seeking Medicare reimbursement for procedures performed between 1988 and 1994 using investigational cardiac devices that had not received marketing approval from the FDA. *See* United States *ex rel*. v. Healthwest Regional Med. Ctr. (W.D. Wash.) (docket number unavailable) (filed Mar. 31, 1994); 7 BNA Medicare Report 8 (Feb. 23, 1996). Prompted in part by this lawsuit, the OIG sent subpoenas to over 100 hospitals in June 1994 requesting information relating to the performance of procedures involving the implantation of cardiac devices that had not received FDA approval. *See* Whistleblower Lawsuit Reveals Hospitals Accused of False Billing, 6 BNA Medicare Report 35, at d21 (Sept. 1, 1995). In response to the subpoenas, a group of hospitals filed a declaratory judgment action against HHS on February 5, 1996 seeking to invalidate the HHS policy barring Medicare reimbursement for procedures using investigational devices that have not received approval by the FDA. *See* Cedars-Sinai Med. Ctr. v. Shalala, No. CV-95-2902 (C.D. Cal.) (filed Feb. 5, 1996). In April 1996, the district court granted summary judgment for the hospitals and ruled that the HHS policy was invalid because it was not promulgated in accordance with rulemaking procedures of the Administrative Procedure Act. *See* Cedars-Sinai Med. Ctr v. Shalala, 939 F. Supp. 1457 (C.D. Cal. 1996); 5 U.S.C. § 553 (1994 & Supp. 2000). This ruling was appealed to the United States Court of Appeals for the Ninth Circuit, which remanded the case to the district court to determine

services which were not rendered as claimed;[128] (4) Medicare billing by teaching physicians for patient care services furnished by residents or interns;[129] (5) Medicare billing by hospitals for non-physician outpatient

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whether the hospital's claim against HHS was barred by a six year statute of limitations. *See* Cedars-Sinai Med. Ctr. v. Shalala, 125 F.3d 765 (9th Cir. 1997). The district court held that the hospital's claims were time-barred and this ruling was upheld by the Ninth Circuit on appeal. *See* Cedars-Sinai Med. Ctr. v. Shalala, 177 F.3d 1126 (9th Cir. 1999).

128. Billing for services which were not rendered as claimed can take a variety of forms. In its most obvious form, this practice encompasses situations where reimbursement claims are submitted and no services have been rendered at all. *See, e.g.*, United States *ex rel*. Fahner v. Alaska, 591 F. Supp. 794 (N.D. Ill. 1984); United States *ex rel*. McCoy v. California Med. Review, Inc.,723 F. Supp. 1363 (N.D. Cal. 1989); United States v. Pani, 717 F. Supp. 1013 (S.D.N.Y. 1989); United States v. Hilliard, 752 F.2d 578 (11th Cir. 1985). A more subtle form of this practice involves the submission of claims for more expensive services than those which were actually furnished to the patient. This practice is commonly referred to as "upcoding," since the reimbursement claims in question contain billing codes that represent more serious or expensive procedures than those actually performed, resulting in higher reimbursement than would otherwise be payable under the billing codes intended for use with the services actually furnished to the patient. *See, e.g.*, United States v. Krizek, 859 F. Supp. 5 (D.D.C. 1994) (physician violated the False Claims Act by submitting Medicare reimbursement claims that inappropriately used a billing code for 45-50 minute "psychotherapy sessions" when a code for 20-30 minute "minimal psychotherapy sessions" should have been used); United States v. Lorenzo, 768 F. Supp. 1127 (E.D. Pa. 1991) (dentist violated False Claims Act by submitting Medicare reimbursement claims that inappropriately used a billing code for "limited consultations" when less extensive "routine screenings" were performed); *see also, e.g.*, United States v. Halper, 660 F. Supp. 531 (S.D.N.Y. 1987), *vacated on other grounds*, 490 U.S. 435 (1989); United States *ex rel*. Hindo v. Univ. of Health Sciences, No. 91-C-1432, 1993 WL 512609, at *1 (N.D. Ill. Dec. 8, 1993); United States v. CAC-Ramsay, 744 F. Supp. 1158 (S.D. Fla. 1990).

129. Part B of the Medicare program reimburses for physician services furnished by clinical faculty in a teaching hospital, provided certain criteria are met, including a requirement that "the physician render[ ] sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the [Medicare] payment is sought." 42 U.S.C. § 1395(u)(b)(7) (1994 & Supp. 2000). There are only limited circumstances in which the Medicare program will separately reimburse teaching physicians for services furnished by residents or interns under the direction of the teaching physicians. Namely, to bill Medicare Part B for services furnished by a resident or intern subsequent to July 1, 1996, a teaching physician must be "physically present" during all critical portions of the procedure and be immediately available to be called upon during the entire service or procedure. *See* 60 Fed. Reg. 63,139, 63,140 (Dec. 8, 1995). Thus, violations of the False Claims Act may occur where teaching physicians submit claims to the Medicare program for patient care services furnished by residents or interns without having been physically present. In fact, the federal government has investigated a number of teaching hospitals and faculty practice plans for allegedly submitting Medicare claims in violation of this requirement. *See id*. For example, in 1995, the University of Pennsylvania Health System agreed to pay $30 million to settle federal government allegations that it submitted false claims to the Medicare program for physician services provided by residents and interns without the adequate supervision of the teaching physicians. *See* Settlement Agreement between the United States and the University of Pennsylvania Health System (Dec. 12, 1995).

services furnished within 72 hours of an inpatient admission;[130] (6) charging Medicare when a patient was covered primarily by private insurance, and/or concealing the existence of private insurance coverage that makes Medicare the secondary payer for services furnished to a Medicare beneficiary;[131] (7) failing to disclose transactions with related parties on cost reports filed with the Medicare program;[132] (8) submitting "fragmented" claims to Medicare;[133]

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130. As part of a national enforcement initiative, the DOJ has investigated hospitals nationwide for allegedly violating the False Claims Act by billing non-physician outpatient services furnished within seventy-two hours of an inpatient admission. *See* "Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies," GAO Report No. GAO/HEHS-99-170 (Aug. 1999). Briefly, the Medicare program uses a Prospective Payment System (PPS) to reimburse acute care hospitals for operating costs incurred from furnishing inpatient services to Medicare beneficiaries. *See* 42 U.S.C. § 1395ww(d) (1994 & Supp. 2000); 42 C.F.R. § 412.40 et seq. (2001). The level of PPS reimbursement is determined, in part, by the diagnosis-related group (DRG) into which each Medicare beneficiary is classified upon admission to the hospital. *See* 42 U.S.C. § 1395ww(d)(4)(A) (1994 & Supp. 2000); 42 C.F.R. § 412.60 (2001). Significantly, PPS reimbursement is intended to encompass not only all inpatient care which the hospital furnishes to the beneficiary, but also any non-physician outpatient services (e.g., diagnostic tests) provided by the hospital (or an entity wholly-owned or operated by the hospital) within seventy-two hours immediately preceding the date of admission if such services were related to the admission. *See* 42 U.S.C. § 1395ww(a)(4) (1994 & Supp. 2000); 42 C.F.R. § 412.2(c)(5) (2001). Consequently, violations of the False Claims Act may occur where a hospital submits a separate claim for a non-physician outpatient service which is provided to a Medicare beneficiary within three days prior to a related inpatient admission, since the hospital would effectively be seeking additional Medicare reimbursement for a service that is already reimbursed through the Medicare PPS payment to the hospital.

131. Medicare reimbursement may not be made for any item or service furnished to a Medicare beneficiary if reimbursement for the item or service has been made, or reasonably can be expected to be made, by a workers' compensation plan, an automobile or liability insurance policy, or an employer group health plan. *See* 42 U.S.C. § 1395y(b)(2) (1994 & Supp. 2000); 42 C.F.R. § 411.20 (2001). In other words, the Medicare program's liability in these circumstances is secondary to the other insurance coverage. Thus, a violation of the False Claims Act may occur where an individual or entity initially bills Medicare for an item or service furnished to a Medicare beneficiary and the beneficiary has other insurance coverage that is primary to the Medicare coverage. *See, e.g.*, United States *ex rel*. Stinson v. Prudential Ins., 944 F.2d 1149 (3d Cir. 1991); United States *ex rel*. Stinson v. Blue Cross Blue Shield of Georgia, Inc., 755 F. Supp. 1055 (S.D. Ga. 1990); United States *ex rel*. Stinson v. Provident Life & Accident Ins. Co., 721 F. Supp. 1247 (S.D. Fla. 1989).

132. Medicare participating providers file cost reports each year with the provider's fiscal intermediary. Cost reports are used to determine the Medicare share of costs incurred by a provider during the cost reporting period and reconcile such costs with total Medicare payments made to the provider over the period. In other words, cost reports summarize the costs incurred by providers in furnishing items and services to Medicare beneficiaries, including costs arising from arrangements with outside suppliers under which the providers obtain items and services (e.g., medical supplies, management services). *See* 42 U.S.C. § 1395g (1994 & Supp. 2000) (Payments to Providers of Services); 42 C.F.R. § 413.20(b) (2001) (Financial Data and Reports); Provider Reimbursement Manual [hereinafter PRM], Part II, Chapter 1 (Cost Reporting). Generally, the

and (9) routine waivers of Medicare beneficiary coinsurance and deductible obligations by "charge-based" providers, suppliers, and practitioners.[134]

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amount paid by the provider to purchase items or services from an outside supplier is used to calculate the provider's Medicare reimbursement. *See* 42 C.F.R. § 413 (2001). However, more restrictive standards apply if the provider purchases the items or services from a related organization. In this regard, a provider is required to disclose in the cost report whether any reported costs are attributable to transactions with organizations related to the provider. *See* 42 C.F.R. § 413.17 (2001). Moreover, subject to a limited exception, the Medicare "related organizations [rule]" states that "costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization." 42 C.F.R. § 413.17(a) (2001). *See* PRM at § 1000. In other words, where the provider is related to the supplier, the provider's Medicare reimbursement is calculated based upon the supplier's costs in furnishing the items or services to the provider, not the supplier's charges to the provider for the items or services. The purpose of this rule is to avoid payment of artificially-inflated costs which may be generated from less than arm's-length bargaining. *See* PRM at § 1000. A violation of the False Claims Act may occur where a provider fails to disclose a transaction with a related organization and, as a result, receives greater Medicare reimbursement than would otherwise be due if the relationship were properly disclosed and reimbursement were calculated based upon the supplier's costs. *See, e.g.*, United States v. Oakwood Downriver Med. Ctr., 687 F. Supp. 302 (E.D. Mich. 1988); United States v. Calhoon, 97 F.3d 518 (11th Cir. 1996); United States v. Alemany Rivera, 781 F.2d 229 (1st Cir. 1985).

133. "Fragmenting" claims arise where a single "global" billing code exists for a group of services, but each of the individual services is billed separately. *See* 42 C.F.R. § 414.40(b)(1) (2001); 58 Fed. Reg. 37,994, 38,008 (July 14, 1993). Fragmentation can result in greater reimbursement being paid than if the appropriate global billing code were used. An example of this practice involves Medicare reimbursement for surgical procedures performed by physicians. Briefly, the Medicare program reimburses physicians for surgical procedures under global billing codes which are intended to reimburse not only for the surgery itself but also for certain pre-operative, intra-operative, and post-operative services that are related to the surgery. *See* 42 C.F.R. § 414.40(b)(1) (2001); 58 Fed. Reg. 37,994, 38,008 (July 14, 1993). Fragmentation may occur if a surgeon claims separate Medicare reimbursement for services reimbursed under a single global billing code, such as biopsies performed during the surgical procedure, treatment of post-surgical complications that do not require additional surgery, or follow-up visits within ninety days of the surgical procedure. Violations of the False Claims Act may occur where a physician fragments services that should be reimbursed pursuant to a single global billing code. *See* "Fragmented Physician Claims," Office of Inspector General, Department of Health and Human Services, OEI-12-88-00901 (Sept. 1, 1992), *reprinted in* Medicare & Medicaid Guide (CCH), ¶40,739. *See, e.g.*, United States v. Brown, 988 F.2d 658 (6th Cir. 1993).

134. Briefly, a "charge-based" provider, supplier, or practitioner is one which is reimbursed by Medicare for an item or service furnished to a Medicare beneficiary based upon the lesser of: (1) a fee schedule amount that has been established for the item or service; (2) the actual charge of the provider, supplier, or practitioner for the item or service; (3) the customary charge of the provider, supplier, or practitioner for the item or service; or (4) the prevailing charge in the same locality for the item or service. *See* 42 U.S.C. § 1395u(b)(3) (1994 & Supp. 2000); 42 C.F.R. § 405.501 (2001). The Medicare copayment amount is the portion of the cost or charge of an item or service which a Medicare beneficiary must pay. Currently, the Medicare Part B copayment amount is generally 20% of the reasonable charge for the item or service. *See* 42 U.S.C.

III. SUMMARY OF CASES

A. *Shalala v. T2 Medical, Inc*.

In *Shalala v. T2 Medical, Inc.*,[135] the Secretary of HHS filed suit under the False Claims Act alleging that the defendant submitted false claims for Medicare and Medicaid payments since the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute. The complaint alleged that the Anti-Kickback Statute was violated because T2, an owner of outpatient infusion therapy centers, provided remuneration to physicians who were in a position to refer patients to facilities owned by T2. Specifically, according to the complaint:

> T2 has entered into a variety of arrangements with physicians who are in a position to refer their patients, including Medicare and Medicaid patients, to infusion therapy centers owned by T2. Through partnerships and Subchapter S corporations, T2 has shared ownership in various infusion therapy entities with referring physicians . . . . [The] physicians have received shares of restricted T2 stock at terms not available to the public . . . . As a result, many physicians who are in a position to refer their Medicare or Medicaid patients to T2 have received remuneration from T2 in the form of profit distributions . . . . [The plaintiff] believes that T2's manner of offering and paying remuneration to physicians who are in a position to refer patients to T2 violates the [Anti-Kickback Statute].[136]

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§ 1395l(a)(1) (1994 & Supp. 2000). The Medicare deductible is the amount that must be paid by a Medicare beneficiary before the Medicare program will pay for any items or services for the beneficiary. Currently, the Medicare Part B deductible is $100. The OIG has taken the position that the routine waiver of copayment and deductible obligations may result in misstating the actual charge for the item or service and, thus, result in the submission of false claims in violation of the False Claims Act. According to the OIG:

> [A] provider, practitioner, or supplier who routinely waives Medicare copayments or deductibles is misstating its actual charge. For example, if a supplier claims that its charge for a piece of equipment is $100, but routinely waives the copayment, the actual charge is $80. Medicare should be paying 80% of $80 (or $64), rather than 80% of $100 (or $80). As a result of the supplier's misrepresentation, the Medicare program is paying $16 more than it should for this item.

OIG Special Fraud Alert: Routine Waiver of Copayments of Deductibles Under Medicare Part B (May 1991), *reprinted in* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994); *see* 61 Fed. Reg. 2,122 (Jan. 25, 1996) ("routine waivers of coinsurance and deductibles are an area of significant abuse in the Medicare program [since] [s]uch waivers result in the submission of false claims to the Medicare program because providers misstate their charges on claims submitted to the program"). *See, e.g.*, United States v. Gieger Transfer Service, Inc., 174 F.R.D. 382 (S.D. Miss. 1997). *See supra* note 49.

135. Shalala v. T2 Med., Inc., No. 1:94-CV-2549, Complaint at 3-4 (N.D. Ga. filed Sept. 26, 1994) [hereinafter T2 Complaint].

136. *T2 Complaint* at 3-4.

Based upon this alleged violation of the Anti-Kickback Statute, the plaintiff argued that claims submitted to the government by the defendant for services furnished to Medicare and Medicaid beneficiaries referred to T2 facilities by physicians with investment interests in T2 were false under the False Claims Act. Specifically, the plaintiff stated that:

> Because T2 has knowingly offered extensive amounts of remuneration to physicians to induce [the physicians] referral of Medicare and Medicaid patients to T2 [centers] in violation of the [A]nti-[K]ickback [S]tatute, T2 has also caused false and fraudulent claims to be presented to the United States in violation of [the False Claims Act].[137]

On September 30, 1994, the parties entered into a settlement agreement.[138] Under the terms of the T2 Settlement Agreement, T2 agreed to pay the United States $500,000 to reimburse the government for the costs of the investigation.[139] Moreover, T2 agreed, among other things, that: (1) Future management agreements with treatment centers owned in whole or in part by physicians would be structured to comply with the personal services and management contracts safe harbor; (2) T2 would not establish or participate in co-ownership or partnership arrangements with physicians to provide home infusion therapy services; (3) Restrictions on the transferability of T2 investment interests held by physicians would be removed; (4) Physicians would only be offered investment interests in T2 through a national securities exchange and only on the same terms available to the public; and (5) Prominent notices would be posted in the waiting rooms and treatment areas of all T2-owned and managed centers informing patients that physicians may hold financial interests in either T2 or the treatment center.[140]

B. *United States* ex rel. *Roy v. Anthony*

In *United States* ex rel. *Roy v. Anthony*,[141] a private qui tam relator filed suit under the False Claims Act alleging that the defendants submitted false claims for Medicare and Medicaid payments since the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute. The defendants in *Anthony* included a number of companies that operated diagnostic imaging centers in Ohio and Kentucky, as well as

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137. *T2 Complaint* at 4.

138. *See* Shalala v. T2 Med., Inc., No. 1:94-CV-2549, Settlement Agreement (N.D. Ga. filed Sept. 30, 1994) [hereinafter T2 Settlement Agreement].

139. *See T2 Settlement Agreement* at 2.

140. *See id*. at 3-4.

141. 914 F. Supp. 1504 (S.D. Ohio 1994) (suit filed Aug. 12, 1993).

physicians who were shareholders or limited partners in the companies and who referred patients to the centers. The relator was a private citizen.

The relator claimed that the Anti-Kickback Statute was violated because the companies provided the physicians with remuneration, in the form of stock dividends and partnership distributions, to induce the physicians to refer patients to the centers operated by the companies.[142] According to the relator, the physician-investors "earned exorbitant profits as a result of this self-referral scheme."[143] Based upon this alleged violation of the Anti-Kickback Statute, the relator argued that claims submitted by the defendants for services furnished to patients referred to the centers by the physician-investors in the companies were false.[144]

The defendants filed a motion to dismiss the complaint on two grounds: (1) the Anti-Kickback Statute does not afford a private right of action, and (2) a violation of the Anti-Kickback Statute cannot form the basis for a False Claims Act violation.[145] The district court denied the defendants' motion.[146] In denying the motion, the court stated that:

> The Plaintiff alleges activity that is clearly illegal, but is not so clearly a violation of the False Claims Act. The Plaintiff does not accuse the Defendants of submitting Medicare claims for patients that do not exist or who were never treated . . . . The Plaintiff claims that because the Defendants were engaged in continuing violations of the [Anti-Kickback] Statute during – and in connection with – their submission of claims for Medicare/Medicaid payments, the claims themselves were false or fraudulent. This vague assertion creates a tenuous connection between the [Anti-Kickback] Statute and the False Claims Act, but the connection is sufficient to overcome the burden of a . . . motion [to dismiss]. Under the facts alleged, the

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142. Specifically, the relator argued that the distributions from the investment interests held by the referring physicians in the companies was prohibited remuneration since the investment interests did not qualify for the investment interests safe harbor. *See* United States *ex rel*. Roy v. Anthony, No. C-1-93-0559, Amended Complaint and Jury Demand, at 8-9 (S.D. Ohio filed Nov. 19, 1993) [hereinafter Roy Complaint]. According to the relator, the safe harbor was not met since more than 40% of the total investment interests in the companies were held by investors in a position to make referrals to the companies or furnish items and services to the companies, as well as the fact that more than 40% of the companies' gross revenues were derived from referrals made by physician-investors. *See Roy Complaint* at 8-9.

143. *Roy Complaint* at 4. For example, the relator claimed that, as a result of referrals by the physician-investors, the common stock of one of the companies, "purchased by various . . . [physicians] for $800 per share, generated [over a $1,800] dividend per share of stock in 1992 alone. This dividend represents an annual profit that is more than double the $800 investment required to buy a share of [the company's] stock. *Id*.

144. *See Roy Complaint* at 10-11.

145. *See* United States *ex rel*. Roy v. Anthony, No. C-1-93-0559, Motion of Defendants to Dismiss at 7, 11 (S.D. Ohio filed May 2, 1994).

146. *See* United States *ex rel*. Roy v. Anthony, 914 F. Supp. 1504 (S.D. Ohio 1994).

> Plaintiff could produce evidence that would show that the kickbacks allegedly paid to the defendant physicians somehow tainted the claims for Medicare.[147]

Following the court's denial of the motion to dismiss, the parties settled and the case was voluntarily dismissed on March 23, 1995.[148] Under the terms of the settlement agreement, the defendants agreed to pay the United States $1,520,000 to settle the relator's allegations; the relator was awarded $440,800 from this amount.[149] The United States did not formally intervene in the lawsuit.

C. *United States* ex rel. *Parker v. Apria Healthcare Group, Inc.*

In *United States* ex rel. *Parker v. Apria Healthcare Group, Inc.*,[150] a qui tam relator filed suit under the False Claims Act alleging that the defendants submitted false claims for Medicare and Medicaid payment since the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute. The defendants in *Parker* included Apria Healthcare Group, Inc. (Apria), which was one of the nation's largest providers of home health care services, including respiratory therapy services, durable medical equipment, and nursing services, a number of individual physicians, and Georgia Lung Associates, P.C. (GLA), which was a physician group practice that employed some of the individual physicians who were named as defendants. The relator was a former Branch Manager for Homedco Group, Inc., one of two companies which merged to form Apria in June 1995.

The relator claimed that the Anti-Kickback Statute was violated because Apria provided GLA, and the physician-employees of GLA, with various forms of remuneration to induce the physicians to refer patients to Apria for various home health care services.[151] In particular, the complaint alleged that:

> Apria entered into a one-year "Medical Consultant Agreement" with GLA. Pursuant to this agreement, GLA received at least $24,000 from Apria in 12 equal payments of $2,000. The "Medical Consulting Agreement" between Apria and GLA was a sham agreement entered into in an attempt to shield fraudulent payments from Apria to GLA from scrutiny and detection.

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147. *United States ex rel. Roy*, 914 F. Supp. at 1506.

148. *See* United States *ex rel*. Roy v. Anthony, No. C-1-93-0559, Stipulation and Order Dismissing Complaint (S.D. Ohio filed Mar. 23, 1995).

149. *See* United States *ex rel*. Roy v. Anthony, No. C-1-93-0559, Settlement Agreement at 2-3 (S.D. Ohio filed Mar. 23, 1995).

150. No. 95-CV-2142 (N.D. Ga. filed Aug. 23, 1995).

151. *See* United States *ex rel*. Parker v. Apria Healthcare Group, Inc., No. 95-CV-2142, Complaint, at 6-8 (N.D. Ga. filed Aug. 23, 1995) [hereinafter Parker Complaint].

> As evidenced by invoices submitted to Apria by GLA, payments made by Apria to GLA pursuant to the "Medical Consultant Agreement" were based upon "review and consultation" services allegedly performed by GLA doctors . . . . However, Apria did not receive documentation, paper work, telephone consultation or any other work product corresponding to said "review and consultation . . . ." Contrary to the terms of the "Medical Consultant Agreement," Apria actually expressly agreed to make the monthly payments of $2,000 in exchange for a promise that the [GLA] [p]hysicians would refer patients to Apria.[152]

Thus, according to the relator:

> Because Apria has offered significant remuneration to certain physicians to induce their referral of Medicare and Medicaid patients to Apria in violation of the Anti-Kickback Statute, Apria has also submitted or caused to be submitted claims to Medicare or Medicaid [for services furnished to those patients] that Apria knows or should know are false or fraudulent, in violation of [the False Claims Act].[153]

On June 27, 1996, the United States formally intervened in the case on behalf of the relator.[154] On July 10, 1996, the United States filed an amended complaint.[155] On July 25, 1996, Apria filed a motion to dismiss both the relator's complaint and the amended complaint filed by the United States.[156] According to Apria, allegations that Apria paid illegal kickbacks to referral sources, "standing alone, do not state a claim under the [False Claims Act], because legitimate claims for [Medicare or Medicaid] reimbursement for [items and services] provided to patients do not automatically become 'false' upon proof that the patients were illegally referred."[157] The motion to dismiss was still pending before the court when the parties reached a settlement agreement, resulting in the case being voluntarily dismissed on February 24, 1997.[158] Under the terms of the final settlement agreement, Apria and GLA denied any wrongdoing but agreed to pay the government and the relator a

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152. *Parker Complaint* at 6-7.

153. *Id.* at 8.

154. *See id*.

155. *See* United States *ex rel*. Parker v. Apria Healthcare Group, Inc., No. 95-CV-2142, Amended Complaint, at 6-8 (N.D. Ga. filed July 10, 1996).

156. *See* United States *ex rel*. Parker v. Apria Healthcare Group, Inc., No. 95-CV-2142, Motion of Defendant Apria Healthcare, Inc. to Dismiss Complaint and Amended Complaint With Memorandum in Support (N.D. Ga. filed July 25, 1996) [hereinafter Apria Motion to Dismiss].

157. *Apria Motion to Dismiss* at 2-3. Apria argued that there were two reasons why liability under the False Claims Act cannot be based upon violations of the Anti-Kickback Statute: (1) The False Claims Act does not incorporate provisions of wholly unrelated statutes, such as the Anti-Kickback Statute; and (2) Congress did not provide any civil remedies, or specify a private right of action in the Anti-Kickback Statute and, therefore, any effort to create a civil remedy by characterizing alleged violations of the Anti-Kickback Statute as false claims under the False Claims Act should be rejected. *See id*. at 5.

158. *See* United States *ex rel*. Parker v. Apria Healthcare Group, Inc., No. 95-CV-2142, Consent to Relator's Dismissal of Qui Tam Action (N.D. Ga. filed Feb. 24, 1997).

total of approximately $2 million to resolve the allegations.[159] Apria also agreed to adopt a corporate compliance plan/program designed to uncover illegal marketing and billing practices within the company.[160]

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159. *See Release and Settlement Agreement* at 1; *Settlement Agreement* at 3.

160. *See* 8 Medicare Report 6 (BNA) d17 (Feb. 7, 1997). Briefly, corporate compliance programs are designed to enable companies to identify specific regulatory requirements and to assess the scope of potential liability thereunder. *See Fraud and Abuse: Health Attorneys See Rapid Growth in Adoption of Compliance Plans*, 7 Medicare Report 33 (BNA) d27 (Aug. 16, 1996). The adoption of corporate compliance programs has become increasingly common, particularly since high profile government settlements with National Medical Enterprises Inc. (NME) and Caremark, Inc. *See id*. In 1994, NME paid $379 million to settle charges it engaged in practices at its psychiatric and substance abuse facilities that violated the Anti-Kickback Statute and the False Claims Act. *See id*. In 1995, Caremark paid $161 million to resolve similar charges. *See id*. Under the terms of both settlement agreements, the DOJ required the companies to adopt corporate compliance plans as a way to avert future violations of the Anti-Kickback Statute and the False Claims Act. Moreover, HHS has published a number of model compliance plans for different segments of the health care industry. These model plans, which are voluntary in nature, suggest that a comprehensive compliance program should include, at a minimum, the following elements: (1) written standards of conduct for employees; (2) the development and distribution of written policies that promote commitment to compliance and that address specific areas of intentional fraud, such as billing, marketing and claims processing; (3) the designation of a chief compliance officer or other appropriate official who is charged with the responsibility of operating the compliance program; (4) the development and offering of education and training programs to all employees; (5) the use of audits and/or other evaluation techniques to monitor compliance and ensure a reduction in problem areas; (6) the development of a code of improper activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws; (7) the investigation and remediation of identified systemic and personnel problems; (8) the promotion of and adherence to compliance as an element in evaluating supervisors and managers; (9) the development of policies addressing the employment or retention of sanctioned individuals; (10) the maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants; and (11) the adoption of requirements applicable to record creation and retention. *See* Compliance Program Guidance for Nursing Facilities, 65 Fed. Reg. 14,289 (Mar. 16, 2000); Compliance Program Guidance for Medicare+ Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 61,893 (Nov. 15, 1999); Compliance Program, Guidance for Hospices, 64 Fed. Reg. 54,031 (Oct. 5, 1999); Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36,368 (July 6, 1999); Compliance Program Guidance for Third-Party Medical Billing Companies, 63 Fed. Reg. 70,138 (Dec. 18, 1998); Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076 (Aug. 24, 1998); Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410 (Aug. 7, 1998); Compliance Program for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998).

D. *United States* ex rel. *Montagano v. Midway Hospital Medical Center*

In *United States* ex rel. *Montagano v. Midway Hospital Medical Center*,[161] a qui tam relator filed suit under the False Claims Act alleging that the defendants submitted false claims for Medicare and Medicaid payment because the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute.[162] The defendants in *Montagano* included Midway Hospital Medical Center, Inc., an acute care hospital in Los Angeles, California, and OrNda Healthcorp, the owner and operator of Midway Hospital.[163] The relator was a physician who had served on the medical staff of Midway Hospital until February 1995.[164]

The plaintiff alleged, in part, that "[f]or years, [the] [d]efendants have attempted to circumvent . . . (laws prohibiting kickbacks to physicians for referrals of patients) by entering into bogus compensation arrangements with high volume physicians, which have as their true purpose the payment of unlawful referral fees to the physicians."[165] Specifically, the plaintiff claimed that until at least February 1995, the defendants had entered into over twenty such bogus agreements, "including bogus leases and medical directorships with lip-service duties or duties for which such physicians were already responsible and compensated as a member of the medical staff . . . . The difference in compensation to each physician depended upon the volume of patients the physician referred to the hospital."[166] The complaint identified a number of specific compensation arrangements that the hospital had with physicians.[167]

On June 25, 1997, the United States, the relator, and OrNda entered into a formal settlement agreement.[168] Pursuant to the settlement agreement, the

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161. *See* United States *ex rel*. Montagano v. Midway Hosp. Med. Ctr., No. CV95-4948-TJH, Complaint (C.D. Cal. filed July 26, 1995) [hereinafter Montagano Complaint].

162. *See Montagano Complaint* at 3.

163. *See id*. at 1-2.

164. *See id*. at 2.

165. *Id*. at 3.

166. *Id*. at 4.

167. *See id*. For example, according to the complaint, Midway agreed to pay one physician $7,000 a month to lease a portion of the physician's office for purposes of recruiting an additional orthopedic surgeon for the "Hand Surgery Center at Midway Hospital." *See Montagano Complaint* at 4. However, the complaint stated that there was no Hand Surgery Center at Midway. *See id*. "Moreover, the purported rental of $7,000 per month [was] more than the fair market rental of the entire [office] suite . . ." *Id*. The complaint describes another arrangement in which Midway compensated a physician $2,560 a month to serve as "Medical Director of Neurology," even though the physician performed no duties and was not a neurologist. *See id*. at 7.

168. *See* United States *ex rel*. Montagano v. Midway Hosp. Med. Ctr., No. CV95-4948-TJH, Settlement Agreement (C.D. Cal. filed June 25, 1997) [hereinafter Montagano Settlement Agreement].

United States and the relator released the defendants from any cause of action based on allegations that Midway Hospital had entered into sham arrangements with physicians to induce patient referrals to the hospital.[169] OrNda did not admit any liability under either the Anti-Kickback Statute or the False Claims Act, but did agree to pay the United States over $12 million to settle the case.[170] The United States agreed to pay the relator over $2 million from this amount.[171] On July 22, 1997, the United States formally intervened in the case to request a dismissal.[172] The court issued an order dismissing the case on the same day.[173]

E. *United States* ex rel. *Pogue v. American Healthcorp, Inc.*

In *United States* ex rel. *Pogue v. American Healthcorp, Inc.*,[174] a qui tam relator filed suit under the False Claims Act alleging that the defendants submitted false claims for Medicare and Medicaid payments since the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute.[175] The defendants in *Pogue* included Diabetes Treatment Centers of America, Inc. (DTCA), which operated a number of freestanding and hospital-based centers providing diabetes treatment services, American Healthcorp, Inc. (AHC), which was the parent company of DTCA, West Paces Medical Center (West Paces), a hospital in which a DTCA treatment center operated, and a number of individual physicians who were

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169. *See Montagano Settlement Agreement* at 2-3. Nevertheless, the settlement agreement makes clear that the United States accepted the allegations and legal theory that were advanced by the relator in the complaint. *See id*. at 5-7. The settlement agreement states that:

> [T]he United States alleges that between 1992-1996, the Hospitals were engaged in directorship, consulting and other contracts, or other financial arrangements with certain physicians and physician entities . . . . [C]ertain of the contracts and arrangements . . . were intended to induce patient referrals in violation of the Anti-Kickback Statute . . . and . . . the hospitals submitted or caused to be submitted claims for payment for patients referred pursuant to these allegedly unlawful contracts and arrangements, to the Medicare program . . . . The United States alleges that these claims . . . were submitted by the Hospitals in violation of the False Claims Act . . . ."

Id. at 2.

170. *See id*. at 3.

171. *See id*. at 7.

172. *See* United States *ex rel*. Montagano v. Midway Hosp. Med. Ctr., No. CV95-4948-TJH, United States' Notice of Intervention and Stipulation for Order of Dismissal and Proposed Order (C.D. Cal. filed July 22, 1997) [hereinafter Montagano Notice of Intervention].

173. *See Montagano Notice of Intervention* at 1.

174. United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 3-94-0515 (M.D. Tenn. filed June 23, 1994).

175. *See Pogue*, No. 3-94-0515.

retained by AHC to serve as medical directors at the treatment centers.[176] The relator was a former Director of Marketing and Development for DTCA.[177]

The relator claimed that the Anti-Kickback Statute was violated because AHC provided the physician medical directors with remuneration in the form of fees "well in excess of the fair market value of the services they provided" to induce the physicians to refer patients to hospitals with which DTCA had contracts.[178] Correspondingly, the relator claimed that the defendant hospitals "paid DTCA a contingent fee based, not upon [any] services provided [by DTCA], but based strictly upon the number of patients who had diabetes and who were admitted to the hospital, regardless of the reason for which they were admitted to the hospital."[179] Thus, the relator contended that "DTCA served as an agent and conduit for the defendant physicians . . . in soliciting and receiving remuneration for the defendant physicians' patient referrals and admissions, and as an agent and conduit for the defendant hospitals . . . in offering and paying remuneration to the defendant physicians for their patient referrals and admissions."[180]

According to the relator, "to the extent [Medicare and Medicaid] claims were filed by the defendant hospitals . . . with which DTCA had contracted . . . for . . . services provided to patients whose admissions were illegally and fraudulently obtained [in violation of the Anti-Kickback Statute], those claims constitute false and fraudulent claims under [the False Claims Act]."[181] The relator argued that such claims were false because if the government had been aware of the violations of the Anti-Kickback Statute, the defendants would not have been allowed to participate in the Medicare and Medicaid programs and, therefore, would not have had the claims reimbursed by the Medicare and Medicaid programs.[182] The relator's position was based on the view that "participation in any federal program involves an implied certification that the participant will abide by and adhere to all statutes, rules, and regulations governing that program."[183] Consequently, according to the relator:

> [A]lthough the claims were not false in the sense that Defendants sought compensation for services that were not rendered or were unnecessary, they were nonetheless fraudulent because by submitting the claims, [the] defendants implicitly

176. *See id*. at 4-10.

177. *See id*.

178. United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 3-94-0515, First Amended Complaint, at 10 (M.D. Tenn. filed July 8, 1994) [hereinafter Pogue Complaint].

179. *Id*. at 10.

180. *Id*. at 11.

181. *Id*.

182. *See id*. at 12.

183. United States *ex rel*. Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1509 (M.D. Tenn. 1996).

> stated that they had complied with all statutes, rules, and regulations governing the Medicare Act, including [the] [F]ederal [A]nti-[K]ickback . . . [S]tatute[.][184]

A number of the defendants in *Pogue* filed a motion to dismiss the complaint on the grounds that a violation of the Anti-Kickback Statute cannot form the basis for a cause of action under the False Claims Act.[185] The court granted the defendants' motion to dismiss because, according to the court, the relator failed to establish two of the four elements necessary to recover damages under the False Claims Act.[186] Specifically, the court stated that:

> First, [the relator] has failed to allege that any of the claims submitted by Defendant . . . were themselves false. He has not alleged that the services were unnecessary, not rendered, or that there was some other miscalculation with regard to the care provided to the patients. Rather, he asserts that the claims are false because they were submitted in knowing violation of [the] . . . [A]nti-[K]ickback . . . [S]tatute[ ] . . . . Even if Defendants submitted these claims in knowing violation of the [A]nti-[K]ickback . . . [S]tatute[ ], however, that would not render the claims themselves false. Second, even if the claims could be considered false or fraudulent . . . Plaintiff has failed to prove that the government was injured by the submission of these claims. Plaintiff does not allege that the services rendered to these patients was unnecessary; therefore, the patients would have been treated at some hospital, even if it was not West Paces. As the government pays the same amount for treatment under the Medicaid and Medicare programs regardless of where the treatment is rendered, it has suffered no injury.[187]

The relator filed a motion to reconsider.[188] Surprisingly, the district court granted the relator's motion and vacated its previous order dismissing the case.[189] In granting the motion, the court reconsidered the two principal conclusions underlying its reasoning for originally granting the motion to dismiss: (1) Claims are not false under the False Claims Act simply because

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184. *Pogue*, 914 F. Supp. at 1509.

185. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 3-94-0515, Motion by Defendants to Dismiss (M.D. Tenn. filed Mar. 17, 1995).

186. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc. (M.D. Tenn. Sept. 14, 1995), *available at* 1995 WL 626514. According to the court, in order "[t]o recover under the [False Claims Act], Plaintiff must establish: (1) the [D]efendants presented or caused to be presented to [the federal government] a claim for payment; (2) the claim was false or fraudulent; (3) the [Defendants] knew the claim was false or fraudulent; and (4) the [government] suffered damages as a result of the false or fraudulent claim." *Id.*

187. *Id.* at *6.

188. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 3-94-0515, Motion for Reconsideration of Decision and Order (M.D. Tenn. filed Sept. 19, 1995). The Federal Rules of Civil Procedure do not specifically refer to a motion to reconsider but such motions, if filed within ten days of judgment, are generally treated as motions to alter or amend judgment under Rule 59(e). *See* Federal Kemper Ins. Co. v. Rauscher, 807 F.2d 345, 348 (3d Cir. 1986); Campbell v. Bartlett, 975 F.2d 1569, 1580 n.15 (10th Cir. 1992).

189. *See Pogue*, 914 F. Supp. at 1508.

they are submitted in violation of other laws; and (2) The False Claims Act requires that the government suffer actual damages as a result of the submitted claims.[190] In this regard, the court stated that "[a] recent trend of cases appear[s] to support Pogue's proposition that a violation of Medicare anti-kickback . . . law[ ] also constitutes a violation of the False Claims Act."[191] The court added that "support for this trend in using violations of [the] federal anti-kickback . . . law[ ] as a basis for a claim under the False Claims Act may be found in the courts' recognition of False Claims Act violations that are based upon violations of other statutes, rules, and regulations."[192] Thus, the court concluded that "it is clear that the False Claims Act was intended to cover not only those situations in which the claims themselves are false but also those situations in which a claimant engages in fraudulent conduct with the purpose of inducing payment by the government."[193] Moreover, according to the court, "the False Claims Act was intended to govern not only fraudulent acts that create a loss to the government but also those fraudulent acts that cause the government to pay out sums of money to claimants it did not intend to benefit."[194]

On March 15, 1996, the defendants filed an interlocutory appeal with the United States Court of Appeals for the Sixth Circuit challenging the district court's decision to grant the plaintiff's motion to reconsider.[195] The Sixth Circuit denied the appeal on April 19, 1996.[196] On July 14, 1997, the district court denied the defendants' motion to dismiss the complaint.[197] Pursuant to a motion filed with the DOJ on August 12, 1999, the Judicial Panel on Multi-District Litigation issued an order on December 12, 1999 transferring all proceedings in the case to the United States District Court for the District of Columbia, where it was consolidated with a number of other qui tam actions

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190. *See id*.

191. *Id*. at 1509 (citing United States *ex rel*. Roy v. Anthony, 914 F. Supp. 1504 (S.D. Ohio 1994)).

192. *Id*. at 1510.

193. *Id*. at 1511.

194. *Id*. at 1513.

195. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 96-8518 (6th Cir. filed Mar. 15, 1996); 28 U.S.C. § 1292 (interlocutory decisions).

196. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc., Order, No. 96-8518 (6th Cir. Apr. 19, 1996).

197. *See* United States *ex rel*. Pogue v. Am. Healthcorp, Inc., No. 3-94-0515 (M.D. Tenn. filed July 14, 1997).

to permit coordinated discovery and pretrial proceedings.[198] The case is currently before the U.S. District Court for the District of Columbia.

F. *United States* ex rel. *Thompson v. Columbia/HCA Healthcare Corp.*

In *United States* ex rel. *Thompson v. Columbia/HCA Healthcare Corp.*,[199] a qui tam relator filed suit under the False Claims Act alleging that the defendants submitted false claims for Medicare and Medicaid payment since: (1) the claims were for services furnished to patients referred to the defendants in violation of the Anti-Kickback Statute; and (2) the defendants filed cost reports which contained false certifications of compliance with applicable laws and regulations (including the Anti-Kickback Statute). The defendants in *Thompson* included Columbia/HCA Healthcare Corporation and a number of its subsidiaries (collectively, Columbia).[200] The relator was a physician in private practice.

The relator claimed that the Anti-Kickback Statute was violated because Columbia provided physicians with various forms of remuneration in order to induce the physicians to refer patients to hospitals and other health care facilities owned and operated by Columbia.[201] The relator argued that the

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198. *See Fraud and Abuse: DOJ Again Seeks to Consolidate Remaining FCA Columbia/HCA Lawsuits*, 10 Medicare Report 1022 (BNA) (Sept. 3, 1999). Briefly, pursuant to 28 U.S.C. § 1407 (1994 & Supp. 2000), the Judicial Panel on Multidistrict Litigation (the Panel) may transfer civil actions pending in multiple districts "involving one or more common questions of fact" to a single transferee district "for coordinated or consolidated pretrial proceedings" upon determining that such a transfer "will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions." Multidistrict litigation seeks to consolidate numerous cases filed against a particular defendant, or group of defendants, for coordinated and uniform pretrial proceedings before one judge. *See* 28 U.S.C. § 1407(a) (1994 & Supp. 2000). *See infra* note 218 and accompanying text.

199. 938 F. Supp. 399 (S.D. Tex. 1996).

200. Columbia has changed its name in 2000 to HCA-The Healthcare Company. *See* Barbara Kirchheimer, *Move Over Columbia, HCA is Back*, MODERN HEALTHCARE, June 19, 2000, at 30. HCA is a for-profit company based in Nashville, Tennessee that owns and operates hospitals, home health agencies and other ancillary service providers. HCA is one of the largest for-profit health care chains in the United States. Since 1997, Columbia has been the focus of ongoing federal and state investigations. *See Health Care Fraud Cases*, 2 HEALTH CARE FRAUD & ABUSE NEWSLETTER, Jan. 2000, at 13; Shari G. Kleiner, *Healthcare Fraud*, 36 AM. CRIM. L. REV. 773 (Summer 1999). In May 2000, the DOJ announced a tentative agreement whereby HCA would pay $745 million to settle certain civil allegations against the company related to various issues, including DRG coding, outpatient laboratory billing and home health issues. *See* 11 Medicare Report 536 (BNA) (May 26, 2000).

201. Specifically, Thompson alleged that Columbia offered physicians the following types of prohibited remuneration: (1) preferential opportunities not available to the general public to purchase equity interests in Columbia; (2) loans, or assistance in obtaining loans, to finance capital investments in Columbia ventures; (3) rental arrangements under which the physicians

violations of the Anti-Kickback Statute caused by these alleged inducements "in turn leads to violations of the [False Claims Act] when [Columbia] seek[s] Medicare reimbursement" for services furnished to patients referred by physicians receiving the inducements, even if such services are shown to be medically necessary.[202]

In addition, the relator alleged that the False Claims Act was also violated because the defendants made false statements by falsely certifying in annual cost reports filed by Columbia hospitals that services were furnished in compliance with applicable laws and regulations, including the Anti-Kickback Statute.[203] In other words, even if the False Claims Act was not violated merely by a violation of the Anti-Kickback Statute, an independent basis for violation of the False Claims Act existed based upon the claimants falsely certifying their compliance with the Anti-Kickback Statute in cost reports filed with Medicare. In effect, the violation of the Anti-Kickback Statute resulted in the claimants engaging in conduct (i.e., falsely certifying compliance on the cost report) which caused the violation of the False Claims Act.

Columbia filed a motion to dismiss the relator's second amended complaint based, in part, on the grounds that: (1) Violations of the Anti-Kickback Statute cannot provide a cause of action under the False Claims Act;

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leased office space from Columbia at less than fair market value rates; (4) rental arrangements under which Columbia leased space from physicians at amounts exceeding fair market value; (5) all-expenses paid vacations; (6) lucrative recruitment and retention packages for practicing at Columbia hospitals; (7) free leasehold improvements to space leased from Columbia; and (8) income guarantees for practicing at Columbia hospitals. *See* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 938 F. Supp. 399, 401 (S.D. Tex. 1996).

202. *Thompson*, 938 F. Supp. at 401.

203. *See id*. Briefly, the cost report serves as the provider's final claim for payment from the Medicare program for the services rendered to program beneficiaries for the fiscal period in question. The cost report sets forth all of the provider's costs, accounts for them under applicable provisions of the Medicare statute, and HHS program instructions, and results in a claim for a total amount of program reimbursement for the fiscal year. The cost report form requires a hospital officer or administrator to certify that he/she is "familiar with the laws and regulations regarding the provision of health care services and that the services identified in [the] cost report were provided in compliance with such laws and regulations." *Id*. The form states that:

> Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

HCFA Form-2552-96 (Hospital and Hospital Health Care Complex Cost Report Form), *reprinted in* [Transfer Binder 1997-1] Medicare & Medicaid Guide (CCH) ¶ 44,919, at 51,693 (emphasis added); *see* 42 U.S.C. § 1395g(a) (1994 & Supp. 2000) (no Medicare payment until the provider furnishes required certification); 42 C.F.R. § 413.24(f) (2001) (requiring certification for cost reports to be processed).

and (2) False certifications in cost reports do not support a cause of action under the False Claims Act since the certifications do not necessarily result in the payment of amounts that the government would not have paid but for the alleged fraud.[204] On July 24, 1996, the district court granted Columbia's motion to dismiss. The court identified the crux of the case, stating that, "[t]he main issue for resolution is whether Medicare claims filed for services which were rendered in violation of the anti-kickback statute . . . are *a fortiori* false claims under the FCA."[205] In granting the motion, the court stated that:

> Thompson contends that the defendants have created investment arrangements and provided financial inducements to physicians for patient referrals in violation of the . . . anti-kickback statute . . . which has resulted in violations of the [False Claims Act] . . . . Thompson has not stated a claim [on which relief can be granted] unless he has sufficiently alleged that the defendants have submitted claims that are false or fraudulent (*i.e.*, claims or claim amounts that the government would not have had to pay but for the fraud). Allegations that medical services were rendered in violation of [the Anti-Kickback] [S]tatute[ ] do not, by themselves, state a claim for relief under the False Claims Act . . . . Since the Court has already concluded that liability under the [False Claims Act] requires that the claims themselves be false or fraudulent, false [certification] statements in the [cost reports] do not render the [cost reports] false . . . .[206]

On September 5, 1996, the relator filed an appeal with the United States Court of Appeals for the Fifth Circuit, challenging the District Court's decision granting Columbia's motion to dismiss.[207] Although the government did not formally intervene in the case, the DOJ filed an amicus curiae brief with the Fifth Circuit in support of the relator's appeal. The DOJ brief states, in part:

> [T]he district court decision, if left standing, could hamper the efforts of the United States in pursuing Medicare fraud . . . because the district court incorrectly limited the scope of the . . . False Claims Act . . . . The district court erred in holding that a claim for services provided in violation of a statute with which compliance is a prerequisite to payment . . . would not make the claim false or fraudulent under the [False Claims Act].[208]

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204. *See* United States *ex rel*. Thompson v. Columbia/HCA Healthcare Corp., No. C-95-0110, Amended Motion of Columbia to Dismiss Plaintiffs' Second Amended Complaint (S.D. Tex. filed Feb. 13, 1996). Specifically, Columbia argued that "even if the defendants violated the Anti-Kickback statute . . . the government would have paid the Medicare claims [which were submitted for services furnished pursuant to the prohibited referrals] since there is no allegation that the services rendered were not medically necessary or otherwise false or fraudulent." In other words, even if prohibited financial inducements might have caused a physician to refer a patient to a Columbia hospital rather than to another hospital, that does not mean the services which were rendered at the Columbia hospital were unnecessary or that the resulting Medicare claim for such services was otherwise false. *See* Thompson, 938 F. Supp. at 402-03.

205. *Id*.

206. *Id*. at 401, 405-06.

207. *See* United States *ex rel*. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997).

208. Amicus Brief of United States at 1, 10, United States *ex rel*. Thompson v.

The Fifth Circuit issued a decision on October 23, 1997 that affirmed in part, vacated in part, and remanded for further proceedings, the district court's dismissal of Thompson's complaint for failure to state a claim.[209] The Fifth Circuit concluded that, although violations of statutes and regulations are insufficient, in themselves, for stating a cause of action under the False Claims Act, false certifications of compliance with statutes and regulations may result in the submission of false claims under the False Claims Act when certification is an express prerequisite to obtaining a government payment. Specifically, the Fifth Circuit stated:

> [W]e agree with the district court that claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the [False Claims Act] . . . . [However,] [w]here the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.[210]

The Fifth Circuit indicated that it was unable to determine from the record to what extent payment for services identified in the defendants' annual cost reports was conditioned on defendants' certifications of compliance with the Anti-Kickback Statute. Consequently, the Fifth Circuit remanded the case to the district court to allow the parties to present factual evidence regarding whether payments were actually conditioned upon the certifications of

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Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997) (No. 96- 40868). A number of well-known individuals, including Rep. Fortney H. Stark (D-Cal.), former U.S. Surgeon General C. Everett Koop, former American Medical Association Executive Vice President James Todd, and Harvard Medical School Professor Arnold S. Relman filed motions to submit amicus curiae briefs in support of the relator's appeal. *See Fraud and Abuse: Stark, Koop, Todd, Relman File Amicus Briefs in False Claims Case*, 8 Medicare Report 1 (BNA) at d21 (Jan. 3, 1997). Moreover, in an April 12, 1997, letter to OIG Inspector General June Gibbs Brown, Rep. Stark urged the OIG to consider requesting that the DOJ "intervene and assume primary responsibility [for the case]." According to Stark, the failure of the government to intervene "creates the erroneous impression that the case against Columbia lacks merit." *Fraud and Abuse: Stark Seeks DOJ Intervention in Columbia/HCA False Claims Case*, 8 Medicare Report 17 (BNA) at d19 (Apr. 25, 1997). The American Hospital Association (AHA) filed an amicus curiae brief with the Fifth Circuit requesting that the district court's decision be affirmed. According to AHA, the relator's suit "disregards the distinction between actual overbillings (such as billings for medically unnecessary services) that are somehow related to a violation of the Anti-Kickback [statute] . . . and technical violations of [the Anti-Kickback Statute] which do not in fact produce loss to the public coffers." *Fraud and Abuse: AHA Calls on Fifth Circuit to Affirm Dismissal of Columbia/HCA qui tam Action*, 8 Medicare Report 13 (BNA) at d23 (Mar. 28, 1997).

209. *See Thompson*, 125 F.3d at 899.

210. *Id*. at 902.

compliance in the annual cost reports.[211] In the course of those proceedings, and in response to the defendants' motion to dismiss or in the alternative for summary judgment, the DOJ submitted an amicus curiae brief to the district court which contained a declaration of David Goldberg, then Acting Chief of the HHS Health Care Financing Administration (HFCA) Provider Audit Operations Branch, Office of Financial Management.[212] In his declaration, Mr. Goldberg stated that:

> HCFA views any false statement contained in a cost report as constituting an abuse of the Medicare program. HCFA conditions both payment and provider eligibility on the veracity of the statements in the cost report. HCFA considers any cost report containing a false statement to be invalid . . . . [HCFA] will not permit providers to retain any amounts claimed for reimbursement on the cost report unless the certification in Form HCFA-2552 is truthfully completed.[213]

On August 18, 1998, the district court issued a decision on remand which denied the defendants' motion for dismissal or in the alternative for summary judgment.[214] The court made a number of significant findings in denying the defendants' motion to dismiss. First, the court ruled that the "Plaintiffs have stated a claim for violation of the FCA by Defendants' alleged false certification that the Medicare services identified in the annual hospital cost reports complied with the laws and regulations dealing with the provision of healthcare services."[215] Second, the court found that "a pecuniary injury to the public fisc

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211. The court stated that it was "unable to determine from the record before [it] whether, or to what extent, payment for services identified in defendants' annual cost reports was conditioned on defendants' certifications of compliance [with laws and regulations]." *Id*. at 902-03.

212. *See* Declaration of David A. Goldberg, Acting Chief of the Provider Audit Operations Branch, Office of Financial Management, HFCA, submitted in support of Amicus Curiae brief filed by the United States of America in *United States* ex rel. *Thompson v. Columbia/HCA Healthcare Corp.*, No. C-95-110 (S.D. Tex. filed June 2, 1998).

213. *Id.*

214. *See* United States *ex rel*. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017 (S.D. Tex. 1998).

215. *Thompson*, 20 F. Supp. 2d at 1046. In reaching this particular conclusion, the court stated its view that:

> The alleged prohibited financial relationships among Defendants and referring physicians made the certifications false statements. In addition to highlighting express statements in the relevant statutes and HCFA form 2552, Plaintiffs have provided evidence in the declaration of David Goldberg that HCFA relied on the certifications in determining the issues of payment and retention of payment as well as continued eligibility for participation in the Medicare program. The declaration also makes clear the nexus between the certifications and the injury to the government.

Id.

is no longer required for an actionable claim under the FCA."[216] Third, the court found:

> [The] Relator has also stated a claim for violation of the [False Claims Act] based on the alleged scheme of self-remuneration in violation of the anti-kickback statute, the Medicare Anti-Fraud and Abuse Act, 42 U.S.C. § 1320a-7b(a) and (b), which prohibits the making of any false statements, failing to disclose material information, or making false statements or representations to qualify as a certified Medicare provider in applying for Medicare payments.[217]

Pursuant to a motion filed with it by the DOJ on August 12, 1999, the Judicial Panel on Multi-District Litigation issued an order on December 12, 1999 transferring all proceedings in the case to the United States District Court for the District of Columbia, where it was consolidated with a number of other qui tam actions in order to permit coordinated discovery proceedings.[218] On February 16, 2001, the motion of the United States to intervene in the case was granted by the court. The case is currently pending before the U.S. District Court for the District of Columbia.

IV. DISCUSSION AND ANALYSIS

A. Regulatory Violations as a Basis for FCA Liability

The legal theory set forth in the cases discussed above concludes that FCA liability may be based solely upon a violation of the Anti-Kickback Statute. Specifically, the pleadings and/or the decisions in these cases all suggest that FCA liability may exist simply based upon a violation of the Anti-Kickback Statute. In other words, there is no need to show that any information on the face of the claim itself is false. This conclusion greatly expands the application and scope of the False Claims Act.

The language of the False Claims Act and its legislative history do not conclusively answer whether a violation of the Anti-Kickback Statute, by itself, is sufficient basis for imposing FCA liability. In this regard, the FCA statutory language does not expressly provide that violations of other statutes or regulations is a basis for establishing FCA liability. The statutory language simply indicates that FCA liability is established, in part, for the submission of

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216. *Id.* at 1047.

217. *Id.* Noting that "there is a dearth of case law on point," the court relied on the decision of the district court in *Pogue*, which it described as "informative in its review of updated, current law, the legislative history, and thoughtful analysis." *Id.* at 1047-48.

218. *See Fraud and Abuse: DOJ Again Seeks to Consolidate Remaining FCA Columbia/HCA Lawsuits*, 10 Medicare Report 1022 (BNA) (Sept. 3, 1999). Among the cases transferred and consolidated with *Thompson* was the *Pogue* case. *See supra* note 198 and accompanying text.

"false or fraudulent claim[s]" and for making "false record[s] or statement[s]."[219] The legislative history also does not conclusively address this question, although a provision in the legislative history to the 1986 amendments to the FCA does state that "each and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, or in violation of any statute or applicable regulation, constitutes a false claim."[220]

The Supreme Court has not expressly ruled on the issue of whether a statutory or regulatory violation is sufficient grounds for imposing FCA liability. However, the Supreme Court has cautioned, in dicta, that "the False Claims Act was not designed to reach every kind of fraud practiced on the Government."[221] Furthermore, most lower federal courts considering the issue in contexts not involving the Anti-Kickback Statute have expressed a general reluctance to conclude that FCA liability arises merely for violations of statutory or regulatory requirements.[222]

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219. 31 U.S.C. § 3729(a)(1)-(3), (7) (1994 & Supp. 2000).

220. S. REP. NO. 99-345, 9-10 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274-75.

221. United States v. McNinch, 356 U.S. 595, 599 (1958).

222. *See generally, e.g.*, United States *ex rel*. Am. Textile Mfrs. Inst., Inc. v. The Limited, Inc., No. C2-97-776, 1997 U.S. Dist. LEXIS 18142, at 38-39 (S.D. Ohio 1997) ("Congress, by amending the False Claims Act in 1986 [did not intend] to convert that Act into an all-inclusive vehicle for the enforcement of any federal statute or government regulation by either the Department of Justice or by a private citizen whenever it can be found that some false statement has been made regarding conduct subject to monetary sanctions."), *aff'd*, 190 F.3d 729 (6th Cir. 1999), *cert. denied*, 529 U.S. 1054 (2000); United States *ex rel*. Luckey v. Baxter Health Care Corp., 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998), *aff'd*, 183 F.3d 730 (7th Cir. 1999), *cert. denied*, 528 U.S. 1038 (1999) (stating that it is a "well-established principle that the [False Claims Act] is not a vehicle for regulatory compliance"); United States *ex rel*. Weinberger v. Equifax, Inc., 557 F.2d 456, 460-61 (5th Cir. 1977), *cert. denied*, 434 U.S. 1035 (1978) (claims submitted by a government contractor who allegedly violated the Anti-Pinkerton Act (5 U.S.C. § 3108) did not necessarily constitute false or fraudulent claims under the False Claims Act); United States *ex rel*. Lamers v. City of Green Bay, 998 F. Supp. 971, 992 (W.D. Wis. 1998) ("The [False Claims Act] is not a vehicle to police compliance with administrative regulations."); United States *ex rel*. Aranda v. Cmty. Psychiatric Ctrs. of Okla., 945 F. Supp. 1485 (W.D. Okla. 1996) (violation of Medicaid quality of care standards does not form the basis for a violation of the False Claims Act); United States v. Shaw, 725 F. Supp. 896, 900 (S.D. Miss. 1989) (where defendant pleaded guilty to bribing a federal agent, "[t]he bare fact that bribes were involved . . . does not necessarily lead to the further conclusion that false or fraudulent claims were made" under the FCA); United States *ex rel*. Hughes v. Cook, 498 F. Supp. 784, 787-88 (S.D. Miss. 1980) (Medicare claims submitted by physicians who failed to timely record their medical licenses were not false or fraudulent within the meaning of the FCA); United States *ex rel*. U.S.-Namibia v. The Africa Fund, 588 F. Supp. 1350, 1351 (S.D.N.Y. 1984) ("The qui tam statute does not authorize a private party to override [the Internal Revenue Code] to recover penalties or damages allegedly sustained by the government by virtue of false income tax statements[,] [since] in essence, plaintiff is attempting to enforce the tax laws through an improper vehicle – the False Claims Act . . . .").

Federal courts have recognized a cause of action under the FCA based upon violations of statutory or regulatory requirements in two very limited circumstances. Courts have been willing to impose FCA liability for violations of statutory or regulatory requirements where it can also be shown that the violation results in false information being reported on the claim form. For example, in cases involving the payment or receipt of kickbacks in violation of the anti-kickback statute applicable to government procurement,[223] courts have found a cause of action to exist under the FCA upon a showing that the payment or receipt of the illegal kickback also resulted in false cost data being reported on the claim form submitted to the government by the contractor.[224]

Courts have also found violations of the False Claims Act when the claim form or application filed with the government expressly requires compliance with a statutory or regulatory requirement as a prerequisite to government payment, the claimant failed to comply with the requirement, and the claimant falsely certified on the claim form or application that it had complied with the requirement. In other words, whenever government payment of a claim is expressly premised upon a certification of compliance with certain laws, the failure to comply with such laws may result in the submission of a false claim within the meaning of the False Claims Act. Thus, it is not the violation of the statutory or regulatory requirement that creates liability under the FCA, but the false representation made to the government that there has been compliance with the requirement. Courts have recognized causes of action under the FCA based on false certifications of compliance with federal statutory or regulatory requirements in a variety of contexts, including environmental requirements,[225]

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223. *See* 41 U.S.C. § 51 (1994).

224. *See, e.g.*, United States v. Gen. Dynamics Corp., 19 F.3d 770, 776-77 (2d Cir. 1994) (violation of the anti-kickback statute applicable to government procurement is a basis for establishing FCA liability where a kickback paid by a subcontractor was passed on to the government by the main contractor in the form of inflated cost data in construction subsidy applications); United States v. Lippert, 148 F.3d 974, 975 (8th Cir. 1998) (violation of the anti-kickback statute applicable to government procurement is a basis for establishing FCA liability where a kickback paid by a subcontractor was passed on to the government by the main contractor in the form of inflated reimbursable shipping costs); United States v. Killough, 848 F.2d 1523, 1525-26 (11th Cir. 1988) (cause of action exists under the FCA where payment of kickbacks resulted in inflated invoices submitted to the government).

225. *See, e.g.*, United States *ex rel.* Fallon v. Accudyne Corp., 880 F. Supp. 636, 638 (W.D. Wis. 1995) (FCA cause of action exists based upon violations of the Clean Air Act, Clean Water Act, and Resource Conservation and Recovery Act where defendant falsely certifies to the Department of Defense that it is in compliance with the various environmental laws in order to obtain government contracts that expressly required compliance with such laws).

housing non-discrimination requirements,[226] and government contracting requirements.[227] Other courts have suggested support for the "express certification theory," although the courts found that the facts in the cases under consideration did not support the theory.[228]

The decision of the Fifth Circuit Court of Appeals in the *Thompson* case follows the line of cases which adopt the "express certification" theory. In other words, the court's decision in *Thompson* recognizes that a violation of the Anti-Kickback Statute, by itself, is not sufficient grounds for establishing FCA liability. Rather, the claimant must expressly certify its compliance with the Anti-Kickback Statute when submitting the claim in order for there to be an FCA violation.[229]

B. Assumptions Underlying Legal Theory That FCA Liability Arises From Violations of the Anti-Kickback Statute

The theory that a violation of the Anti-Kickback Statute is grounds for imposing FCA liability is based upon a number of underlying assumptions. Among other things, the theory assumes that: (1) FCA liability can be based on "implied certifications" of compliance with the Anti-Kickback Statute where claim forms do not require express certifications of compliance; (2) FCA liability can be imposed for regulatory violations that are not material to the government's payment decision; (3) FCA liability can be based upon a

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226. *See, e.g.*, United States v. Vill. of Island Park, 888 F. Supp. 419, 434-36, 440-41 (E.D.N.Y. 1995) (FCA cause of action exists based upon violations of the non-discrimination requirements of the Fair Housing Act (42 U.S.C. § 3601-31) where municipality falsely certifies to the Department of Housing and Urban Development that it is in compliance with a Housing Assistance Plan that meets certain statutory requirements).

227. *See, e.g.*, United States *ex rel.* Sutton v. Double Day Office Servs., Inc., 121 F.3d 531, 534 (9th Cir. 1997) (FCA cause of action exists based upon violations of the Service Contract Act, 41 U.S.C. §§ 351-58, which requires government contractors to pay service employees minimum wages and benefits determined by the Secretary of Labor, where defendant submits a claim for payment to the United States falsely stating that it had complied with the Service Contract Act); Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429 (1994).

228. *See, e.g.*, United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996) (stating that "[v]iolations of laws, rules, or regulations alone do not create a cause of action under the FCA [since] [i]t is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit," but concluding that express certification of compliance was not a prerequisite to federal special education funding); United States *ex rel.* Joslin v. Cmty. Home Health of Md., Inc., 984 F. Supp. 374, 383-84 (D. Md. 1997) (accepting express certification theory, but finding no falsity existed).

229. *See* United States *ex rel.* Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899 (5th Cir. 1997) ("[W]here the government has conditioned payment of a claim upon a claimant's certification of compliance with . . . a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation.").

failure by the claimant to disclose regulatory violations to the government; (4) FCA liability may exist for regulatory violations which do not cause injury to the public fisc; and (5) A private right of action to enforce the Anti-Kickback Statute may be created. However, as discussed below, the legal basis for each of these assumptions is questionable.

1. *FCA Liability Based on "Implied Certifications" of Compliance with the Anti-Kickback Statute Where Claim Forms do not Require Express Certifications*

The theory that FCA liability may be imposed for violations of the Anti-Kickback Statute means that liability may arise even where claim forms do not require express certifications of compliance with law. In cases where claim forms do not contain express certifications of compliance with regulatory requirements, some courts have nevertheless "implied" certifications of compliance with such requirements in order to establish FCA liability.

a. Requirements of Medicare/Medicaid Claim Forms

As discussed in *Thompson*, Medicare cost reports filed by hospitals contain express certifications of compliance with "laws and regulations regarding the provision of health care services."[230] However, certain other claim forms used by providers and physicians when requesting Medicare or Medicaid reimbursement merely require an express certification that the information reported on the claim form is correct. In other words, these particular claim forms do not require a certification of compliance with specific statutory and regulatory requirements. An overview of the types of certifications required by specific claim forms follows.

I. *Cost Report Forms*

Various types of institutional providers that participate in the Medicare program are required to file annual cost reports with Medicare fiscal intermediaries.[231] These forms contain various disclosures and require certain

230. *Thompson*, 125 F.3d at 899.

231. For example, hospitals participating in the Medicare program annually file the HCFA-2552 cost report form. *See* Medicare & Medicaid Guide (CCH) ¶ 44,919 (copy of Hospital and Hospital Health Care Complex Cost Report HCFA-2552). Skilled nursing facilities participating in the Medicare program annually file the HCFA-2540S cost report form. *See* Medicare & Medicaid Guide (CCH) ¶ 9500 (copy of Skilled Nursing Facility Cost Report Form HCFA-2540S). Home health agencies participating in the Medicare program annually file the HCFA-1728 cost report form. *See* Medicare & Medicaid Guide (CCH) ¶ 9450 (copy of Home

certifications be made by the claimant. For example, the hospital cost report form (HCFA-2552) states:

> [M]isrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.[232]

The HCFA-2552 cost report form also requires the hospital's administrator or designated officer to certify to the following:

> I have read the above statement and . . . have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet and Statement of Revenue and Expenses prepared by . . . [Provider Name(s) and Number(s)] for the cost reporting period beginning [Date] and ending [Date] and . . . to the best of my knowledge and belief, it is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.[233]

The cost report forms filed by other types of institutional providers contain somewhat similar disclosures and certification requirements to those in the hospital HCFA-2552 form.

II. *HCFA-1450 Claim Form*

Institutional providers use the HCFA-1450 claim form to submit individual claims to Medicare and Medicaid for certain inpatient and/or outpatient services.[234] The HCFA-1450 claim form states that "[a]nyone who misrepresents or falsifies essential information requested by this form may upon conviction be subject to fine and imprisonment under federal and/or state law."[235] Furthermore, the form requires the provider's authorized

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Health Agency Cost Report Form HCFA-1728). Comprehensive Outpatient Rehabilitation Facilities participating in the Medicare program annually file the HCFA-2088 cost report form. *See* Medicare & Medicaid Guide (CCH) ¶ 9360 (copy of Outpatient Rehabilitation Provider Cost Report Form HCFA-2088).

232. Medicare & Medicaid Guide (CCH) ¶ 44,919.

233. *Id*.

234. *See id*. at ¶ 10,190 (copy of HCFA-1450 Uniform (Institutional Provider) Bill (UB-92)). Institutional providers which are required to use the HCFA-1450 when submitting individual claims to Medicare include hospitals, skilled nursing facilities, home health agencies, hospices, and comprehensive outpatient rehabilitation facilities.

235. *Id*.

representative to certify that the provider "understand[s] that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."[236]

III. *HCFA-1500 Claim Form*

Physicians use the HCFA-1500 claim form to submit claims to Medicare.[237] The HCFA-1500 claim form requires the physician to certify that the physician "understand[s] that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."[238]

b. "Implied" Certifications of Compliance

In order to establish FCA liability for statutory and regulatory violations where the claim forms do not require express certifications of compliance with laws, some courts have "implied" certifications of compliance. In other words, according to these courts, by submitting a claim to the government the claimant impliedly certifies its compliance with applicable statutory and regulatory requirements even if the claim form does not require an explicit certification of such compliance.

The "implied" certification theory was derived from the decision of the Federal Court of Claims in *Ab-Tech Construction, Inc. v. United States*.[239] In this case, Ab-Tech Construction, Inc., a minority-owned small business, was awarded a government subcontract by the Small Business Administration (SBA) to construct an automated data processing facility for the Army Corps of Engineers. The contract was awarded pursuant to § 8(a) of the Small Business Act.[240] Ab-Tech Construction was paid under the subcontract through the periodic submission of payment vouchers to the government over the course of contract performance.

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236. *Id.*

237. Medicare & Medicaid Guide (CCH) ¶ 10,261 (copy of Health Insurance Claim Form HCFA-1500).

238. *Id.*

239. 31 Fed. Cl. 429 (1994).

240. *See* 15 U.S.C. § 637 (1997). Section 8(a) authorizes the SBA to enter into contracts with other government departments and agencies for the procurement of supplies and services, with the intent that the SBA will subcontract the performance of these contracts to small businesses owned and controlled by "socially and economically disadvantaged individuals." *Id.*

SBA regulations provide that a basis for termination from the § 8(a) program is the "[f]ailure by the [small business] concern to obtain prior SBA approval of any management agreement, joint venture agreement or other agreement relative to the performance of a section 8(a) subcontract."[241] Ab-Tech Construction failed to obtain prior SBA approval of two subcontracts which it had entered into. Consequently, the United States brought an action against Ab-Tech Construction alleging that the company's failure to obtain prior approval of the two subcontracts rendered the payment vouchers submitted to the government false claims within the meaning of the False Claims Act. There were no allegations by the government that the services for which Ab-Tech Construction was claiming payment were not performed, that the government was overcharged for the services, or that any information on the payment vouchers themselves was false.

The court in *Ab-Tech Construction* concluded that the submission of the payment vouchers resulted in an implied certification of compliance with the continuing eligibility requirements imposed by the SBA regulations and that, therefore, the vouchers were false claims.[242] The court relied on an "implied" certification of compliance because the payment vouchers themselves did not contain an "express" certification of compliance with the SBA requirements that were violated. The court cited no legal authority to support its finding of an implied certification of compliance. Rather, the court stated:

> [T]he payment vouchers represented an implied certification by Ab-Tech of its continuing adherence to the requirements for participation in the 8(a) program. Therefore, by deliberately withholding from SBA knowledge of [a] prohibited contract arrangement . . . Ab-Tech not only dishonored the terms of its agreement with [the SBA] but, more importantly, caused the Government to pay out funds in the mistaken belief that it was furthering the aims of the [SBA] program.[243]

The court assessed the maximum allowable penalty under the FCA of $10,000 per payment voucher.

The decision of the district court in *Pogue* adopts the implied certification theory announced by the court in *Ab-Tech Construction*.[244] In other words, the *Pogue* court relied upon the decision in *Ab-Tech Construction* to conclude that FCA liability can exist for violations of the Anti-Kickback Statute regardless of whether there is an express certification of compliance on the claim form.[245]

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241. Ab-Tech Constr., Inc. v. United States, 31 Fed. Cl. 429, 432 (1994) (alteration in original) (citing 13 C.F.R. § 124.209(a)(16)).

242. *See Ab-Tech Constr., Inc.*, 31 Fed. Cl. at 433-34.

243. *Id*. at 434.

244. *See* United States *ex rel*. Pogue v. Am. Healthcorp., Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996).

245. *See Pogue*, 914 F. Supp. at 1508-10.

In fact, the *Pogue* court cites the *Ab-Tech Construction* decision as support for using a violation of the Anti-Kickback Statute as a basis for FCA liability.[246]

Reliance upon the "implied" certification theory to establish FCA liability for statutory and regulatory violations is questionable. The theory has not been widely endorsed by other courts and, therefore, should not be relied upon in those cases where an express certification of compliance with law is not required by the claim form. In fact, the "implied" certification theory espoused by the court in *Ab-Tech Construction* has been expressly rejected by a number of other courts considering the issue. For example, in *United States* ex rel. *Joslin v. Community Home Health of Maryland, Inc.*,[247] the court expressed reservations about the concept of an implied certification of compliance with law.

The defendant in *Joslin* was a provider of home health care services in Maryland and participated in the Medicare program. Subject to certain limited exceptions, Maryland requires home health care providers to obtain a certificate of need (CON) in order to operate.[248] The relator in *Joslin* alleged that the defendant failed to comply with the state CON requirements, resulting in a violation of the False Claims Act when the defendant submitted reimbursement claims to the Medicare program.[249] Specifically, the relator argued that the defendant's submission of Medicare claims to the government constituted an "implied certification" of compliance with the state CON law, and that these claims were false since the defendants allegedly failed to satisfy the CON requirements.[250] The court disagreed, stating that "[e]ven if Defendants had violated Maryland's CON requirements, . . . Relator has failed to demonstrate that such violations trigger liability under the FCA."[251] Notably, the court recognized that the HCFA-1450 claim form used by the defendants requires no express certification of compliance with state laws and that, therefore, FCA liability could only be imposed based upon a finding of "implied certification."[252] However, the court stated:

> [T]he case most directly addressing the implied certification issue is *Ab-Tech Const., Inc. v. United States* . . . . The holding of *Ab-Tech*, however, causes the Court some concern . . . . To hold that the mere submission of a claim for payment, without more,

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246. *See id*. at 1510 (vacating prior dismissal of an FCA action based on the theory that by submitting Medicare claims defendants impliedly certified compliance with the statutes, rules, and regulations governing the Medicare program).

247. 984 F. Supp. 374 (D. Md. 1997).

248. *See* MD. CODE ANN., Health-Gen. §§ 19-115, 19-116 (2000).

249. *See* United States *ex rel*. Joslin v. Cmty. Home Health of Md., Inc., 984 F. Supp. 374, 384-85 (D. Md. 1997).

250. *See Joslin*, 984 F. Supp. at 384-85.

251. *Id*. at 383.

252. *See id*. at 384.

> always constitutes an "implied certification" of compliance with the conditions of the Government program seriously undermines [the] principle [that the FCA is not a "stalking horse" for enforcement of every statute, rule or regulation] by permitting FCA liability potentially to attach every time a document or request for payment is submitted to the Government, regardless of whether the submitting party is aware of its non-compliance . . . . [T]he Court declines to follow this case.[253]

Other courts have expressed similar reservations about the "implied certification" theory.[254]

2. *FCA Liability for Regulatory Violations That Are Not Material to the Government's Payment Decision*

The theory that FCA liability may be imposed for violations of the Anti-Kickback Statute means that liability can be based upon a statutory violation that is arguably not material to the government's payment decision. In this regard, payment of a claim is not necessarily conditioned upon compliance with the Anti-Kickback Statute. In other words, a violation of the Anti-Kickback Statute does not automatically result in nonpayment of the claim.

a. Materiality is an Element of the False Claims Act

A fact is considered "material if it 'has a natural tendency to influence, or was capable of influencing, the decision of' the decisionmaking body to which it was addressed."[255] Therefore, in the context of the FCA, a fact would be

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253. *Id.* at 384-85.

254. *See, e.g.*, United States *ex rel.* Hopper v. Anton, 91 F.3d 1261, 1265-66 (9th Cir. 1996) (school district's receipt of federal funds pursuant to submission of forms containing calculations allegedly performed in violation of California Education Code regulations is not actionable under the FCA based on implied certification theory), *cert. denied*, 519 U.S. 115 (1997); United States *ex rel.* Mikes v. Strauss, 84 F. Supp. 2d 427, 435-36 (S.D.N.Y. 1999) (physicians' alleged failure to meet professionally recognized standards of care in performing spirometry tests for which Medicare reimbursement claims were submitted is not actionable under the FCA based on implied certification theory); Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1045 (N.D. Ill. 1998) ("A finding of a false implied certification under the FCA for every request for payment accompanied by a failure to comply with all applicable regulations, without more, improperly broadens the intended reach of the FCA."); United States v. Shaw, 725 F. Supp. 896, 900 (S.D. Miss. 1989) (implied certification theory is not a basis for bringing an FCA action against a person previously convicted of bribing a federal official in connection with loan applications submitted to the Farmers Home Administration, because "[t]he bare fact that bribes were involved in this case . . . does not necessarily lead to the further conclusion that false or fraudulent claims were made in connection with each of the loan applications").

255. Kungys v. United States, 485 U.S. 759, 770 (1988); *see also* United States v. Norris, 749 F.2d 1116, 1122 (4th Cir. 1984) (materiality turns on "whether the false statement has a natural tendency to influence agency action or is capable of influencing agency action"); United

material if that fact were relied upon by the government in deciding whether to pay a claim. In other words, a claim is "false" under the FCA only if the government would not have paid the claim if the facts about the alleged misconduct were known. As a matter of logic, it cannot be that a claim is "false" under the FCA if it would have been paid despite the alleged misconduct.[256]

The statutory language of the FCA does not expressly state that "materiality" is a required element for imposing FCA liability.[257] The language of the FCA imposes liability simply for any knowing submission of a false or fraudulent claim.[258] The Supreme Court has never expressly ruled on the issue of whether materiality is a required element under the FCA.[259] At the federal appellate court level, one of the leading cases on this issue is *United States* ex rel. *Berge v. Board of Trustees of the University of Alabama.*[260] In *Berge*, the Fourth Circuit expressly held that materiality was an element of liability under

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States v. Beer, 518 F.2d 168, 171 (5th Cir. 1975) (a statement is material if it "has a natural tendency to influence, or was capable of influencing, the decision of [the government] in making a determination required to be made").

256. *See* United States *ex rel*. Lamers v. City of Green Bay, 998 F. Supp. 971, 985 (E.D. Wis. 1998) ("The key inquiry is whether the 'claim' in question has the practical purpose and effect, and poses the attendant risk, of inducing wrongful payment.") (quoting United States v. Rivera, 55 F.3d 703, 710 (1st Cir. 1995)).

257. *See* 31 U.S.C. § 3729 (1983).

258. *See id*.

259. The Office of the Solicitor General of the United States has previously taken the position before the Supreme Court that materiality is an essential element of FCA liability. On February 25, 1997, Solicitor General Seth Waxman had the following exchange with Justice Antonin Scalia during oral argument in a case involving construction of the False Claims Act:

> [Court:] . . . What if there's just a violation of a contract term that is so minor that it would not be a basis for the Government's refusal to pay the contract price?
>
> [SG.:] . . . Justice Scalia, if the misstatement could not as a matter of law have borne on the . . . entitlement to payment, it would not be a violation of the [FCA] . . . . In the ordinary case, unless it was made an express or implied . . . condition of payment, it wouldn't relate to a false claim.
>
> [Court:] . . . So you're willing to be committed to that. It has to be the condition of payment.
>
> [SG.:] . . . Yes. It has to bear on the entitlement to payment in some way.
>
> [Court:] . . . Is that another way of saying it must be material?
>
> [SG.:] . . . Yes . . . . In fact, I think, although the courts have torn themselves inside out trying to determine whether in this provision and the criminal false claims provision materiality is an element, in fact, to the extent materiality is an element, it really is embedded in the test of whether it bears on entitlement to payment or benefit.

Transcript of Oral Argument at 39-40, Hughes Aircraft Co. v. United States *ex rel*. Schumer, 520 U.S. 939 (1997).

260. 104 F.3d 1453 (4th Cir. 1997).

the FCA.[261] The Fourth Circuit overturned a jury verdict awarding $1.66 million in damages and penalties under the FCA in a qui tam case brought by a doctoral candidate who had performed research with three scientists at the University of Alabama.[262] The jury found that the University had made false statements to the National Institutes of Health (NIH) when seeking funding for the research program conducted by the three scientists by failing to reference the work of the doctoral candidate.[263] The Fourth Circuit held that none of the alleged false statements would have been material to NIH's decision to fund the University's research.[264] According to the court, "[a]ssuming *arguendo* that all of [relator's] allegations were true and [the University] had made these false statements, it is hard to imagine that NIH's decision-making would have been influenced by them."[265] Thus, the court concluded that "[i]f previously unclear, we now make explicit that the current Civil False Claims Act imposes a materiality requirement."[266] The Fourth Circuit's decision in *Berge* is consistent with the decisions of other federal courts.[267]

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261. *See* United States *ex rel*. Berge v. Bd. of Trustees of the Univ. of Ala., 104 F.3d 1453, 1459 (4th Cir. 1997).

262. *See Berge*, 104 F.3d at 1459.

263. *See id*.

264. *See id*. at 1460-62.

265. *Id*. at 1462.

266. *See id*.

267. *See, e.g.*, Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 785 (4th Cir. 1999) ("Liability under each of the provisions of the False Claims Act is subject to the . . . requirement that the false statement or claim be material."); United States v. Q Int'l Courier, Inc., 131 F.3d 770, 772 (8th Cir. 1997) (stating that the FCA "gives the United States a means to recover from someone who makes a material misrepresentation to avoid paying some obligation owed to the government"); United States v. TDC Mgmt. Corp., 24 F.3d 292, 298 (D.C. Cir. 1994) ("To prevail under the [FCA], the government must prove either that TDC actually knew it had omitted material information from its monthly progress reports or that it recklessly disregarded or deliberately ignored that possibility."); United States v. Data Translation, Inc., 984 F.2d 1256, 1267 (1st Cir. 1992) (stating that materiality is an element of a FCA action); United States *ex rel*. Weinberger v. Equifax, Inc., 557 F.2d 456, 461 (5th Cir. 1977) ("The [FCA] . . . interdicts material misrepresentations made to qualify for government privileges or services."); *Luckey*, 2 F. Supp. 2d at 1045 (requiring a showing that compliance with statutes or regulations was "a material condition to receiving payment from the government"); United States *ex rel*. Durcholz v. FKW, Inc., 997 F. Supp. 1159, 1167 (S.D. Ind. 1998) ("Although the Seventh Circuit has not yet addressed the issue, we believe [that a materiality] . . . requirement is appropriate and consistent with the FCA."); United States v. Frierson, No. 95 C 503, available at 1997 WL 136280, at *9 (N.D. Ill. 1997) ("[A] plaintiff may establish the claim's falsity by showing that the defendant omitted material information or that the defendant recklessly or deliberately ignored that possibility."); United States *ex rel*. Walle v. Martin Marietta Corp., 1997 U.S. Dist. LEXIS 138, at *4-5 (E.D. La. Jan. 3, 1997) (stating that qui tam plaintiff must show submission of "materially false claim"); *Joslin*, 984 F. Supp. at 383-84 (false certification of compliance with statute or regulation violates the FCA if the

b. Violations of the Anti-Kickback Statute are not Material to the Government's Payment Decision

A violation of the Anti-Kickback Statute is not material to the government's payment decision because a violation of the statute will not necessarily result in nonpayment of a claim even if the government is made aware of the violation. Thus, notwithstanding the Goldberg declaration in the *Thompson* case, a violation of the Anti-Kickback Statute is simply not legally relevant to whether the government will pay the claim. This conclusion derives from the fact that nonpayment of a claim is not a mandatory or automatic sanction for a violation of the Anti-Kickback Statute. In other words, the statutory and regulatory framework of the Anti-Kickback Statute indicates that the government would not have been precluded from paying the claim even if it knew of the violation of the Anti-Kickback Statute.[268]

The sanctions which may be imposed for violations of the Anti-Kickback Statute are limited. A violation of the Anti-Kickback Statute can result in imprisonment for up to five years and criminal fines of up to $25,000.[269] Furthermore, a violation of the Anti-Kickback Statute constitutes grounds for imposition of a CMP and other civil monetary assessments.[270] Finally, violation of the Anti-Kickback Statute can result in the exclusion of an individual or entity from participation in Federal Health Care Programs, which means that the individual or entity becomes ineligible to receive payment for a claim submitted to a Federal Health Care Program.[271] There are two types

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government conditions payment upon certification of compliance); Tyger Const. Co. v. United States, 28 Fed. Cl. 35, 55 (1993) ("[T]he FCA covers only those false statements that are material."); United States *ex rel*. Butler v. Hughes Helicopter Co., 1993 U.S. Dist. LEXIS 17844, at *42 (C.D. Cal. Aug. 25, 1993) ("[W]hile the Ninth Circuit has not explicitly ruled on the issue of whether or not alleged false statements must be material, it has so implied."); United States v. Foster Wheeler Corp., 316 F. Supp. 963, 974 (S.D.N.Y. 1970) (setting forth that defendant intentionally made false statements that were material and upon which the government relied).

268. *See* 42 U.S.C. § 1320a-7(b) (Supp. 1997). As a general matter, one should consult the underlying statutory and regulatory scheme in order to determine whether the government would pay a claim if it were aware of a statutory or regulatory violation. In other words, if the statute or regulations state that nonpayment is a mandatory penalty for a violation, an adequate basis would seem to exist for concluding that the claim is false and that, therefore, FCA liability should be imposed. On the other hand, if the underlying statutory and regulatory scheme does not mandate nonpayment in the event of a violation, there seems less basis for concluding that the claim is false and that, therefore, FCA liability should be imposed.

269. *See* 42 U.S.C. § 1320a-7b(b)(1), (2).

270. *See id*. § 1320a-7a(a).

271. HHS has the authority to "exclude" individuals and entities from participation in Federal Health Care Programs. *See id*. § 1320a-7. Subject to a number of narrow exceptions, an exclusion prohibits an individual or entity from being reimbursed by a Federal Health Care

of exclusions: mandatory and permissive. Mandatory exclusions must be imposed by HHS for various types of criminal convictions, including a conviction of a criminal offense related to the delivery of an item or service reimbursable under Medicare or Medicaid.[272] Permissive exclusions may be imposed at the discretion of HHS for a variety of reasons, including an HHS administrative determination that an individual or entity has violated the Anti-Kickback Statute.[273]

Program for any item or service furnished on or after the effective date of the exclusion. *See* 42 U.S.C. § 1395y(e)(1) (1994); 42 U.S.C. § 1320a-7(c)(2); 42 C.F.R. § 1001.1901(c) (1998) (stating exceptions to payment ban for exclusions). An excluded individual or entity that submits claims to a Federal Health Care Program for items or services furnished during the exclusion period may be subject to civil monetary penalties and criminal liability. *See* 42 U.S.C. § 1320a-7a(a)(1)(D) (1994) (setting forth civil monetary penalty for submitting claims to a Federal Health Care Program for items or services furnished during the exclusion period); 42 U.S.C. § 1320a-7b(a)(3) (Supp. 1997) (setting forth criminal fines and/or imprisonment for knowingly submitting claims to a Federal Health Care Program during the exclusion period).

272. *See* 42 U.S.C. § 1320a-7(a)(1) (1994); 42 C.F.R. § 1001.101(a) (1998). Mandatory exclusions may also be imposed for: (1) conviction of a criminal offense related to the neglect or abuse of patients in connection with the delivery of a health care item or service. *See* 42 U.S.C. § 1320a-7(a)(2) (1994); 42 C.F.R. § 1001.101(b) (1998); (2) conviction of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service, or with respect to any act or omission under any federal, state, or local health care program other than Medicare and Medicaid. *See* 42 U.S.C. § 1320a-7(a)(3) (Supp. 1997); 42 C.F.R. § 1001.101(c) (1998); and (3) conviction of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. *See* 42 U.S.C. § 1320a-7(a)(4) (Supp. 1997); 42 C.F.R. § 1001.101(d) (1998). Generally, mandatory exclusions are for a minimum period of five years, although a minimum ten year exclusion is imposed for a second conviction and a permanent exclusion is imposed for a third conviction. *See* 42 U.S.C. § 1320a-7(c)(3) (Supp. 1999); 42 C.F.R. § 1001.102 (1998).

273. *See* 42 U.S.C. § 1320a-7(b)(7) (1994); 42 C.F.R. § 1001.951 (1997). Permissive exclusions may also be imposed for: (1) conviction of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service, or with respect to any act or omission under any federal, state, or local health care program, other than Medicare and Medicaid. *See* 42 U.S.C. § 1320a-7(b)(1)(A) (Supp. 1997); 42 C.F.R. § 1001.201(a)(1) (1998); (2) conviction of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission under any federal, state, or local program (other than a health care program). *See* 42 U.S.C. § 1320a-7(b)(1)(B) (Supp. 1997); 42 C.F.R. § 1001.201(a)(2) (1997); (3) conviction relating to obstruction of an investigation of a criminal offense. *See* 42 U.S.C. § 1320a-7(b)(2) (1994); 42 C.F.R. § 1001.301) (1998); (4) conviction of a misdemeanor relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance. *See* 42 U.S.C. § 1320a-7(b)(3) (Supp. 1997); 42 C.F.R. § 1001.401 (1998); (5) license revocation or suspension. *See* 42 U.S.C. § 1320a-7(b)(4) (Supp. 1997); 42 C.F.R. § 1001.501 (1998); (6) exclusion or suspension under a federal or State Health Care Program for reasons bearing on professional competence, professional performance, or financial integrity. *See* 42 U.S.C. § 1320a-7(b)(5)

Thus, absent a criminal conviction for violating the Anti-Kickback Statute, Federal Health Care Program exclusion, and ineligibility to receive payment for a claim, are not automatically imposed for a violation of the Anti-Kickback Statute. In other words, even if the Anti-Kickback Statute is violated, absent a criminal conviction for violation of the statute, a claimant is not automatically barred from receiving payment on the submitted claim. Moreover, even if HHS were to determine that the Anti-Kickback Statute is violated, the claimant is still not prohibited from receiving payment on the submitted claim unless HHS takes the additional step of imposing a permissive exclusion. Thus, violation of the Anti-Kickback Statute, by itself, cannot be viewed as material to the government's payment decision.

3. *FCA Liability Based Upon a Failure to Disclose Regulatory Violations to the Government*

The theory that FCA liability may be imposed for violations of the Anti-Kickback Statute means that liability can arise from a claimant's failure to disclose a statutory or regulatory violation when submitting a claim. In other words, the theory seems premised on the notion that the claimant is under some duty to disclose the alleged violation to the government when submitting the claim and that the failure to make such disclosure results in a false claim.

(1994); 42 C.F.R. § 1001.601 (1998); (7) claims for excessive charges or unnecessary services, or failure to furnish medically necessary services. *See* 42 U.S.C. § 1320a-7(b)(6) (1994); 42 C.F.R. § 1001.701 (1998); (8) being an entity controlled by a sanctioned individual. *See* 42 U.S.C. § 1320a-7(b)(8) (1994); (9) failure by an entity to disclose certain information regarding ownership by sanctioned individuals. *See* 42 U.S.C. § 1320a-7(b)(9) (1994); (10) failure to supply requested information on subcontractors and suppliers. *See* 42 U.S.C. § 1320a-7(b)(10) (1994); (11) failure to supply payment information regarding items furnished under Medicare or a State Health Care Program. *See* 42 U.S.C. § 1320a-7(b)(11) (1994); (12) failure to grant immediate access to federal or state officials to ensure compliance with conditions of participation or payment, surveys and record review. *See* 42 U.S.C. § 1320a-7(b)(12) (1994); (13) failure by a hospital to take corrective action regarding certain inappropriate medical practices. *See* 42 U.S.C. § 1320a-7(b)(13) (1994); (14) a default on health education loan or scholarship obligations. *See* 42 U.S.C. § 1320a-7(b)(14) (1994); (15) controlling a sanctioned entity. *See* 42 U.S.C. § 1320a-7(b)(15) (Supp. 1997); and (16) failure by an HMO to furnish medically necessary items and services. *See* 42 C.F.R. § 1001.801) (1998). Generally, absent aggravating or mitigating factors, permissive exclusions are for a minimum period of three years, although no minimum period of exclusion is specified where the exclusion is based upon an HHS administrative determination that there has been a violation of the Anti-Kickback Statute. *See* 42 U.S.C. § 1320a-7(c)(3) (Supp. 1997); 42 C.F.R. § 1001.951(b) (1998) (the length of an exclusion based upon an administrative determination that a violation of the Anti-Kickback Statute has occurred will depend upon the nature and circumstances of the party's actions, the effect of the party's actions on beneficiaries, the party's prior criminal, civil, or administrative sanction record, and any other facts bearing on the nature and seriousness of the party's misconduct).

However, imposing FCA liability for a failure to disclose such alleged violations seems misplaced because the FCA does not impose a general duty on claimants to disclose information.

a. False Claims Act Imposes Liability for Failing to Disclose Information in Limited Circumstances

The False Claims Act imposes liability on a party for withholding or concealing information in three limited circumstances. First, and most obviously, the failure to disclose information is actionable under the FCA where the claim form expressly requires inclusion of the omitted information. For example, the HCFA-2552 cost report form requires providers to disclose certain transactions entered into with organizations related to the provider by "common ownership" or "control."[274] Thus, the failure of a provider to report a transaction with a related party can result in FCA liability.[275] Second, the failure to disclose information is actionable under the FCA where the claimant has a specific statutory or regulatory duty to disclose the information. For example, a duty to disclose information would arise if a claimant sought to avail itself of the safe harbor for "discounts," which requires certain types of claimants to disclose on the claim form the amount of the discount received.[276] Third, the failure to disclose information is actionable under the FCA where the nondisclosure is intended to avoid or reduce some financial obligation already owed to the government. Specifically, under 31 U.S.C. § 3729(a)(7), FCA liability arises where one "knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government."[277] Significantly, this provision imposes liability for failing to disclose information only in situations where a debt is already owed to the government.[278] Thus, the mere possibility that penalties could be imposed at

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274. *See* Medicare & Medicaid Guide (CCH) ¶ 44,919 (copy of Hospital and Hospital Health Care Complex Cost Report HCFA-2552).

275. *See, e.g.*, United States v. Oakwood Downriver Med. Ctr., 687 F. Supp. 302 (E.D. Mich. 1988) (finding FCA liability based on defendant's failure to disclose on the HCFA-2552 the existence of transactions with related organizations).

276. *See* 42 C.F.R. § 1001.952(h) (1998).

277. 31 U.S.C. § 3729(a)(7).

278. *See Q Int'l Courier, Inc.*, 131 F.3d at 773. The court held that in order to recover under 31 U.S.C. § 3729(a)(7), the government "must demonstrate that it was owed a specific, legal obligation at the time that the alleged false record or statement was made, used, or caused to be made or used." *Id.* This obligation cannot be "merely a potential liability," but instead a defendant must have a present duty to pay money or property that was created by a statute, regulation, contract, judgment, or acknowledgment of indebtedness. *Id; see also* United States *ex rel*. Am. Textile Mfrs. v. The Limited, Inc., 1997 U.S. Dist. LEXIS 18142 (S.D. Ohio Nov. 13, 1997);

some point in the future for a violation of the Anti-Kickback Statute is an insufficient basis for requiring a claimant to disclose a potential violation of the statute when submitting a claim.

b. False Claims Act does not Impose a General Duty to Disclose Information

The False Claims Act imposes no general duty on a claimant to disclose information to the government when submitting a claim. The leading case on this issue is *United States* ex rel. *Milam v. Regents of the University of California*.[279] In *Milam*, a relator alleged that the University of California submitted false data and false claims for payment in connection with a series of federal grants. Specifically, the relator alleged that the university had failed to inform NIH of certain problems with the research, including retractions of certain cited articles, the erroneous nature of certain previously disclosed data, and the possible contamination of one of the cell lines used in the research. The court rejected these allegations, stating that the FCA "does not impose liability for omissions unless the defendant has an obligation to disclose the omitted information . . . . The [FCA] includes no duty to disclose certain information."[280] A number of other federal courts have also concluded that the False Claims Act does not impose a general duty to disclose information to the government when submitting a claim.[281]

4. *FCA Liability May Exist for Regulatory Violations Which Do Not Cause Injury to the Public Fisc*

The theory that FCA liability arises from a violation of the Anti-Kickback Statute means that FCA liability can exist where the violation of the Anti-Kickback Statute does not result in any financial injury to the

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United States *ex rel*. Prawer & Co. v. Verrill & Dana, 946 F. Supp. 87 (D. Me. 1996).

279. 912 F. Supp. 868 (D. Md. 1995).

280. United States *ex rel*. Milam v. Regents of the Univ. of Cal., 912 F.2d 868, 883 (D. Md. 1995).

281. *See, e.g*., *Data Translation, Inc.*, 984 F.2d at 1267 ("The GSA form cannot reasonably be interpreted to require, in the circumstances, disclosure of [certain price information] beyond the disclosure [the defendant] actually made."); Pickens v. Kanawha River Towing, 916 F. Supp. 702, 708 (S.D. Ohio 1996) ("[A] reverse false claim [under the FCA] requires more than a mere failure to report a violation of another statute."); *Hughes Aircraft Co.*, 1991 WL 133569, at *1 ("The Court finds no authority for placing a 'duty of due diligence' on defendant, outside of its affirmative statutory duties . . . ."); United States v. Bd. of Educ., 697 F. Supp. 167, 175 n.9 (D. N.J. 1988) ("It is stated that supporting documents, applications and certifications were missing with respect to said claims. However, nothing is supplied to show that these documents were required, or that their absence renders a claim to be false.").

government. In other words, the theory imposes FCA liability even in cases where the violation of the Anti-Kickback Statute does not cause the government to pay out additional amounts which it would not otherwise have paid absent a violation of the Anti-Kickback Statute. However, the question of whether the FCA is violated when there is no financial harm to the government remains unresolved. Consequently, the theory may effectively transform the FCA from a remedial statute to a punitive statute.

a. All Anti-Kickback Law Violations do not Cause Injury to the Public Fisc

Not all violations of the Anti-Kickback Statute result in financial injury to a Federal Health Care Program. A simple example illustrates this fact. The Anti-Kickback Statute is clearly violated where a physician agrees to refer a Medicare beneficiary to a hospital for inpatient surgery in return for a cash payment from the hospital. The hospital submits a claim form to the Medicare program seeking reimbursement for the inpatient operating costs associated with the surgery. Although the referral to the hospital constitutes a violation of the Anti-Kickback Statute, this violation does not necessarily result in financial harm to the Medicare program. If the surgery was medically necessary, and therefore would have been performed regardless of the unlawful kickback arrangement between the hospital and the referring physician, the Medicare program would still have paid the claim. In other words, although the kickback arrangement may have affected the decision regarding the hospital to which the patient would have been referred for the surgery, the arrangement did not affect the level of Medicare reimbursement that was ultimately paid for medically necessary services furnished to an eligible Medicare beneficiary. Nevertheless, under the theory that FCA liability arises from a violation of the Anti-Kickback Statute, the hospital in this example would be subject to FCA liability in claiming reimbursement for the inpatient services even though the Anti-Kickback Statute violation did not result in financial injury to the government as a result of its paying the claim.

b. Financial Harm as an Element of FCA Liability

It is unsettled whether financial injury to the government must be shown in order to impose FCA liability. The FCA statutory language does not clearly answer this question. On the one hand, the statute identifies two seemingly separate and distinct types of financial recovery to which the government may be entitled: (1) a civil penalty of $5,000 to $10,000 per claim; and (2) three times the amount of damages sustained by the

government.[282] On the other hand, the statute also suggests that damages are part of the burden of proof for establishing FCA liability.[283] Likewise, the legislative history of the FCA offers somewhat ambiguous, if not contradictory, statements regarding this issue.[284]

Courts have split on the question of whether FCA liability may be imposed only for false claims that result in financial injury to the government. A number of federal courts have concluded that proof of actual damages by the government is not required in order for the government to recover monetary penalties under the FCA.[285] Conversely, other federal courts have emphasized

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282. *See* 31 U.S.C. § 3729(a).

283. *See id*. § 3731(c) ("In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.").

284. *Compare* S. REP. NO. 99-345 (1996), *reprinted in* 1986 U.S.C.C.A.N. 5226, 5273 (The United States is entitled to recover such [civil penalty] solely upon proof that false claims were made, without proof of any damages.") (emphasis added), *with* S. REP. NO. 99-345 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5226, 5283 ("[t]he Committee strongly endorses [the Supreme Court's] opinion in . . . *Neifert-White* . . . that the False Claims Act 'was intended to reach all types of fraud, without qualification, that might result in financial loss to the government'" (quoting United States v. Neifert-White, 390 U.S. 228 (1968) (emphasis added))).

285. *See, e.g.*, *In re* Schimmels, 85 F.3d 416, 419 n.1 (9th Cir. 1996) (setting forth that a court may award a civil penalty "for each false claim or statement submitted to the government, even if no damages were caused by the false submissions"); United States *ex rel*. Schwedt v. Planning Res. Corp., 59 F.3d 196, 199 (D.C. Cir. 1995) ("[T]he [FCA] imposes two sorts of liability. First, the submitter of a 'false claim' or 'statement' is liable for a civil penalty, regardless of whether the submission of the claim actually causes the government any damages; even if the claim is rejected, its very submission is a basis for liability."); *Rivera*, 55 F.3d at 709 ("[A] contractor who submits a false claim for payment may still be liable under the FCA for statutory penalties, even if it did not actually induce the government to pay out funds or to suffer any loss."); United States *ex rel*. Hagood v. Sonoma County Water Agency, 929 F.2d 1416, 1421 (9th Cir. 1991) ("No damages need be shown in order to recover the penalty."); United States v. Miller, 645 F.2d 473, 475-76 (5th Cir. 1981) (while the statute clearly requires the government to demonstrate the element of causation between the false statements and the loss before it may recover double damages, even where a complaint does not allege that a false claim caused the government to incur any damages it still states a claim for the recovery of the statutory penalty); United States v. Hughes, 585 F.2d 284, 286 n.1 (7th Cir. 1978) ("A false claim is actionable under the Act even though the United States has suffered no measurable damages from the claim."); Fleming v. United States, 336 F.2d 475, 480 (10th Cir. 1964) ("Proof of damage to the Government resulting from a false claim is not a necessary part of the Government's case under the Act."); United States v. Rainwater, 244 F.2d 27, 28 (8th Cir. 1957) ("[E]ven if no damages were shown at the time of trial the United States could still recover the statutorily fixed sum . . . for each of the proscribed acts."), *aff'd on other grounds*, 356 U.S. 590 (1958); United States v. Rohleder, 157 F.2d 126, 129 (3d Cir. 1946) (stating that the statute "permits recovery of a forfeiture . . . without actual damages being proven"); *Bd. of Educ.*, 697 F. Supp. at 177 (finding that a civil penalty "could be levied even in the event that the United States suffered no actual damages"); Blusal Meats, Inc. v. United States, 638 F. Supp. 824, 827 (S.D.N.Y. 1986) (stating that the government may recover costs and penalties "for each FCA violation in the absence of proof of damage to the United States"); United

that the FCA is not a punitive statute but a remedial statute designed to remedy the government's pecuniary and proprietary losses suffered as a result of the false claim and, therefore, have ruled that some evidence of financial injury to the government is required in order to impose FCA liability.[286]

The Supreme Court has not ruled on the issue of whether financial harm must be proven before a cause of action is stated under the FCA. The Supreme Court had an opportunity to address this issue in the case of *United States* ex rel. *Schumer v. Hughes Aircraft Co*.[287] In *Schumer*, a qui tam relator employed by Hughes Aircraft Company alleged, inter alia, that the defendant failed to comply with the requirements of applicable Cost Accounting

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States v. CFW Const. Co., 649 F. Supp. 616, 618 (D.S.C. 1986) ("[A] showing of measurable damage to the United States is not an essential element of a cause of action for submission of false claims or for conspiracy to submit false claims under the [FCA]."); United States v. Cherokee Implement Co., 216 F. Supp. 374, 375 (N.D. Iowa 1963) ("The courts have always rejected the argument that the United States must suffer actual damages before the penalties under [the statute] may be collected."); United States v. Ben Grunstein & Sons Co., 127 F. Supp. 907, 912 (D.N.J. 1955) ("[D]amage need not accrue in fact to the United States before a [civil penalty] is recoverable."); United States v. Ridglea State Bank, 357 F.2d 495, 497 (5th Cir. 1966) (rejecting the argument that no cause of action is stated under the False Claims Act if the government has not incurred actual damages by paying money on the false claim).

286. *See, e.g.*, United States v. Cohn, 270 U.S. 339, 345-47 (1926) (stating that the FCA does not prohibit fraudulent obtaining of property from the government in its capacity as bailee, because the public fisc does not suffer any pecuniary or property loss); *Berge*, 104 F.3d at 1458 (stating that "the government, as the real party in interest, must still have suffered an injury in fact"); Young-Montenay, Inc. v. United States, 15 F.3d 1040, 1043 (Fed. Cir. 1994) (holding that proof of damages is required under the FCA); United States *ex rel.* Glass v. Medtronic, Inc., 957 F.2d 605, 608 (8th Cir. 1992) (holding that an alleged violation of medical device reporting requirement incapable of establishing a "false claim" because there is no injury to the government); United States v. Azzarelli Const. Co., 647 F.2d 757, 759 (7th Cir. 1981) ("[T]he allegedly false claim must be one that is capable of causing an injury to the funds or property of the United States if the claim is in fact paid."); United States v. Hibbs, 568 F.2d 347, 350-51 (3d Cir. 1977) (finding that the United States is required to prove all essential elements of the cause of action, including damages); Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975) ("A claim is within the purview of the False Claims Act if it is grounded in fraud which might result in financial loss to the Government."); *Mikes*, 931 F. Supp. at 261 ("Even if it is not necessary for plaintiff to demonstrate monetary damages, plaintiff must still prove that the United States has been injured by the filing with knowledge of a false or fraudulent claim."); Daff v. United States, 31 Fed. Cl. 682, 695 (1994) (limiting the government's recovery under the False Clims Act to those costs established with specificity); United States *ex rel.* Stinson v. Provident Life & Accident Ins. Co., 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989) (holding that proof of damages is required under the FCA); Thevenot v. Nat'l Flood Ins. Program, 620 F. Supp. 391, 394 (W.D. La. 1985) (finding that a claim is within the purview of the False Claims Act if it is grounded in fraud which might result in financial loss to the government).

287. 63 F.3d 1512, 1525 (9th Cir. 1995).

Standards (CAS) reports filed by Hughes with the government.[288] The Ninth Circuit held that "[a]lthough the Administrative Contracting Officer found that this noncompliance had an 'immaterial impact' on costs, the lack of a determination of actual harm from the CAS violation does not preclude a claim under the FCA."[289] In other words, despite a showing that Hughes' regulatory violation cost the government nothing, such a violation "creates a genuine issue of material fact relating to a violation of the False Claims Act."[290] Thus, the Ninth Circuit concluded that "the lack of a determination of actual harm . . . does not preclude a claim under the FCA."[291] The Supreme Court granted the petition for certiorari to consider, among other things, "whether harm to the public fisc is an essential element of a qui tam action under the FCA."[292] However, the Supreme Court decided the case on another issue: whether the 1986 amendments to the FCA, which relaxed the restrictions on qui tam lawsuits by eliminating the requirement that the relator's suit be based on information not already known to the government, apply retroactively to actions challenging pre-1986 conduct.[293]

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288. Briefly, Northrop Corporation had awarded Hughes Aircraft Company a subcontract to design and develop a radar system for the B-2 bomber, which Northrop was then constructing under a contract with the Air Force. Both Northrop's subcontract with Hughes and the Air Force's contract with Northrop were "cost-plus" contracts, which provided that the subcontractor and the contractor, respectively, were to be reimbursed for all costs properly incurred plus a reasonable profit. Several months after Hughes was awarded the B-2 subcontract, the McDonnell-Douglas Corporation awarded Hughes a "fixed-price" subcontract to design and develop an upgraded radar system for the F-15 fighter aircraft, which McDonnell-Douglas was then building for the Air Force. Under the fixed-price contract, Hughes was to receive a set price, regardless of its costs. When it became apparent to Hughes that the projects overlapped in significant respects, Hughes adopted two internal "commonality agreements" allocating between its F-15 and B-2 divisions various costs that were common to the two projects. After costs in the B-2 program escalated, Northrop requested a government audit of Hughes' accounting practices to ascertain whether Hughes had improperly shifted costs from the fixed-price F-15 subcontract to the cost-plus B-2 subcontract. The Defense Contract Audit Agency prepared a series of unclassified audit reports which concluded that Hughes had misallocated costs between the two programs and had not adequately disclosed the company's commonality accounting practices in a Cost Accounting Standards report it had submitted to the government. The government ultimately concluded, however, that the commonality agreements had actually benefited the government by charging costs to the fixed-price F-15 program that otherwise would have been borne solely by the cost-plus B-2 program.

289. *Schumer*, 63 F.3d at 1525.

290. *Id*..

291. *Id*.

292. Hughes Aircraft Co. v. United States *ex rel.* Schumer, 520 U.S. 939, 945 (1997).

293. *See id*. at 945.

5. *Private Right of Action to Enforce the Anti-Kickback Statute*

The theory that FCA liability arises from a violation of the Anti-Kickback Statute effectively creates a private right of action to enforce the Anti-Kickback Statute. In other words, the theory means that private citizens, i.e., relators, can bring a lawsuit under the FCA's qui tam provisions based upon alleged violations of the Anti-Kickback Statute. However, courts have held that neither the language nor the legislative history of the Anti-Kickback Statute demonstrates that Congress intended for the Anti-Kickback Statute to be enforced by private parties. Moreover, attempts by relators to characterize the cause of action in these cases as actually arising under the FCA, and not under the Anti-Kickback Statute, are questionable because other courts have consistently rejected FCA actions that are based solely upon violations of other statutes.

a. No Private Right of Action Exists Under the Anti-Kickback Statute

A private right of action to enforce a statute may be implied by courts where the statute does not expressly establish such a private right of action.[294] In other words, in some limited circumstances, courts will allow private parties to bring suit to enforce the provisions of a federal statute even if the statute does not expressly provide for such private enforcement. In *Cort v. Ash*,[295] the Supreme Court enunciated a four-part test for determining whether a private right of action may be implied under a statute. Pursuant to this test, a private right of action will be implied where: (1) the plaintiff is in a class intended to be protected by the statute; (2) the legislature intended to create a private right of action; (3) a private right of action is consistent with the legislative scheme; and (4) the cause of action is not in an area traditionally relegated to state law.[296] In applying this test, "courts seldom imply [that] a private right of action" exists under a statute absent some evidence in the

294. *See generally* Susan J. Stabile, *The Role of Congressional Intent in Determining the Existence of Implied Private Rights of Action*, 71 NOTRE DAME L. REV. 861 (1996); Richard J. Pierce, *Agency Authority to Define the Scope of Private Rights of Action*, 48 ADMIN. L. REV. 1 (1996); Bradford C. Mank, *Is There a Private Cause of Action Under EPA's Title VI Regulations?: The Need to Empower Environmental Justice Plaintiffs*, 24 COLUM. J. ENVTL. L. 1 (1999); Lauren Levy, *Stretching Environmental Statutes to Include Private Causes of Action and Extraterritorial Application: Can it be Done?*, 6 DICK. J. ENVTL. L. & POL'Y 65 (1997); David P. Kunstle, *Kadic v. Karadzic: Do Private Individuals have Enforceable Rights and Obligations Under the Alien Tort Claims Act?*, 6 DUKE J. COMP. & INT'L L. 319 (1996).

295. 422 U.S. 66 (1975).

296. *See* Cort v. Ash, 422 U.S. 66, 78 (1975).

statute's language, structure, and legislative history that Congress intended such a right to exist.[297] The Supreme Court has held that private rights of action do not exist in the enforcement of various federal statutes, including statutes relating to securities, government contracting, civil rights, conservation, and recordkeeping.[298]

On its face, the Anti-Kickback Statute makes no provision for enforcement actions by private parties.[299] Furthermore, the statute's legislative history does not indicate that Congress intended to provide private parties with a right of action under the statute.[300] Although the Supreme Court has never ruled on whether a private right of action exists under the Anti-Kickback Statute, a number of lower federal courts have ruled on this issue. The leading case is *West Allis Memorial Hospital, Inc. v. Bowen*,[301] where the

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297. Statland v. Am. Airlines, Inc., 998 F.2d 539, 540 (7th Cir. 1993).

298. *See, e.g.*, Cent. Bank of Denver, N.A. v. First Interstate Bank, 511 U.S. 164 (1994) (a private right of action for aiding and abetting a violation of § 10(b) of the Securities Exchange Act of 1934 does not exist); Cal. v. Sierra Club, 451 U.S. 287, 298 (1981) (no private cause of action was intended by the adoption of the Rivers and Harbors Act of 1899); Northwest Airlines, Inc. v. Transp. Workers Union, 451 U.S. 77, 91-95 (1981) (no implied right of action exists with respect to violations in Title VII of the Civil Rights Act of 1964 and the Equal Pay Act of 1962); Universities Research Ass'n v. Coutu, 450 U.S. 754 (1981) (no private cause of action will be implied to permit employees to seek higher wages under a federal contract that has been administratively-determined not to call for work covered by the Davis Bacon Act); Kissinger v. Reporters Comm. for Freedom of the Press, 445 U.S. 136 (1980) (the Federal Records Act does not create an implied private right of action to force a federal agency to recapture records improperly removed from its control); Touche Ross & Co. v. Redington, 442 U.S. 560 (1979) (investors do not have an implied cause of action under § 17(a) of the Securities and Exchange Act of 1934 against an accounting firm alleged to have conducted an improper audit and certification of financial statements); Chrysler Corp. v. Brown, 441 U.S. 281 (1979) (no private right of action will be implied under the Trade Secrets Act); Santa Clara Pueblo v. Martinez, 436 U.S. 49 (1978) (Title I of the Indian Civil Rights Act of 1968 does not authorize a civil action for declaratory or injunctive relief against tribal officials); Piper v. Chris-Craft Industries, Inc., 430 U.S. 1 (1977) (a tender offeror does not have a private cause of action for damages for violations by the successful offeror of § 14(e) of the Securities and Exchange Act of 1934); SIPC v. Barbour, 421 U.S. 412 (1975) (there is no implied right of action for customers of a failed securities firm to force the Securities Investor Protection Corporation to exercise its authority for their benefit).

299. *See* 42 U.S.C. § 1320a-7b(b) (1994).

300. *See* Social Security Amendments of 1972, Pub. L. No. 92- 603, § 242(b), (c), 86 Stat. 1329, 1419 (1972); Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175, 1182 (1977); H.R. REP. NO. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039; Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625; H.R. REP. NO. 96-1167 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 1128, 101 Stat 680, 680-81; S. REP. NO. 100-109 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682.

301. 660 F. Supp. 936 (E.D. Wis. 1987).

district court expressly held that no private right of action exists under the Anti-Kickback Statute.[302]

In *West Allis*, the plaintiff hospital sought injunctive relief against a competing hospital for alleged violations of the Anti-Kickback Statute. The competitor, St. Luke's Hospital, instituted a financial incentive program, known as the "Freedom 55/65 Program," that West Allis feared would attract Medicare beneficiaries to St. Luke's.[303] The Freedom 55/65 Program was essentially a copayment/deductible waiver program under which St. Luke's offered to waive Medicare copayment and deductible obligations for any Medicare patient treated at St. Luke's who did not have a supplemental insurance policy that paid these expenses.[304] The district court in *West Allis* held that the plaintiff lacked standing to prosecute the case. According to the district court,

> [West Allis] simply seeks to have the court substitute its judgment regarding prosecutorial decisions for that of the Department of Justice. It is up to prosecutors to exercise their discretion and to determine who should be prosecuted under valid statutes. If a decision to prosecute is made, the issue of the applicability of the statute to the conduct can be raised in the context of a criminal case.[305]

The Seventh Circuit Court of Appeals affirmed the district court decision.[306] In refusing to imply a private right of action under the Anti-Kickback Statute, the Seventh Circuit concluded that "neither the . . . [Anti-Kickback Statute] nor its legislative history suggests that Congress intended to provide a private remedy to Medicare providers . . . which may be injured as a result of a competitor's noncompliance with the provisions of that statute."[307] According to the appeals court, the legislative history of the statute supports the conclusion that it is the government, not private parties, that is charged with enforcement of the statute.[308] In this regard, the court stated that the purpose of the Anti-Kickback Statute is "to amend the Social Security Act to strengthen the capability *of the Government* to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs."[309] The *West Allis* decision has been followed by other federal courts.[310]

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302. *See* W. Allis Mem'l Hosp. v. Bowen, 660 F. Supp. 936 (E.D. Wis. 1987).

303. *See W. Allis*, 660 F. Supp. at 938.

304. *See id*.

305. *Id*. at 940.

306. *See* West Allis Mem'l Hosp., Inc. v. Bowen, 852 F.2d 251 (1988).

307. *West Allis*, 852 F.2d at 255.

308. *See id*.

309. *Id*. at 255 (quoting H.R. REP. NO. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3040) (emphasis in original).

310. *See, e.g.*, Kent County Mem'l Hosp. v. Balasco, No. CIV.A.89-00, *reprinted in* 1990 WL 17157, at *75B (D. R.I. Feb. 13, 1990) (Anti-Kickback Statute "does not create a private right of action and cannot be used as a basis for federal court jurisdiction.").

b. Courts Have Rejected Claims Brought under the FCA That Are Based Solely upon Violations of Other Statutes

Qui tam relators and the government contend that they are not claiming a private right of action to enforce the Anti-Kickback Statute. Rather, according to the relators and the government, the cause of action is to enforce the FCA because claims are rendered false due to the violation of the Anti-Kickback Statute. In this regard, use of the FCA to prosecute violations of the Anti-Kickback Statute is similar to attempts by private parties to bring civil actions under the FCA based upon alleged violations of other statutes and regulations. As previously discussed, however, courts have held that a violation of one statute cannot form the sole underlying basis for a cause of action under the FCA.[311]

The rationale for not allowing FCA actions to be based solely upon violations of other statutes appears clear. To permit such actions would mean that private parties could use the FCA qui tam provisions to effectively enforce statutes with existing penalty frameworks which do not authorize private rights of action. By not granting private parties a private right of action to enforce statutes with existing penalty frameworks, government agencies are ensured a certain degree of prosecutorial discretion in the enforcement of these statutes. Such discretion is especially important when a regulatory regime is complex or when it is not clear what conduct constitutes a violation.

The court in *United States* ex rel. *American Textile Manufacturers v. The Limited*[312] addressed the rationale for why violations of one statute should not form the sole underlying basis for a cause of action under the FCA. The relator in *American Textile Manufacturers* alleged that the defendants knowingly permitted manufacturers to misidentify the country of origin of goods imported into the United States in order to import amounts in excess of quotas imposed by the United States.[313] According to the relator, this conduct violated statutes and regulations under which the United States could assess fines and penalties. Thus, when the defendants falsified the entry documents for the excess imported goods, they attempted to avoid obligations owed to the United States government, in violation of 31 U.S.C. § 3729(a)(7).[314] The district court rejected this argument. The court reviewed the legislative

311. *See supra* note 222 and accompanying text.

312. No. C2-97-776, *available at* 1997 U.S. Dist. LEXIS 18142 (S.D. Ohio Nov. 13, 1997).

313. *See* United States *ex rel*. Am. Textile Mfrs. v. The Ltd., No. C2-97-776, *available at* 1997 U.S. Dist. LEXIS 18142, at *6-7 (S.D. Ohio Nov. 13, 1997).

314. *See Am. Textile Mfrs*. at *10-16.

history and case law before concluding that Congress did not intend, by the 1986 amendments to the FCA, "to convert that Act into an all-inclusive vehicle for the enforcement of any federal statute or government regulation . . . whenever it can be found that some false statement has been made regarding conduct subject to monetary sanctions."[315] According to the court:

> In this day of pervasive government regulation of both public and private conduct, it is impossible even to estimate the number of times each day, each month, or each year that private citizens create or submit some type of document required by the government or subject to government review or the number of times that such document, if not completely accurate, could lead to the filing of a False Claims Act case . . . . Congress and regulatory agencies have set forth specific sanctions for the violations of these laws and regulations, and the False Claims Act, in this Court's view, is not intended to be some super enforcement tool with a private right of action for the imposition of some new and additional penalty.[316]

The district court went on to give several examples of how a contrary interpretation of the FCA, in the context of environmental statutes, occupational safety and health regulations, and civil rights actions, would create a "super enforcement tool with a private right of action for the imposition of some new additional penalty beyond those already available under federal laws."[317]

CONCLUSION

The legal theory that FCA liability may be based solely upon violations of the Anti-Kickback Statute greatly expands the scope of the False Claims Act. Specifically, the theory means that FCA violations can arise from violations of other statutory and regulatory provisions. Furthermore, the theory is based upon a number of underlying assumptions whose legal basis is questionable. Consequently, the theory will likely continue to be contested absent Congress or the Supreme Court addressing this issue in a definitive manner.

315. *Id.* at *38.
316. *Id.* at *38-39.
317. *Id.*