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I. Introduction

Medicare and Medicaid combined comprise the largest payer of health care services in the world, and account for over 20 percent of all U.S. government spending. As a result, efforts to combat fraud and abuse in these programs have become a congressional and administrative priority.1

A. “Fraud” -- Refers to intentional acts to obtain payments to which someone is not entitled, including through making or causing to be made false statements or misrepresentations which are material to receiving a program entitlement or payment. Examples are knowingly filing claims for reimbursement for services not rendered, intentional “upcoding,” double billing, and billing for services resulting from a kickback. Violators may be perpetrated by a participating provider, a beneficiary, or other person or business entity.2

B. “Abuse” -- Describes incidents or practices that, although not considered fraudulent, are inconsistent with accepted sound medical, business or fiscal practices, directly or indirectly result in unnecessary costs, improper reimbursement, or program reimbursement for services which fail to meet professionally recognized standards of care or which are medically unnecessary. An example is overutilization of medical and health care services. Both the federal anti-kickback statute and Stark anti-referral laws (discussed below) are intended to combat overutilization of medical services.3

II. Enforcement and Jurisdiction

A. HHS -- Medicare is administered by the Secretary of Health and Human Services (“HHS”).

B. CMS -- The Secretary of HHS has delegated the responsibilities of administering Medicare to the Administrator of the Centers for Medicare and Medicaid Services (“CMS”).

C. OIG -- The jurisdiction over abusive business practices of Medicare and Medicaid is charged to the Office of Inspector General (“OIG”). The OIG is an independent office within HHS that was established by Congress in 1976. Congress created OIG to identify and eliminate

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2 See Medicare Carriers Manual § 14006.2; Swendiman, CRS Report for Congress, Health Care Fraud: A Brief Summary of Law and Federal Anti-Fraud Activities (September 24, 1997).
3 See Medicare Carriers Manual § 16006.1.
fraud, abuse, and waste in HHS programs. The OIG is also supposed to promote efficiency and economy in departmental operations.

1. OIG carries out this mission through audits, investigations and inspections. To help reduce fraud in the Medicare and Medicaid programs, the OIG actively investigates violations of the Medicare and Medicaid anti-kickback statute.

2. The OIG is led by the Inspector General (“IG”) and Deputy Inspector General. The IG is responsible for: (i) conducting investigations into business practices involving suspected fraud and abuse; (ii) developing cases and initiating punitive action against individuals and entities and referring such cases to the U.S. Justice Department for criminal or civil prosecution; (iii) enforcing administrative sanctions, including exclusion of convicted providers from the Medicare and Medicaid programs; (iv) performing audits and inspection of Medicare programs; (v) conducting special studies and projects; and (vi) collecting and analyzing information pertaining to the operation and administration of the Medicare and Medicaid programs.4

3. The OIG issues Annual Work Plans that describe forthcoming audit and enforcement initiatives.

D. Department of Justice -- “DOJ,” including Main Justice and U.S. Attorneys Offices located in each judicial district throughout the United States, has prosecutorial discretion to bring criminal and civil action under the various federal fraud and abuse healthcare laws (most prominently including the False Claims Act).

E. Federal Bureau of Investigation

F. Postal Inspectors

G. State Attorney Generals and Medicaid Fraud Control Units (“MFCUs”)

III. The Anti-Kickback Statute

A. General

1. Illegal Remuneration

   Section 1128B(b) of the Act, known as the anti-kickback statute (“AKS”), prohibits the offer, solicitation, payment, or receipt of any remuneration, in cash or in kind, in return for, or to induce, the referral of a patient for any service that may be paid by a Federal Healthcare Program (most notably, Medicare and Medicaid).5 Prohibited conduct also includes remuneration in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item reimbursed under Medicare or a state health care program. Remuneration has been broadly defined to encompass anything of value. The OIG opined in Advisory Opinion in 2008 that an “opportunity to generate fees”

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4 See Medicare Carriers Manual § 1400.2.
5 42 U.S.C. § 1320a-7(b).
can constitute remuneration.\textsuperscript{6} One court even ruled that an “opportunity to bill” for patient services constituted remuneration.\textsuperscript{7} Statutory “exceptions” to prohibited remuneration are discussed below at III.B.

2. Sanctions for AKS Violations

a. The AKS provides criminal penalties for individuals or entities who knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or kind, in return for referring an individual to a person for the furnishing or arranging of any item or medical service reimbursed under Medicare or a state health care program.

b. Violations are classified as a felony and, upon conviction; violators may be fined not more than $25,000 or imprisoned for not more than five years, or both. AKS violations also can give rise to program exclusions, civil monetary penalties (“CMPs”) of up to $50,000 per offense, and false claims act liability (as discussed at III.D. below).

c. The broad reach of the AKS prompted concerns that many innocuous commercial arrangements would be subject to criminal prosecution.\textsuperscript{8} In response, Congress provided an alternative civil remedy under the Medicare and Medicaid Patient and Program Protection Act of 1987\textsuperscript{9} that authorized the OIG to exclude persons or entities from participation in the Medicare and state Medicaid programs. The MMPPA also required the OIG to promulgate “Safe harbor” rules designed to shield beneficial business arrangements from potential AKS prosecution.

3. “Intent to Induce” -- The gravamen of a violation of the AKS is “inducement,” not necessarily the structure of the arrangement.\textsuperscript{10} Consequently, the relevant inquiry in each case focuses on the subjective intent of the parties to exchange remuneration for referrals.\textsuperscript{11} Intent need not be expressed but may be inferred. For example, one court inferred that where the purchase price of a private medical practice or payment for services rendered under a compensation arrangement exceeds fair market value, the amount paid in excess of fair market value was “intended” as payment for the referral of program-related business.\textsuperscript{12}

\textsuperscript{6} Advisory Opinion 08-10, August 26, 2008.
\textsuperscript{7} See United States ex rel. Fry v. The Health Alliance of Greater Cincinnati, et al. (Christ Hospital of Cincinnati), No. C-1-03-167 (S.D. Ohio Feb. 2, 2010). In this case, an AKS violation was based on the hospital providing priority access to unassigned heart station patients to community cardiologists based directly on the volume of their referrals to the hospital.
\textsuperscript{9} P.L. No. 100-93, 100 Stat. 688 (1987).
\textsuperscript{10} United States v. Bay State Ambulance & Hosp. Rental Serv., 874 F.2d 20, 30 (1st Cir. 1989).
\textsuperscript{12} United States v. Lipkis, 770 F.2d 1447 (9th Cir. 1985).
4. “Knowing and Willful” Standard -- The AKS imposes a “knowing and willful” intent requirement.\textsuperscript{13} The Patient Protection and Affordable Care Act of 2010 (“PPACA”)\textsuperscript{14} amended the law to clarify that the knowledge of a specific intent to violate the AKS statute need not be proven. The PPACA amendment legislatively reversed a decision by the Ninth Circuit Court of Appeals\textsuperscript{15} holding that a person could not be liable for an AKS violation unless the violator (1) subjectively knew that the statute prohibited offering or paying remuneration to induce referrals, and (2) engaged in the prohibited conduct with the specific intent to disobey the law.\textsuperscript{16} Therefore, post-PPACA, a successful AKS action can be brought against an individual without proving his or her actual knowledge of the statute or specific intent to violate it.

B. Exceptions -- Statutory Exceptions to prohibited remuneration under the AKS include:

1. Discounts or reductions in price if properly disclosed and appropriately reflected in costs claimed or charges made.

2. Payments made to employees under a bona fide employer/employee relationship.

3. Waiver of coinsurance for certain limited Medicare Part B services with respect to an individual who qualifies for subsidized services under a Public Health Service Act.

4. Group purchasing vendor agreements in which: (i) there is a written contract specifying the amounts paid to a purchasing agent; (ii) compensation is set at either a fixed amount or a fixed percentage; (iii) and the purchasing agent discloses to the contracting provider the amounts received from the vendors with respect to purchases made on behalf of the provider.

5. Any practice for which the Secretary creates a regulatory “safe harbor.”

6. A risk-sharing arrangement pursuant to a written agreement between an organization and any individual or entity providing services to the organization. To qualify, the organization must be an eligible organization under Section 1876 of the Social Security Act, or the service provider must be at a substantial financial risk for the cost or utilization of the items or services that it is obligated to provide. This exception, which is intended to cover withholds, capitation agreements, incentive pools, per diem payments, and similar arrangements, was added by P.L. 104-191, Section 216(a), and is effective for agreements entered into on or after January 1, 1997.

\textsuperscript{13} 42 U.S.C. § 1320a-7b(b)(1).


\textsuperscript{15} \textit{Hanlester Network v. Shalala}, 51 F.3d 1390 (9th Cir. 1995). \textit{See also United States v. Jain}, 93 F.3d 436 (8th Cir. 1996), \textit{cert. denied} 520 U.S. 1273 (1997) (proof’s required that defendant “knew his conduct was wrongful”).

\textsuperscript{16} \textit{Hanlester Network v. Shalala}, 51 F.3d 1390, 1399 (9th Cir. 1995)
C. Case Law Interpretation

The AKS is worded broadly, and prohibits business and financial arrangements that might otherwise be acceptable business practices in other settings, where Medicare or Medicaid is not involved. In *United States v. Greber*, the leading case interpreting the AKS’ broad statutory prohibition, Dr. Greber was paid by a diagnostic testing service provider for readings of his patients’ holter monitor tests. The payments were admitted, in part, to be payments for services, and, in part, payment for referrals. The Third Circuit upheld Dr. Greber’s conviction by interpreting the anti-kickback statute broadly and holding that liability attaches as long as one of the subjective purposes of the remuneration is to induce referrals. The any “one purpose” test enunciated in *Greber* has been upheld with slight variations, by other circuit courts. *Greber* also is noteworthy for equating payments for professional services in excess of the Medicare professional component (and thereby fair market value) with a quid pro quo for patient referrals.

D. AKS Violation As False Claims Act Violation -- Prior to the PPACA amendment, the Federal Circuits were split as to whether billing for services arising out of an AKS violation was a predicate for a FCA claim. Legislatively resolving the split among the federal courts, the PPACA amended the Act to specify that claims submitted in violation of the AKS constitute a false or fraudulent claim in violation of the FCA. Therefore, in addition to civil and criminal liability through the AKS, violators of the AKS are now subject to liability under the FCA. The case law is still relevant to FCA claims arising out of conduct predating the PPACA amendment.

E. Safe Harbor Protections -- The Medicare and Medicaid Patient and Program Protection Act of 1987 required HHS’ to promulgate regulations specifying and protecting payment practices encompassing legitimate business practices (so-called “safe harbors”) that will not be subject to criminal prosecution, or exclusion from the Medicare and Medicaid as involving prohibited remuneration.

1. Criteria for Protection -- The safe harbor regulations protect certain specified arrangements from prosecution under the Anti-Kickback Statute. An arrangement must meet all of the elements of a safe harbor to be protected from prosecution.

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18 Id. at 69.
19 See, e.g., *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (“one of the material purposes”); *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 30 (1st Cir. 1989) (“the improper purpose is the primary purpose”); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)(similar); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998)(similar).
21 PPACA § 6402(f)(1)(g), amending 42 U.S.C. 1320a-7b (claims for items or services “resulting from” a violation of the AKS constitute “false or fraudulent claims” under the FCA).
2. Failure to Satisfy a Safe Harbor -- If a payment practice fails to comply with any of the promulgated safe harbors, it is not thereby deemed unlawful. However, the payment practice will be measured against the statute, and unlawful remuneration may be found to exist based on the parties' subjective intentions under the particular facts and circumstances presented.23

3. Multiple Purposes -- When a payment practice serves “multiple purposes” (e.g., a payment to compensate for personal services and equipment rental), the payment practice will be protected only if (in the above example) it fits into both the personal service and equipment rental safe harbors. Thus, compliance with only one safe harbor will not insulate payment practices serving multiple purposes, if another purpose of the payment practice is implemented in a manner that violates the statute.24

F. Select Safe Harbor Regulations

1. Investment Interests Safe Harbors25
   a. Large Investment Interests

   Any payment made as a return on an investment to an investor, such as a dividend or interest, will be protected only under very narrow circumstances. First, the safe harbor protects investments in large publicly traded corporations, listed on a registered national securities exchange, that own more than $50 million in non-depreciated net tangible assets.26 The OIG clarified in its 1999 regulations that only assets or revenues related to the furnishing of healthcare items or services will be counted for purposes of qualifying for the $50 million asset threshold.

   b. Small Investment Interests

   This safe harbor encompasses limited and general partnership interests, shareholders, and holders of debt securities where either of two standards is met.27 The two standards set forth in the small entities safe harbor are known as the “60-40” rules. Under the first 60-40 rule (the “60-40 investor rule”), no more than 40% of the value of the investment interest in each class of investment may be held in the previous fiscal year or 12-month period by investors who were in a position to make or influence referrals, furnish items or services to, or otherwise generate business for the entity.28 Under the second rule (the “60-40 revenue rule”), no more than 40% of the gross revenue of the entity in the previous fiscal year or previous 12-month period may come from referrals, items or services furnished, or business otherwise

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23 *Id.* at 35957.
24 *Id.* at 35957.
25 42 C.F.R. § 1001.952(a).
26 42 C.F.R. § 1001.952(a)(1). The July 21, 1994, proposed regulations would require that the minimum $50 million in assets be “related to the furnishing of health care.”
27 42 C.F.R. § 1001.952(a)(1). The July 21, 1994, proposed regulations would require that the minimum $50 million in assets be “related to the furnishing of health care.”
generated from investors. The OIG clarified in its 1999 regulations that only assets or revenues related to the furnishing of healthcare items or services will be counted for purposes of qualifying for the 60/40 gross revenue test.

Other requirements of the safe harbor include:

(i) The investment terms for an investor who is in a position to influence referrals must be no different than those offered to a passive investor.

(ii) The investment terms must not be related to the expected value or volume of referrals.

(iii) The investment terms may not require that a passive investor make referrals to the entity.

(iv) All marketing of the entity’s items or services must be on the same terms to passive investors as to non-investors.

(v) Neither the entity nor any investor may loan funds to an investor or guarantee a loan for an investor who is in a position to influence referrals or otherwise generate business for the entity, for the purpose of using any part of the loan proceeds to purchase an investment interest in the entity.

(vi) The return on the investor’s return for the investment interest must be proportionate to the amount of capital contributed by the investor.

c. Investment in Medically Underserved Areas

This safe harbor expands protection to investments in medically underserved areas (“MUA”), which may include either rural or urban areas. Under the MUA safe harbor, the 60/40 investor rule is modified to a 50/50 rule. The 50/50 rule provides that no more than 50% of the value of the investment interest in each class of investment can be held by investors who are in a position to influence referrals to the entity or to furnish or provide items or services to the entity. Those investors (i.e., up to 50%) who are in a position to influence referrals (e.g., physicians) can be responsible for up to 100% of referral revenues. In addition, 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 the service of persons who reside in an underserved area or are members of medically underserved area populations. Any entity offering an opportunity for investment to a passive investor who is in a position to make or furnish referrals, to furnish items or services to,

29 42 C.F.R. § 1001.952(a)(2)(vi). The July 21, 1994, proposed regulations would clarify that the 40% test is applied to gross revenue “related to the furnishing of health care items,” and not to all gross revenue.

30 Underserved area means any geographic area that is designated as a Medically Underserved Area (MUA) in accordance with regulations issued by the Department of Health and Human Services. A medically underserved population means a MUP in accordance with regulations issued by the Department of Health and Human Services. 42 C.F.R. §1001.952(a)(4).

31 42 C.F.R. § 1001.952(a)(3).
or otherwise generate business for the entity, must offer the opportunity in a nondiscriminatory manner to all passive investors.

d. Investment Interests in Solo or Group Practices Composed Exclusively of Active Investors

Physicians are protected when they invest in their own solo or group practices, as long as the practice meets the specified requirements. The equity interests in the practice or group must be held by licensed professionals who practice as part of the group and those interests must be in the practice or group itself rather than in a subdivision. In addition, the group practice must be organized as a “unified business with centralized decision-making, pooling of expenses and revenues, and a comprehensive/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.” The group practice must also meet the Stark Law definition of a “group practice” (set forth in 42 C.F.R. § 411.352), and the revenues from ancillary services must be derived from “in-office ancillary services” that meet the Stark Law requirements (described below).\(^\text{32}\)

2. Space, Equipment, and Personal Service Arrangements

a. There are three separate safe harbors for space rentals, equipment leases and personal service and management contracts.\(^\text{33}\) The requirements of these three safe harbors are substantially the same.

b. To qualify for these safe harbors, (i) the agreement must be in writing, sets out all the relevant terms, is signed by the parties; (ii) is for a term of not less than one year; (iii) the aggregate services or space contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the personal services or rental; (iv) and the charge reflects fair market value.

c. Note -- To fully comply with this safe harbor, the agreement must be for a term of “at least one year.” An agreement terminable before one year may be acceptable if the other requirements of the safe harbor are met, particularly where termination is for cause. However, if the contract is cancelled before the anniversary date, the parties may not enter into a similar arrangement before the anniversary date of the original contract.

3. Sale of Practice

a. This safe harbor protects the sale of a practice by one practitioner to another practitioner and is extremely narrow. It requires that the selling practitioner not be in a position to make referrals or otherwise generate business for the purchasing practitioner after one year from the date of sale.\(^\text{34}\) As a practical matter, this safe harbor is only available if the selling practitioner is retiring from the practice or leaving the service area.

\(^{32}\) 42 C.F.R. § 1001.952(p). There are additional requirements for group practices.

\(^{33}\) 42 C.F.R. § 1001.952(b),(c),(d)

\(^{34}\) 42 C.F.R. § 1001.952(e).
b. In 1999, OIG expanded the safe harbor protection to include the sale of a practice by a practitioner to a hospital in an underserved area. For payments made to a practitioner by a hospital to qualify under the safe harbor and not be treated as remuneration: (1) the sale must be completed within three years; (2) the selling practitioner must not be in a position to make referrals to or generate business for the purchasing hospital or entity after the sale; (3) the practice must be located in a Health Professional Shortage Area (“HPSA”) for the practitioner’s particular specialty; and (4) the hospital or other purchasing entity must, in good faith, engage in recruitment activities to find a new practitioner to take over the acquired practice.

4. Referral Services -- This safe harbor protects payments between an individual or entity and an entity that provides referral services to the public for medical or physicians’ services. The referral service cannot exclude any qualified physicians or entities from participation and must make certain disclosures. The fee must be assessed and collected equally as to all participants and must be based only on the cost of operating the referral service. The referral service cannot impose requirements on the manner in which the participant provides services to a referred person, but the referral service may require that the participant charge the same rates it charges persons not referred by the referral service. Additionally, the referral service may not furnish the services for free or at a reduced charge.

5. Warranties -- This safe harbor protects any payment or exchange of anything of value by a manufacturer or supplier of an item to the buyer (such as a health care provider or beneficiary) to compensate for any loss due to failure of the item to operate or perform as intended. To qualify for safe harbor protection, both the buyer and the manufacturer or supplier must comply with specified reporting standards. A buyer must report any price reduction or free item obtained as part of the warranty in its cost report or claim for payment. A supplier or manufacturer must report such price reductions or free items on the buyer’s invoice and inform the buyer of its reporting obligations. The protection from this safe harbor only covers the cost of the item itself and payment must be according to a written affirmation made at the time of sale.

6. Discounts -- This safe harbor interprets Section 1128B of the Act. Protected discounts include reductions by the seller for charges to a buyer for medical goods or services based on an arm’s length transaction. Protection provided under this safe harbor is categorized based upon the type of party involved (i.e., buyers, sellers and offerors). A “discount” may include both point of sale discounts and rebates, but does not include cash payments, cash equivalents, warranties, price reductions applicable to one payor but not Medicare, Medicaid or other federal healthcare programs, routine reductions or waivers of any coinsurance or deductible owed by a program beneficiary, services provided under a personal or management services contract, or other remuneration not specifically described. A discount does not include furnishing one good or service without charge or at a reduced charge for any

35 42 C.F.R. § 1001.952(e)(2).
36 42 C.F.R. § 1001.952(f). The July 21, 1994, proposed regulations would provide that the fee must be assessed and collected equally as to all participants, and that it can be based only on the cost of operating the referral service.
37 42 C.F.R. § 1001.952(g).
agreement to buy a different good or service, unless the goods and services are reimbursed by the same federal healthcare program, using the same methodology, and the reduced charge is fully disclosed to such program and accurately reflected in the reimbursement methodology. A discount may include a rebate check if the discount terms are fixed and disclosed in writing to the buyer at the time of the initial purchase but the discount is not given at that time. OIG has indicated that Prompt payment discounts are not considered a form of prohibited remuneration and require no safe harbor protection.

7. Employees -- In general, remuneration does not include amounts paid by an employer to an employee if the employee has a bona fide employment relationship with the employer. The term “employee” has the same meaning for purposes of satisfying the safe harbor as it has for federal employment tax purposes (See XIII, below, for a detailed discussion of who constitutes an employee for federal employment tax purposes.). Therefore, independent contractor arrangements ordinarily are not safe harbored unless structured to qualify under the personal services and management services safe harbor. Under this provision an employee may be for example, paid on a percentage commission basis for sales of medical supplies, whereas the same arrangements with independent contractors would not be entitled to safe harbor protection.

8. Group Purchasing Organizations -- Remuneration does not include any payment by a vendor for goods or services to a group purchasing organization (GPO). A GPO is an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services. GPO payments are protected if certain criteria are met and disclosure requirements followed.

9. Waiver of Beneficiary Coinsurance and Deductible Amounts -- This safe harbor protects any reduction or waiver of a Medicare or Medicaid program beneficiary’s obligation to pay coinsurance or deductible amounts, provided that such amounts are covered under the Public Health Services Act, are owed to the hospital for inpatient hospital services, and the hospital’s offer to reduce or waive the coinsurance or deductible amounts are not made as part of a price reduction agreement between a hospital and a third-party payor. Waivers of Part B cost-sharing are outside the scope of the safe harbor, and may constitute prohibited remuneration under the Civil Monetary Penalty (“CMP”) provisions of the Act.

10. Practitioner Recruitment in Underserved Areas -- There is a safe harbor for a recruitment payment by an entity to a physician who has been practicing his or her current specialty for less than one year. The purpose of the payment must be to induce the physician to

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38 42 C.F.R. § 1001.952(h). The July 21, 1994, proposed regulations define a rebate as a discount which is not given at the time of the sale. The proposed regulations would exclude rebates from the safe harbor if the rebate was being paid to a buyer in whose name a Medicare or Medicaid claim may be made. This change would prevent the buyer from submitting a Medicare or Medicaid claim for the gross amount of the purchase and then retaining the rebate.

39 42 C.F.R. § 1001.952(i).

40 42 C.F.R. § 1001.952(j).

41 42 C.F.R. § 1001.952(k).

42 42 C.F.R. § 1001.952.

relocate his or her primary practice place into a health professional shortage area for such specialty that is served by the entity. Under these circumstances, a payment is acceptable if the following are met:\textsuperscript{44}

a. The recruitment benefits must be set out in writing and specify each respective party's obligations.

b. At least 75% of the revenues must be generated from patients residing in a HPSA or a MUA or who are part of a MUA.

c. If the physician is leaving an existing practice, at least 75% of the revenues of the new practice must be generated from new patients not previously seen by the physician at his or her former practice.

d. The period of the arrangement cannot exceed three years.

e. The arrangement must not require the physician to refer or generate business for the hospital, however, the hospital may require the physician to maintain staff privileges.

f. The physician may not be restricted as to which hospitals he or she maintains staff privileges.

g. The benefits provided to the physician must not be determined or based on the value of the volume of expected referrals to the hospital or business generated for the hospital.

h. The physician must agree to treat Medicare, Medicaid, and any other patients receiving benefits from a federal healthcare program in a nondiscriminatory manner.

i. Except for the benefit provided to the physician who is being recruited, no other payment or exchange of value may be given to any other person or entity in a position to make or influence referrals.

\textit{Note:} Many of the AKS safe harbor conditions are similar but not identical to those included in parallel Stark exceptions (described in IV.C below).

11. Obstetrical Malpractice Insurance Subsidies in Underserved Areas -- A hospital or other entity is protected when it pays any or all of the malpractice insurance premiums for a practitioner (including a certified nurse-midwife) who engages in obstetrical

\textsuperscript{44} 42 C.F.R. § 1001.952(n). According to the preamble to the proposed regulations, the safe harbor does not cover arrangements between hospitals and physicians that are, in reality, payments to obtain the referrals of established practitioners who work, in part, at another hospital in the same area.
practice, as a routine part of his or her medical care, in a health professional shortage area, and at least 75% of the practitioner's obstetrical patients who are treated reside in a HPSA or MUA.45

12. Cooperative Hospital Service Organizations -- Certain payments between a tax-exempt patron hospital and its tax-exempt cooperative hospital service organization (“CHSO”) are protected where the CHSO is wholly owned by two or more patron-hospitals.46 If the payment is made by the patron-hospital to the CHSO, the payment must be for a bona fide operating expense of the CHSO. If the payment is by the CHSO to the patron-hospital, the payment must be a distribution of net earnings required under § 501(e)(2).47

13. Investment Interests in Ambulatory Surgical Centers -- Four kinds of ambulatory surgical centers (“ASCs”) are covered:48 (1) surgeon-owned; (ii) single-specialty; (iii) multi-specialty; and (iv) hospital/physician. While there are specific requirements for each type of ASC setting, in general, the entity must be Medicare-certified. In addition, physicians will be protected when investing in an ASC if the ASC is a legitimate extension of their office practice and hospital investors cannot make or influence referrals.49 HHS believed that safe harbor protection was warranted for such investment interests because the facility fee to be derived from the procedure done at the ASC is substantially less than the referring physician's professional fee. Thus, this investment interest poses no “significant improper inducement to make referrals.”50

The remaining standards of the ASC safe harbor include:51

(i) Investment interests may not be offered on terms related to the previous or expected volume of referrals, services furnished, or amount of business otherwise generated from the investor to the entity;

(ii) At least 1/3 of each physician investor’s medical practice income (from all sources) for the previous 12-month period (of the previous fiscal year) must be derived from the physician's performance of ASC procedures;

(iii) 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;

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45 42 C.F.R. § 1001.952(o).
46 42 C.F.R. § 1001.952(q), referencing § 501(e). See also Regs. § 1.501(e)-1. The preamble to the proposed regulations specifically stated that to the extent a CHSO acts as a group purchasing organization or a patron-hospital obtains discounts as a result of the CHSO’s activities, CHSOs and patron-hospitals must comply with the respective safe harbor provisions applicable to group purchasing organizations and discounts to be fully protected.
47 § 501(e)(2) requires a CHSO to distribute “all net earnings to patrons on the basis of services performed.”
48 For the full range of standards applicable to ASCs, see generally 42 C.F.R. Part 416.
49 42 C.F.R. § 1001.952(r).
50 64 Fed. Register 63534 (November 19, 1999).
51 42 C.F.R. § 1001.952(r)(2).
(iv) The amount of payment to an investor in return for the investment must be directly proportional to the amount of the capital investment of that investor;

(v) 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.

(vi) The entity and any physician investors must treat patients receiving medical benefits or assistance under any Federal health care program in a non-discriminatory manner.

(vii) The ASC must also be a “certified ASC” under federal regulations, its operating and recovery room space must be dedicated exclusively to the ASC, and patients referred to the investment entity must be fully informed of the investor’s investment interest. Under these rules, the ASC would need a separate Medicare provider agreement, would need to be licensed by the applicable state agency (or meet “deemed” status otherwise), and only be able to perform “covered surgical procedures.”

14. Referral Agreements for Specialty Services -- This safe harbor protects providers who refer a patient back and forth between each other. The safe harbor applies as long as the referrals are medically based, and the physicians do not split a global fee from a federal program for the patient’s care. Unless the parties to the arrangement belong to the same group practice, the only “exchange of value” is the remuneration the parties receive from a third-party payor or the patient for services furnished to the patient.

15. Ambulance Replenishing -- To attain safe harbor protection under the regulation, ambulance replenishing arrangements must meet all of the conditions in one of three categories pertaining to emergency ambulance services and non-emergency runs if the ambulance is also used for emergency runs. The first category protects general replenishing, whether free or for a charge. The second category protects fair market value replenishing arrangements. The third category protects government-mandated replenishing.

16. Managed Care Safe Harbors -- The safe harbor covering business arrangements with managed care plans applies to “health plans,” as defined under 42 C.F.R. Section 1001.952(l)(2), as amended, which is any entity that furnishes (or arranges to furnish) items or services to enrollees, or furnishes insurance coverage for the provision of such items or services in exchange for a premium or fee. In addition, the health plan must: (1) operate under a contract approved by CMS or a state program; (2) be an insurer, HMO, or PPO regulated under state law; (3) be an employer, if the enrollees are current or retired employees; (4) be a union, if the enrollees are union members; or (5) be licensed by the state, and under contract with an

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52 42 C.F.R. § 1001.952(r).
54 42 C.F.R. § 1001.952(s).
55 42 C.F.R. § 1001.952(v).
employer, union welfare fund, or an insurer, HMO, or PPO regulated under state law to
administer a plan for a fair market value fee.

a. Waiver of Beneficiary Coinsurance and Deductible Amounts

The first managed care safe harbor revises the safe harbor regarding Waiver of Beneficiary Coinsurance and Deductible Amounts and focuses on incentives offered to beneficiaries to encourage the use of the managed care provider’s network. The safe harbor adds that a hospital’s offer to reduce or waive the coinsurance must not be made as part of a price reduction agreement between a hospital and a third-party payor, unless the agreement is part of a contract for the furnishing of items or services to a Medicare beneficiary.

b. Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans

In general, this safe harbor excepts from the definition of remuneration additional coverage of any item or service offered by a health plan to an enrollee (i.e., an HMO subscriber), or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts. This safe harbor applies so long as the health plan, healthcare prepayment plan, prepaid health plan, or other health plan that has an executed contract with CMS, or a state program to receive payment for enrollees on a reasonable cost or similar basis, fulfills the following requirements: (i) offer the same increased coverage or reduced cost-sharing or premiums to all covered Medicare or state healthcare program enrollees (unless otherwise approved by CMS or the state healthcare program); and (ii) cannot claim the cost as bad debt for payment purposes under the Medicare or state healthcare program or otherwise shift any resulting burden or increased obligations to the Medicare or state healthcare program.

c. Price Reductions Offered to Health Plans

In general, this safe harbor protects any reduction in price an HMO offers to a health plan, pursuant to a written contract, for items or services that are otherwise covered under the Medicare or state health program, so long as the HMO complies with certain standards.

17. E-Prescribing and Electronic Health Records -- On August 8, 2006, the OIG published final rules, effective October 10, 2006, that provide safe harbor protection for certain arrangements involving hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations that provide to recipient certain nonmonetary remuneration in the form of hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information. In addition, the OIG created a separate new safe harbor for certain arrangements involving the provision of

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56 42 C.F.R. § 1001.952(k).
57 42 C.F.R. § 1001.952(k).
58 42 C.F.R. § 1001.952(l).
59 42 C.F.R. § 1001.952(m).
nonmonetary remuneration in the form of electronic health records software or information technology and training services necessary and used predominantly to create, maintain, transmit, or receive electronic health records.

G. Other Authoritative OIG Guidance

1. Advisory Opinions
   a. The OIG will issue advisory opinions with respect to the following matters: (i) what constitutes prohibited remuneration under the anti-kickback statute; (ii) whether an arrangement comes within any of the exceptions to prohibited remuneration; (iii) whether an arrangement satisfies any regulatory exception to the anti-abuse statute; and (iv) what constitutes an inducement to reduce or limit services to individuals under Section 1128B of the Social Security Act. The statute further provides that any such advisory opinion may not address the fair market value of goods, services, or property, or whether an individual is an employee under Section 3121(d)(2).60

   b. Regulations governing the issuance of advisory opinions were issued by the OIG on February 19, 1997.61 In general, an advisory opinion will be issued in response to a written request that clearly and thoroughly describes the facts for which the opinion is being sought. The request must include copies of all relevant documents, as well as a narrative description of the arrangement, and be accompanied by a non-refundable $250 deposit. However, the final fee will be based on the time the agency staff spent on the advisory opinion. An advisory opinion may be rescinded prospectively if the agency later learns that the arrangement may result in fraud or abuse and may not be relied upon by a third party. Such rescission would be prospective only, unless the requester omitted a material fact. In addition, the regulations state that, while the advisory opinion is binding on the OIG with respect to the requesting party, it may not be relied upon by a third party.

2. Special Fraud Alerts -- OIG has issued several special fraud alerts commenting on practices that it believes may violate the anti-kickback statute. OIG distributes the special fraud alerts to providers and suppliers of medical services and goods.
   a. The Special Fraud Alerts are not binding as law but express OIG’s view of the application of the anti-kickback statute to particular practices. Nevertheless, Special Fraud Alerts are highly informative about OIG’s positions and regulatory concerns about specific business practices.

60 § 1128D(b) of the Social Security Act, enacted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191. The Social Security Act, §1128D(b)(6), originally provided for the expiration of the authority to issue anti-kickback advisory opinions on Aug. 21, 2000. However, the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (Enacted as part of the Consolidated Appropriations Act, 2001, P.L. 106-554), §543, made the authority permanent by deleting the time limitation. Regulations governing advisory opinions under the anti-kickback statues were published at 42 C.F.R. Part 1008, 62 Fed. Reg. 7350 (2/19/97).

b. The Special Fraud Alert of December 19, 1994, pertaining to Joint Venture Arrangements, is both illustrative and particularly noteworthy. It identified the following physician joint venture features as posing a “high risk”: selection or size of investment opportunity is based on anticipated levels of referrals; volume of physicians investor referrals is “tracked” and distributed to investors; investment interests are nontransferable and may be called when the investor stops practicing medicine; physician investors receive disproportionate returns; referring physician investment interests are sold for nominal amounts or pursuant to loans from the joint venture (payable out of future returns); the joint venture is formed to provide services that one of the investors already is providing. Physician joint ventures and compensation arrangements are discussed in detail in Chapters V and VII below.

c. Other Special Fraud Alerts have addressed hospital incentives to referring physicians; routine waivers of Part B co-payments and deductibles; prescription drug marketing practices; arrangements for the provision of clinical laboratory services; DME telemarketing; rental of space in physician offices by referring persons or entities; physician liability for certifications of DME supplies and home health services; and nursing home/hospice arrangements.

3. Medicare Fraud Alerts -- OIG has issued a number of fraud alerts to field offices, Medicare intermediaries, and Medicare carriers. These alerts have warned of potentially illegal schemes involving weight loss programs, suppliers of hospital beds, billing practices for psychological testing, double billing of Veterans Administration and Medicare for nursing home services, and a kickback scheme involving physical therapy clinics in California.

4. Special Advisory Bulletins -- The OIG periodically issues Special Advisory Bulletins to provide guidance to Medicare and Medicaid providers about suspect industry practices or arrangements that potentially impact the fraud and abuse law subject to enforcement by the OIG.

5. Corporate Compliance Guidance -- The OIG has developed a series of compliance program guidance (“CPG”) directed at various healthcare providers, including hospitals, nursing facilities, hospices, clinical laboratories, billing companies, physician group practices, home health agencies, durable medical equipment companies, and pharmaceutical manufactures. The CPG is intended to assist healthcare organizations in identifying and evaluating significant risk areas. Additionally, as necessary, the CPG assists in refining ongoing compliance efforts. The suggestions in the CPG are not mandatory, BUT all healthcare organizations are strongly advised to adopt and implement corporate compliance programs.

IV. Physician Anti-Referral Statute (Stark)

A. General

1. Prohibited Conduct

   a. Effective for referrals made after December 31, 1994, if (i) a physician (or an immediate family member of such physician) has (ii) a “financial interest” in an

62 P.L. 103-66, 13562(b)(2).
(iii) entity, (iv) the physician may not make a referral to that entity (v) for the furnishing of “designated health services” (vi) for which payment is sought under Medicare or Medicaid, and the entity may not present a claim or bill to any individual, third party payor, or other entity for designated health services.

b. All six of the elements of Stark must be present to implicate the statute. If all six elements are present, the referral will only be protected if an applicable exception applies. There are no safe harbors excluding a referral from the self-referral ban. If a referral arrangement is not specifically excluded by the statute, it is subject to the ban.

c. Stark is violated when DHS services are billed, not when the referral itself is made; thus, the ban is on billing not the referral.

2. Purpose

Having a financial interest, either by ownership or through a compensation arrangement, in an entity that provides DHS, might override objective medical judgment and entice physicians to refer patients to these entities and to order items or services that may be unnecessary or result in overutilization of the Medicare and Medicaid programs.63

3. Enforcement and Sanctions

a. CMS is responsible for promulgating regulations interpreting the Stark law. Enforcement of Stark is charged to the OIG. The mandatory penalty for violating the self-referral prohibition is denial of payment for the designated health service.64

b. In cases where the physician has billed and collected for designated health services in violation of the ban, the physician is required to refund the inappropriately collected amount in a timely manner.65

c. The OIG may also impose a civil penalty of up to $15,000 for each service provided by a person who knew or should have known that the service was rendered in violation of the anti-referral prohibition.66

d. In addition, any physician or entity that enters into a “circumvention scheme” (such as cross-referral arrangements), that the physician or entity knows

63 See, e.g., 57 Fed. Reg. 8588 (1992); 66 Fed. Reg. 856, 859 (Jan. 4, 2001) (noting that “there were a number of studies, primarily in academic literature, that consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships”).
64 42 U.S.C. § 1395nn(g)(1).
65 42 U.S.C. § 1395nn(g)(2).
66 42 U.S.C. § 1395nn(g)(3).
or should know has a principal purpose of inducing referrals in violation of the self-referral ban, is subject to a civil penalty of up to $100,000 for each such arrangement or scheme.\textsuperscript{67}

e. Any physician or entity that enters into an arrangement or scheme in violation of the self-referral ban may also be subject to an assessment of not more than twice the amount claimed for each designated health service rendered in violation of the ban, and may also be excluded from participation in the Medicare and Medicaid programs.\textsuperscript{68}

f. A Stark violation also may be a predicate for a FCA claim.

4. Voluntary Self-Referral Disclosure Protocol -- On September 23, 2010, as required by PPACA, CMS released the Voluntary Self-Referral Disclosure Protocol (“SRDP”) to facilitate the resolution of matters that are actual or potential violations of Stark.\textsuperscript{69}

a. Disclosing DHS providers are required to explain in detail how the conduct violated or potentially violated Stark, while identifying in detail any potentially applicable exceptions. Details must be supplied about the financial impact involved, describe any preexisting compliance programs, how the violation was discovered and what corrective measures have been taken.

b. Although the SRDP requires providers to quantify potential DHS overpayments realized during periods of non-compliance (\textit{i.e.}, until the referrals cease or all applicable prongs of an exception are met), it advises providers not to enclose a payment (since the Secretary is authorized to compromise Stark liability by settlement under the SRDP). Significantly, the filing of an SRDP tolls the 60-day time limit for repayments of identified “overpayments” under 42 U.S.C. § 1320a-7b(a)(3) (as discussed below).

c. The PPACA also authorized CMS to reduce a disclosing party's repayment obligations under Stark.\textsuperscript{70} Despite this provision, CMS has not promulgated implementing regulations, nor responded favorably to comments from the American Hospital Association and other stakeholders requesting CMS to provide generally for the imposition of only nominal repayments in cases involving purely “technical” Stark violations (for example, where a physician’s service or consulting agreement with a DHS provider has expired, but the overall arrangement is otherwise compliant with Stark and all other elements of the personal service exception). The SRDP indicates that the statutory mitigation criteria will be considered and applied on a case-by-case basis. Factors that CMS must consider in determining the repayment amount include: the nature and extent of the illegal practice; the timeliness of the self-disclosure; the provider's cooperation in presenting additional information related to the disclosure; the litigation risk associated with the disclosed information; the financial position of the disclosing provider; and other appropriate factors.

\textsuperscript{67} 42 U.S.C. § 1395nn(g)(4). In \textit{U.S. ex rel. Barbera v. Tenet Healthcare Corp.} (S.D. Fla. March 2004), a claim that exorbitant salaries were paid to physicians of purchased practices resulted in a $22.5 million settlement.

\textsuperscript{68} \textit{Id.}; 42 U.S.C. § 1320a-7(a(a).

\textsuperscript{69} PPACA § 6409(a).

\textsuperscript{70} PPACA § 6409(b).
d. Self-disclosure may limit the disclosing party’s financial and legal exposure, including the possibility of reduced penalties and protection from a qui tam whistleblower action but is not risk-free. Disclosing parties must waive appeal rights to claims related to the disclosed conduct. In addition, CMS shares information presented by the provider with the OIG and the DOJ, which could lead to potential civil and criminal liabilities, including possible FCA liability.

e. SRDP forms are available at: https://www.cms.gov/physicianselfreferral/65_self_referral_disclosure_protocol.asp.


5. Reporting Rules -- Under Stark, DHS must report to HHS certain information concerning ownership arrangements, including (i) the covered items and services provided by the entity, and (ii) the names and identification numbers of all physicians who have (either directly or through an immediate relative) an ownership or investment interest in the entity.71 Any person who fails to comply with the reporting requirements is subject to a civil penalty of up to $10,000 a day.72 The Phase II regulations significantly reduced the burden imposed on entities that furnish Medicare-reimbursable services to report to CMS or OIG their investment, ownership, and compensation arrangements with physicians (and physicians’ immediate family members). For instance, CMS only requires that information be submitted upon request, rather than requiring updated information every twelve months.73

B. Key Definitions and Concepts

1. Designated Health Services (“DHS”)

a. Clinical laboratory services (Stark I)

b. Physical therapy services*

c. Occupational therapy services*

d. Radiology or other diagnostic services, including MRI, CAT scans, and ultrasound services

e. Radiation therapy services*

f. Durable medical equipment

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72 42 U.S.C. § 1395nn(g)(5).
73 Section 6401 of the PPACA independently adopted comprehensive reporting requirements that must be satisfied when providers enroll or reenroll in Medicare. A final rule with comments implementing this provision was published at 76 Fed. Reg. 5802 (Feb. 2, 2011).
g. Parenteral and enteral nutrients, equipment, and supplies

h. Prosthetics, orthotics, and prosthetic devices

i. Home health services

j. Outpatient prescription drugs

k. Inpatient and outpatient hospital services

CMS has published specific lists of the Current Procedural Terminology ("CPT") and HCFA Common Procedure Coding System ("HCPCS") codes to define the following DHS: (i) clinical laboratory services, (ii) physical therapy, occupational therapy and speech-language pathology services, (iii) radiology and certain other imaging services, and (iv) radiation therapy services. These codes are used by physicians and providers to identify services for purposes of submitting claims to Medicare for payment. The list is updated annually by CMS in the physician fee schedule and posted on the CMS Web Site.

“DHS” is defined as being limited to items and services payable under Medicare unless otherwise specified in the rules.74 Services are not considered DHS when they are paid for only as part of a “bundled” (or “composite”) payment (for example imaging services or implants included within a bundled ASC payment). Also excluded from DHS are imaging services used incidental to invasive, non-DHS procedures, such as imaging as a guide for a cath procedure. Note, also that the statute establishes an exception for revenues from Medicare Advantage plans that are coordinated care plans.75

2. “Entity”

The August 2009 Hospital Inpatient Prospective Payment System Final Rule,76 revised the definition of “entity” to curtail the ability of referring physicians to hold an ownership interest in entities providing DHS services “under arrangement.”

a. Under the prior rules, an entity was considered to furnish DHS subject to Stark only if it “billed” Medicare for the DHS. This exempted, for example, a physician owned diagnostic center to the extent that diagnostic services were purchased and billed by a hospital “under arrangement” as a hospital service.

b. Under the amended definition, a person or entity “furnishes” DHS either by performing DHS or billing Medicare for the DHS service. Under the preceding example, the imaging center would now be considered an “entity” for purposes of Stark, and the referral would now be prohibited, unless the relation between the referring physician and the diagnostic center fits within a Stark exception. In this regard, the in-office ancillary exception, which typically protects physician investment interests, will not protect “under arrangement”

74 42 C.F.R. § 411.351
DHS. One of the three basic requirements to qualify for the in-office exception is that the billing for the DHS is under the name of the group practice or physician performing the DHS. Billing “under arrangement” is done by the hospital and not the group practice. Legislative history also indicates that Congress did not intend to protect inpatient and outpatient hospital services under the in-office ancillary services exception.

c. The rule also effectively converts non-DHS into DHS where billed as inpatient or outpatient services. Lithotripsy and kidney dialysis are not listed as DHS, but if either is provided “under arrangement” by a hospital, it will constitute an inpatient/outpatient hospital service and thus a DHS.

d. An entity does not “perform” DHS if it merely sells space or equipment; furnishes supplies that are not separately billable; or provides management, billings services or personnel to a DHS entity.

3. “Immediate Family Member” -- includes spouse; birth or adoptive child; parent or sibling; step-parent or step-child-sibling; grand-child, grand-parent; spouse of grand-child or grand-parent; mother, father, brother or sister-in-law.

4. “Physicians” -- Includes MDs, DOs, dentists, podiatrists, optometrists, and chiropractors.

5. “Referrals”

a. A “referral” includes any request by a physician for an item of service for which payment may be made under Medicare Part B, including a request by a physician for a consultation with another physician, any test or procedure ordered by another physician, or any test to be performed by or under the supervision of another physician. It also includes a request or establishment of a plan of care by a physician that includes the provision of DHS.

b. The Phase II rules modified the definition of “referring physician” to include the referring physician and his/her wholly owned professional corporation as “the same” for Stark purposes.

c. A referral is imputed to a physician for a service over which he/she exercises control or influence. Requests for services by nurse practitioners and other licensed professionals can be deemed referrals of a physician under Stark. Other professionals also may be licensed to provide care and able to make independent referral decisions. The legal authority to make a referral is not the determinative factor; facts and circumstances surrounding the referral and the relationship between the physician and the other professional must be analyzed to determine whether the physician controlled or influenced the referral.

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77 42 U.S.C. § 1395x(r)
80 42 C.F.R. § 411.351
d. A number of services are expressly exempt under the statute from the definition of referrals. These include: (i) a request by a pathologist for clinical diagnostic laboratory tests and pathological examination; (ii) a request by a radiologist for diagnostic radiology services; and (iii) a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologists, radiologist, or radiation oncologist pursuant to a consultation requested by another physician. The final Phase I regulation amended the definition to make it clear that the term “referral” does not include services personally performed by the referring physician. Therefore, a referral does not include services physically performed by the referring physician.

e. A referral for a DHS resulting from a consult considered is a referral by the original physician. Thus, a referral by Dr. A to Specialist B, who in turn, refers a patient to Hospital C is not deemed a referral by A to C unless the patient is referred to specialist B for a consultation. Otherwise, an outright referral to a specialist breaks the “referral” chain.

6. “Remuneration”

a. Includes any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.

b. Remuneration does not include the following:

(i) The forgiveness of amounts owed for inaccurate tests or procedures, mistakenly performed procedures, or the correction of minor billing errors;

(ii) The provision of items, devices, or supplies that are used solely to (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply; or (ii) to order or communicate the results or procedures for such entity;

(iii) A fee for service payment by an insurer or self-insured plan to a physician to satisfy a claim for the furnishing of health services by that physician to a patient covered by the insurer or self-insured plan. The exception applies if: (1) the payment is made to the physician on behalf of the covered individual; and (2) the amount of the payment is set in advance, does not exceed fair market value, does not take into account, directly or indirectly, the volume or value of any referrals, and complies with any federal regulations that may be promulgated in the future to protect against program or patient abuse.

7. Financial Relationships

Financial relationships of a physician (or an immediate family member of such physician) with an entity that are covered by the prohibition include (i) an ownership or investment interest, or (ii) a compensation arrangement.

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a. “Ownership Interest” -- An ownership or investment interest (but
not a compensation interest) in an entity may be through equity, debt, or other means. In
addition, attribution rules are provided in the case of an ownership or investment interest to
include an interest in an entity that holds an ownership or investment interest in any entity
providing the designated services.87 For example, if Physician A has an equity interest in J
partnership that owns stock in B laboratory, which provides designated health services, a referral
by Physician A to B laboratory will be denied reimbursement from the Medicare or Medicaid
program.

b. “Compensation Arrangement” -- A compensation arrangement
covered by the self-referral ban includes any remuneration, directly or indirectly, overtly or
covertly, in cash or kind, between a physician (or an immediate family member of such
physician) and an entity.88 In consequence, the prohibition could be triggered under the
compensation arrangement provisions, where a physician is provided office space or equipment
usage for free or at amounts below fair rental value, by recruitment arrangements, or in private
practice acquisition situations.

c. Attribution Rule -- A physician’s financial relationship with an
entity will not be imputed to his or her group practice. Thus, other members of the group
practice can continue to make referrals to the entity, provided the other members do not have
financial relationships with the entity and the physician with the financial relationship is not in a
position to control the referrals of other group members.89 Absent unusual circumstances,
common owners of an entity will not, by virtue of their common ownership, have an ownership
or investment interest in each other.

d. Indirect Financial Interest --

(i) A “financial arrangement” between a referring physician or
immediate family member and a DHS entity will trigger the application of the Stark law’s
referral prohibition. The financial relationship may exist either “directly” between the DHS
entity and the referring physician or “indirectly,” that is, where other individual(s) or entity(ies)
are interposed in a chain of financial relationships, through ownership, investment interest, or
compensation arrangement, between the DHS entity and the referring physician.

For an indirect compensation arrangement to exist, the relationship must meet the
following three-part test:90

(a) An unbroken chain of financial arrangements
between the DHS entity and a referring physician (that is, each link in the chain has either an
ownership or investment interest, or compensation arrangement with the preceding link);

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88 42 U.S.C. § 1395nn(h)(1)(A) and (B).
90 42 C.F.R. § 411.354(c)(2).
(b) Aggregate compensation paid to the referring physician varies based on the volume or value of referrals, or other business generated for the DHS entity; and

(c) The DHS entity must have actual knowledge that the aggregate compensation received by the referring physician from the entity with which the physician has a financial relationship, varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS, or has acted in reckless disregard or deliberate ignorance of the existence of such relationship.

A determination whether compensation varies based on the volume or value of referrals is “measured by the non-owner or noninvestment interest closest to the referring physician.”91

(ii) Stand-in-the-Shoes Rule (“SITS”)

(a) Effective December 4, 2007, Phase III regulations introduced a broader “stand in the shoes” rule for purposes of determining whether a physician has a direct or indirect financial relationship with a DHS entity.92 Under the new regulations, a physician is deemed to “stand in the shoes” of his or her “physician organization” if the only entity between the referring physician and the DHS entity is the physician's physician organization. In such cases, the referring physician will be deemed to have a direct financial interest with the DHS entity. If a group practice in which a physician has an ownership contract to provide services to a hospital, the relationship between the group and the hospital is a direct financial relationship. For example, where a DHS entity pays fees under a service agreement to an undifferentiated medical group, the fees will be treated as having been paid to each physician. In such cases, the financial arrangement must satisfy an applicable direct compensation exception (e.g., lease, personal services, fair market value, etc.) and not the indirect compensation exception.

(b) Grandfather Clause -- Arrangements that qualified for an indirect compensation exception prior to September 5, 2007 are protected during original term of agreement, or renewal term, if applicable. The grandfather clause does not protect any compensation arrangement that did not create an indirect compensation arrangement prior to September 5, 2007.

(c) The 2009 Hospital Inpatient Prospective Payment System Final Rule limited the expansive application of the SITS rule. Effective October 1, 2008, non-owner physicians and “titular” owners are not required to (but may) stand in the shoes of their physician organizations. A titular ownership interest is defined as an interest that does not give the physician the ability or right to receive any financial benefits of ownership or investment (including, without limitation, profit distributions, dividends, sale proceeds, or similar investment returns). The titular exception provides that physicians who are shareholders

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91 42 C.F.R. § 411.354(c)(2)(ii).
of “captive” or “friendly” PCs (established because of corporate practice of medicine laws) would likely not be treated as owners of the PC. CMS loosened its standard and limited the application of the SITS rule to truly ownership investments because it felt that non-owners generally have no control over the financial relationships of their employers and DHS providers. Therefore, it would be inappropriate to hold non-owners – such as employees, independent contractors and titular owners – accountable for financial relationships of their employers that may violate Stark.

(d) Example: A DHS entity leases office space to a group practice. The lease will be deemed a direct compensation arrangement with each physician owner, and the lease terms will have to meet the requirements of the exception for rental of office space in § 411.357(a). The financial interest of any employee of the group practice will still be evaluated under the indirect compensation rules, unless the employee physician elects to be treated under the SITS rules and wishes to be covered under a direct compensation exception.

8. “Set in Advance”

a. Several Stark Law exceptions require that compensation be “set in advance.” The Phase I regulations define this term to require that the payment formula or methodology, not necessarily the aggregate compensation, be set at the outset of an arrangement. Phase II altered the definition of “set in advance” to delete the Phase I language prohibiting percentage-based compensation and acknowledged that most percentage compensation arrangements will satisfy this standard.93

b. The 2009 Hospital Inpatient Prospective Payment System Final Rule includes several significant changes to Stark. Space and equipment leases that include percentage compensation will no longer satisfy the space and equipment lease exceptions, the fair market value exception, or the indirect compensation arrangement exception. This reflects CMS’ concern that lease payments based on a percentage of revenues earned by the lessee provide an incentive for the lessor to increase referrals for DHS to the lessee. By contrast, personally performed physician services – clinical and administrative – may continue to use percentage-based arrangements, so long as the formula is based on the revenues directly resulting from the physicians’ services rather than on some other factor, such as percentage of savings by a hospital. Although the provision does not prohibit the use of percentage-based compensation formulae in management agreements, billing services arrangements, and gains sharing (or shared savings) arrangements, CMS has vowed to watch these arrangements closely.

c. The Hospital Inpatient Prospective Payment System Final Rule also prohibits the use of “per-click” leases for office space or equipment, to the extent that the per-click payment is for office space or equipment used by the lessee to treat patients referred by the lessor. CMS makes clear that the prohibition on per-click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician, applies regardless of whether the physician is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. The prohibition also applies where the lessor

93 42 C.F.R. § 411.354(d)(1).
is a DHS entity that refers patients to a physician lessee or a physician organization lessee. If the referring physician is not an owner of a physician organization, the referral is not subject to the prohibition. Of course, segregating these referrals from non-owner lessor referrals may be problematic. In any case, per click/per unit office space and equipment leases need to be reviewed and, if necessary, restructured to comply with the Final Rule by October 1, 2009. Again, there is no grandfathering relief for any affected lease arrangements.

9. “Volume or Value” and “Other Business” Standards

   a. A key provision in many Stark exceptions is that compensation may not vary with the volume or value of referrals, and, in some instances, may not take into account other business generated between the parties. In the Phase I final regulations, CMS stated that time based, per unit or per click based payments do not run afoul of the volume or value standards as long as payment is set at fair market value at the inception of the arrangement, and the payment does not change during the course of the arrangement in any manner that takes into account DHS referrals.

   b. The limitation prohibiting compensation based on other business generated between the parties has been interpreted to include non federal health care business generated by the referring physician. Phase II clarifies that personally performed services are not considered “other business generated.” However, the “technical component” of any personally performed service would be considered “other business generated.” CMS adopted this interpretation to establish some consistency between the volume or value of referrals and the other business generated standards.

10. Period of Disallowance -- This term covers the period during which referrals violate Stark, and was incorporated under 42 C.F.R. § 411.353(c) in the August 19, 2008 Final Hospital Inpatient Prospective Payment System rules (the Final Phase III Rules). When a Stark violation is based on an overpayment or underpayment, the period of disallowance is not ended until after the entire underpayment or overpayment is repaid. Nevertheless, CMS stated that all Stark exception requirements must be met at the time the referral is made and “that the statute does not contemplate that parties have the right to back-date arrangements, return compensation, or otherwise attempt to turn back the clock so as to bring arrangements into compliance retroactively.” Therefore, CMS’ stated position is that non-compliance cannot be “cured” retroactively.

C. Exceptions

Exceptions are codified and organized under the rules based upon the nature of the financial interest. All elements of an applicable exception must be satisfied. Exceptions include the following:

1. Exceptions to Ownership and Compensation Arrangements

94 42 C.F.R. § 411.354(d)(2), (3).
a. Physician Services

Physician services provided by personally (or under the personal supervision of) another physician in the same group practice as the referring physician is not subject to the Stark ban.97

b. In-Office Ancillary Services

(i) “Same” or “Central” Building Location

To qualify for the in-office ancillary services exception, the designated health services (other than DME, excluding infusion pumps) must be furnished (i) in a building in which the referring physician or another physician who is a member of the same group practice furnishes physicians’ services unrelated to the furnishing of designated health services, or (ii) in another building that is used by the group practice to provide some or all of the group’s DHS.98 The exception is “designed to protect the in office provision of certain DHS that are truly ancillary to the medical services being provided by the physician practice.

(a) The Final Phase I regulation relaxed the DME prohibition provided in a physician's office and extended the in-office ancillary exception to include the following DME furnished in a physician’s office: crutches, canes, walkers, folding manual wheelchairs, and blood glucose monitors.99 The preamble to the Phase I final regulations specifically state that the regulations will not protect part-time, intermittent arrangements that functionally are nothing more than shared off-site facilities. To qualify under the “centralized building” standard, Phase I of the regulations requires, among other things, that the group practice own or lease and use the space exclusively on a full-time basis.100

(b) In Phase II, CMS retains the core structure of the “same building” test that was set forth in Phase I, but abandons the use of the “substantial services” standard. In response to the public’s concerns, CMS adopts three new, alternate “same building” tests. Only one of the three tests needs to be satisfied in order to meet the “same building” requirement of the in office ancillary services exception. All three tests are available to solo practitioners and group practices.

(c) Under the first test, a DHS is considered to be furnished in the “same building” if: (a) the referring physician or his or her group practice (if applicable) has an office in the building that is “normally” open to patients at least 35 hours per week; and (b) the referring physician or one or more “members of his or her group” regularly practices medicine and furnishes physician services to patients in that office at least 30 hours per week.101 Some of the services furnished must be unrelated to the provision of DHS.

(d) Under the second test, a DHS is considered to be furnished in the “same building” if: (a) the building is one in which the referring physician or his or her group practice (if applicable) has an office that is “normally” open to patients at least 8 hours per week; and (b) the referring physician regularly practices medicine and furnishes physician services to patients in that office at least 6 hours per week. Some of the services furnished must be unrelated to the provision of DHS. Unlike the first test, physician services furnished by members of the referring physician's group practice do not count toward the 6 hour threshold.102

(e) Under the third test, a DHS is considered to be furnished in the “same building” if: (a) the building is one in which the referring physician or his or her group practice (if applicable) has an office that is “normally” open to patients at least 8 hours per week; and (b) the referring physician or a member of his or her group practice (if any) regularly practices medicine and furnishes physician services to patients in that office at least 6 hours per week. Some of the services furnished must be unrelated to the provision of DHS. In addition, unlike the second test, the referring physician must be present and order the DHS in connection with a patient visit during the time that the office is open or the referring physician or a member of his group practice (if any) must be present while the DHS is furnished during the time that the office is open.

A solo practitioner can furnish DHS under the in office ancillary services exception through a shared facility in the same building, so long as the other requirements of the in office ancillary services exception are satisfied.

(ii) Billing

In addition, to qualify for the in office ancillary exception, the designated health services must be billed by (i) the physician performing or supervising the services, (ii) the group practice under its billing number, or (iii) an entity that is wholly owned by the physician or group practice.103

(iii) Special Treatment for Group Practices

With the emerging popularity of physician group practices, commonly referred to as “clinics without walls,” group practice designation will have broad applicability. Under Stark, a physician who is a member of the group may personally provide health services, including “designated health services,” to an individual who has been referred by another member of the same group practice.104 In addition, a group physician may provide in-office ancillary services (other than durable medical equipment (excluding infusion pumps) and parenteral and enteral nutrients, equipment, and supplies) to an individual referred by another member of the group practice or by individuals who are directly supervised by the physician, or by another physician in the group practice.105 Direct supervision by a physician includes a lab, for example, which is

located in a physician’s office and is personally supervised by a lab director, or a physician, even if the physician is not always on site.\textsuperscript{106}

To qualify as a group practice, the entity must meet the following requirements pertaining to where the designated health services are provided and how they are billed.\textsuperscript{107}

i) A group practice means a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan or similar association that meets the following requirements:

ii) Each physician who is a member of the group practice must provide substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

iii) substantially all of the services of the group physicians are provided through the group and are billed under the group’s billing number, and revenues received are treated as belonging to the group;

iv) income and overhead expenses must be distributed in accordance with previously determined methods;

v) no physician who is a member of the group practice may receive, directly or indirectly, compensation based on the volume of referrals by the physician; and

vi) group physicians must conduct no less than 75% of the medical services provided by the group practice.

Physicians counted toward the “two or more physicians” test can be part time employees and leased employees.\textsuperscript{108} An independent contractor can qualify as a “physician in the group practice.” However, Phase III regulations require independent contractor to have a contractual arrangement directly with the group practice. Therefore, it is unlikely that leased physicians who merely contracts directly with an agency or some other intermediary and not “directly” with the group practice will qualify as “physicians in the group practice.”

While income may not be based directly or indirectly on DHS referrals, it is permissible under a “special rule for productivity bonuses and profit shares”\textsuperscript{109} for a group practice physician to be paid a productivity bonus based on services personally performed or “incident to” services that are personally supervised by the physician (or another physician in the group), as long as the bonus is not determined in any manner based on the volume of referrals by

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\textsuperscript{106} House Conf. Rep. No. 103-213, 103d Cong., 1st Sess. 810.  \\
\textsuperscript{107} 42 U.S.C. § 1395nn(h)(4)(A).  \\
\textsuperscript{108} 42 C.F.R. § 411.352(b).  \\
\textsuperscript{109} 42 C.F.R. § 411.35(i)
\end{flushright}
the physician.\textsuperscript{110} Services that may be included in a productivity bonus as “incident to” a physician’s personal services must fit within the requirements for “incident to” billing set forth in 42 C.F.R. § 410.26, which generally precludes “incident to” billing when a service is independently included under a separate statutory billing category (such as the technical component of x-ray services). There is an exception to this exception services specifically described in the Act as services that may be provided incident to a physician’s service (such as physical therapy). A physician in a group practice may also be paid a share of the overall profits of the group (defined as profits derived from DHS payable by Medicare or Medicaid), so long as the allocation of shares is made in a “reasonable and verifiable manner” and not in a manner that is “directly related to the volume or value of the physician's referrals of DHS.”\textsuperscript{111} If a group elects to establish subgroups for allocation of profits (as opposed to dividing all profits among members of the entire group), it may do so only if the subgroup consists of at least five physicians.

Group practices are required to have the data used to establish compliance with the “substantially all” test “available to the Secretary upon request.”

Practices are provided a 12 month “start up” grace period, during which new group practices need not strictly comply with the “substantially all” requirements, so long as the group practice makes a good faith effort to do so.\textsuperscript{112} The grace period does not apply, however, when an existing group practice admits a new member or reorganizes.

(iv) PPACA Disclosure Requirements

The PPACA amended the “in-office ancillary service” exception to require a mandatory freedom of choice disclosure statement.\textsuperscript{113} In order to qualify for the exception, a referring physician must inform a patient (in writing) that the patient may obtain the service from a person other than (1) the referring physician, or (2) a physician who is a member of the same group practice as the referring physician, or (3) an individual who is directly supervised by the physician.\textsuperscript{114} The disclosure must provide a list of alternative suppliers who furnish the subject service(s).\textsuperscript{115} Initially, this new disclosure requirement applies only to: magnetic resonance imaging (“MRI”), computed tomography (“CT”), and positron emission tomography (“PET”) services.\textsuperscript{116} HHS is authorized to add services to which the new disclosure applies by future

\textsuperscript{111} These principles are detailed in 42 C.F.R. § 411.352. They include, per capita distributions of profits from DHS paid for by Medicare and Medicaid, distributions of DHS revenues based on pro rata revenue generated by group practice members exclusive of those derived from DHS payable by any Federal health care program, and where DHS revenues satisfy certain 5 percent de minimus tests.
\textsuperscript{112} 42 C.F.R. § 311.352(d)(6)(i).
\textsuperscript{113} PPACA § 6003, amending 42 U.S.C. 1395nn(b)(2).
\textsuperscript{114} PPACA § 6003, amending 42 U.S.C. 1395nn(b)(2).
\textsuperscript{115} PPACA § 6003, amending 42 U.S.C. 1395nn(b)(2).
\textsuperscript{116} PPACA § 6003, amending 42 U.S.C. 1395nn(b)(2).
regulations. Final Regulations implementing this provision were published on November 29, 2010.

c. Prepaid Plans

An exception of limited applicability is provided for referrals made between physicians who have an ownership or investment interest in, or a compensation arrangement with, certain Medicare or federally qualified health maintenance organizations, or other prepaid plans under a demonstration project.

d. Academic Medical Centers

The Phase I final regulations added a new separate exception protecting services referred within academic medical centers (AMCs). An AMC is defined as an accredited medical school; an affiliated faculty practice plan that is a nonprofit, tax-exempt organization under section 501(c)(3) or (4) of the Internal Revenue Code; or one or more affiliated hospital(s), where a majority of the hospital medical staff consists of physicians who are faculty members, and a majority of all the hospitals’ admissions are made by physicians who are faculty members. In addition, the AMC must meet the following requirements:

(a) All monetary transfers between “components” of the AMC must directly or indirectly support the missions of teaching, indigent care, research, or community services. A “component” is defined as an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation.

(b) There must be a written agreement between the components of the AMC that has been approved by the governing body of each component.

(c) All money paid to a referring physician for research must be used solely to support bona fide research.

(d) The physician’s compensation arrangement does not violate AKS.

An “accredited academic hospital” can be substituted for an accredited medical school for purposes of meeting the definition requirements. An accredited academic hospital is required to have four or more programs to ensure that it has a substantial teaching mission. AMCs are permitted to have more than one faculty plan and to aggregate multiple practice plans.

2. General Exceptions to Ownership or Investment Interests

The following types of financial interests do not qualify as “ownership or investment interests” for purposes of the self-referral prohibition:

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120 42 C.F.R. § 411.355(e).
a. Ownership In Publicly Traded Securities and Mutual Funds

There is an exception for ownership of publicly traded investment securities, including shares or bonds, debentures, notes, or other debt instruments, in a corporation that has equity exceeding $75 million at the end of its most recent fiscal year, or an annual average of $75 million during the previous three fiscal years. Also, qualifying for this exception requires ownership in shares of a regulated investment company (i.e., mutual funds) with total assets exceeding $75 million at the end of the corporation's most recent fiscal year, or on average during the previous three fiscal years. Stock options received as compensation will not be considered ownership or investment interests until they are exercised.

b. Hospitals in Puerto Rico

Designated health services provided by a hospital in Puerto Rico, which a referring physician has an ownership or investment interest, are excluded from the self-referral ban.

c. Rural Provider Exception and PPACA Discontinuation

There is an exception to the self-referral prohibition for designated health services furnished in a rural area (as defined in Section 1886(d)(2)(D) of the Social Security Act) by an entity in which a physician has an ownership or investment interest, if substantially all of the designated health services furnished by the entity are furnished to individuals residing in the rural area. Phase II defines “rural provider” as an entity that furnishes at least 75 percent of its total DHS to residents of a rural area (existing law already provides that the hospital may not be a specialty hospital). A “rural area” is defined as an area that is outside a Metropolitan Statistical Area. Phase II provides a new exception for intra-family rural referrals to an entity, which the referring physician’s immediate family member has a financial relationship, if the patient resides in a rural area and there is no DHS entity available to provide services in a timely manner at the patient's home or within 25 miles of the patient’s residence.

Just as the “whole hospital” exception (discussed below), the PPACA effectively discontinues the “rural provider” exception for any newly formed hospitals. However, hospitals in existence prior to December 31, 2010 are grandfathered and can still qualify for the “rural provider” exception. To qualify, hospitals are required to have provider agreements in place by December 31, 2010. Additionally, these grandfathered hospitals cannot increase in size after March 23, 2010 (without approval from HHS) and must follow steps to prevent potential conflict of interests, ensure bona fide investments, and protect patient safety.

121 42 U.S.C. § 1395nn(c).
124 42 C.F.R. § 411.356(c)(1).
125 PPACA § 6001(i), amending 42 U.S.C. 1395nn.
Hospitals wishing to qualify under the grandfather clause must comply with the new requirements within 18 months of the PPACA enactment (or October 22, 2011).\textsuperscript{129}

d. “Whole Hospital” Ownership Exception and PPACA Discontinuation

An exception is provided for designated health services provided by a hospital (other than a hospital in Puerto Rico) if the referring physician is authorized to perform services at the hospital, and the ownership or investment interest is in the “entire” (rather than a part) hospital itself, rather than merely in a subdivision of the hospital.\textsuperscript{130} The PPACA effectively discontinued the “whole hospital” exception for any newly formed hospitals (same as the “rural provider” exception).\textsuperscript{131} A grandfather clause allows hospitals in existence before December 31, 2010 to still qualify under the exception,\textsuperscript{132} but the PPACA imposed significant conditions for qualifying for the exception.\textsuperscript{133} For example, grandfathered hospitals cannot increase in size by adding new beds or operating or procedure rooms (in the aggregate) after March 23, 2010 (without a waiver from HHS).\textsuperscript{134} Additionally, the grandfathered hospitals must follow steps to prevent potential conflict of interests, ensure bona fide investments, and protect patient safety.\textsuperscript{135} Hospitals must comply with the new requirements within 18 months after March 23, 2010 (or October 22, 2011). There also are limited exceptions to rule against expansions and increases for certain “applicable hospitals” and “high Medicaid facilities.”\textsuperscript{136} Final regulations implementing the PPACA whole hospital requirements were published in November 2010.

3. Exceptions Relating to Other Compensation Arrangements

a. Rental of Office Space and Equipment

Stark provides for two distinct exceptions for space and equipment leases, but they are substantially the same. In general, payments made by a lessee to a lessor for the use of premises or equipment will be covered under the statutory exception, provided the following factors are met:\textsuperscript{137}

(i) The lease is set out in writing by the parties and specifies the premises or equipment covered;

(ii) The space or equipment does not exceed that which is reasonable and necessary for the legitimate purposes of the lease and is used exclusively by the lessee.

\textsuperscript{129} PPACA § 6001(a)(D), amending 42 U.S.C. 1395nn.
\textsuperscript{130} 42 U.S.C. § 1395nn(d)(3).
\textsuperscript{131} PPACA § 6001, amending 42 U.S.C. 1395nn.
\textsuperscript{133} PPACA § 6001(a)(i)(B), amending 42 U.S.C. 1395nn.
\textsuperscript{135} PPACA § 6001(a)(i)(C)-(F), amending 42 U.S.C. 1395nn.
\textsuperscript{136} PPACA § 6001(a)(i)(3).
\textsuperscript{137} 42 U.S.C. § 1395nn(e)(1)(A) and (B).
(iii) The lease is for a term of at least one year. Phase II permits termination clauses, however, if the lease is terminated in the first year, the parties are not permitted to enter into a new lease until that year has ended.

(iv) The rental charges over the term of the lease are set in advance, are consistent with fair market value, and are not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(v) The lease would be commercially reasonable if no referrals were made between the parties.

(vi) A lessee is permitted a holdover not to exceed 6 months, so long as the lease payment terms remain the same. 138

Per unit service rental charges (so called “per-click”) payments are not permitted for services where the lessor of the equipment (for example, a hospital that owns an MRI) is renting the equipment for use in services provided by a lessee who is a referring physician. (In contrast, per-unit prohibition is inapplicable for personal service arrangements). Similarly, lease payments may not be based on a percentage of revenue raised, earned, billed, collected or otherwise attributable to services generated in the leased space. For example, an ophthalmologist may not pay an optometrist for a periodic lease of office space based on a percentage of professional revenues earned in the leased space.

Note: United States ex rel. Ted D. Kosenske, M.D. v. Carlisle HMA, Inc., 554 F.3d 88 (2009), held that a contract that had met the Stark exception for leases and personal services, but was subsequently modified to expand the scope of services and never memorialized in writing, failed to qualify for the written agreement requirement under the relevant Stark exceptions. The written agreement requirement also was analyzed in detail and found not to have been met in U.S. ex rel. Singh, M.D. v. Bradford Reg’l Med. Ctr., 752 F. Supp. 2d 602 (W.D. Pa. 2010). The lesson learned in these cases is that even when an agreement is in writing and may originally meet all the other the relevant criteria of a particular Stark exception, the contract must be reviewed at times and possibly reformed if the duties or scope of services are modified over time.

b. Bona Fide Employment Relationships

There is an exception for any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for identifiable services. The amount must be consistent with fair market value, not determined in a manner that takes into account the value of any referrals, and commercially reasonable, even if no referrals were made to the employer. 139

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138 42 C.F.R. § 411.357(a) and (b).
139 42 U.S.C. § 1395nn(e)(2).
c. Personal Service Arrangements

An independent contractor arrangement will be exempt from the self-referral prohibition if the arrangement meets the following qualifications:140

(i) The arrangement is set out in writing, signed by the parties, and specifies the covered services.

(ii) The arrangement covers all services to be provided by the physician.

(iii) The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

(iv) The term is for at least one year. Phase II modified the one-year requirement to permit a termination clause (with or without cause); however, if the agreement is terminated within the first year of the original term, the parties are not permitted to enter into another agreement for the same or similar services for the remainder of the first year.

(v) The compensation is set in advance, does not exceed fair market value,141 and is not determined in a manner that takes into account the volume of referrals or other business generated between the parties.

(vi) The services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal laws.

(vii) A contract for personal service is permitted a holdover not to exceed 6 months so long as the payment terms remain the same.

In the case of a physician incentive plan that may directly or indirectly reduce or limit services provided with respect to individuals enrolled with the entity for medical services, the compensation may be determined in a manner (through withholding, capitation, bonus, or otherwise) that takes into account directly or indirectly the volume or value of any referrals or other business generated between the parties, so long as no payment under the plan is intended as an inducement to reduce or limit medically necessary services.142

d. Remuneration Unrelated to the Provision of Designated Health Services

140 42 U.S.C. § 1395nn(e)(3).
141 As to fair market value guidance, the preamble suggests that the analysis should first determine what the service could have been bought for in the absence of an arrangement with a referring physician. However, in the absence of reasonable market comparables, the fair market analysis looks at the supplier’s costs plus a reasonable return. Relative to the need to obtain an outside appraisal, the preamble suggests that internal audits are susceptible to manipulation and do not have strong evidentiary value.
The self-referral ban does not apply to any remuneration provided by a hospital to a physician if such payment does not relate to the provision of designated health services.\textsuperscript{143}

e. Physician Recruitment

The ban on self-referrals does not apply to any remuneration paid by a hospital, federally qualified health center, or rural health clinic (collectively, “hospitals”) to a physician for the purpose of inducing the physician to relocate to the geographic area served by the hospital and become a member of the medical staff of the hospital. For the exception to apply, the hospital cannot require the physician to refer patients to the hospital, and the remuneration amount cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals.\textsuperscript{144}

(i) Physician must move his/her medical practice at least 25 miles, or physician’s new medical practice (in hospital’s service area) must derive 75% of its revenues from professional services to patients not previously seen by the physician during the prior three years;

(ii) Arrangement is set out in writing and signed by the parties;

(iii) Arrangement is not conditioned on referrals;

(iv) Remuneration for recruitment is not determined on the basis of volume or value of actual or anticipated referrals or other business generated between the parties; and

(v) Physician is permitted to establish staff privileges at any other hospital and to refer business to other entities except as may be restricted under an employment agreement.\textsuperscript{145}

If recruitment payments are paid indirectly through another physician or group practice or directly to physicians joining an existing physician or group practice, the following additional conditions must be met:

(i) The recruitment exception does not apply to recruitment of physicians who join an existing practice when the recruited physician is merely co-locating or sharing space with an existing practice;

(ii) Remuneration must be passed directly through to the recruited physician, except the conduit party may retain an amount to cover actual cost to recruit the physician. (Phase III provided that such expenses include headhunter fees, tail malpractice insurance from the recruited physician's previous practice, moving expenses, airfare, hotels and other costs incurred for visits to the new practice group area by the physician and his/her family.);

(iii) The group practice may impose practice restrictions on the recruited physician that do not “unreasonably restrict” the recruited physician’s ability to practice in the

\textsuperscript{143} 42 U.S.C. § 1395nn(e)(4).
\textsuperscript{144} 42 U.S.C. § 1395nn(e)(5); 42 C.F.R. § 411.357(e).
\textsuperscript{145} See 42 C.F.R. § 411.354(d)(4).
geographic service area. (Such restrictions could include, for example, liquidated damages; repayment of losses; a limited, reasonable non-compete clause; and a prohibition on moonlighting.);146

   (iv) In the case of an income guarantee, the cost allocated by the physician or group practice to the recruited physician may not exceed the actual additional incremental costs attributable to the recruited physician. (Phase III permits per capita allocation not to exceed 20% of GP’s aggregate costs if replacing physician who is deceased, retiring, or relocating in a rural area or HPSA);

   (v) Records of actual costs and passed-through amounts must be maintained for at least five years; and

   (vi) The arrangement may not violate the AKS or any federal or state law or regulation governing billing or claims submissions.

Physician recruitment arrangements cannot qualify for the fair market value exception.

f. Isolated Transactions

The self-referral ban does not apply to isolated transactions, such as a one-time sale of property or sale of a physician’s practice, if

   (i) the amount is consistent with the fair market value of the services;

   (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals;

   (iii) the remuneration is provided pursuant to an agreement that is commercially reasonable, even if no referrals were made by the physician to the entity; and

   (iv) the parties not engage in any transactions not specifically exempted by the regulations for a period of six months.147

If, however, part of the compensation paid for the physician’s practice, for example, is in the form of debt (e.g., an installment sale), the debt will constitute a financial relationship and the isolated sale exception will not apply. Installment payments are permitted, provided the parties set the total aggregate payment in advance and independently of the volume

146 Stark Advisory Opinion No. CMS-AO-2011-01 found that 42 U.S.C. § 1395nn(e)(5) was not violated by recruitment benefits conditioned on a 25-mile radius, one-year non-compete clause that was certified as being reasonable and enforceable under state law, and was intended to protect the financial interests of the group recruiting the new practitioner. The non-compete effectively prevented the recruited physician from practicing at all but one other area hospital.

147 42 U.S.C. § 1395nn(e)(6).
or value of any referrals, and assure payment (through a negotiable promissory note or similar means) even in the event of a default by the purchaser.\textsuperscript{148}

g. Group Practice Arrangements with a Hospital

The prohibition does not apply to amounts paid by a hospital to a group practice under an arrangement, where designated health services are provided by the group but are billed by the hospital, and the following conditions are satisfied:\textsuperscript{149}

(i) The arrangement is for inpatient hospital services;

(ii) The arrangement began before December 19, 1989, and has continued in effect without interruption since that date;

(iii) Substantially all of the designated health services covered under the arrangement are furnished to hospital patients by the group;

(iv) The arrangement is pursuant to an agreement that is set out in writing and specifies the services to be provided and the compensation for such services;

(v) The amount of compensation paid over the term of the agreement is consistent with fair market value, is fixed in advance, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties; and

(vi) The agreement is commercially reasonable, even if no referrals were made to the entity.

h. Payments by a Physician for Items and Services

There is an exception for payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services, or to an entity as compensation for other items or services, if the items or services are furnished at a price consistent with fair market value.\textsuperscript{150}

i. Non-Monetary Compensation Up to $300\textsuperscript{151}

Stark will not apply in the case of non-monetary compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed $300 per year, if the following conditions are met:\textsuperscript{152}

(i) The compensation is not determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician;

\textsuperscript{148} 42 C.F.R. § 411.357(f).
\textsuperscript{149} 42 U.S.C. § 1395nn(e)(7).
\textsuperscript{150} 42 U.S.C. § 1395nn(e)(8).
\textsuperscript{151} These amounts are updated annually by CMS. The limit was $355 for 2010.
\textsuperscript{152} 42 C.F.R. § 411.357(k).
(ii) The compensation may not be solicited by the physician or the physician practice (including employees and staff members); and 

(iii) The arrangement does not violate the AKS.

Note: Phase II provides that the $300 limit on non-monetary compensation will be indexed and revised annually. The increases will be adjusted by the “Consumer Price Index - Urban All Items.” The revisions are published by CMS on the web at: http://www.cms.hhs.gov/physicianselfreferral/10-CPI-U-Updates.asp. The adjusted limit for 2011 is $359.

Note: Phase III regulations permit inadvertent remuneration in excess of annual limit, up to 50%, to be returned by the earlier of 180 days from receipt or within the calendar year in which it was received by the physician.

j. Fair Market Value Exception

Transactions involving compensation paid by a referring physician to a DHS entity or from a DHS entity to a referring physician may be protected where the arrangement does not otherwise qualify for other exceptions described above (e.g., personal services for less than one year term) if the arrangement meets the following conditions:

(i) The agreement is in writing, signed by the parties and covers only identifiable items or services that are specified in the agreement;

(ii) It specifies the terms of the agreement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year;

(iii) It specifies the compensation, which must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician;

153 42 C.F.R. § 411.357(l).

154 Fair market value exists “where the price or compensation has not been determined in any manner that take into account the volume or value of anticipated or actual referrals,” and is consistent with “general market value” established by arms-length negotiations by parties not in a position to generate business for one another. 42 C.F.R. § 411.351. The fact that a piece or value has been negotiated between the parties does not in itself establish that it is based on FMV. U.S. ex rel. Kosenke v. Carlisle HMA, Inc., 554 F.3d 88, 97 (3d Cir. 2009). Independent “valuations” often are commissioned to validate FMV. CMS has stated that “we will not consider the value or volume standard implicated by otherwise acceptable compensation arrangements for physician services solely because the arrangement requires the physician to refer to a particular provider as a condition of payment,” so “long as the payment is fixed in advance for the term of the agreement, is consistent with [FMV],” and not based on the volume or value of anticipated referrals. 66 Fed. Reg. at 877.
(iv) The transaction is commercially reasonable and furthers the legitimate interests of the parties;

(v) It does not violate the AKS;

(vi) The services to be performed do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law; and

(vii) Phase III denies the FMV exception to lease arrangements; such arrangements must meet lease exception.

k. Medical Staff Incidental Benefits

A hospital may furnish to their medical staff certain incidental benefits of low value, such as parking, meals, or free computer/internet access, if the following conditions are met:\footnote{42 C.F.R. § 411.357(m).}

(i) The benefits are offered to all members of the medical staff without regard to the volume or value of referrals or other business generated between the parties;

(ii) May be offered only when the medical staff members are making rounds or performing duties that benefit the hospital or its patients;

(iii) The compensation is provided by the hospital and used only on the hospital campus;

(iv) The compensation is reasonably related to the provision medical services at the hospital;

(v) The compensation is consistent with industry practice;

(vi) The compensation is of low value (i.e., less than $25) with respect to each occurrence,\footnote{This amount is updated annually by CMS.} and

(vii) The compensation is not determined in a manner that takes into account the volume or value of any referrals or any other business generated between the parties.

Phase II provides that the $25 limit with respect to each occurrence will be indexed and revised annually. The increases will be adjusted by the “Consumer Price Index - Urban All Items.” The revisions will be done on or immediately after September 30 each year and will be published by CMS on the web at: http://www.cms.hhs.gov/physicianselfreferral/10-CPI-U-Updates.asp. The limit for 2010 is $30. The requirement that incidental medical staff benefits be provided and used “on campus” includes electronic devices, such as pagers and internet access, used by physicians.
when away from a hospital campus exclusively for the purpose of accessing hospital information or personnel. Phase II commentary clarifies that the provision of transcription services by a hospital for hospital records is not a benefit, incidental or otherwise, to the physician.

Note: The incidental medical staff benefits exception is not restricted to hospitals. Any entity with a bona fide medical staff (such as a clinic or long term care facility) may provide incidental benefits to its medical staff under this exception.

1. Risk Sharing Arrangements

In response to unintended effects of the Stark ban on commercial managed care plans, Phase I of the final regulations created a new compensation exception for remuneration pursuant to a bona fide “risk sharing arrangement” (including, but not limited to, withholds, bonuses, and risk pools) between a managed care organization or an independent physicians association and a physician for the provision of items or services to enrollees of the health plan, provided that the arrangement does not violate the AKS or any law or regulation governing billing or claims submission. The exception applies even when such arrangement does not fall within existing statutory exceptions.

m. Compliance Training

(i) Compensation (for Stark purposes) does not include compliance training provided by a DHS entity to a physician (or the physician's immediate family member) who practices in the DHS entity’s local community or service area.

(ii) Compliance training is broadly defined to cover general compliance and the basic elements of a compliance program.

(iii) Training may include training of physicians’ office staff and may include compliance training addressing the requirements of any federal, state or local law or rule governing the physician and staff.

(iv) Online training acceptable if accessing online training while in a location that is the entity's local community or service area. DHS entities are not permitted to reimburse out-of-pocket expenses (e.g., travel) for physicians to obtain training outside entity's local community or service area.

(v) Phase III permits compliance training to include continuing medical education (CME) programs, provided that compliance training is the primary purpose of the program.

n. Indirect Compensation -- If a financial interest constitutes an indirect compensation interest, the arrangement may qualify for the indirect compensation exception that meets all of the following requirements:

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157 42 C.F.R. § 411.357(n).
158 42 C.F.R. § 411.357(o).
159 42 C.F.R. § 411.357(p).
(i) The compensation received by the physician from the person or entity is fair market value for the services and items actually provided without taking into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

(ii) The compensation arrangement is set out in writing, signed by the parties, and specifies the services to be performed (except for bona fide employment arrangements, which need not be in writing).

(iii) The compensation arrangement does not violate the AKS.

Note: If the stand-in-the-shoes rules apply to a particular financial arrangement, the indirect compensation exception is not available to protect the arrangement and must rely on an direct compensation exception.

o. Charitable Donations By Physicians

Remuneration will not include certain charitable donations by physicians. CMS responded in Phase II to concerns raised by commentators that legitimate charitable contributions by a physician to a DHS entity (such as the purchase of a hospital charity ball ticket) can create a financial relationship between the donor physician and the DHS entity for which there was no exception under Stark for such arrangements. CMS concluded that an exception was appropriate for donations by physicians, where the following requirements are satisfied:

(i) The donation is made to an organization exempt from federal income tax under the Internal Revenue Code (or to an exempt supporting organization, such as a hospital foundation);

(ii) The donation is neither solicited nor made in any manner that reflects the volume or value of referrals or other business generated by one party for the other; and

(iii) The donation arrangement does not otherwise violate the AKS or federal or state laws or regulations governing billing or claims submission.

Note: Broad-based solicitations not targeted specifically at physicians, such as sales of charity ball tickets or general fund-raising campaigns, will qualify under this exception. Practices such as a “dean’s tax” fall outside the scope of the exception.

p. Professional Courtesy

Hospitals and other entities furnishing DHS may offer professional courtesies if all of the following conditions are met:

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160 42 C.F.R. § 411.357(j).
161 42 C.F.R. § 411.357(s).
(i) The professional courtesy is offered to all physicians on the entity’s bona
fide medical staff or in the entity’s local community without regard to volume or value of
referrals or other business generated between the parties;

(ii) The health care items and services provided are of a type routinely
provided by the entity;

(iii) The professional courtesy policy is set out in writing and approved in
advance by the entity’s governing body;

(iv) The professional courtesy is not offered to a physician (or immediate
family member) who is a federal health care program beneficiary, unless there is a good faith
showing of financial need;

(v) If the professional courtesy involves any whole or partial reduction of any
coinsurance obligation (for example, a waiver of co-pays), the reduction or waiver is disclosed to
the insurer in writing; and

(vi) The arrangement does not violate the AKS or any federal or state laws and
regulations covering billing or claims submission.

Note: Professional courtesy arrangements may also be covered under the employee
exception.

q. Physician Retention Programs

Hospitals, federally qualified health clinics (“FQHCS”) in certain rural and inner
city areas, and rural health clinic may make retention payments to physicians, if the following
requirements are met:162

(i) The physician must be on the hospital’s medical staff;

(ii) The exception is only available to hospitals in a HPSA, without regard to
the physician’s particular specialty, or in an area with demonstrated need for the physician, as
determined through a CMS Advisory Opinion;

(iii) The physician (A) has a bona fide firm, written recruitment offer from a
hospital that is not related to the hospital that is making the retention payment; (B) the bona fide
offer specifies the remuneration offered; and (C) the offer would require the physician to relocate
his or her medical practice at least 25 miles from and outside of the geographic area served by
the hospital making the retention payment;

(iv) Written Documentation

A. Written Bona Fide Offer -- The retention payment is limited to the
lower of (A) the amount obtained by subtracting (i) the physician's current income from

162 42 C.F.R. § 411.357(t).
physician and related services from (ii) the income the physician would receive from comparable physician and related services in the bona fide recruitment offer, as calculated based on a reasonable methodology over no more than a 24-month period; or (B) the reasonable cost the hospital would otherwise have to expend to recruit new physicians to replace the physician to be retained in the geographic area served by the entity making the retention payment;

B. Absence of written bona fide offer -- Phase III provides that a physician may “certify” in writing to a hospital's terms of verbal offer. If certified, retention payment limited to lesser of (a) 25% of physician’s current annual income (any over previous 24 months); or (b) reasonable cost the entity would have to incur to replace the physician;

(v) The arrangement is set out in writing and signed by the parties;

(vi) The arrangement is not conditioned on referrals or other business generated between the parties;

(vii) The retention payment is not determined based on the value of actual or anticipated referrals or other business generated between the parties;

(viii) The physician is not prohibited from establishing staff privileges at other hospitals or from referring business to other entities;

(ix) The retention payment must be subject to the same obligations and restrictions on repayment or forgiveness of indebtedness as the bona fide recruitment offer;

(x) The hospital may not enter into a retention arrangement with a particular referring physician more frequently than once every 5 years and the amount and terms of the retention payment are not altered during the term of the arrangement in a manner that takes into consideration the volume or value of referrals or other business generated by the physician; and

(xi) The retention arrangement does not otherwise violate the AKS or federal or state laws or regulations governing billing or claims submissions.

The new exception for retention payments in underserved areas does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice. In other words, the retention exception is limited to payments made directly to the physician to be retained and “does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice.”

Retention arrangements involving physicians in underserved areas, but outside a HPSA, will be reviewed on a case-by-case basis through the advisory opinion process.

Note: CMS cautions that all retention arrangements must be carefully structured so they do not implicate the AKS.

Intra-Family Referrals

This new exception, added to the category of ownership/investment interests and compensation exceptions, permits a referring physician to cross-refer to an immediate family member or to an entity, which the immediate family member has a financial relationship, if the following conditions are met:\textsuperscript{164}

(i) The patient resides in a rural area;

(ii) No other person or entity is available to furnish the services in a timely manner, considering the patient’s condition within 25 miles of the patient's residence; and

(iii) The financial relationship does not violate the AKS or any federal or state laws or regulations governing billing and claims submissions.

The referring physician or the immediate family member must make reasonable inquiries as to the availability of other persons or entities to furnish the DHS. Depending on the circumstances, reasonable inquiry might include consulting telephone directories, professional associations, other providers, or internet resources. The focus of the exception is on the location where the services are furnished, not where the DHS entity is located. Thus, if a physician knows that a home health agency located 50 miles away is willing to provide home health services to the patient, the patient may not be referred to a family-owned health agency under this exception.

s. Temporary Lapses in Compliance

A “grace” period is provided to accommodate situations when parties to an arrangement fall out of compliance with aspects of an exception through events outside their control or are unable to comply with an exception for temporary periods of time if the arrangement meets the following requirements:\textsuperscript{165}

(i) The financial relationship must have satisfied another exception for at least 180 consecutive days prior to the date the arrangement fell out of compliance;

(ii) The financial relationship fell out of compliance for reasons beyond the control of the entity, and the entity promptly took steps to rectify the noncompliance;

(iii) The noncompliance is rectified within 90 calendar days following the date in which the financial relationship became noncompliant with an exception (or otherwise has terminated the prohibited arrangement);

(iv) The temporary lapse of compliance exception may only be used by an entity once every three years; and

(v) The financial relationship does not violate the AKS or other federal or state laws and regulations governing billing and claims submission.

\textsuperscript{164} 42 C.F.R. § 411.355(j).
\textsuperscript{165} 42 C.F.R. § 411.353(f).
This exception does not apply to arrangements that previously complied with the exceptions for non-monetary compensation up to $300 or incidental medical staff benefits. According to CMS, to provide otherwise, would have effectively negated the monetary limits set in those exceptions. 166

Proposed: Incentive Payment and Shared Savings ("Gainsharing")

On July 7, 2008, CMS published a proposed exception to Stark for incentive payments and shared savings programs and set forth certain safeguards and elements related to the design of an incentive payments or shared savings programs. 167 The proposed exception would protect remuneration only in the form of cash (or cash equivalent) payments made by a hospital for properly designed shared-savings programs. In addition, the proposed exception would be limited to payments to physicians who actually participate ("participating physicians") in the achievement of the patient care quality measures or cost savings measures (collectively referred to in this proposal as the "performance measures") that are the subject of the particular program. Under the proposed regulations, any distributions of incentives or shared savings payments by the hospital must be paid on a per capita basis to the participating physicians. CMS attached to the proposed rule specific design guidelines, Requirements Related to the Design of an Incentive Payment or Shared Savings Program, which detail gainsharing program elements recommended by CMS.

D. Advisory Opinions

1. Section 4314 of the Balanced Budget Act of 1997 amended Section 1877(g) of the Social Security Act to require that the Secretary of Health and Human Services provide advisory opinions with respect to the application of the anti-referral statutes. Regulations governing advisory opinions by the Department of Health and Human Services were published as 42 C.F.R. part 411. 63 Fed. Reg. 1646 (January 9, 1998).

2. The regulations are based on the OIG advisory opinion rules and contain a similar application process. The request must be accompanied by an initial fee of $250, with the final fee to be based upon the time spent by HHS personnel on the request. The preamble to the regulations states that it is expected that the hourly fee for HHS staff will be approximately $75. An advisory opinion will be issued in most cases within 90 days of the receipt of the request.

3. As in the case of OIG opinions, HHS retains the right to revoke an opinion if it should be later determined that the arrangement may result in fraud or abuse. In addition, the regulations make it clear that only the requesting party, and no third party, may rely upon the advisory opinion.

E. Recent Stark Case Law


167 73 FR 23692 through 23693. This proposal was not finalized.
connection with a claims submitted to a federally funded insurance program is actionable under the FCA.” Accord *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997) (same) (certification of compliance found to exist in cost report.

2. In *Colorado Heart Institute, LLC v. Johnson*, 609 F.Supp. 30 (D.D.C. 2009), cardiac cath labs provided services, personnel and equipment for which they were paid a flat fee by a hospital “under arrangement,” and the hospital billed Medicare. The cath labs and their physician owners sought a declaration that the revised definition of an DHS “entity” subject to Stark exceeded the Secretary’s statutory authority. The court dismissed the claim for lack of subject matter jurisdiction because the rule could be challenged through an administrative appeal by the hospital, contesting the denial of payment. The court found that prescribed statutory review was available to the plaintiffs indirectly, through the hospital, and rejected the argument that “exhaustion” of administrative remedies was not required under the *Michigan Academy* doctrine simply because the plaintiffs did not have a right to review on their own behalf.

3. In *U.S. ex rel. Drakeford, M.D. v. Tuomey d/b/a/ Tuomey Health Systems, Inc.* D.S.C. No. 3:05-cv-2858-MJP (June 3, 2010), appeal pending, the trial court upheld a jury verdict awarding the government $44.8 in Medicare overpayments resulting from referrals that violated Stark. Referring physicians were subject to non-competes and received salary and bonus payments that exceeded fair market value in relation to community standards and given the program reimbursement rates for the services involved. The court also reversed the jury’s finding that the arrangement did not violate the FCA. In the new trial – assuming the order is not reversed on appeal – the central issue is likely to be whether the hospital was aware that the employment arrangements violated Stark. Based on the original record, the hospital can be expected to rely on an advice of counsel defense.

4. In *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009), the Third Circuit concluded that an exclusive agreement between an anesthesiology group and hospital did not satisfy the Stark personal services exception because the written agreement between the parties had not been updated to include all services rendered and cover all facilities at which services were provided by the medical group. Documentation of fair market value of space, personnel and equipment was deemed inadequate and was not established solely by virtue of the parties having negotiated the terms of the agreement.

5. *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008), upheld a $64 million AKS and Stark penalty against the manager of Edgewater Medical Center for payments to referring physicians in excess of fair market value through personal service, medical director and teaching agreements, loans, and payment for EKG services.

6. *U.S. ex rel. Singh v. Bradford Reg’l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010), found Stark violations arising out of a nuclear camera sublease arrangement between a hospital and referring physician practice and its members. Ruling on the parties’ cross-motions for summary judgment, the court found lease payments to have taken into account the value or volume of anticipated referrals, and that proposal letter and invoices between the parties did not comprise a compliant written agreement. The former conclusion is noteworthy in that the payments to the medical group were based on a fixed aggregate amount that did not vary with the value or volume of referrals. However, as part of the arrangement, the physician group was
paid for a non-compete, based on fair market valuations which had taken into account the value of referrals from the physician group, and of the referrals that would be lost in the absence of the non-compete. This decision should be carefully considered when practice valuations are being done, including for non-competes. The court also found a direct financial relationship between the physicians and their P.C. because BRMC paid an early termination fee on a camera lease, and thereby relieved the physicians, of responsibility for individually guaranteeing that payment, which the court found to be a substantial benefit that qualifies as remuneration.

V. Distinctions between the Anti-Referral and the Anti-Kickback Statutes

A. Policy Similarities -- The AKS and the anti-referral statute are intended to curb many of the same abuses, that is, to avoid overutilization of the health care system, provide healthcare consumers with the freedom to choose medical services and providers, and to reduce cost to the Medicare and Medicaid programs. However, the reach of the two statutes varies.

B. Differences re: Scope and Intent -- The AKS overlaps with but is broader in scope than Stark. It applies to whoever “knowingly and willfully” offers or pays any remuneration to induce an individual to furnish or arrange to furnish any item or service for which payment is to be made under a Federal Healthcare Program (e.g., the Medicare or Medicaid programs). In contrast, Stark applies only to referrals by physicians to other physicians or entities with which the referring physician has a financial relationship and is limited to referrals involving only DHS, not to all covered items and services. Stark liability is absolute and may be triggered regardless of the party's underlying intentions. Failing to meet a safe harbor under the AKS does not mean that the arrangement is per se illegal, rather the particular facts and circumstances must be reviewed to determine if any one intent influencing the arrangement was to induce referrals; under Stark, on the other hand, a failure to qualify for all elements of a particular exception renders all DHS billings resulting from the referrals improper.

VI. Civil Monetary Penalty Provisions and Program Exclusion

A. General -- The Social Security Act authorizes the Secretary of HHS to seek civil monetary penalties (“CMPs”) and assessments for many types of conduct. The Secretary of HHS has delegated many of these CMPs to the OIG. In most cases for which the OIG may seek CMPs, the OIG may also seek exclusion from participation in all federal health care programs. Many of the OIG’s CMPs are in the Civil Monetary Penalties Law (“CMPL”), 42 U.S.C. § 1320a-7a, and the OIG’s CMPs codified elsewhere in the Social Security Act adopt by reference many of the provisions of the CMPL.

B. Sanctioned Conduct -- Under provisions of the Act that were substantially augmented by the PPACA, the OIG may seek CMPs for a wide variety of conduct, including the following:

1. Presenting or causing to be presented claims to a federal health care program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.169

168 See 42 C.F.R. § 1003.102.
2. Violating the AKS, 42 U.S.C. § 1320a-7(b), by knowingly and willfully: (1) offering or paying remuneration to induce the referral of Federal health care program business; or (2) soliciting or receiving remuneration in return for the referral of federal health care program business.170

3. Presenting or causing to be presented a claim that the person knows or should know is for a service for which payment may not be made under the Stark law, 42 U.S.C. § 1395nn.171

4. Negligently violating obligations under EMTALA to provide screening and appropriate stabilizing treatment for persons with emergency medical conditions or to women in active labor.172

5. Offering to or transferring remuneration to any Medicare/Medicare beneficiary by a person who knows or should know is likely to influence such individual to order or receive items or services payable, in whole or in part, by a federal healthcare program (e.g., Medicare or Medicaid).173

6. Arranging or contracting (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a federal healthcare program.174

7. Payments by a hospital to a physician, directly or indirectly, as an inducement to reduce or limit services provided to Medicare/Medicare beneficiaries.175

8. Providing unnecessary items or services (i.e., items or services in excess of the patient's individual needs) or substandard items or services (i.e., items or services of a quality that fails to meet professionally recognized standards of health care).176

9. Failing to report an overpayment within the later of 60 days after the overpayment is identified or when the cost report is due.177

10. “Ordering or prescribing a medical or other item or service during a period in which the person was excluded from a federal health care program with knowledge that payment will be made by the program.”178

169 42 U.S.C. § 1320a-7(a)(1)(A) and (B).
170 42 U.S.C. § 1320a-7a(a)(7).
171 42 U.S.C. § 1395nn(g)(3).
172 42 U.S.C. § 1395dd(d)(1)(A)
173 42 U.S.C. § 1320a-7a(a)(5).
174 42 U.S.C. § 1320a-7a(a)(6).
175 42 U.S.C. § 1320a-7a(b).
176 Social Security Act § 1128(b)(6)(B).
177 PPACA § 6402(d)(2), amending 42 U.S.C. 1320a-7a(a).
178 PPACA § 6402(d)(2), adding 42 U.S.C. 1320a-7a(a)(8).
11. Any person who “knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid or contract to participate or enroll as a provider of services or a supplier under a Federal health care program.”

12. Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a federal health care program.

13. Failing to grant the OIG timely access for the performance of audits, investigations, evaluations, or other statutory functions. Note: Under this provision, the OIG must provide a reasonable request before CMP liability can attach.

C. Certain Charitable and Other Innocuous Programs Not Subject to CMP Liability

The PPACA amended the definition of remuneration to clarify that CMPs should not prohibit certain beneficial and charitable activities. Under the amendment, that a CMP will not be assessed in situations where 1) remuneration promotes access to care and poses a low risk of harm to patients and federal health care programs, or 2) the offer or transfer of items or services is for free or less than fair market value and certain requirements are met, or 3) as of January 1, 2011 (or later as specified by the Secretary), to the waiver by a Part D sponsor of a prescription drug plan or by a Medicare Advantage organization offering a prescription drug plan under Part C of any copayment for the first fill of a covered generic drug.

D. Penalties -- The OIG is authorized to seek different amounts of CMPs and assessments based on the type of violation at issue. The regulations describe the administrative appeals process.

E. Exclusion -- The OIG may also seek exclusion of a person or entity from the participation in the Medicare or Medicaid programs.

1. Effect of Exclusion
   a. No payment will be made by any federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity.
   b. Items or services prescribed by an excluded physician are not reimbursable when the individual or entity furnishing the item or services knew or should have known of the exclusion. These payment prohibitions apply even when the payment itself is

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179 PPACA § 6402(d)(2), amending 42 U.S.C. 1320a-7a(a).
180 PPACA § 6408(a), amending 42 U.S.C. 1320a-7a(a).
181 PPACA § 6408(a), amending 42 U.S.C. 1320a-7a(a)
182 PPACA § 6408(a), amending 42 U.S.C. 1320a-7a(a).
183 PPACA § 6402(d)(2)(B), amending 42 U.S.C. 1320a-7a(i)(6).
184 6402(d)(2)(B)-(I), amending 42 U.S.C. 1320a-7a(i)(6).
185 See 42 C.F.R. § 1005.
made to a non-excluded provider, such as the group practice. Providers who file claims for items or services furnished by an individual or entity that the provider knew or should have known was excluded may be required to repay all amounts received from such claims, and, potentially, false claims liability.

c. The OIG has the authority to impose CMPs on any provider that contracts with, by employment or otherwise, an individual or entity that the provider knows or should know is excluded from program participation. The OIG has repeatedly stated that this “knowledge” standard imposes an affirmative obligation on providers to check the exclusion status of individuals and entities prior to hiring and/or contracting with them.

d. There is a limited exception to exclusions for the provision of certain emergency items or services not provided in a hospital emergency room.187

2. Permissive Exclusion -- “Permissive” exclusion authority gives the OIG discretion whether or not to impose an exclusion from participation in federal health care programs. Events that can trigger permissive exclusions include license revocation or suspension, a previous exclusion or suspension from a state healthcare program, or certain other types of behavior which the OIG considers abuse against the Medicare program. The basis for the exclusion, as well as the existence of certain aggravating or mitigating factors, is used to determine how long the exclusion will last. Some exclusions are imposed for only a couple of years, others have lasted ten and fifteen years or have barred the provider from billing Medicare indefinitely. The PPACA authorized permissive exclusions for obstructing OIG investigations or audits, and for false statements or omissions in an application agreement, agreement, bid, or contract to participate or enroll as a provider or supplier of services under a Federal health care program.188

3. Mandatory Exclusion -- For certain conditions, the OIG is required by law to impose exclusions. The bases for these mandatory exclusions vary, and include a provider’s conviction for patient abuse, and convictions for submitting false claims. Mandatory exclusions also vary in length, depending upon the circumstances. Under the PPACA, States were required to terminate any provider or supplier that has been terminated by Medicare or another State’s Medicaid program, or has failed to repay overpayments.189 The PPACA also had required States to exclude any individual or entity that owns, controls or manages an entity that has unpaid overpayments, or is suspended, excluded or terminated from Medicaid or is “affiliated” with a suspended, excluded or terminated individual or entity.190 This provision was later repealed by the Medicare and Medicaid Extender Act of 2010.191

4. List of Excluded Individuals/Entities (“LEIE”) -- The OIG LEIE database provides information to the health care industry, patients, and the public regarding individuals and entities currently excluded from participation in Medicare, Medicaid, and all other federal

187 See 42 C.F.R. § 1001.1901(c).
188 PPACA § 6402(d), amending 42 U.S.C. § 1320a-7(b).
190 PPACA § 6502, adding 42 U.S.C. § 1396a(a)(78).
health care programs. Individuals and entities who have been reinstated are removed from the LEIE. The LEIE can be found on the OIG’s website at: http://oig.hhs.gov/fraud/exclusions/listofexcluded.html.

F. Suspension of Payments --

1. The Secretary may suspend payments to a Medicare provider or supplier during fraud investigations, and the States were obligated to enact Medicaid payment suspension procedures which parallel those for Medicare. The Secretary also can suspend payment to a Medicaid provider or supplier if a state fails to suspend payments during a fraud investigation. In both scenarios, the pending fraud investigation must be based on a “credible” allegation of fraud. As such, the Secretary is required to consult with the OIG to determine whether there is a credible allegation of fraud.

2. The PPACA mandates suspensions of payments when there are credible allegations of fraud in the absence of good cause not to do so. Payment suspension can be halted if the Secretary determines that there is a good cause not to suspend such payments or if the investigation is not concluded within a specified time frame. Payment suspensions are reevaluated every 180 days.

VII. Other Federal Fraud Statutes

Other federal statutes impose civil or criminal consequences for health care fraud. Significant among these statutes are Sections 287 and 1347 of Title 18 of the United States Criminal Code, 18 U.S.C. § 1347, which makes it a crime to defraud any health care benefit program, and the civil False Claims Act (the “FCA”), 31 U.S.C. §§ 3729-30, which imposes civil liability for fraudulent claims presented to governmental programs.

A. Criminal Liability Under Title 18 for “Private” Health Care Fraud

1. The general federal criminal fraud statute, 18 U.S.C. § 287, makes it a federal crime to present fraudulent claims to federal agencies. While Section 287 may be used to prosecute those who commit health care fraud, such prosecutions are more commonly brought under 18 U.S.C. § 1347, which specifically addresses health care fraud.

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192 PPACA § 6402(h)(1), amending 42 U.S.C. 1395y. Regulations implementing the PPACA payment suspension requirements were published on February 2, 2011. The Medicaid requirements which must be implemented by the States parallel the Medicare payment suspension rules which are codified at 42 C.F.R. § 455.23.


194 PPACA § 6402(h)(1)-(2), amending 42 U.S.C. 1395y & 42 U.S.C. 1396b(i)(2). Credible allegations of fraud may derive from hotlines, claims data mining, billing patterns identified through audits, or FCA claims or law enforcement investigations. 75 Fed. Reg. 58204, 58222 (proposed rule, Sept. 23, 2010).

2. Under Section 1347, as added by the Health Insurance Portability and Protection Act of 1996, it is a crime to defraud any health care benefit program, or to obtain by false or fraudulent pretenses, representations, or promises, any money or property owned by, or under the custody or control of, a health care benefit program. Convictions under Section 1347 can lead to both fines and prison terms up to 20 years. Section 1347 is not limited to federal benefit programs such as Medicare, Medicaid, and Social Security, but applies to defrauding “any health care benefit program.” This encompasses fraud against private health insurance providers as a federal crime subject to investigating and prosecution by the DOJ and FBI.

3. Intent requirement -- Title 18 includes a “knowing and willfully” intent requirement. The PPACA specifically provided that this intent requirement does not necessitate actual knowledge of Section 1347 or specific intent to violate the statute. Therefore, Section 1347 actions can be successfully brought against individuals who have no knowledge of the statute or intention to violate the it.

4. AKS violations as healthcare fraud violations -- The PPACA amended the definition of health care fraud offenses to include violations of the AKS.

B. Civil Liability Under the FCA

1. The Civil FCA provides for treble damages and civil penalties in any case where a person knowingly submits claims or makes a false record or statement in order to seek payment by the federal government. “Knowingly” is not limited to actual knowledge, but may also include acting in deliberate ignorance of, or in reckless disregard of, the truth or falsity of information provided.

2. The FCA creates two alternate routes to civil liability for fraud against the United States government. The FCA authorizes the Attorney General of the United States to bring a civil action based upon fraud. If the Attorney General declines to bring an action, a private party may bring a “qui tam” action on behalf of the government.

3. Civil penalties under the FCA can be as high as $5,500-$11,000 per claim, plus three times the amount of actual damages sustained by the government. A qui tam plaintiff may recover up to twenty-five percent (25%) of the proceeds in a case in which the government intervenes and twenty-five to thirty percent (25-30%) in a case in which the government does not intervene. Since a defendant may be liable for treble damages, the consequences of an FCA civil action can be substantial, and there is a significant incentive for qui tam plaintiffs to assert FCA claims.

4. FCA exposure may be reduced through a voluntary self-disclosure. To qualify for a reduction from “treble damages” to “double damages,” a cooperating person must

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notify the government within 30 days after the date when the provider first obtained the information about the FCA violation of all information such person knows about the violation. For this reduction in damages to apply, the information must be furnished prior to the commencement of any civil or administrative action and without knowledge of any investigation into such violation. 31 U.S.C. § 3729(a)(2).

5. “Whistleblower” suits may be filed by private “relators” on behalf of the government under seal.201 To file an FCA suit, the underlying facts may not be a matter of public knowledge, or the whistleblower must be an “original source” of material facts. The definition of an original source, for FCA purposes, was substantially expanded by the PPACA. Whereas the original source requirement previously was a jurisdictional prerequisite to a relator’s suit, under the PPACA amendments, DOJ can decide whether a case may be brought. Under another PPACA provision, a relator is deemed an original source based on knowledge that materially adds to publically disclosed information, when voluntarily provided to the government before suit is filed.

6. The FCA also provides protection for whistleblowers. Employers may be exposed to liability if they take adverse action against FCA whistleblowers, whether or not the whistleblower’s fraud allegations have merit. The Fraud Enforcement and Recovery Act of 2009 (“FERA”) expanded protection of employee whistleblowers to include contractors and agents.

7. FERA also amended several FCA provisions to legislatively reverse Allison Engine Co. v. U.S. ex rel, Sanders, 553 U.S. 662 (2008), which rejected an FCA suit for fraud against a government contractor, and the broad theory that payment of federal money is enough to comprise a claim against the United States. Under the FERA amendments, a false claim can include a claim presented to a government contractor, such as a Medicare Advantage Plan or a Medicaid Managed Care Organization, and the plaintiff need not prove specific intent to defraud an agency or officer of the United States, or that the defendant specifically caused a false claim to be presented to a federal government employee for payment or approval.

8. It is generally accepted that, because Medicaid is jointly funded by the State and Federal governments, FCA liability attaches to fraudulent claims against State Medicaid agencies.203

9. The FCA establishes liability for any person making a fraudulent statement for the purpose of avoiding or decreasing an obligation to pay money to the government. This section of the statute is commonly referred to as the “reverse false claim” provision. FERA expanded the FCA’s “reverse false claim” provision by creating liability for persons who knowingly conceal the retention of an overpayment of government money. Accordingly, the FCA now prohibits making a fraudulent statement for the purpose of avoiding, decreasing or concealing an obligation to pay or refund money to the government.

201 See generally U.S. ex rel. Summer v. LHC Group Inc., 623 F.3d 287 (6th Cir. 2010), cert. denied.
10. The PPACA also added FCA liability for failing to timely report and return overpayments which creates a new category of FCA liability when combined with the “reverse false claims” provisions of the Act added by FERA.204 Under the new provision, overpayments must be returned by the later of either 60 days after the overpayment is identified or the date any corresponding cost report is due.205 A “person” includes a provider of services, supplier, Medicaid managed care organization, or PDP sponsor.206 Any overpayment that is not returned by the deadline becomes an FCA obligation.207

a. On February 16, 2012, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule (the “Proposed Rule”) implementing the statutory requirement of Section 6402(a) of the Affordable Care Act that providers and suppliers report and return overpayments from Medicare and Medicaid. The proposal imposes significant risks and burdens, including that providers and suppliers promptly investigate potential overpayments occurring within an extended, 10-year lookback period.

b. While the Proposed Rule applies only to Medicare Part A and Part B overpayments, CMS underscores that entities receiving other types of overpayments, such as from Medicaid and Medicare Advantage programs, are still subject to the underlying statutory requirement. Adhering to the Proposed Rule to the extent possible, moreover, would appear to be a reasonable means of resolving questions in dealing with Medicaid and Medicare Advantage overpayments as well.

c. The Proposed Rule sets forth a laundry list of thirteen items that must be included with the overpayment report. That list includes everything from the name of the reporting person, the reason for the overpayment, and the date of the service in question, to a description of the corrective action being taken to ensure that the error that led to the overpayment does not recur, a description of the statistically valid methodology used to determine any overpayment estimated through the use of statistical sampling, and a refund in the amount of the overpayment.

d. CMS makes clear that a report under the Proposed Rule, like a report under the OIG’s Self-Disclosure Protocol, is not a proper means of resolving an overpayment resulting from a violation of law, as opposed to from a simple payment error.

e. As to the all-important practical question of when a person has identified an overpayment and the 60-day clock starts to run, the Proposed Rule clarifies that this happens when the person has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the existence of the overpayment. To avoid potential liability for acting with reckless disregard or deliberate ignorance, moreover, a person must conduct a “reasonable inquiry” with “all deliberate speed” after receiving information – such as a tip from a compliance hotline – concerning a potential overpayment. The proposal furnishes several examples of when overpayments should be deemed to have been identified, including when a provider or supplier

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204 PPACA § 6402(d).
205 PPACA § 6402(d)(2).
206 PPACA § 6402(d)(4)(C).
207 PPACA § 6402(d)(3).
learns that a patient died prior to the date on which it billed for services provided to the patient, or when it verifies information from a government audit indicating that a potential overpayment exists.

f. The Proposed Rule also acknowledges potential overlapping obligations to report and return overpayments under Section 1128J(d), on the one hand, and under Medicare’s Self-Referral Disclosure Protocol (SRDP) and the OIG’s Self-Disclosure Protocol (SDP), on the other hand. Accordingly, CMS provides that a proper submission under the SRDP suspends the repayment deadline under Section 1128J(d), while such a submission under the SDP suspends both the repayment and reporting deadlines.

g. Enforcement

(1) The Proposed Rule has significant enforcement implications in at least two respects. First, and most fundamentally, it echoes the statutory language to the effect that retaining an overpayment beyond the applicable reporting deadline can lead to liability under the FCA. It also provides that a person that knows of and fails to report and return an overpayment in accordance with the rule may be liable under the Civil Monetary Penalties Law, and therefore excluded from participation in the Medicare and Medicaid programs.

(1) Second, the Proposed Rule requires that a person report and return any overpayment within 10 years of the date the overpayment was received. CMS explains that it has adopted this expansive lookback period because it is consistent with the outer limit of the FCA statute of limitations. It is not clear, however, that attempts to impose FCA liability for overpayments made prior to the March 23, 2010 enactment of the Affordable Care Act, which added Section 1128J(d) of the Social Security Act, will withstand judicial scrutiny. In U.S. ex rel Stone v. Omnicare, No. 09 C 4319, 2011 WL 2669659 (N.D. Ill. July 7, 2011), for example, a federal trial court dismissed counts alleging that the defendant had violated the FCA by retaining overpayments for services, on the ground that defendant submitted the claims for reimbursement at issue prior to the effective date of the amendments to the statute that first made the return of such overpayments “obligations” that could lead to FCA liability.

11. In the absence of an expressly factually false certification, a party can make a legally false certification by certifying more generally in a claim form that it has complied with certain conditions of law. See, e.g., Rodriguez v. Our Lady of Lourdes Med. Ctr., 552 F.3d 297, 303 (3d Cir. 2008), overruled in part on other grounds by U.S. ex rel. Einstein v.
City of New York, 129 S. Ct. 2230 (2009). Whether an FCA claim may be based on an “implied false certification” has been a recurring issue, where a party allegedly submits a claim in violation of a regulatory condition whose satisfaction is not an express condition of a claim for payment, and with which compliance is not expressly certified in a claim for payment. An “implied false certification” thus occurs when the submission of a claim for payment in itself implies that the party has complied with “federal rules that are a precondition to payment.”

Mikes v. Straus, 274 F.3d 687, 699 (2d Cir. 2001). These classifications of false claims, and the positions adopted by various circuits with regard to implied false claims, were reviewed in U.S. ex rel. Wilkins v. United Health Group, Inc., 2011 U.S. App. LEXIS 13322 (3d Cir. June 30, 2011). In Wilkins, the Third Circuit sided with several other Circuits that have adopted the “implied false certification” liability theory, but found the theory inapplicable on the facts where a health plan was alleged to have billed the program while violating certain Medicare Part D plan marketing guidelines. The guidelines in question were part of the plan’s general conditions of participation, the violation of which gave rise to specific remedies and sanctions, including an opportunity to care violations through the development of a corrective action plan. The Third Circuit concluded that violations of such general regulatory requirements did not render the plan’s invoices implied false claims.

C. Federal Criminal Provisions of Section 1128B of the Act (42 U.S.C. § 1320a-7b)

1. Prohibition of False Claims/False Statements -- Knowingly and willfully making or causing to be made any false statement or representation of material fact in any claim or application for benefits under federal health care programs. Examples of prohibited conduct include:

   (i) Billing for services not rendered.

   (ii) Misrepresenting the services actually rendered.

   (iii) Falsely certifying that certain services were medically necessary.

This provision also makes it a crime to perpetrate a fraud by concealing or failing to disclose occurrences (which themselves may not have been fraudulent) with the intent of securing the continued receipt of unauthorized benefits or payments. An example is the discovery, followed by concealment, of a data error resulting in an inflated Medicare nursing home base rate which continues in effect after the error is discovered. Penalties include imprisonment and fines of up to $10,000 or $25,000 depending on the specific violation.

2. Prohibition of False Statements to Obtain Certification -- Knowingly and willfully making or causing to be made, or inducting or causing to be induced, the making of any false statements of material facts with regard to an institution’s compliance with conditions of

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208 Wilkins also concluded that an AKS violation pre-dating the effective date of the PPACA amendments could support a FCA claim where the provider/plan had certified, legally, its compliance with the AKS – which the Third Circuit did regard as a condition of payment.

209 42 U.S.C. § 1320a-7b(a).
participation for the purposes of certification as a hospital, SNF, home health agency or other specified entity.\footnote{210}{42 U.S.C. § 1320a-7b(c).}

3. **Excessive Charges (Anti-Supplementation)**

   a. The Act criminalizes ($25,000, penalty and felony conviction of up to five years) knowingly and willfully charging a patient for any services in excess of the amount provided under a State Medicaid plan or a contract with a Medicaid managed care organization operating under Section 1903(m) of the Act.\footnote{211}{42 U.S.C. § 1320a-7b(d)(1).}

   b. The Act also criminalizes knowingly and willfully soliciting or accepting gifts, money or donations in excess of Medicaid program payments (other than charitable, religious or philanthropic contributions from an organization or person unrelated to the patient) as a condition of admitting or continuing the stay of a hospital patient or nursing home resident.\footnote{212}{42 U.S.C. § 1320a-7b(d)(2).}

4. **Assignment Prohibition -- Criminal liability also attaches to knowing, willful and repeated violations of the Act’s anti-assignment prohibitions.**\footnote{213}{42 U.S.C. § 1320a-7(b)(e).}

   Note: Under § 1320a-b(h) none of the above violations of section 1128B of the Act require actual knowledge of or specific intent to violate the applicable provision.

**VIII. Corporate Compliance Plan**

A. **Benefits of a Compliance Plan**

   A successful compliance program addresses the public and private sectors’ mutual goals of reducing fraud and abuse; enhancing health care providers’ operations; improving the quality of health care services; and reducing the overall cost of health care services. Attaining these goals benefits the hospital industry, the government, and patients alike. A hospital may gain important additional benefits by voluntarily implementing a compliance program, including:

   1. Demonstrating the hospital’s commitment to honest and responsible corporate conduct;

   2. Increasing the likelihood of preventing, identifying, and correcting unlawful and unethical behavior at an early stage;

   3. Encouraging employees to report potential problems to allow for appropriate internal inquiry and corrective action; and

   4. Through early detection and reporting, minimizing any financial loss to government and taxpayers, as well as any corresponding financial loss to the hospital.
The OIG recognizes that implementation of a compliance program may not entirely eliminate improper or unethical conduct from the operations of health care providers. However, an effective compliance program demonstrates a hospital’s good faith effort to comply with applicable statutes, regulations, and other Federal health care program requirements, and may significantly reduce the risk of unlawful conduct and corresponding sanctions.

B. Basic Elements of Compliance Plan -- The OIG compliance plan guidance is structured after the seven elements set forth in the Federal Sentencing Guidelines and includes the following elements:214

1. Designation of a corporate compliance officer and board compliance committee.

2. Development and implementation of policies and procedures, including standards of conduct that establish bright-line rules to ensure compliance with the federal healthcare program requirements.

3. Encouraging open communication, including utilizing anonymous hotline or similar mechanism, periodic newsletter, or intranet website.

4. Appropriate training and education of staff to ensure that staff are fully capable of executing his/her role in compliance with rules, regulations and other standards.

5. Internal monitoring and auditing of the organization to assess risk and compliance to avoid the submission of incorrect claims to the federal healthcare program.

6. Develop effective corrective action plans in response to detected deficiencies.

7. Enforcing disciplinary standards against those who have been determined to have violated the organization’s rules, regulations and standards of conduct.

C. Voluntary Disclosure

1. General -- In 1998, the OIG established a self-disclosure protocol (“SDP”) for healthcare providers.215 When a healthcare provider appropriately self-discloses potentially fraudulent conduct, the OIG takes the self-disclosure and the provider’s level of cooperation into account when determining the appropriate settlement terms. Specifically, the OIG will require less money to be paid in settlement for conduct that has been self-disclosed, timely, and in good faith. Furthermore, in self-disclosure cases, the OIG is more likely to settle without requiring integrity provisions or to require more limited integrity provisions. The OIG has noted that the presumption in favor of not requiring a compliance agreement appropriately recognizes the provider’s commitment to integrity and advances the OIG’s goal expediting the resolution of self-disclosures.

2. Purpose -- The SDP is intended to facilitate resolution of matters that potentially violate federal criminal law, civil law, or administrative laws for which exclusion or civil monetary penalties are authorized. Disclosures that are characterized as mere billing errors or overpayments are not appropriately addressed by the SDP and should be submitted directly by the provider to the appropriate claims-processing entity, such as the Medicare contractor.

3. Effective Disclosure -- The disclosure must be made in writing and must be submitted to the Assistant Inspector General for Investigative Operations, Office of Inspector General, Department of Health and Human Services, within a reasonable period, but not later than 60 days after determining that there is credible evidence of a violation. However, according to the OIG, some violations may be so serious that they warrant immediate notification to governmental authorities prior to, or simultaneous with commencing an internal investigation.

4. Assignment Prohibition -- As part of its participation in the disclosure process, the disclosing health care provider will be expected to conduct an internal investigation and a self-assessment, and then report its findings to the OIG. The internal review may occur after the initial disclosure of the matter. A voluntary disclosure report should demonstrate that a full examination of the practice has been conducted. The report should contain a written narrative that -

   a. Identifies the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or Government regulations);
   
   b. Describes the incident or practice in detail, including how the incident or practice arose and continued;
   
   c. Identifies the division, departments, branches or related entities involved and/or affected;
   
   d. Identifies the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed, with sufficient information to allow the OIG to assess the immediacy of the impact and risks, the steps that should be taken to address them, as well as the measures taken by the disclosing entity;
   
   e. Delineates the period during which the incident or practice occurred;
   
   f. Identifies the corporate officials, employees or agents who knew of, encouraged, or participated in, the incident or practice and any individuals who may have been involved in detecting the matter;
   
   g. Identifies the corporate officials, employees or agents who should have known of, but failed to detect, the incident or practice based on their job responsibilities; and
   
   h. Estimate the monetary impact of the incident or practice upon the Federal health care programs.
5. Minimum Initial Submission Requirements -- In An Open Letter to Health Care Providers\textsuperscript{216}, released on April 15, 2008, the Inspector General stated that the OIG has concluded that the initial submission under the SDP must contain the following information:

   a. a complete description of the conduct being disclosed;

   b. a description of the provider’s internal investigation or a commitment regarding when it will be completed;

   c. an estimate of the damages to the federal health care programs and the methodology used to calculate that figure or a commitment regarding when the provider will complete such estimate; and

   d. a statement of the laws potentially violated by the conduct.

6. Discovery and Response to the Matter -- The internal investigation report should relate the circumstances under which the disclosed matter was discovered and fully document the measures taken upon discovery to address the problem and prevent future abuses. In this regard, the report should -

   a. Describe how the incident or practice was identified, and the origin of the information that led to its discovery.

   b. Describe the entity’s efforts to investigate and document the incident or practice.

   c. Describe in detail the chronology of the investigative steps taken in connection with the entity's internal inquiry into the disclosed matter.

   d. Describe the actions by the health care provider to stop the inappropriate conduct.

   e. Describe any related health care businesses affected by the inappropriate conduct in which the health care provider is involved, all efforts by the health care provider to prevent a recurrence of the incident or practice in the affected division.

   f. Describe any disciplinary action taken against corporate officials, employees, and agents as a result of the disclosed matter.

   g. Describe appropriate notices, if applicable, provided to other Government agencies (e.g., Securities and Exchange Commission and Internal Revenue Service) in connection with the disclosed matter.

7. The internal investigation report must include a certification by the health care provider, to the best of the individual’s knowledge, the internal investigation report contains

\textsuperscript{216} See http://oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf.
truthful information and is based on a good faith effort to assist the OIG in its inquiry and verification of the disclosed matter.

Note: Self-reporting and repayment of overpayments was made obligatory by the PPACA, as discussed above.

D. PPACA Requirements

Under the PPACA, health care providers must develop and implement, as a condition of enrollment in Medicare, Medicaid and/or CHIP, compliance programs that satisfy requirements established by the Secretary of HHS pursuant to regulations issued in consultation with the OIG.\textsuperscript{217} Prior PPACA, a compliance program was only mandatory for certain categories of providers and for a health care provider that was operating under a corporate integrity agreement or had a contract with the federal government that exceeded five million dollars and lasted longer than 120 days.

IX. Corporate Integrity Agreements

The Office of Inspector General (OIG) often negotiates compliance obligations with health care providers and other entities as part of the settlement of federal health care program investigations arising under a variety of civil false claims statutes. A provider or entity consents to these obligations as part of the civil settlement and in exchange for the OIG’s agreement not to seek an exclusion of that health care provider or entity from participation in Medicare, Medicaid and other federal health care programs. False claims submitted in violation of the False Claims Act or Civil Monetary Penalties law, give rise to the OIG’s permissive exclusion authority under 42 U.S.C. 1320a-7(b)(7). Providers who settle these cases often deny that they were liable or that they committed the alleged conduct.

The typical term of a comprehensive corporate integrity agreement (CIA) is five years (three years for national project cases). These compliance measures seek to ensure the integrity of federal health care program claims submitted by the provider. The more comprehensive integrity agreements include requirements to:

1. Hire a compliance officer/appoint a compliance committee;
2. Develop written standards and policies;
3. Implement a comprehensive employee training program;
4. Review claims submitted to Federal health care programs;
5. Establish a confidential disclosure program;
6. Restrict employment of ineligible persons; and

\textsuperscript{217} PPACA § 6401(a). The Secretary solicited comments for purposes of implementing this requirement on September 20, 2010, 75 Fed. Reg. 5804.
7. Submit a variety of reports to the OIG.

In addition to CIAs, the OIG also may negotiate a Certification of Compliance Agreement (CCA) with health care providers and other entities, in lieu of a comprehensive CIA, under appropriate circumstances. The relevant considerations for whether an entity may be permitted to enter into a CCA, instead of a comprehensive CIA, include those set forth in the November 20, 2001 Open Letter to Health Care Providers. The terms of a CCA include a requirement that the entity maintain its existing compliance program, as described in a Declaration that is attached to the CCA. In addition, the entity is required to agree to certain compliance obligations that mirror those found in a comprehensive CIA, including reporting overpayments, reportable events, and ongoing investigations and legal proceedings to the OIG, and providing annual reports regarding the entity's compliance activities to the OIG during the term of the CCA.

X. Deferred Prosecution Agreements

Federal prosecutors have increasingly relied upon “deferred prosecution agreements” as a form of pre-trial diversion to exact corporate reforms, large-dollar restitution, and cooperation from companies under investigation. Deferred prosecution agreements give corporations a period of probation, during which time charges are held in abeyance, so that they can clean house and cooperate.

Under a deferred prosecution agreement, a corporation is given a period of time, usually 18 months to several years, during which the Justice Department will hold off on filing an indictment. In exchange, the corporation will acknowledge that the government can prove its case, will fully cooperate with the investigation of its culpable employees, and will enact Sarbanes-Oxley-style reforms relating to management, reporting requirements, and audit procedures. If the company can demonstrate reform at the end of the probationary period, the Justice Department will dismiss all charges.