

HEALTHCARE FRAUD AND ABUSE LAWS

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I. INTRODUCTION

For the providers, suppliers, manufacturers, payors and others who provide services or do business in the modern American health care industry, the risks and legal liabilities associated with the so-called “fraud and abuse” laws have become more and more pressing in recent years. During this period, these laws have become exponentially more complex and related enforcement efforts (both by the government and by private parties) have become more common-place and aggressive.

In general, when health care attorneys discuss “fraud and abuse” laws, they are referencing a group of federal and state civil and criminal laws, along with their related regulations and guidance. These laws address the following areas: remuneration in exchange for referrals or business generation; self-referrals; the submission of false claims; beneficiary inducement; and related civil monetary penalty provisions.

Despite the wide range of laws that implicate healthcare fraud and abuse, three federal laws account for the majority of fraud and abuse issues analyzed by health care attorneys: the Medicare Anti-kickback Statute, the Ethics in Patient Referrals Act (commonly known as the “Stark Law”), and the federal False Claims Act. For that reason these three laws receive more attention in this chapter than other related laws.

This chapter only provides an introduction to healthcare fraud and abuse laws. A moderately thorough analysis of any one of these laws alone could easily exceed the size of this entire chapter. Therefore, all topics are necessarily addressed in less than complete detail. The reader is strongly advised to consult the original reference materials cited in this chapter, as well as to speak with a qualified health care attorney, when attempting to analyze any specific healthcare fraud and abuse issue.

II. KICKBACKS AND ILLEGAL REMUNERATION: THE MEDICARE ANTI-KICKBACK STATUTE

A. In General

The Anti-kickback Statute (“AKS”)² is a criminal statute that prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. According to the OIG, the Anti-Kickback Statute was originally enacted in 1972 to protect patients and federal health care programs from fraud and abuse.

Specifically, the AKS provides that—

[W]hoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—(A) to refer an individual to a person for the furnishing or arranging for the

² 42 U.S.C. § 1320a-7b(b) (Section 1128B(b) of the Social Security Act).

*furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony*³

The AKS is an intent-based statute, but it has been broadly interpreted by the government and some courts. For example, it has been held that an agreement to make a referral is not required to establish a violation of the AKS.⁴ A violation of the AKS may occur when there is the existence of an arrangement intended to induce referrals of Medicare, Medicaid, or other federal program business. The term “induce,” as used in the AKS, means more than mere encouragement and is defined as “an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of [federal health care] business.”⁵ Courts have stated that, under certain circumstances, the AKS is violated when just *one purpose*, as opposed to the primary purpose, of a payment is to induce referrals.⁶ Actual payment is not required for a violation, just the solicitation of or offer to make payment or agreement to pay, coupled with the prohibited intent, is enough to constitute a violation.

Furthermore, the “Patient Protection and Affordable Care Act” of 2010, amended the intent provision of the AKS to state that “a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”⁷

A violation of the AKS constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both.⁸ In addition, where a party commits an act described in the AKS, the Office of the Inspector General of the Department of Health and Human Services (“OIG”)—the government agency charged with enforcing many of the federal government’s health care fraud and abuse laws, including the AKS—may initiate administrative proceedings to impose civil monetary penalties and to exclude the party from participation in the federal health care programs.⁹ Both parties to an impermissible kickback may be liable: the party offering or paying the kickback, as well

³ 42 U.S.C. § 1320a-7b(b)(2).

⁴ Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995).

⁵ Id. at 1398.

⁶ See, e.g., United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985).

⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010).

⁸ There are additional statutory provisions relating to criminal penalties of up to \$250,000 for each offense for individuals, and up to \$500,000 for each offense for a corporation. See 18 U.S.C. § 3571. There is precedent of courts using section 3571 in the sentencing process for defendants convicted of AKS violations. See United States v. Singhvi, No. 01 CR. 835 (RWS), 2006 WL 1062133 (S.D.N.Y. Apr. 20, 2006); United States v. Celestin, No. 03 CR. 0597 (RWS), 2004 WL 1348993 (S.D.N.Y. June 15, 2004); United States v. Skodnek, 933 F. Supp. 1108 (D. Mass. 1996).

⁹ See 42 U.S.C. § 1320a-7b(b)(1), (2); see also 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

as the party soliciting or receiving it.¹⁰ However, it is not necessary to find both parties liable in order to determine that one party is liable.

Because the AKS is so broad, Congress included several statutory exceptions. Furthermore, the OIG has adopted safe harbor regulations to specify certain acts or arrangements that will not be subject to prosecution under the AKS. The fact that an arrangement does not meet all the requirements of a safe harbor does not mean that the arrangement violates the AKS, but the arrangement would be subject to analysis of all its facts and circumstances to determine if it violated the Statute. In reviewing arrangements that do not fit a safe harbor, the OIG has indicated that it is particularly concerned about arrangements that:

- (1) result in over-utilization of the federal health care system and thereby increase costs to the federal programs;
- (2) skew clinical decision-making in favor of the donor of the remuneration;
- (3) decrease patient freedom of choice;
- (4) increase concerns about patient safety or care; or
- (5) create unfair competition.¹¹

Where an arrangement does not meet all of the requirements of a safe harbor, these factors should be evaluated to determine whether the arrangement presents an opportunity for conduct that would be of concern to the government. In addition, the OIG has issued many Advisory Opinions and other guidance documents identifying “safeguards,” or features of arrangements that the OIG believes would help to reduce the risk of fraud and abuse posed by the arrangements.

B. Key Definitions and Interpretations

1. **Remuneration.** In order for an arrangement to implicate the AKS, there must be “remuneration” (as defined in the Statute) either offered, solicited, or actually conveyed from one party to another in exchange for referrals of business under a federal health care program. For purposes of the AKS, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. As indicated above, according to one court’s interpretation, such remuneration is prohibited if even one purpose of the payment is to induce referrals, so that the presence of a legitimate business purpose for the arrangement is not dispositive of whether a violation of the Statute is present.¹² Thus, a threshold issue in any AKS analysis is

¹⁰ OIG Compliance Program Guidance for Ambulance Suppliers, 68 Fed. Reg. 14,245, 14,251 (Mar. 24, 2003).

¹¹ See, e.g., OIG Adv. Op. 98-3 (Apr. 6, 1998), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_3.pdf; see also OIG Adv. Op. 98-13 (Sept. 23, 1998), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_13.htm.

¹² Hanlester Network, 51 F.3d at 1398.

whether there is any remuneration between the parties that would trigger an application of the AKS prohibition.

2. “Knowingly and Willfully.” The AKS is an intent-based statute requiring the party “knowingly and willfully” engage in the prohibited conduct. Prior to the Patient Protection and Affordable Care Act (“PPACA”),¹³ a uniform standard for the definition did not exist across the circuits. PPACA clarified the ambiguity surround the intent requirement by adding a provision stating that actual knowledge of an AKS violation or specific intent to commit a violation of the AKS is not required for conviction under the statute. While the government must still prove that a defendant intended to violate the law, it no longer has to prove the defendant intended to violate the AKS itself. This amendment eliminates a great deal of the uncertainty regarding the requisite *scienter* needed to support a conviction under the Anti-Kickback Statute.

3. Inducement. To constitute a violation of the AKS, the conduct must rise to the level of an inducement. For a payment of remuneration to constitute an inducement for referrals, there must be a correlation between the payment and the desired conduct. *Hanlester Network v. Shalala*, the leading federal court case interpreting the inducement requirement, defined inducement somewhat narrowly. In holding that partnership profit distributions to physicians did not constitute an inducement for the physicians to refer laboratory tests to the partnership, where dividends were paid to limited partners based on each individual’s ownership share of profits and not on the volume of their referrals, the Hanlester court noted: “[T]he term ‘induce’ is not defined simply by reference to influence or encouragement.”¹⁴

Further, in order to constitute an inducement, the remuneration must be “sufficient to interfere with the [recipient’s] judgment based on legitimate considerations, such as cost, quality, and necessity of the services.”¹⁵ The “inducement” requirement has been described as requiring facts showing the use of “economic motivation in an effort to influence . . . referrals.”¹⁶ Significantly, defendants “‘cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes.’”¹⁷ Many other appellate court decisions confirm the need for a clear correlation between payments and referrals.¹⁸

¹³ Pub. L. No. 111-148, § 6402(f)(2), 124 Stat 119, 759 (2010).

¹⁴ *Hanlester Network*, 51 F.3d at 1398.

¹⁵ *Hanlester Network*, Decision No. 1275, 1991 WL 634852, at *33 (H.H.S. Dept. App. Bd.), Sept. 18, 1991).

¹⁶ *Hanlester Network*, Decision No. 1347, 1992 WL 685464, at *7 n.11 (H.H.S. Dep’t App. Bd., July 24, 1992).

¹⁷ *United States v. McClatchey*, 217 F.3d at 823, 834 (10th Cir. 2000) (emphasis omitted).

¹⁸ *Greber*, 760 F.2d 68; *Kats*, 871 F.2d 105; *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.* 874 F.2d 20 (1st Cir. 1989); *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996); *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998).

4. The “One Purpose” Rule. In *United States v. Greber*, the landmark case regarding the scope of the AKS, the U.S. Court of Appeals for the Third Circuit established the “one purpose” test. Under the “one purpose” test, “if one purpose of the payment was to induce future referrals, the medicare [sic] statute has been violated.”¹⁹ This test has also been adopted by the Fifth, Ninth, and Tenth Circuits.²⁰ In *United States v. Bay State Ambulance & Hospital Rental Service, Inc.*, the First Circuit stopped short of explicitly adopting the “one purpose” test, instead instructing the jury that the “primary purpose” must be improper in order to obtain a conviction under the Anti-Kickback Statute.²¹ The U.S. Supreme Court has not yet directly addressed the scope of the Anti-Kickback Statute.

5. Free Goods and Services. There is some guidance from the OIG on “free” goods and services. In a 1997 letter, the OIG clearly articulates its “view that the provision of free goods by a seller to an actual or potential referral source can violate the anti-kickback statute depending on the circumstances.”²² Further, the OIG explains what it views as suspect any “free good or service” by providing examples on both ends of the spectrum. In making this distinction, the OIG has discussed the practice of giving free computers to physicians. According to the OIG, in some situations, “it appears that the computer has no independent value [to the referral source] . . . and that the purpose of the free computer is not to induce an act prohibited by the statute,” whereas in other situations, “the computer has a definite value to the physician,” *e.g.*, because it is a “regular personal computer, which the physician is free to use for a variety of purposes,” “and, depending on the circumstances, may well constitute an illegal inducement.”²³ The OIG also often draws this distinction between suspect and non-suspect free goods or services in the context of laboratories’ provision of free phlebotomy services to physicians. Specifically, the OIG has stated: “While the mere placement of a laboratory employee in the physician’s office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist

¹⁹ *Greber*, 760 F.2d at 69 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985).

²⁰ *See United States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *Kats*, 871 F.2d 105; *McClatchey*, 217 F.3d 823.

²¹ 874 F.2d at 32.

²² OIG Letter, “Free Computers, Facsimile Machines and Other Goods” (July 3, 1997), [available at http://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm](http://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm); *see also* OIG Letter, “Free Prostate Biopsy Needles” (Aug. 4, 1997), [available at http://oig.hhs.gov/fraud/docs/safeharborregulations/freeneedles%20080497.htm](http://oig.hhs.gov/fraud/docs/safeharborregulations/freeneedles%20080497.htm).

²³ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,978 (July 29, 1991) (codified at 42 C.F.R. pt. 1001); *see also, e.g.*, OIG Letter, “Provision of Free Goods and Services” (July 1, 1997), [available at](http://oig.hhs.gov/fraud/docs/safeharborregulations/provision070197.htm)

<http://oig.hhs.gov/fraud/docs/safeharborregulations/provision070197.htm>; *Fourth in a Series on Health Care Information Technology: Hearing before the Subcomm. on Health of the H. Comm. on Ways and Means*, 109th Cong. 16-21 (2006) (statement of Lewis Morris, Chief Counsel to the Inspector Gen., U.S. Dep’t of Health & Human Servs.), [available at http://purl.access.gpo.gov/GPO/LPS7932](http://purl.access.gpo.gov/GPO/LPS7932) [hereinafter Morris Hearing Testimony].

performs additional tasks that are normally the responsibility of the physician's office staff.”²⁴

When discussing each of these examples, the OIG raises anti-kickback concerns in the situations in which the goods or services provided to the referral source are any of the following:

- (1) goods or services that provide a “tangible benefit” or “financial benefit” to the referral source²⁵;
- (2) “any gift to a referral source that has independent value to such source”²⁶;
- (3) “services that the recipient would otherwise be obligated to provide”²⁷
- (4) “services and supplies for which the [referral source] would otherwise be obligated to incur costs”²⁸; or
- (5) services that will “substitute for services currently provided by [the referral sources] at their own expense.”²⁹

Similarly, in a broader discussion of the risks posed by the provision of free goods and services to referral sources, the OIG has stated:

*In our enforcement experience, arrangements that result in avoided overhead expenses (such as, free support staff, free rent or equipment, or reduced administrative expenses) can form the basis of a kickback. These arrangements provide a clear economic benefit to the recipient in the form of savings.*³⁰

It is worthy of note that in virtually all of the situations reviewed by the OIG involving free goods and services, the free items were given directly to the potential referral source by the party that stood to benefit from the referrals. In other words the

²⁴ Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994); see also, e.g., OIG Adv. Op. 98-16 (Nov. 3, 1998), available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_16.htm; OIG Letter, “Free Services Performed by Clinical Laboratories” (Oct. 2, 1997), available at <http://oig.hhs.gov/fraud/docs/safeharborregulations/freelabs100297.htm>.

²⁵ OIG Adv. Op. 98-16; OIG Adv. Op. 04-16, at 4,5 (Nov. 18, 2004), available at [http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao\)416.pdf](http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/ao)416.pdf); OIG Adv. Op. 08-06, at 5 (May 2, 2008), available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-06.pdf>.

²⁶ OIG Letter, “Free Prostate Biopsy Needles.”

²⁷ OIG Letter, “Free Services Performed by Clinical Laboratories.”

²⁸ OIG Adv. Op. 04-16, at 5; see also OIG Adv. Op. 08-06, at 5.

²⁹ OIG Adv. Op. 04-16, at 4; OIG Adv. Op. 08-06, at 5; see also OIG Adv. Op. 98-16.

³⁰ See Morris Hearing Testimony, *supra* note 23, at 19.

“gift” was given in a scenario in which it could be seen as a *quid pro quo* for the referrals. However, since the AKS contains the words “directly or indirectly,” it would appear that the Statute could reach beyond the direct gift scenario.

6. Federal Health Care Program. “Federal health care program” is defined as “(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the [Federal employee health benefits program]); or (2) any State health care program”³¹ Thus, federal health care programs include Medicare, Medicaid, other state health care programs, and TRICARE/CHAMPUS, Veterans, and the Public Health Service programs,³² but do not include private insurance programs that do not receive any federal funds.

C. Statutory Safe Harbors

Given the breadth of the AKS and the wide variety of payments that could potentially fall within its purview, Congress enacted ten safe harbors within the AKS itself to permit the following payments to continue.

1. Discounts or Other Reductions. Discounts that Federal health care programs provide to health care providers are exempt from the AKS so long as the providers disclose the receipt of these discounts and accurately account for them when submitting claims for reimbursement from Federal health care programs.³³

2. Employment Relationships. The AKS will not apply to payments from an employer to an employee in consideration for the employee’s provision of items or services that are understood to be part of the bona fide employment relationship.³⁴

3. Payments from Vendors to Purchasing Agents. Vendors of goods or services may be permitted to give monetary inducements to individuals making purchases on behalf of service providers that are eligible for Federal health care program reimbursements. However, to qualify, the purchasing individual must have a written contract with all individuals and entity service providers specifying the amount the purchaser will receive in exchange for purchasing the goods or services. The AKS permits this amount to either be “a fixed amount or a fixed percentage of the value of the purchases.” Furthermore, should the purchaser have a written contract with an entity that provides services, the purchaser must disclose to the entity, and to the Secretary of the

³¹ 42 U.S.C. § 1320a-7b(f); see also 42 C.F.R. § 1001.2.

³² See Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From the Health Insurance Portability and Accountability Act of 1996, 63 Fed. Reg. 14,393, 14,394 (proposed Mar. 25, 1998) (to be codified at 42 C.F.R. pts. 1003, 1005 and 1006).

³³ 42 U.S.C. § 1320a-7b(3)(A).

³⁴ 42 U.S.C. § 1320a-7b(3)(B).

Department of Health and Human Services (HHS) upon request, the amount received from each vendor for purchases made on behalf of the entity.³⁵

4. Waiver of Coinsurance. Federally qualified health care centers are permitted to waive coinsurance for individuals who qualify for subsidized services under the Public Health Act³⁶ without violating the AKS.³⁷

5. Payment Practices that the Secretary of HHS Specifies. Any payment practices that the Secretary of HHS specifies in regulations promulgated pursuant to (1) Section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or (2) under the electronic prescription program set forth in 42 U.S.C. §1395w-104(e)(6) are exempt from the AKS.³⁸

6. Risk Sharing or Eligible Organization. The AKS exempts from its purview remuneration between an organization and individuals or entities providing goods, services, or a combination thereof, provided there is a written agreement memorializing the provision of services. A written agreement, however, is insufficient to qualify for this safe harbor. Rather, (1) the organization must qualify as an eligible organization³⁹ or (2) “the written agreement [must], through a risk-sharing arrangement, place the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof.”⁴⁰

7. Pharmacy Waiver. Pharmacies who waive or reduce cost-sharing amounts “imposed under part D of subchapter 18 of this chapter” will not be in violation of the AKS so long as (1) the waiver is not made pursuant to an advertisement or solicitation, (2) the pharmacy authorizing the waiver does not typically waive coinsurance or deductible amounts and (3) the pharmacy (i) authorizes the waiver only after making a good faith determination that the individual is in financial need or (ii) is unable to recover the coinsurance or deductible amount despite making a good faith effort to collect.⁴¹

8. Remuneration Between a Federally Qualified Health Center and an MA Organization. “Any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization” will not violate the AKS provided that a written agreement exists between the two parties specifying that the health center will provide such services to individuals who are enrolled in the MA organization’s plan.

³⁵ 42 U.S.C. § 1320a-7b(3)(C).

³⁶ 42 U.S.C. § 201.

³⁷ 42 U.S.C. § 1320a-7b(3)(D).

³⁸ 42 U.S.C. § 1320a-7b(3)(E).

³⁹ Eligible organization, as it pertains to this safe harbor, is defined in 42 U.S.C. § 1395mm.

⁴⁰ 42 U.S.C. § 1320a-7b(3)(F).

⁴¹ 42 U.S.C. § 1320a-7b(3)(G).

9. Remunerations Between Health Centers and Service Providers. “Any remuneration between a health center⁴² entity and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health enter entity pursuant to a contract, lease, grant, loan, or other agreement” will not violate the AKS provided that this agreement aids the health center’s ability to “maintain or increase the availability, or enhance the quality, of services provided to the medically underserved population.”

10. Applicable Drugs and Applicable Beneficiaries. Any discounts given on applicable drugs⁴³ to an applicable beneficiary⁴⁴ under the Medicare coverage gap discount program will not constitute remuneration.⁴⁵

D. Regulatory Safe Harbors

The language of the original Anti-Kickback Statute contained specific exceptions to the law for certain discounts, payments to an employee, payments to group purchasing organizations, and waivers of Medicare Part B co-insurance.⁴⁶

To ensure that certain acts or arrangements will not be subject to prosecution under the AKS, the OIG has adopted safe harbor regulations. If an arrangement meets all of the requirements of a safe harbor, the entities involved are assumed to be in compliance and generally will not be prosecuted or sanctioned under the AKS. Merely coming close to the requirements does not protect an arrangement.⁴⁷ If an arrangement has multiple compensation components, then each component must meet the requirements of an applicable Safe Harbor for the arrangement to receive Safe Harbor protection.⁴⁸

The fact that an arrangement does not meet all of the requirements of a safe harbor does not necessarily mean that the arrangement is illegal or will be prosecuted under the AKS. Rather, the government will look at the facts and circumstances of the arrangement on a case-by-case basis to determine whether a violation has occurred.

⁴² Health center as it pertains to this section is defined in 42 U.S.C. § 1396d(1)(2)(B)(i)-(ii).

⁴³ 42 U.S.C. § 1395w-114a(g)(1).

⁴⁴ 42 USC § 1395w-144a(g)(2).

⁴⁵ 42 U.S.C. § 1320a-7b(3)(J).

⁴⁶ 42 U.S.C. § 1320a-7b(b)(3)(A)-(D).

⁴⁷ Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954. (July 29, 1991)(“If a person participates in an arrangement that fully complies with a given [Safe Harbor] provision, he or she will be assured of not being prosecuted criminally or civilly for the arrangement that is the subject of that provision.”); see also Bay State Ambulance, 874 F.2d at 31 (substantial compliance with propose Safe Harbor not sufficient for protection under Safe Harbor). But see 56 Fed. Reg. at 35,954 (“Certainly, in many (but not necessarily all) instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor, but for reasons beyond their control are not in compliance with the terms of that safe harbor.”).

⁴⁸ 56 Fed. Reg. at 35,957.

1. Investment Interests. The AKS regulations include a safe harbor that protects certain investment interests in health care entities. Indeed, payments that constitute returns on investment interests are exempt from the AKS definition of remuneration under these safe harbors if they fall into one of the following three categories and meet all applicable standards for that category: (1) the Large Investment Safe Harbor, (2) the Small Investment Safe Harbor and (3) the Safe Harbor for Entities in Rural Areas.

(a) *Large Investment Safe Harbor.* The Large Investment Safe Harbor⁴⁹ is available to entities that have possessed more than \$50 million in undepreciated net tangible assets within the last fiscal year or 12-month period, provided that these entities comply with the following five requirements. First, if the entity offers investment interests in the form of equity securities, these securities must be registered with the Securities and Exchange Commission pursuant to 15 U.S.C. § 781(b) or (g). Second, if an investor is in a position to make or influence referrals, furnish items or services, or otherwise generate business for the entity, the investment interest must be offered at the same price as those interests trading on a registered securities exchange. Third, the entity and its investors must market the entity's items or services to non-investors just as they would to investors. Fourth, neither the entity nor any investor can lend funds to or guarantee a loan to acquire interests in the entity for an investor who is in a position to make or influence referrals or generate business for the entity. Finally, the sum of the payment made on an investment interest must be directly proportional to the investor's initial capital investment in the entity.

(b) *Small Investment Safe Harbor.* To qualify for the Small Investment Safe Harbor,⁵⁰ no more than 40 percent of all investment interests in an entity can have been held in the previous fiscal year or 12-month period by investors who are in a position to make or influence referrals to the entity. Furthermore, no more than 40 percent of the gross revenue of the entity in the previous fiscal year or previous 12-month period may have come from referrals or business otherwise generated from investors.

Once these threshold requirements are met, the entity must comply with the following six requirements. First, the terms of an investment interest offered to a passive investor who is in a position to make or influence referrals must be no different from the terms offered to other passive investors. Second, the terms of an investment interest offered to an investor who is in a position to make or influence referrals must not be related to the previous or expected volume of referrals from that investor to the entity. Third, no investor can be required to make referrals to the entity as a condition for remaining as an investor. Fourth, the entity must not market the entity's services to investors differently than to non-investors. Fifth, neither the entity nor any investor may lend funds to or guarantee a loan to acquire interests in the entity for an investor who is in a position to make or influence referrals or generate business for the entity. Finally, the

⁴⁹ 42 C.F.R. § 1001.952(a)(1).

⁵⁰ 42 C.F.R. § 1001.952(a)(2).

amount of payment to an investor in return for the investment interest must be proportional to the amount of capital investment (including the fair market value of any pre-operational services rendered) of that investor.

(c) *Safe Harbor for Entities in Rural Areas.* The only entities that qualify for this safe harbor⁵¹ are those located in underserved areas. These entities must generate at least 75 percent of the dollar volume of their business within the last fiscal year or 12-month period from residents of these underserved areas or members of medically underserved populations (“MUPs”). Furthermore, payments made on investment interests will only be exempt from the AKS definition of remuneration if no more than 50 percent of the value of the investment interests of each class of investments has been held in the previous fiscal year or 12-month period by investors in a position to make referrals, provide items or services, or otherwise generate business for the entity. Restricting the influence investors with referral power have is a continuing theme in this safe harbor, as it explicitly prohibits entities from varying the terms of the investment interests that investors hold on the basis of their referral-making capacity. Indeed, investors may not be required to make referrals or otherwise be in a position to induce or generate business for the entity. They must use their own money, not money obtained via loans from the entity or other investors, to invest in the entity. The return on their investment interest will be directly proportional to the amount of their capital investment. The investors (and the entity) are prohibited from marketing the entity’s items or services to investors differently than to non-investors.

2. Space Rental. Under the space lease safe harbor,⁵² “remuneration” does not include any payment made by a lessee to a lessor for the use of premises. To qualify, however, the lease must be memorialized in a writing signed by both parties that specifies the premises to be rented for a minimum of one year at a rate that reflects fair market value. The rate cannot consider the volume or value of any referrals or business otherwise generated between the parties. Finally, if the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease must specify exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.

3. Equipment Rental. The Equipment Rental Safe Harbor⁵³ provides that “remuneration” does not include any payment made by a lessee of equipment to the lessor of the equipment, provided that the agreement is set forth in a writing both parties have signed that specifies the equipment to be leased for a minimum of one year. The equipment to be leased must not exceed the amount of equipment reasonably necessary to achieve the purpose of the lease. Furthermore, the aggregate rental rate specified in the written agreement must be consistent with the fair market value and cannot reflect the volume or value of any referrals or business otherwise generated between the parties for which the federal government will pay. If the lease is intended to provide the lessee with

⁵¹ 42 C.F.R. § 1001.952(a)(3).

⁵² 42 C.F.R. § 1001.952(b).

⁵³ 42 C.F.R. § 1001.952(c).

use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.

4. Personal Services and Management Contracts. The personal services and management contracts safe harbor⁵⁴ protects payments made for personal services if the agreement is set forth in a signed writing that covers all services the contractor is to provide. The aggregate services cannot exceed the amount reasonably necessary to accomplish the purpose motivating the procurement of these services. The writing must also specify a previously agreed upon aggregate compensation rate that is consistent with the fair market value for these services, and not based on the volume or value of referrals generated between the parties. If the services are part-time or sporadic, the specific times of performance are clearly identified. Finally, the services do not involve promotion of an arrangement that violates any State or Federal Law.

5. Sale of Practice. The Sale of Practice safe harbor⁵⁵ permits the sale of a medical practice to (1) a medical practitioner or (2) hospital or other entity. Indeed, under this safe harbor, payments made to complete the transaction are exempt from the AKS definition of remuneration if the sale satisfies certain conditions. These conditions vary depending on whether the purchaser is another medical practitioner or is instead a hospital or other entity.

If the purchaser is another medical practitioner, the period of time between the date of the first agreement made with respect to the sale and the completion of the sale must not exceed one year. In addition, the practitioner who is selling his or her practice will not be in a professional position to make referrals to, or otherwise generate business for, the purchasing practitioner for which payment may be made in whole or in part under Medicare or a State health care program after one year from the date of the first agreement pertaining to the sale.

If the purchaser is a hospital or other entity, however, only practices that are located in a Health Professional Shortage Area (“HPSA”), which the Health Resources and Services Administration (“HRSA”) has designated as having a geographic, demographic or institutional shortage of primary medical, dental or mental health care providers,⁵⁶ are eligible for protection under the safe harbor. While completing the purchase, the hospital must (1) engage in commercially reasonable recruitment activities to secure a new practitioner to lead the acquired practice within one year of the purchase and (2) meet the conditions of the Practitioner Recruitment safe harbor discussed in paragraph (n) below. Ultimately, in order to satisfy the safe harbor requirements, purchase of these practices must be completed within three years, at which point the

⁵⁴ 42 C.F.R. § 1001.952(d).

⁵⁵ 42 C.F.R. § 1001.952(e).

⁵⁶ *Find Shortage Areas: HPSA by State & County*, U.S. Dep’t of Health & Human Servs. Health Res. & Servs. Admin. <http://hpsafind.hrsa.gov/> (last visited Oct. 23, 2013).

selling practitioner cannot make or generate referrals for the purchasing hospital that will qualify for federal government reimbursement.

6. Referral Services. Referral services that receive payment or anything of value in exchange for providing referrals may operate without implicating the AKS definition of remuneration provided they treat all participants and patients seeking referrals equally and meet the other requirements of the safe harbor.⁵⁷ Indeed, with respect to participants, this safe harbor requires that all individuals or entities who qualify for participation be permitted to participate and that the service levy equal fees for all participants based solely on the service's operating costs, not the volume or value of past or expected referrals. Furthermore, the referral service must make the following five disclosures to each person seeking a referral from the service and maintain a written record signed either by the person seeking a referral or the individual making the disclosure on behalf of the referral service certifying that such disclosures have been made:

- The manner in which the referral service selects its participants;
- Whether the participant has paid a fee to the referral service;
- The manner in which the referral service selects a particular participant for the individual seeking a referral;
- The nature of the relationship between the referral service and the group of participants to whom it could make the referral; and
- The nature of any restrictions that would exclude such individual from continuing as a participant of the referral service.

Once referrals have been made, the referral service will not control how the participant provides services to patients the service refers. It may, however, require the participant to charge the referred patient (1) the same rate as it would a patient not referred by the referral service, (2) a reduced rate or (3) free of charge.

7. Warranties. Under the Warranties safe harbor,⁵⁸ if a manufacturer or supplier of an item makes a payment or gives an item of value to the buyer of that item pursuant to a warranty, that payment or transfer will not constitute remuneration provided the buyer complies with two standards and the manufacturer or supplier complies with two standards. However, even if both parties comply with these standards, payments made for any medical, surgical, or hospital expenses that the beneficiary incurs are strictly prohibited.

(a) *The buyer's standards.* The buyer must fully and accurately report any reimbursement or receipt of a free item that he or she obtains

⁵⁷ 42 C.F.R. § 1001.952(f).

⁵⁸ 42 C.F.R. § 1001.952(g).

pursuant to the seller's warranty. This report should be made in the applicable cost reporting mechanism or claim for payment filed with the Department of Health and Human Services ("HHS") or a state agency. In addition, the buyer must, upon request from the Secretary of HHS ("Secretary") or a state agency, provide any information the buyer receives from the manufacturer pursuant to the manufacturer's obligations below.

(b) *The seller's standards.* The manufacturer must fully and accurately report any reimbursement or free item it gives to a buyer pursuant to the warranty on the accompanying invoice or statement submitted to the buyer. Furthermore, it must inform the buyer of its reporting obligations, described above.⁵⁹ Should the terms of the warranty pertaining to the amount of the price reduction be undetermined at the time of sale, the manufacturer must note the existence of the warranty on the invoice, inform the buyer of its obligations, and subsequently provide the buyer with documentation describing the calculation of the price reduction under the terms of the warranty.

8. Discounts. The Discount Safe Harbor⁶⁰ exempts from the definition of remuneration those discounts on items or services for which the federal government may pay either fully or in part under Medicare, Medicaid, or another federal health care program. "Discount" refers to either (1) the lowering of the amount the buyer must pay upfront for an item or service that is determined on the basis of an arms-length transaction or (2) a rebate, which is an amount that is described in writing at the time of purchase but is paid at a later date. The safe harbor specifically excludes the following from the definition of discount:

- Cash payments or cash equivalents (except rebate checks);
- Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal Programs using the same methodology and the reduced charge is fully and appropriately disclosed to the Federal Programs;
- A reduction in price applicable to one payer, but not to Medicare, Medicaid, or other Federal Programs;
- A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary;
- Warranties;

⁵⁹ The statutory language in 42 C.F.R. § 1001.952(g)(3) require the manufacturer to inform the buyer of its obligations as listed "under paragraphs (a)(1) and (a)(2)." Paragraphs (a)(1) and (a)(2), however, pertain to Investment Interests and do not discuss any obligations the buyer may have under any scenario, including under warranties. The authors therefore presume that Congress intended for the manufacturer to inform the buyer of those obligations listed in paragraphs (g)(1) and (g)(2).

⁶⁰ 42 C.F.R. § 1001.952(h).

- Services provided in accordance with a personal or management services contract;⁶¹ or
- Other remuneration, in cash or in kind not explicitly described by the Safe Harbor.⁶²

(a) *Buyers, Sellers and Offerors.* This safe harbor applies to three types of parties to the sale: (1) buyers, (2) sellers and (3) offerors. Each category has a separate list of requirements that must be met in order for this safe harbor to apply.

Buyers

The Discount Safe Harbor envisions three types of “buyers” – (1) an entity that is a health maintenance organization (“HMO”) or competitive medical plan (“CMP”), (2) an entity that reports its costs on a cost report required by DHHS or a state health care program and (3) an individual or entity in whose name a claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid, or other Federal Programs.

Sellers

A “seller” refers to “an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare, Medicaid or other Federal health care programs to the buyer and who permits a discount to be taken off the buyer’s purchase price.”⁶³

Offerors

Finally, an “offeror” is an individual or entity who is not a “seller” as defined under the Discount Safe Harbor, but promotes the purchase of an item or service by a buyer.

(b) *Discount Arrangements that Qualify for this Safe Harbor.* The AKS provides both a statutory and regulatory safe harbor for discounts; the statutory safe harbor is much easier to satisfy than the regulatory safe harbor.

Simple Price Reductions

The simplest discount is a price reduction given on a single good or service or a volume discount given on the purchase of a specified volume of goods or services. To qualify for this discount, the seller must meet several basic disclosure requirements of the Discount Safe Harbor, depending on the type of buyer. For a Health Maintenance

⁶¹ But note that there is a separate safe harbor for personal services and management contracts. 42 C.F.R. § 1001.952(d).

⁶² 42 C.F.R. § 1001.952(h)(5).

⁶³ 42 C.F.R. § 1001.952(h)(2).

Organization (HMO) or Competitive Medical Plan (CMP) buyer, no disclosure or report of the discount is required. However, for cost-reporting buyers and buyers of all other types, the seller must fully and accurately report the discount on the invoice, coupon or other statement submitted to the buyer. Furthermore, the seller must inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report the discount and to provide information upon request by the Secretary of DHHS or a state agency. Finally, the seller must refrain from doing anything that would impede the buyer from meeting its obligations under this safe harbor

With a sale of a single item or single shipment of the same item at a discount, the seller should disclose the discount clearly on the invoice, coupon, or statement submitted to the buyer for the item. This disclosure can be made either in the form of an explanation of the computation that led to the discount (i.e., list price less discount yielding actual price) or it can merely state the actual price after application of the discount.

Rebates

To be eligible for Discount Safe Harbor protection, a rebate must be a specific and fixed arrangement that is disclosed in writing to the buyer at the time of the initial sale transaction and is refunded to the purchaser at a later date in the form of a check, not cash or a cash equivalent. A rebate can generally be earned over any period of time and can be paid or refunded at any time. However, cost-reporting buyers have time restrictions imposed upon them. Indeed, these buyers (1) may only earn rebates on purchases of the same good or service bought within a single fiscal year and (2) must claim the rebate within either the same fiscal year in which it is earned or the following year.

Sellers must also comply with specific requirements when disclosing a rebate arrangement. For all buyers except for cost-reporting buyers, these requirements mirror those required for a simple discount. For a buyer that files cost reports, however, in addition to informing the buyer of its obligations to report the discount and refraining from impeding the buyer from reporting appropriately, the seller must also (1) fully and accurately disclose the existence of a discount program on the invoice, coupon or statement submitted to the buyer and (2) when the value of the rebate becomes known, provide the buyer with documentation of the calculation of the rebate identifying the items to which the rebate will be applied.

9. Employees. Payments an employer makes to an employee pursuant to a *bona fide* employment agreement do not constitute “remuneration,” even if payment for the item or service the employee provides may be made in whole or in part under Medicare, Medicaid, or other federal health care programs.⁶⁴

10. Group Purchasing Organizations. A Group Purchasing Organization (“GPO”) is an entity that is authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be

⁶⁴ 42 C.F.R. § 1001.952(i).

made in whole or in part under Medicare, Medicaid or other federal health care programs. To satisfy the definition in the safe harbor, these entities cannot be wholly-owned by the GPO or subsidiaries of a parent corporation that wholly owns the GPO. The term vendor is undefined in the regulation, but it appears from the context of the GPO Safe Harbor that it means an entity that sells products or services to the members of the GPO.

For an arrangement to qualify for this safe harbor,⁶⁵ the GPO must have a written agreement with each individual or entity for which items or services are furnished that specifies that vendor fees paid to the GPO are (1) limited to 3% or less of the purchase price of goods or services provided by the vendor to the buyer or (2) limited to another amount specified in the agreement (which may either be a fixed sum or fixed percentage of the value of purchases made from the vendor by the GPO members). Furthermore, if the entity receiving the goods is a health care company, the GPO must disclose to its members annually (and to the Secretary of the Department of Health and Human Services upon request) the actual amount received from each vendor with respect to purchases made by or on behalf of the member.

11. Waiver of Beneficiary Coinsurance and Deductible Amounts. This safe harbor⁶⁶ exempts from the AKS definition of remuneration any reduction or waiver of the coinsurance or deductible amounts a beneficiary of a Medicare or state health care program is obliged to pay, subject to the additional requirements of the safe harbor. The standards that must be met to qualify for this safe harbor vary based on whether the health care provider is (1) a hospital providing inpatient services or (2) a federally qualified health center or other health care facility under any Public Health Services Act grant program or under Title V of the Social Security Act.

When hospitals that provide inpatient hospital services for which Medicare pays under the prospective payment system are the recipients of coinsurance and/or deductible amounts, they cannot shift the burden to Medicare, a state health care program, other payers or individuals by claiming the reduced or waived amount as bad debt. Furthermore, when offering to reduce or waive the coinsurance or deductible amounts they may not consider the reason for admission, the length of the beneficiary's stay or the diagnostic related group (DRG) for which Medicare reimbursement will be filed. Finally, the hospital's offer to waive or reduce coinsurance or deductible amounts cannot be part of a broader price reduction agreement between the hospital and a third party payor unless the agreement is part of a contract to provide items or services to a beneficiary of a Medicare supplemental policy.

When the recipient of the coinsurance or deductible amount is a federally qualified health center or other health care facility under any Public Health Services Act grant program or under title V of the Social Security Act, that recipient is permitted to reduce or waive the amounts for items or services for which payment will be made in whole or in part under Medicare Part B or a state health care program. The person paying

⁶⁵ 42 C.F.R. § 1001.952(j).

⁶⁶ 42 C.F.R. § 1001.952(k).

these amounts, however, must be an individual who qualifies for subsidized services under a provision of the Public Health Services Act or titles V or XIX of the Social Security Act.

12. Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans. Under certain circumstances, a health plan's offer to provide an enrollee with additional coverage for its items or services or reduce the cost-sharing amount the enrollee is required to pay (including coinsurance, deductible, or copayment amounts) will not constitute remuneration under the AKS.⁶⁷ This exemption, however, only applies to health plans that comply with all of the standards in one of two categories.

A health plan that is a (1) risk-based health maintenance organization, (2) competitive medical plan, (3) prepaid health plan or (4) other health plan under contract with Centers for Medicare & Medicaid Services ("CMS") or a state health care program operating pursuant to § 1876(g) or § 1903(m) of the Act, under a federal statutory demonstration authority, or under other federal statutory or regulatory authority must extend its offer of increased coverage or reduced cost-sharing or premium amounts to all Medicare or state health care plan enrollees. These plans are only permitted to make such offers to some enrollees and not others after obtaining approval from CMS or the appropriate state health care program.

A health plan that is a (1) health maintenance organization, (2) competitive medical plan, (3) prepaid health plan or (4) other health plan that has a contract with CMS or a state health care program to be paid for enrollees on a reasonable cost or similar basis must extend any offer to increase coverage or reduce cost-sharing or premium amounts to all Medicare or state health care program enrollees whose care falls within the contract's purview. CMS or the applicable state health care program is required to approve any extensions of such offers that are limited to only some enrollees. Furthermore, the costs these plans incur cannot be claimed as bad debt for Medicare or state health care program reimbursement purposes, nor may the plans submit claims to Medicare or a state health care program for increased payments to cover the costs of offering increased coverage or reduced cost-sharing or premium amounts.

13. Price Reductions Offered to Health Plans. This safe harbor protects certain price reductions between health care providers and health care plans for covered items and services provided to Federal healthcare program beneficiaries (e.g., marketing services would not be eligible for safe harbor protection).⁶⁸ The safe harbor requirements vary, depending on whether the plan is holds risk-based or cost-based contracts with Federal healthcare programs. In both cases, however, neither the provider nor the plan may submit a separate claim to the Federal healthcare program for the covered items and services. The safe harbor also provides protection for plans that do not hold a contract with Federal healthcare programs, but the requirements are much more

⁶⁷ 42 C.F.R. § 1001.952(l).

⁶⁸ 42 C.F.R. § 1001.952(m).

restrictive than for plans that hold contracts with Federal healthcare programs. Notably, risk-sharing arrangements are not protected under this safe harbor provision.

14. Practitioner Recruitment. Payments or exchanges of value from an “entity” used to induce practitioners to locate or relocate to a practice in a HPSA will not constitute remuneration under the AKS if the parties enter into a written agreement that specifies the benefits to be provided and a term that is not more than three years, along with other specified requirements.⁶⁹ Indeed, the purpose of this safe harbor appears to be improving access to medical care in underserved areas. Therefore, 75 percent of the new practice’s revenues must come from patients who reside in a HPSA, Medically Underserved Area (MUA) or belong to a Medically Underserved Population (MUP). Furthermore, if the practitioner is leaving an established practice, the recruiting practice must generate at least 75 percent of its revenues from patients the practitioner did not previously see at the old practice. Finally, the recruited practitioner may not discriminate against patients who receive medical benefits or assistance from any federal health care program.

The safe harbor bars the recruiting entity from determining the value of the benefits to be given on the basis of the volume or value of the practitioner’s expected referrals. Indeed, the practitioner may not be required to make referrals to or otherwise generate business for the entity as a condition for receiving the benefits, and the practitioner must be allowed to make referrals to and establish staff privileges at any other entity. Furthermore, the payments may not directly or indirectly benefit any person other than the practitioner being recruited.

15. Obstetrical Malpractice Insurance Subsidies. Hospital payments made to secure malpractice insurance on behalf of a practitioner (including a certified nurse-midwife) who routinely practices obstetrics in a primary care HPSA are exempt from the AKS definition of remuneration if certain conditions are met.⁷⁰ Under this safe harbor, which is available only if a written agreement exists between the hospital making payments and the practitioner, the insurance secured must be a *bona fide* malpractice insurance policy whose premiums are calculated solely on the basis of the practitioner’s liability risk. Therefore, the amount of each payment cannot vary according to the volume or value of previous or expected referrals or business the practitioner otherwise generates for the hospital for which Medicare, Medicaid or other federal health care programs will pay either in whole or in part. Indeed, pursuant to agreements that qualify for this safe harbor, practitioners may not be required to refer patients to or otherwise generate business for the hospital. They must be permitted to refer patients and generate business for any other entity and allowed to establish staff privileges at other hospitals if they wish.

There are two requirements the safe harbor places on practitioners. First, the practitioner must certify that for the initial coverage period (a maximum of one year), he

⁶⁹ 42 C.F.R. § 1001.952(n).

⁷⁰ 42 C.F.R. § 1001.952(o).

or she reasonably believes that a minimum of 75 percent of the patients he or she treats while covered by the malpractice insurance will either reside in a HPSA or a MUA or be part of a MUP. In each subsequent coverage period (also not to exceed one year), at least 75 percent of the practitioner's obstetric patients treated under the prior coverage period must have resided in a HPSA or MUA or been part of a MUP. Second, the practitioner is prohibited from discriminating against obstetrics patients who receive medical benefits or assistance under a federal health care program.

16. Investments in Group Practices. Payments made as returns on an investment interest—such as dividends or interest income—to a solo or group practitioner who has invested in his or her own practice or group practice, are exempt from the definition of remuneration under the AKS if (1) the equity interests in the practice or group are required to be held by licensed health care professionals who practice in the practice or group, (2) the equity interests are in the practice or group itself, and not a subdivision of the practice or group and (3) the practice group meets the definition of “group practice” as established in § 1877(h)(4) of the Social Security Act (the Stark Law) and is a unified business with centralized decision-making, pooling of expenses and revenues, and a compensation/profit distribution system that is not based on satellite offices operating substantially as if they were separate enterprises or profit centers.⁷¹

17. Cooperative Hospital Service Organizations. Payments between a cooperative hospital service organization (“CHSO”)⁷² and its patron-hospital, both of which are tax exempt under § 501(a) and § 501(c)(3) of the Internal Revenue Code (IRC), do not constitute remuneration under the AKS if any payment the patron-hospital makes to the CHSO necessarily go towards the CHSO's operating expenses or any payment the CHSO makes to the patron hospital is to comply with the requirement in § 501(e)(2) that CHSOs pay a distribution of their net-earnings to the patron-hospital.⁷³

18. Ambulatory Surgical Centers. Ambulatory Surgical Centers (ASC) are health care facilities that provide same-day surgical care, often on an outpatient basis, for both diagnostic and preventive purposes. Four types of ASCs are referenced under this safe harbor: (1) Surgeon-Owned ASCs, (2) Single-Specialty ASCs, (3) Multi-Specialty ASCs and (4) Hospital/Physician ASCs. To ensure that payments made on investment interests, including dividends and interest income, do not violate the definition of remuneration under the AKS,⁷⁴ (1) the ASC's operating and recovery rooms must exist solely for the ASC and (2) patients referred to the ASC by an investor in that

⁷¹ 42 C.F.R. § 1001.952(p).

⁷² Defined in Section 501(e) of the Internal Revenue Code (IRC) as an organization that exists solely to (1) perform data processing, purchasing, warehousing, billing and collection, etc. and (2) perform such services solely for two or more patron-hospitals, which are both tax-exempt under § 501(a) of the IRC; are constituents of organizations that are tax-exempt under §501(a); or are owned and operated by the United States, a particular state, or the District of Columbia or are possessions of the United States or political subdivision or agency. 26 U.S.C. § 501(e).

⁷³ 42 C.F.R. § 1001.952(q).

⁷⁴ 42 C.F.R. § 1001.952(r).

ASC must be informed of the investor's investment interest. The ASC must also meet additional conditions, depending on the category of ASC.

(a) *Surgeon-Owned ASCs.* To qualify for protection under the safe harbor, all investors in a "Surgeon-owned ASC" must be (a) general surgeons or surgeons of the same specialty who can refer patients to the ASC and perform these patients' surgeries; (b) surgical group practices composed exclusively of such surgeons; or (c) investors who are not employed by the entity or by any investor, are not in a position to provide items or services to the entity or any of its investors and are not in a position to make or influence referrals to the entity or any of its investors.⁷⁵

In addition, all investors, regardless of the category into which they fall, must meet the following six standards to qualify for the safe harbor:

(i) Investment terms cannot be related to the value or volume of past or future referrals, services rendered or business generated;

(ii) At least one-third of an investing surgeon's income from the previous year must come from performing procedures (meaning any procedure on the list of Medicare-covered procedures for ASCs);

(iii) The entity or any investor may 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 in the ASC;

(iv) Payments resulting from the investment interest must be directly proportional to the investor's capital investment (including the fair market value of any pre-operational services provided);

(v) All ancillary services the ASC performs must bear a direct relationship with its primary services and must not be separately billed to Medicare or other federal health care program; and

(vi) The ASC and its surgeon investors cannot discriminate against patients receiving medical benefits from federal health care programs.

(b) *Single-Specialty ASCs.* The conditions investors must meet to be exempt from the AKS definition of remuneration while investing in single-specialty ASCs are identical to those in surgeon-owned ASCs, except that the physicians who invest need not be surgeons. Rather, they must simply be physicians who practice the same medical practice specialty.⁷⁶

(c) *Multi-Specialty ASCs.* Similarly, the safe harbor for multi-specialty ASCs shares the same six requirements as Surgeon-Owned and Single-Specialty

⁷⁵ 42 C.F.R. § 1001.952(r)(1).

⁷⁶ 42 C.F.R. § 1001.952(r)(2).

*ASC, plus two key differences. First, there is no requirement that the investing physicians belong to the same medical specialty. Second, at least one-third of the procedures each physician investor performed in the last year must be performed at the ASC.*⁷⁷

(d) *Hospital/Physician ASCs. Hospital/Physician ASCs differ from the previous three types of ASCs in that hospitals can invest in the ASC, as long as all of the remaining investors are physicians who meet the requirements of surgeon-owned ASCs, single-specialty ASCs, or multi-specialty ASCs. In addition, the ASC must meet eight additional standards:*

(i) Investment terms cannot be related to the value or volume of past or future referrals, services rendered or business generated;

(ii) The entity or any investor may 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 in the ASK;

(iii) Payments resulting from the investment interest must be directly proportional to the investor's capital investment (including the fair market value of any pre-operational services provided);

(iv) The ASC and its hospital or physician investors cannot discriminate against patients receiving medical benefits from federal health care programs;

(v) The following restrictions apply to the ASC's use of space and equipment: the ASC may not use space, including but not limited to, operating and recovery space located in or owned by a hospital investor, unless the ASC has leased the space from the hospital pursuant to the standards laid out in paragraph (b) of this section pertaining to Space Rentals; and the ASC may not use equipment owned by or services provided by the hospital unless the equipment has been leased in compliance with the requirements set forth in paragraph (c) of this section pertaining to Equipment Rentals and the provision of services complies with the personal services and management contracts safe harbor outlined in paragraph (d);

(vi) All ancillary services the ASC performs must bear a direct relationship with its primary services and must not be separately billed to Medicare or other federal health care program;

(vii) The hospital cannot claim payment for costs associated with the ASC from a federal health care program unless the program requires that such costs be claimed; and

(viii) The hospital may not be in a position to make or influence referrals either directly or indirectly to the ASC or any investor.⁷⁸

⁷⁷ 42 C.F.R. § 1001.952(r)(3).

19. Referral Arrangements for Specialty Services. Remuneration does not include any exchange of value among individuals and entities where one party agrees to refer a patient to another party for a specialty service for which Medicare, Medicaid, or any other federal health care program may pay in full or in part in exchange for an agreement to refer of that patient back at a mutually agreeable time in the future if (1) the mutually agreed upon time for the referral back is clinically appropriate, (2) the service offered following the initial referral is one in which the receiving, not the referring, practitioner, specializes, (3) the parties do not exchange payments for the referral and do not split a global fee from any federal health care program for the referred patient and (4) unless both parties practice in the same group, the only value exchanged is the remuneration from third-party payors or the patient for the services rendered.⁷⁹

20. Price Reductions Offered to Eligible Managed Care Organizations. This safe harbor protects various financial arrangements between eligible managed care organizations that hold fixed or capitated payment contracts with Federal healthcare programs and such organizations' first tier and downstream providers furnishing covered items and services to Federal healthcare program beneficiaries, provided that certain requirements are met. Notably, safe harbor protection is not available if the arrangement is part of a broader agreement to steer fee-for-service Federal healthcare program business to the entity providing the discount (e.g., swapping arrangement).⁸⁰

21. Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations. This safe harbor protects contractual relationships between qualified managed care plans and first tier and downstream providers where such providers are at substantial financial risk for the cost or utilization of items or services the providers are obligated to provide to Federal healthcare program beneficiaries. Substantial financial risk may be established through one of four payment methodologies, which include but is not limited to, bonus and withhold arrangements.⁸¹

22. Ambulance Replenishing. Under this safe harbor,⁸² hospitals and other receiving facilities may transfer drugs and/or medical supplies (including linens) to ambulance providers who provide emergency ambulance services an average of three times per week (as measured over a reasonable period of time) to replenish supplies used while transporting patients to the hospital. Specifically, hospitals and other receiving facilities can replenish supplies under any of the following three standards: (1) general replenishing, (2) fair market value replenishing or (3) government-mandated replenishing.

(a) *General replenishing.* In order to qualify under this method, hospitals and other receiving facilities must replenish medical supplies or drugs

⁷⁸ 42 C.F.R. § 1001.952(r)(4).

⁷⁹ 42 C.F.R. § 1001.952(s).

⁸⁰ 42 C.F.R. § 1001.952(t).

⁸¹ 42 C.F.R. § 1001.952(u).

⁸² 42 C.F.R. § 1001.952(v).

equally to all ambulance providers that bring patients to the facility within any of the following categories – facilities may offer different replenishing arrangements to different categories, so long as the replenishing is conducted uniformly within each category: (1) ambulance providers that do not bill any patient or insurer for ambulance services, (2) all not-for-profit and state or local government ambulance service providers or (3) all ambulance service providers.

Ultimately, however, regardless of the terms hospitals and other receiving facilities adopt, the arrangements must be carried out openly and publicly. HHS has determined that either of the following two conditions will satisfy this open and public requirement.

(i) The receiving hospital discloses the existence of the replenishing programs in its emergency room or other location where ambulance providers unload patients, noting the categories of providers for whom replenishment arrangements exist, the drugs and medical supplies to be replenished pursuant to the arrangement and the procedures for documenting all replenishment activities. Copies of the arrangement will be given to ambulance providers, government representatives, and members of the public; or

(ii) The replenishment arrangement conforms to a plan or protocol of general application which an Emergency Medical Services (EMS) Council or comparable entity has created, and a copy of the agreement is available upon request to ambulance providers, government representatives, and members of the public.

(b) Fair Market Value Replenishing. Under this method, the ambulance provider must pay the replenishing facility the fair market value for all drugs and medical supplies provided upon their receipt. The receiving facility and the ambulance provider must make prior arrangements in order to permit payments made after receipt of the drugs and medical supplies.

(c) Government-mandated Replenishing. This method relies on standards set forth in a state or local statute, ordinance, regulation or binding protocol that requires hospitals and other receiving facilities to replenish ambulance services with drugs and medical supplies used to treat patients en route to that facility.

(d) Additional Requirements. Upon selecting a replenishing standard, hospitals and other receiving facilities must comply with the following four standards to fit within the safe harbor:

(i) Either the ambulance provider or the receiving entity, but not both, may claim payment from a federal health care program for the drugs and medical supplies given for replenishment purposes. These claims must comply with all applicable federal health care program payment and coverage rules and regulations, irrespective of whether the receiving facility or ambulance provider processes the submission;

(ii) The receiving hospital, ambulance provider or both must keep records of the drugs and medical supplies given for replenishment and identify the patient whose ambulance trip necessitated the replenishment. Unless both entities elect to keep their own records, the party maintaining the records must share them with the other party as well as with the Secretary should the Secretary request them. A pre-hospital care report that the ambulance provider prepares and files with the receiving hospital will satisfy this documentation requirement provided it notes the specific type and amount of medical supplies the ambulance provider used on the patient and later had replenished;

(iii) The replenishing arrangement cannot consider the volume or value of referrals or business otherwise generated between the parties for which a federal health care program may pay, either fully or in part; and

(iv) The receiving facility and the ambulance provider must comply with all other federal, state and local laws regulating ambulance services.

23. Health Centers. HHS permits health centers—which, pursuant to Section 1905(l)(2)(B)(i) or Section 1905(l)(2)(B)(ii) of the Social Security Act, either directly receive a grant or receive grant funding to serve medically underserved populations, including migratory and seasonal agricultural workers, the homeless and residents of public housing⁸³—to receive goods, items, services, donations or loans that are either medical or clinical in nature or relate directly to the services the health center provides from any individual or entity without being considered remuneration for purposes of the AKS.⁸⁴ This safe harbor is conditioned upon the health center’s reasonable belief that the arrangement will enable it to increase the availability or enhance the quality of the services it provides. Having this belief just once in its operational history, however, is insufficient for continuing to satisfy the safe harbor. Rather, HHS requires the health center to re-evaluate the arrangement periodically to ensure that it will continue to improve the services it offers to the underserved.

HHS also requires the individual or entity offering the goods, items or services to demonstrate its commitment to treating the underserved, mandating that it furnish these items to all patients who clinically qualify for them. While the individual or entity may, as part of the arrangement, restrict the aggregate volume or value of goods, items and services it furnishes, it must do so on a basis other than patients’ payor status and ability to pay.

Apart from requiring the demonstration of a strong commitment to aiding the underserved, the mechanics for qualifying for this safe harbor are similar to procedures seen in other safe harbors thus far. Indeed, an arrangement to provide goods, items, services, donations or loans to a health center must be memorialized in a written contract,

⁸³ Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbor for Federally Qualified Health Centers Under the Anti-Kickback Statute, 70 Fed. Reg. 38,081, 38,083 (proposed July 1, 2005) (to be codified at 42 C.F.R. pt. 1001).

⁸⁴ 42 C.F.R. § 1001.952(w).

lease, grant, loan or other agreement that is signed by both parties and describes both the type and amount of goods, items, services, donations or loans to be provided. The value of the amount can be specified as a fixed sum, fixed percentage or expressed using a fixed methodology. However, the amount to be given cannot be determined on the basis of the volume or value of business to be generated between the parties that will be eligible for payment by a federal health care program.

In addition, given the nature of health centers' mission, individuals and entities seeking to enter into this type of arrangement cannot impose any restrictions on health center operations. Indeed, each health center is free to enter into agreements with other providers or suppliers of comparable goods, items or services or with other lenders or donors. Furthermore, the individual or entity cannot require the health center to refer patients to it or otherwise restrict the health center from referring patients to any other medical practitioner or hospital. But should the health center refer patients to the individual or entity, it can require that individual or entity to charge the health center patient the same rate it charges other similarly situated patients not referred by the health center (or a reduced rate).

Furthermore, health centers are required to notify their patients of their freedom to select any willing provider or supplier and to disclose the existence and nature of any arrangement that falls under the safe harbor to all patients who inquire.

24. Electronic Prescribing Items and Services. The transfer of hardware, software or information technology and training services necessary and used solely to receive and transmit electronic prescription information that are provided for, or used to access, an electronic prescription drug program that complies with Medicare Part D will not constitute remuneration if the transfers occur between (1) a hospital and a physician who is a member of the hospital's medical staff, (2) a group practice and a prescribing health care professional who is a member of the group practice or (3) a PDP sponsor or MA organization and pharmacists and pharmacies participating in the network of such sponsor or organization and prescribing health care professionals.⁸⁵ Irrespective of the category into which the donor and recipient fall, the parties must memorialize the arrangement in a signed, written agreement, which specifies the hardware, software and services to be provided, indicates the cost the donor incurs and mentions any other items or services to be provided.

In addition, donors cannot know of or recklessly disregard the fact that a potential recipient possesses services equivalent to that the donor wishes to transfer. Furthermore, donors are also prohibited from considering the volume or value of referrals or other business that a particular recipient could generate. Donors are prohibited from restricting the compatibility of the hardware, software or services with other electronic prescribing or electronic health records systems. Finally, post-transfer, donors may not limit the recipient's right to use the hardware, software or services as they wish with respect to any patient, regardless of payor status.

⁸⁵ 42 C.F.R. § 1001.952(x).

Recipients, on the other hand, face only one restriction when attempting to structure a transfer that falls within this safe harbor. Specifically, HHS prohibits the recipient from conditioning the prospect of doing business with the donor on the receipt or amount of hardware, software and services transferred.

25. Electronic Health Records Items and Services. This safe harbor⁸⁶ exempts from the definition of “remuneration,” arrangements between (1) individuals or entities that provide services covered by a federal health care program or health plans and (2) medical health practitioners, for the transfer of electronic health records software, information technology and training services. To qualify for the safe harbor, the agreement must be memorialized in a writing signed by both parties by December 31, 2013 that specifies the services and software to be transferred, indicates the total cost the donor will incur and provides for the recipient to pay 15 percent of the donor’s cost prior to receiving the technology or services. There is currently a proposed rule pending that would extend this date to December 31, 2016. The items and services, however, cannot include staffing in the recipient’s office or involve assisting with personal business or business deemed unrelated to the recipient’s clinical practice or obligations. In addition, the parties must also satisfy the following requirements to satisfy the safe harbor:

(a) *Software requirements.* The electronic health records software, in addition to being able to create, maintain, transmit and receive electronic health records, must either possess an electronic prescribing function or be compatible with the recipient’s existing electronic prescribing system such that the recipient can satisfy the applicable standards of Medicare Part D. Further underscoring the importance of compatibility, HHS also expressly prohibits the donor from restricting the software’s compatibility with other electronic prescribing and health systems prior to transfer.

In addition, to qualify for the safe harbor, the software must be interoperable at the time of transfer, meaning a recognized certifying body must have certified it within the twelve months preceding the transfer.

(b) *Recipient Requirements.* Recipients are prohibited from making provision of software or services, or the number of software licenses or services provided, conditions for doing business with the donor.

(c) *Donor Requirements.*

Selecting Recipients

When selecting recipients, donors cannot know of or recklessly disregard the fact that the recipient possesses services equivalent to that the donor wishes to transfer.

Furthermore, donors cannot select recipients or determine the number of software licenses or services to be transferred based directly on (1) the volume or value of referrals or (2) business otherwise generated between the parties. However, if the determination is

⁸⁶ 42 C.F.R. § 1001.952(y).

based on any of the following, HHS will deem it not to be “directly based on volume or value of referrals or business otherwise generated, and thus, allowed under the safe harbor:

1. The number of prescriptions the recipient writes;
2. The size of the recipient’s medical practice;
3. The total number of hours the recipient practices medicine;
4. The recipient’s overall use of automated technology in his or her medical practice;
5. Whether the recipient is a member of the donor’s medical staff, if the donor has a formal medical staff;
6. The level of uncompensated care the recipient provides; or
7. Any other reasonable and verifiable manner that does not directly consider the volume or value of referrals or other business generated between the parties.

Usage of software post-transfer

Once the software has been transferred, the donor is prohibited from restricting in any way the recipient’s use of the software or services for any patient, regardless of payor source.

Costs

Apart from the 15 percent payment from the recipient, the donor is prohibited from seeking payment for the cost of the software and services from any federal health care programs.

E. Guidance as to Enforcement

1. Enforcement Factors. If an arrangement meets all safe harbor requirements, the entities involved likely would not be prosecuted or sanctioned under the AKS, provided that unlawful intent were not present.

The fact that an arrangement does not meet all of the requirements of a safe harbor does not necessarily mean that the arrangement is *per se* illegal or will be prosecuted under the AKS. Rather, the government will look at the facts and circumstances of such an arrangement on a case-by-case basis to determine whether a violation has occurred. In reviewing arrangements that do not fit a safe harbor, the OIG has indicated that it is particularly concerned about arrangements that: 1) result in over-utilization of the Federal health care system and thereby increase costs to the Federal programs; 2) skew clinical decision-making in favor of the donor of the remuneration; 3)

decrease patient freedom of choice; 4) increase patient safety or care concerns; or 5) create unfair competition.⁸⁷ Where an arrangement does not meet all of the requirements of a safe harbor, these factors should be evaluated to determine whether the arrangement presents an opportunity for conduct that would be of concern to the government.

2. Fraud Alerts and Special Fraud Alerts. From time to time, the OIG may publish Fraud Alerts and Special Fraud Alerts. Fraud Alerts are issued internally and help government agencies identify fraudulent and abusive practices within the healthcare industry. Special Fraud Alerts are published on the OIG's website and provide general guidance on violations of federal law in relation to industry-wide healthcare practices.

Each Special Fraud Alert provides insight into how the OIG believes the AKS (or another federal healthcare statute) may apply to conduct or relationships prevalent within the healthcare industry at the time the alert is issued.

The OIG has issued the following Special Fraud Alerts:

- Joint Venture Arrangements;⁸⁸
- Routine Waiver of Copayments or Deductibles Under Medicare Part B;⁸⁹
- Hospital Incentives to Physicians;⁹⁰
- Prescription Drug Marketing Schemes;⁹¹
- Arrangements for the Provision of Clinical Lab Services;⁹²
- Home Health Fraud;⁹³
- Providing Medical Supplies to Nursing Facilities;⁹⁴
- Providing Services to Nursing Facilities;⁹⁵

⁸⁷ See, e.g., OIG Advisory Opinion 98-3 (Apr. 6, 1998) available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_3.pdf; see also OIG Advisory Opinion 98-13 (Sept. 23, 1998) available at http://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_13.htm.

⁸⁸ Originally issued in August 1989 and reprinted at Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372 65,373 (Dec. 19, 1994). The value of this Special Fraud Alert as a tool for analyzing the compliance of joint ventures with the Anti-Kickback Statute may have been diminished by the subsequent publication of the Investment Interests Safe Harbor and Hanlester, 51 F.3d 1390.

⁸⁹ Originally issued in May 1991 and reprinted at 59 Fed. Reg. 65,374.

⁹⁰ Originally issued in May 1992 and reprinted at 59 Fed. Reg. at 65,375.

⁹¹ Originally issued in August 1994 and reprinted at 59 Fed. Reg. at 65,376.

⁹² Originally issued in October 1994 and reprinted at 59 Fed. Reg. at 65,377.

⁹³ Originally issued in June 1995 and reprinted at Publication of OIG Special Fraud Alerts, 60 Fed. Reg. 40,847 40,847 (Aug. 10, 1995).

⁹⁴ Originally issued in August 1995 and reprinted at 60 Fed. Reg. 40,849.

- Home Health Fraud;⁹⁶
- Provision of Services in Nursing Facilities;⁹⁷
- Fraud and Abuse in Nursing Home Arrangements with Hospices;⁹⁸
- Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services;⁹⁹
- Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer;¹⁰⁰
- Telemarketing by Durable Medical Equipment Suppliers;¹⁰¹
- Updated Special Fraud Alert: Telemarketing by Durable Medical Equipment Suppliers;¹⁰² and
- Physician-Owned Entities.¹⁰³

3. Special Advisory Bulletins. The OIG also periodically issues Special Advisory Bulletins to alert and inform the healthcare industry about potential problems or areas of special interest. To date, the OIG has issued the following Special Advisory Bulletins related to healthcare fraud and abuse, either individually or in cooperation with other government agencies:

- OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans.¹⁰⁴

⁹⁵ Originally issued in May 1996 and reprinted at Publication of OIG Special Fraud Alert, 61 Fed. Reg. 30,623 (Jun. 17, 1996).

⁹⁶ 60 Fed. Reg. 40,847 and available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/081095.html>.

⁹⁷ Id.

⁹⁸ Issued in March 1998 and published at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/hospice.pdf>.

⁹⁹ Issued in January 1999 and published at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/dme.htm>.

¹⁰⁰ Issued on February 2000 and published at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm>.

¹⁰¹ Issued on March 2003 and published at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/Telemarketingdme.pdf>.

¹⁰² Issued in January 2010 and published at http://oig.hhs.gov/fraud/docs/alertsandbulletins/fraudalert_telemarketing.pdf.

¹⁰³ Issued on March 26, 2013 and published at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

¹⁰⁴ OIG Letter, "Hospital-Physician Incentive Plans for Medicare and Medicaid Beneficiaries Enrolled in Managed Care Plans" (Aug. 19, 1999), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm> (last visited Oct. 23, 2013).

- Special Advisory Bulletin: Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries;¹⁰⁵ and
- Special Advisory Bulletin: The Effect of Exclusion From Participation in Federal Health Care Programs Press Release;¹⁰⁶
- Special Advisory Bulletin: Practices of Business Consultants;¹⁰⁷
- Special Advisory Bulletin: Offering Gifts and Other Inducements To Beneficiaries;¹⁰⁸
- Special Advisory Bulletin: Contractual Joint Ventures;¹⁰⁹
- Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees;¹¹⁰
- Special Advisory Bulletin: Average Manufacturer Price and Average Sales Reporting Requirements;¹¹¹
- Updated Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs;¹¹²

4. Compliance Program Guidance Documents. The OIG has also developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and DME suppliers, to encourage the development and use of internal controls to monitor adherence to applicable statutes, regulations, and program requirements. To date, the OIG has issued the following Compliance Program Guidance Documents:

¹⁰⁵ 64 Fed. Reg. 37,985 (July 14, 1999); see also OIG Special Advisory Bulletin: Recent Commentary Distorts HHS IG's Gainsharing Bulletin, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/bnagain.htm> (last visited Oct. 23, 2013).

¹⁰⁶ 64 Fed. Reg. 52,791 (Sept. 30, 1999).

¹⁰⁷ 66 Fed. Reg. 36,583 (July 12, 2001).

¹⁰⁸ 67 Fed. Reg. 55,855 (Aug. 30, 2002), as corrected by 67 Fed. Reg. 57063 (Sept. 6, 2002).

¹⁰⁹ 68 Fed. Reg. 23,148 (Apr. 30, 2003). This Special Advisory Bulletin focuses on contractual arrangements where a health care provider in one line of business (“A”) expands into a related health care business by contracting with an existing provider of a related item or service (“B”) to provide the new item or service to A’s existing patient population. The OIG questions the practice of provider A contracting contracts out substantially the entire operation of the expanded line of business to provider B – otherwise a potential competitor – receiving in return the profits of the business as remuneration for its federal healthcare program referrals.

¹¹⁰ 70 Fed. Reg. 70,623 (Nov. 22, 2005).

¹¹¹ Issued in September 2010, available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2010/SpAdvBulletin AMP ASP.pdf>.

¹¹² Issued May 8, 2013, available at <http://oig.hhs.gov/exclusions/files/sab-05092013.pdf>.

- Compliance Program Guidance for Hospital; (63 Fed. Reg. 8987, Feb. 23, 1998)
- Compliance Program Guidance for Home Health Agencies; (63 Fed. Reg. 42410, Aug. 7, 1998)
- Compliance Program Guidance for Clinical Laboratories; (63 Fed. Reg. 45076, Aug. 24, 1998)
- Compliance Program Guidance for Third-Party Medical Billing Companies; (63 Fed. Reg. 70138, Dec. 18, 1998)
- Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry; (64 Fed. Reg. 36368, July 6, 1999)
- Compliance Program Guidance for Hospices; (64 Fed. Reg. 54031, Oct. 5, 1999)
- Compliance Program Guidance for Medicare + Choice Organizations; (64 Fed. Reg. 61893, Nov. 15, 1999)
- Compliance Program Guidance for Nursing Facilities; (65 Fed. Reg. 14289, March 16, 2000)
- Compliance Program Guidance for Individual and Small Group Physician Practices; (65 Fed. Reg. 59434, Oct. 5, 2000)
- Compliance Program Guidance for Ambulance Suppliers; (68 Fed. Reg. 14245, March 24, 2003)
- Compliance Program Guidance for Pharmaceutical Manufacturers; (68 Fed. Reg. 23731, May 5, 2003)
- Supplemental Compliance Program Guidance for Hospitals; (70 Fed. Reg. 4858, Jan. 31, 2005)
- Draft Compliance Program Guidance for Recipients of PHS Research Awards; (70 Fed. Reg. 71312, Nov. 28, 2005)
- NSTC Launches Government-Wide Initiative Based on OIG Draft Guidance for HHS Research Grants; (June 7, 2006)
- Supplemental Compliance Program Guidance for Nursing Facilities; (73 Fed. Reg. 56832, Sep. 30, 2008)

5. Preambles to Safe Harbors Regulations. In promulgating its safe harbor regulations, the OIG offered useful language in several preambles. Most notably,

the OIG offers useful guidance in the preambles to (1) the 1991 Final Rulemaking in which OIG promulgated the ten (10) original safe harbor provisions (56 Fed. Reg. 35952, July 29, 1991) and (2) the 1999 Final Rule clarifying the initial OIG safe harbor provisions and establishing additional safe harbor provisions (64 Fed. Reg. 63518, Nov. 19, 1999). The OIG's website lists several additional preambles to proposed, interim and final rules relating to AKS safe harbors.

F. OIG Advisory Opinions

In accordance with 42 U.S.C. § 1320a-7d(b) and 42 C.F.R. pt. 1008, OIG regularly issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing or proposed business arrangement. As required by the statute, these advisory opinions are made available to the public through this OIG Web site. One purpose of the advisory opinion process is to provide meaningful advice on the application of the AKS and other OIG sanction statutes in specific factual situations. It is important to remember that advisory opinions are binding and may legally be relied upon only by the requestor. While OIG advisory opinions may be persuasive to other parties, OIG specifically disclaims the ability of other parties to rely on its advisory opinions in each opinion that it publishes.

OIG has published a checklist of requirements to follow when submitting a request for an advisory opinion (technical, substantive and certifications).¹¹³ The requestor must be a party to the arrangement and the request must be for an existing arrangement or one which the requestor in good faith plans to undertake.¹¹⁴ The request should include:

- A declaration of the subject category or categories for which the opinion is requested;
- A complete and specific description of all relevant information bearing on the arrangement and on the circumstances of the conduct;
- All relevant background information;
- Complete copies of all operative documents, if applicable, or narrative descriptions of those documents; and
- Detailed statements of all collateral or oral understandings (if any).

¹¹³ OIG, Preliminary Checklist for Advisory Opinion Requests (July 1999) available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/precheck.htm>; see also Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311 (July 16, 1998).

¹¹⁴ 42 C.F.R. § 1008.11; 42 C.F.R. § 1008.15(a).

The completed request for an advisory opinion must include a certification signed by the requestor, CEO or managing partner.¹¹⁵

III. SELF-REFERRAL STATUTES

A. The Ethics in Patient Referrals Act of 1989 (“Stark Law”)

1. General Provisions. The Ethics in Patient Referrals Act of 1989,¹¹⁶ or “Stark Law,” prohibits a physician from: (1) making a “referral” of a Medicare patient to an entity; (2) for the furnishing of “designated health services,” (“DHS”) (3) if there is a “financial relationship” between the referring physician or an immediate family member of the physician and the entity; (4) unless an exception applies.¹¹⁷

Unlike the AKS, the Stark Law is not intent-based; it is a strict liability statute. If a financial relationship exists, the physician cannot make a referral for DHS and the service provider cannot bill the government for the service, even when there is no intent to induce referrals, unless an exception applies. The strict liability aspect is a challenge for attorneys and healthcare providers because the definitions in and exceptions to the Stark Law are excruciatingly detailed, and many are subject to additional exceptions and even exceptions to exceptions. A thorough analysis of the Stark Law is beyond the scope of this chapter and would easily form the basis for a separate, lengthy treatise. The reader is advised to refer to the Stark Law regulations before analyzing its application to any particular transaction.

Unlike the AKS, the Stark Law is not a criminal statute. However, significant civil monetary and administrative penalties may be assessed for violations of the Stark Law, and a person violating the law may be excluded from participation in Medicare and Medicaid. The potential penalties for a Stark Law violation include: denial of payment for the service; civil fines of \$15,000 per service; civil fines of \$100,000 per arrangement for circumvention schemes; potential exclusion from Medicare or Medicaid; and potential False Claims Act liability.¹¹⁸

2. History. As originally enacted in 1989, the Stark Law applied only to physician referrals for clinical laboratory services. In 1993 and 1994, Congress expanded the prohibition to additional DHS. Since that time, CMS has promulgated numerous sets of regulations related to the Stark Law, including a number of significant rules that were issued as part of other, unrelated regulations, such as the annual Hospital Inpatient Prospective Payment System or Medicare Physician Fee Schedule regulations.

The practical effect of this history is that analysis of the applicability of the Stark Law or an exception to a particular transaction often requires determining which

¹¹⁵ 42 C.F.R. § 1008.38.

¹¹⁶ 42 U.S.C. § 1395nn.

¹¹⁷ 42 U.S.C. § 1395nn(a)(1).

¹¹⁸ 42 U.S.C. § 1395nn.

exceptions were in effect at the time of key event, whether any relevant exceptions were then proposed or final, the exact language of the exception at the relevant time, and CMS's published interpretation of the exception at the relevant time. This conceivably requires consideration of the preamble, commentary, and regulatory changes in the proposed Stark I, final Stark I, proposed Stark II, Phase I final Stark II, and Phase II interim final Stark II regulations, proposed and final Stark II, Phase III regulations as well as subsequent proposed and final Physician Fee Schedules and Hospital Inpatient Prospective Payment System Rules.

3. Definitions.

(a) *“Designated Health Services.”*

The following items or services are currently considered DHS:

1. Clinical laboratory services.
2. Physical therapy services.
3. Occupational therapy services.
4. Outpatient speech-language pathology services.
5. Radiology and certain other imaging services.
6. Radiation therapy services and supplies.
7. Durable medical equipment and supplies.
8. Parenteral and enteral nutrients, equipment, and supplies.
9. Prosthetics, orthotics, and prosthetic devices and supplies.
10. Home health services.
11. Outpatient prescription drugs.
12. Inpatient and outpatient hospital services.¹¹⁹

CMS publishes annually in the Physician Fee Schedule final rule an updated list of CPT and HCPCS codes for the relevant DHS. However, it is important to note that this list is not an exclusive list of all DHS.

(b) *“Entity.”* Stark III changed the definition of “entity” to specifically include not only the entity that presents the claim to Medicare (*e.g.*, the hospital), but also the entity that performs the designated health services for which the

¹¹⁹ 42 C.F.R. § 411.351. As a result of American Lithotripsy Society et. al. v. Thompson, No. 01-01812 (D.D.C., July 12, 2002), lithotripsy is not considered a DHS.

claim was presented. Thus, physician-owned companies that provide services and supplies to hospitals pursuant to under arrangements contracts now fall under the definition of “entity,” and such companies must meet the requirements of an exception for compensation arrangements as well as, for the first time, ownership and investment interests.¹²⁰

(c) “*Fair market value.*” The Stark Law defines “fair market value” as meaning the value in arm’s-length transactions, consistent with the “general market value.”¹²¹ Usually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.

With respect to rentals and leases, fair market value means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of the fair market value definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

CMS further clarified in the Stark Phase III final rule that

*A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed. We note that the fair market value of administrative services may differ from the fair market value of clinical services.*¹²²

It is important to note that fair market value and commercial reasonableness are different terms.

¹²⁰ 42 C.F.R. § 411.351.

¹²¹ 42 C.F.R. § 411.351. “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyer and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement. Id.

¹²² 72 Fed. Reg. at 51,016.

(d) *“Financial relationship.”* The Stark Law defines a “financial relationship” to mean either (a) an ownership or investment interest (including an option or nonvested interest), direct or indirect (no matter how many levels removed from a direct interest), through equity, debt or other means or (b) a compensation arrangement between the physician (or an immediate family member) and the entity. Under the “Stand in the Shoes” doctrine, for purposes of determining whether a direct or indirect financial relationship exists, physicians are deemed to “stand in the shoes” of their Physician Organizations. A “Physician Organization” means a physician, a physician practice or a “group practice” (as further defined in the Stark regulations). This means a physician standing in the shoes of his or her Physician Organization must satisfy a direct compensation exception rather than being able to take advantage of the easier-to-satisfy definition of an indirect compensation relationship.¹²³

(e) *“Group practice.”* The Stark Law (and related regulations) defines a “Group Practice” as an entity that meets a list of specific regulatory requirements, including: (a) the practice consists of a single legal entity; (b) there are a minimum of two (2) physicians who are either owners or employees of the Group Practice (a “Member”); (c) each Member physician furnishes substantially the full range of patient care services that the physician routinely furnishes through the Group Practice; (d) substantially all (meaning at least 75%) of the total patient care services of the Members are furnished through the Group Practice and billed under the Group Practice billing number;¹²⁴ (e) overhead expenses and income are distributed according to methods determined before the receipt of payment for the services giving rise to the overhead expense or producing the income; (f) the Group Practice is a unified business; (g) no Member directly or indirectly receives compensation based on the volume or value of referrals for DHS by the Member, except to the extent allowed in the special compensation rules, described below; and (h) Members personally conduct at least 75% of the physician-patient encounters of the Group Practice.¹²⁵

Qualifying as a Group Practice provides two primary advantages, including access to special compensation rules for physicians in the Group Practice and the “In-Office Ancillary Services” exception to the Stark Law (“IOAS”).¹²⁶ These two advantages of the Group Practice definition are distinct: (1) group practice status allows certain revenue sharing that would otherwise implicate the prohibition on referrals, and (2) only members of a group practice may qualify for the IOAS exception, which allows group physicians to refer patients to the group for DHS. The IOAS is an important exception to the Stark Law’s general prohibition on self-referrals. Note that there is no group practice “exception” as such – rather it is a status that allows for special compensation models and is a pre-requisite for taking advantage of the IOAS.

¹²³ 42 C.F.R. § 411.351.

¹²⁴ 42 C.F.R. § 411.352. Note that there is an exception to the “substantially all” test for practices located in Health Professional Shortage Areas (“HPSAs”).

¹²⁵ 42 C.F.R. § 411.352

¹²⁶ 42 C.F.R. § 411.355(b).

While the group practice’s productivity bonus and profit sharing special compensation rules are discussed separately, they are not mutually exclusive. CMS has indicated that “[a] group practice may compensate physicians with overall profit shares or productivity bonuses, or some combination of the two”¹²⁷

It is also interesting to note that the special compensation rules under the Group Practice definition do not include fair market value, commercial reasonableness, “set in advance,” or written agreement requirements, as is true for many of the other Stark compensation exceptions. CMS commented on this issue, indirectly, in the Preamble to the Stark II Phase I final rule: “Congress recognized that in the case of group practices, revenues derived from DHS must be distributed to the group practice members in some fashion, even though the members generate the DHS revenue.”¹²⁸

This commentary seems to recognize that there is a qualitative difference between compensation paid out to group practice members and other types of compensation arrangements, such as between a hospital and a medical director. In those other types of arrangements, the DHS entity is purchasing a service from the physician, such that fair market value may reasonably be established. But distributions to owners of a group practice represent a return on ownership investment as well as compensation for services rendered, thus the concept of fair market value does not, and realistically cannot, apply. Congress understood that a fair market value requirement would not make any sense in the context of a *bona fide* group practice, because it could result in a scenario where excess funds could not be distributed to the members of the group practice – or possibly to anyone.

(i) Special Compensation Rules – Profit Sharing. The regulations allow “a physician in a Group Practice” to be paid a share of overall profits of the group, as long as the share is not determined in a manner that is directly related to the volume or value of referrals for DHS by the physician and certain other requirements are met.

“Overall profits” means either (1) the group’s entire profits derived from DHS payable by Medicare or Medicaid or (2) the profits derived from DHS payable by Medicare or Medicaid of any component of the Group Practice that consists of at least five (5) physicians. CMS has stated that “any grouping of five physicians is permissible.”¹²⁹ Overall profits must be divided in a reasonable and verifiable manner that is not directly related to the volume or value of the physician’s referrals of DHS.

The share of overall profits is deemed not to relate directly to referrals if any of the following conditions is met (but other methods are also allowed):

¹²⁷ Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,024 (Sept. 5, 2007) (to be codified at 42 C.F.R. pts. 411 and 424). Note that the special compensation rules are included both in the Stark Law itself as well as in regulations promulgated by CMS, implementing the statute. See 42 U.S.C. § 1395nn(h)(4)(B)(i).

¹²⁸ 66 Fed. Reg. at 876.

¹²⁹ 69 Fed. Reg. at 16,081.

- The group’s profits are divided on a per capita basis;
- Revenues derived from DHS are distributed based on the distribution of the group’s revenues attributed to non-DHS services; or
- Revenues derived from DHS constitute less than 5% of the group’s total revenues, and the allocated portion of those revenues to each physician in the practice constitutes 5% or less of his or her total compensation from the group.¹³⁰

Supporting documentation verifying the method used to calculate the profit share, as well as the resulting amount of compensation, must be made available to the Secretary of HHS upon request.

(ii) Special Compensation Rules – Productivity

Bonuses. A physician in a Group Practice may be paid a productivity bonus based on services that he or she personally performs (including services “incident to” those personally performed services), provided that the bonus is not determined in any manner that is directly related to the volume or value of referrals for DHS by the physician.¹³¹

A productivity bonus will be deemed not to relate directly to the volume or value of referrals of DHS by the physician if one of the following conditions is met:

- The bonus is based on the physician’s total patient encounters or relative value units (RVUs);
- The bonus is based on the allocation of the physician’s compensation attributable to services that are not DHS (payable by either Federal programs or private payers); or
- Revenues derived from DHS are less than 5% of the Group Practice’s total revenues and the allocated portion of those revenues to each physician in the group constitutes 5% or less of his or her total compensation from the Group Practice.¹³²

Supporting documentation verifying the method used to calculate the productivity bonus, as well as the resulting amount of compensation, must be made available to the Secretary of HHS upon request.

(f) “*Immediate family member.*” The Stark regulations define “immediate family member” as follows:

¹³⁰ 42 C.F.R. § 411.352(i).

¹³¹ Note that other Stark compensation exceptions, such as personal services, employment, and fair market value do not allow for the inclusion of “incident to” services in determining a physician’s productivity bonuses.

¹³² 42 C.F.R. § 411.352(i).

Immediate family member or member of a physician's immediate family means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.¹³³

This definition was adopted from the longstanding definition of “immediate relative” used by the Medicare program to implement 42 U.S.C. § 1395y(a)(11), which excludes from Medicare coverage services furnished by an immediate relative.¹³⁴ The definition has remained virtually unchanged since 1995.¹³⁵

Despite repeated requests by commenters, CMS has refused to narrow the definition of “immediate family member.”¹³⁶ CMS has purposely used the above definition because, according to CMS, “the definition encompasses the range of relatives who could be in a position to influence the pattern of a physician’s referrals.”¹³⁷

(g) “*Physician.*” “Physician” means a doctor of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, or optometry, or a chiropractor.¹³⁸

(h) “*Referral.*” The Stark Law (and related regulations) defines a “referral” to mean a request by a physician for, or the ordering of, or the certifying of the need for, or the establishment of a plan care including, any designated health service (“DHS”) for which payment may be made under the Medicare program.¹³⁹

Alternatively, “referral” is further defined to mean a request for a designated health service (including a physician’s request for a consultation with another physician and any test or procedure ordered by or performed by or under the supervision of the other physician, and also including the certifying or recertifying of the need for such designated health service) or the request for or establishment of a plan of care that includes provision of the designated health service or the certifying or recertifying of the need for such designated health service.¹⁴⁰

¹³³ 42 C.F.R. § 411.351.

¹³⁴ 60 Fed. Reg. at 41,938.

¹³⁵ In reference to the parent-child relationship, “natural” was changed to “birth” in the 2001 final rule to conform to common usage. 66 Fed. Reg. at 946.

¹³⁶ For instance, commenters have proposed the following modifications: eliminating references to grandparents, grandchildren and assorted-in-laws and only including natural or adoptive parent, child or sibling. 60 Fed. Reg. at 41,938.

¹³⁷ *Id.*; see also 57 Fed. Reg. at 8,594.

¹³⁸ 42 C.F.R. § 411.351.

¹³⁹ 42 C.F.R. § 411.351.

¹⁴⁰ 42 U.S.C. § 1395nn(h)(5).

(i) “Set in advance.” Compensation is considered “set in advance” for the purposes of the Stark Law if

*The aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set in an agreement between the parties before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the agreement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.*¹⁴¹

4. Exceptions to Ownership or Investment Interests.

(a) *Publicly-Traded Securities.* Ownership of investment securities, such as shares, bonds or other debt instruments do not constitute a financial relationship if the security could be purchased on the open market at the time the DHS referral was made.¹⁴² The security must also be:

- Listed for trading on the New York Stock Exchange, the American Stock Exchange or any regional exchange in which quotations are published on a daily basis; or
- A foreign security listed on a recognized foreign, national or regional exchange in which quotations are published on a daily basis; or
- Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or
- In a corporation that had stockholder equity exceeding \$75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.¹⁴³

(b) *Mutual Funds.* Ownership of shares in a mutual fund do not constitute a financial relationship if the company had, at the end of its most recent fiscal year, or on average during the previous 3 fiscal years, total assets exceeding \$75 million.¹⁴⁴

(c) *Specific Providers.* An ownership or investment interest in certain entities does not constitute a financial relationship.¹⁴⁵ First, an ownership or

¹⁴¹ 42 C.F.R. § 411.354(d)(1).

¹⁴² 42 C.F.R. § 411.356(a).

¹⁴³ “Stockholder equity” is the difference in value between a corporation's total assets and total liabilities.

¹⁴⁴ 42 C.F.R. § 411.356(b).

¹⁴⁵ 42 C.F.R. § 411.356(c).

investment interest in a rural provider does not constitute a financial relationship. A rural provider is an entity that is located in a rural area, that furnishes substantially all (not less than 75 percent) of its DHS to residents of a rural area and is not a specialty hospital.

Second, ownership or investment in a hospital located in Puerto Rico does not violate the statute.

Finally, while prior to PPACA, physicians were allowed to own interests in “whole hospitals,” PPACA eliminated this exception for entities that did not meet physician ownership or investment requirements as of March 23, 2010. Physician-owned hospitals that met the deadline under PPACA are considered to be grandfathered as long as they meet additional regulatory requirements.¹⁴⁶

5. Exceptions to Compensation Arrangements.

(a) *Rental of Office Space.* Payments for the use of office space do not constitute a financial relationship if certain conditions are met.¹⁴⁷ The lease agreement must be in writing, signed by the parties and specify the premises to be used. The term of the agreement must be for at least one year.

The space rented must not exceed what is reasonable and necessary for the legitimate business purposes of the lease. The space must be used exclusively by the lessee; however, the lessee can make certain payments for the use of common space. The payments must not exceed the lessee’s pro rata share for use of the common space in relation to other lessees.

The rental charges must be set in advance and consistent with fair market value. The rental charges cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. The agreement must be commercially reasonable even if no referrals were made between the lessee and the lessor.

(b) *Rental of Equipment.* Payments made by a lessee to a lessor for the use of equipment do not constitute a financial relationship under Stark if certain conditions are met.¹⁴⁸ The rental or lease agreement must be set out in writing, signed by the parties and specify the equipment covered. The equipment rented or leased must not exceed that which is reasonable and necessary for the legitimate business purposes of the lease or rental. The equipment must be used exclusively by the lessee.

The term of rental or lease must be for at least 1 year. If the agreement is terminated during the term with or without cause, the parties may not enter into a new agreement during the first year of the original term of the agreement. A holdover month-to-month rental for up to 6 months immediately following the expiration of the agreement

¹⁴⁶ 42 C.F.R. § 411.362(b).

¹⁴⁷ 42 C.F.R. § 411.357(a).

¹⁴⁸ 42 C.F.R. § 411.357(b).

is allowed provided that the holdover rental is on the same terms and conditions as the immediately preceding agreement.

The rental charges must be set in advance and consistent with fair market value. The charges cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. Furthermore, the charges cannot be determined using a formula based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to the services performed using the equipment or per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee. The agreement must be commercially reasonable even if no referrals were made between the parties.

(c) *Bona Fide Employment Relationships.* Compensation paid by an employer under a *bona fide* employment relationship to an employee does not constitute a financial relationship if certain conditions are satisfied.¹⁴⁹ The physician or his or her immediate family member must have a *bona fide* employment relationship with the employer for the provision of identifiable services, however, unlike many Stark exceptions, there is no requirement that the employment agreement be reduced to writing.

The amount of remuneration must be consistent with the fair market value of the services. It cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician. The remuneration must be provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

This section does not prohibit payment of remuneration in the form of a productivity bonus based on services performed personally by the physician or immediate family member of the physician.

(d) *Personal Service Arrangements.* Personal service arrangements do not constitute a financial relationship if certain conditions are satisfied.¹⁵⁰ The arrangement must be set out in writing and specify the services covered. It must cover all of the services to be furnished by the physician to the entity. The services must not involve counseling or promotion of a business arrangement or other activity that violates Federal or State law. The aggregate services contracted for must not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.

Compensation under the agreement must be set in advance, not exceed fair market value and not be determined in a manner that takes into account the volume or value of any referrals between the parties.

¹⁴⁹ 42 C.F.R. § 411.357(c).

¹⁵⁰ 42 C.F.R. § 411.357(d).

The term of the arrangement must be for at least one year. If it is terminated early the parties may not enter into a substantially similar arrangement during the first year of the original term.

This exception also sets forth special rules apply to physician incentives plans between a physician and an entity.

(e) *Physician Recruitment.* The Stark regulations provide an exception for remuneration provided by a hospital to a physician for recruitment purposes if certain conditions are satisfied.¹⁵¹ The payment must be made directly to the physician (except for a recruitment to join an existing practice) with the intent to induce the physician to relocate his or her medical practice to the geographic area served by the hospital. The “geographic area served by the hospital” is the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 75 percent of its inpatients. However, if a hospital is located in a rural area, then the “geographic area served by the hospital” may also be the area composed of the lowest number of contiguous zip codes from which the hospital draws at least 90 percent of its inpatients.

A physician will be considered to have relocated his or her medical practice if the practice was located outside the geographic area served by the hospital and the physician moved his or her practice at least 25 miles.

If the physician moves his or her practice into the geographic area served by the hospital, but the move is less than 25 miles, the physician can still qualify for the exception. The physician’s new medical practice must derive at least 75 percent of its revenues from DHS furnished to patients not seen or treated by the physician at his or her prior medical practice site during the preceding 3 years.

In certain situations, a physician may be exempt from the relocation requirement. These include: (1) a resident or a physician who has been in practice 1 year or less; and (2) physicians employed on a full-time basis for at least 2 years immediately prior to the recruitment arrangement by a Federal or State bureau of prisons to serve prisoners; the Department of Defense or Department of Veterans Affairs to serve active or veteran military personnel and their families; or a facility of the Indian Health Service to serve patients who receive medical care exclusively through the Indian Health Service. The Secretary of Health & Human Services may also issue an advisory opinion determining that a particular physician recruitment arrangement is exempt from meeting the requirement.

The recruitment payment arrangement must be set out in writing and signed by all parties. The arrangement cannot be conditioned on the physician's referral of patients to the hospital. The physician must be allowed to establish staff privileges at any other hospitals and refer business to any other entities.

¹⁵¹ 42 C.F.R. § 411.357(e).

The hospital cannot determine (directly or indirectly) the amount of the remuneration to the physician based on the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties.

If a hospital provides remuneration to a physician indirectly through payments made to a practice that the recruited physician has joined or directly to a physician who joins a physician practice, additional conditions must be met. First, the written agreement between the hospital and physician must also be signed by the practice. Second, the remuneration must remain with, or be passed directly to, the recruited physician. The physician practice must not impose on the recruited physician practice restrictions that *unreasonably restrict* the recruited physician's ability to practice medicine in the geographic area served by the hospital.

If the hospital makes an income guarantee to a recruited physician joining an existing physician practice, the costs allocated to the physician by the practice must not exceed the actual additional incremental costs associated with recruiting the physician. Different limitations may apply if the physician joins a physician practice located in a rural area or HPSA to replace another physician who has retired or died.

Records of the actual costs and the passed-through amounts must be maintained for a period of at least 5 years and made available to the Secretary upon request.

The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

(f) *Isolated Transactions.* Isolated financial transactions, such as a one-time sale of property or a practice, do not constitute a financial relationship if certain conditions are satisfied.¹⁵²

The amount of remuneration in the transaction must be consistent with the fair market value of the transaction. It cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician or other business generated between the parties. The remuneration must be provided under an agreement that would be commercially reasonable even if the physician made no referrals.

There must not be any additional transactions between the parties for 6 months after the isolated transaction unless the additional transaction is specifically excepted under another Stark exception. Commercially reasonable post-closing adjustments that do not take into account (either directly or indirectly) the volume or value of referrals or other business generated by the referring physician are permissible within the 6 month time frame.

(g) *Certain Relationships with Hospitals.* Remuneration paid by a hospital to a physician does not constitute a financial relationship if it does not relate

¹⁵² 42 C.F.R. § 411.357(f).

(directly or indirectly) to the furnishing of DHS.¹⁵³ To qualify as “unrelated,” remuneration must be wholly unrelated to the furnishing of DHS and must not in any way take into account the volume or value of a physician's referrals.

Remuneration relates to the furnishing of DHS if it is an item, service or cost that could be allocated in whole or in part to Medicare or Medicaid under cost reporting principles. Remuneration also relates to the furnishing of DHS if it is furnished directly or indirectly, explicitly or implicitly, in a selective, targeted, preferential, or conditioned manner to medical staff or other persons in a position to make or influence referrals. Finally, remuneration relates to the furnishing of DHS if it otherwise takes into account the volume or value of referrals or other business generated by the referring physician.

(h) *Group Practice Arrangements with a Hospital.* Certain group practice arrangements with a hospital do not constitute a financial relationship.¹⁵⁴ Arrangements between a hospital and a group practice under which DHS are furnished by the group but are billed by the hospital do not constitute a financial relationship if certain conditions are satisfied.

The arrangement must have begun before, and continued in effect without interruption since December 19, 1989. At least 75 percent of DHS covered under the arrangement must be furnished to patients of the hospital by the group.

There must be a written agreement that specifies the services to be furnished and compensation to be paid. The compensation must be consistent with fair market value and fixed in advance. The compensation must be commercially reasonable even if no referrals were made to the entity. The compensation cannot be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.

(i) *Payments by a Physician.* Two types of payments by a physician or his or her immediate family member do not constitute a financial relationship.¹⁵⁵ First, a payment to a laboratory in exchange for the provision of clinical laboratory services does not constitute a financial relationship. Second, a payment to an entity as compensation for any other items or services that are furnished at a price that is consistent with fair market value do not constitute a financial relationship so long as the payments are not specifically excepted by another provision.

(j) *Charitable Donations by a Physician.* *Bona fide* charitable donations made by a physician (or immediate family member) to an entity do not constitute a financial relationship if certain conditions are satisfied.¹⁵⁶ First, the donation must be made to a tax exempt organization. Second, the donation must not be solicited or

¹⁵³ 42 C.F.R. § 411.357(g).

¹⁵⁴ 42 C.F.R. § 411.357(h).

¹⁵⁵ 42 C.F.R. § 411.357(i).

¹⁵⁶ 42 C.F.R. § 411.357(j).

offered in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity. Finally, the donation arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

(k) *Nonmonetary Compensation.* Nonmonetary compensation provided to a physician by an entity will not constitute a financial relationship if it satisfies certain conditions.¹⁵⁷ The compensation cannot exceed an aggregate of \$300 per calendar year, as adjusted annually for inflation (the amount for 2013 is \$380) (“Annual Amount”).¹⁵⁸ The compensation must not be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician. The compensation cannot be solicited by the physician or the physician's practice (including employees and staff members). The compensation arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission. If an entity inadvertently provides nonmonetary compensation to a physician in excess of the Annual Amount, the payment may be allowed if certain conditions are met. First, the value of the excess nonmonetary compensation was no more than 50 percent of the limit. The physician must return the excess nonmonetary compensation or an amount equal to the value of the excess nonmonetary compensation. The compensation must be returned by the end of the calendar year in which the excess nonmonetary compensation was received or within 180 consecutive calendar days following the date the excess nonmonetary compensation was received by the physician, whichever is earlier. An entity may use this provision only once every three years with respect to the same physician.

In addition to the Annual Amount, an entity that has a formal medical staff may provide one local medical staff appreciation event per year for the entire medical staff. Note however, any gifts or gratuities provided in connection with the medical staff appreciation event should be counted against the Annual Amount.

(l) *Fair Market Value Compensation.* Certain fair market value compensation agreements do not constitute a financial relationship.¹⁵⁹ Compensation resulting from an agreement between an entity and a physician, the physician's immediate family or a group of physicians to provide items or services to the other party will not constitute a financial relationship if certain conditions are satisfied. The arrangement must be in writing, signed by the parties and cover only identifiable items or services, all of which are specified in the agreement. The services to be performed cannot involve the counseling or promotion of a business arrangement or other activity that violates a Federal or State law.

¹⁵⁷ 42 C.F.R. § 411.357(k).

¹⁵⁸ The current dollar limit can be found at: http://www.cms.gov/medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_updates.html.

¹⁵⁹ 42 C.F.R. § 411.357(l).

The writing must specify the timeframe for the arrangement. If the parties enter into an agreement only once in the year, then the agreement can be for any period of time and may contain a termination clause. If an arrangement is made for less than 1 year, it may be renewed any number of times if the terms and compensation remain the same.

The writing must specify the compensation that will be provided. The compensation must be set in advance, consistent with fair market value and not take into account the volume or value of referrals or other business generated by the referring physician. Compensation for the rental of equipment may not be determined using a formula based on either (1) the percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed or business generated through the use of the equipment or (2) per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred by the lessor to the lessee.

The arrangement must be commercially reasonable given the nature and scope of the transaction. The arrangement must also further the legitimate business purposes of the parties.

The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

(m) *Medical Staff Incidental Benefits.* Certain incidental benefits provided to the medical staff of a hospital do not constitute a financial relationship.¹⁶⁰ The compensation must be offered to all members of the medical staff practicing in the same specialty without regard to the volume or value of referrals or other business generated between the parties.

The compensation must only be provided during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

The compensation must be provided by the hospital and used by the medical staff members only while on the hospital's campus. "On campus" includes compensation, such as internet access, pagers or two-way radios that are used away from the campus to access hospital medical records or information or to access patients or personnel who are on the hospital campus. "On campus" also includes identification of the medical staff on a hospital website or in hospital advertising.

The compensation must be reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the hospital. The compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. The compensation must be of low value, i.e. less than \$32 (as of CY 2013).¹⁶¹

¹⁶⁰ 42 C.F.R. § 411.357(m).

¹⁶¹ This number is adjusted for inflation annually. The current dollar limit can be found at: http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html.

The compensation arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

This exception is also available to other facilities and health care clinics that have *bona fide* medical staffs.

(n) *Risk-Sharing Arrangements.* Certain risk-sharing arrangements do not constitute a financial relationship.¹⁶² The compensation from a risk-sharing arrangement between a managed care organization or an IPA and a physician (either directly or indirectly through a subcontractor) for services provided to enrollees of a health plan do not constitute a financial relationship so long as the arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

(o) *Compliance Training.* The provision of compliance training does not constitute a financial relationship if certain conditions are met.¹⁶³ Compliance training includes training regarding the basic elements of a compliance program, such as training of staff, internal monitoring or reporting; specific training regarding the requirements of Federal and State health care programs such as billing, coding or documentation; or training regarding other Federal, State or local laws, regulations or rules governing the conduct of the party for whom the training is provided. Compliance training also includes programs that offer continuing medical education credit as long as compliance training is the primary purpose of the program. The training must be provided by an entity to a physician (or to the physician's immediate family member or office staff) who practices in the entity's local community or service area. The training must be held in the local community or service area.

(p) *Indirect Compensation Arrangements.* An arrangement that would otherwise be considered an “indirect compensation arrangement,” (based on the definition found in 42 C.F.R. § 411.354(c)(2)), will not constitute a financial relationship if certain conditions are met.¹⁶⁴ First, the compensation received by the referring physician (or immediate family member) must be fair market value for services and items actually provided. The compensation cannot be determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the entity furnishing DHS.

To meet this requirement, compensation for the rental of office space or equipment may not be determined using a formula based on a percentage of the revenue raised, earned, billed, collected or otherwise attributable to the services performed on or business generated in the office space. Furthermore, compensation for the rental of office space or equipment may not be determined using a formula based on services provided to patients referred by the lessor to the lessee.

¹⁶² 42 C.F.R. § 411.357(n).

¹⁶³ 42 C.F.R. § 411.357(o).

¹⁶⁴ 42 C.F.R. § 411.357(p).

Second, the compensation arrangement must be set out in writing, signed by the parties and specify the services covered by the arrangement. In the case of a *bona fide* employment relationship between an employer and an employee, the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

The compensation arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

(q) *Referral Services.* Remuneration that satisfies the requirements of the anti-kickback statute safe harbor for referral services, found at 42 C.F.R. § 1001.952(f) will not create a financial relationship for purposes of the Stark Law.¹⁶⁵

(r) *Obstetrical Malpractice Insurance Subsidies.* Obstetrical malpractice insurance subsidies do not constitute a financial relationship if the remuneration satisfies certain conditions.¹⁶⁶ The exception applies in two situations. First, a subsidy will not be considered a “financial relationship” for Stark Law purposes if it satisfies the comparable anti-kickback safe harbor. Second, subsidies will not be considered a “financial relationship” if they are paid to physicians practicing in rural areas, a primary care HPSA, or an area with demonstrated need for the physician’s obstetrical services as determined by the Secretary, and the subsidy meets certain additional requirements as described below. Payments must be made by a hospital or other entity to pay for some or all of the costs of malpractice insurance premiums for a physician who engages in obstetrical practice as a routine part of his or her medical practice. The payment must be made to the person or organization that is providing malpractice insurance, not to the physician.

The payment must be made in accordance with a written agreement between the entity paying the premiums and the physician. The agreement must set out the payments to be made by the entity and the terms under which the payments are to be provided. The agreement must be signed by all parties. The agreement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

The physician must certify that for the initial coverage period he or she reasonably believes that at least 75 percent of the obstetrical patients treated under the coverage of the malpractice insurance will reside in a HPSA or a medically underserved area (MUA) or be a member of a medically underserved population (MUP). After the first year, at least 75 percent of the physician’s obstetrical patients must reside in a HPSA or MUA or be part of a MUP. Alternatively, physicians may show that 75% of their patients reside in a rural area or an area with a demonstrated need to satisfy this condition.

¹⁶⁵ 42 C.F.R. § 411.357(q).

¹⁶⁶ 42 C.F.R. § 411.357(r).

The agreement cannot require the physician to make referrals to, or generate business for, the entity as a condition for receiving the benefits. The physician cannot be restricted from establishing staff privileges at, referring any service to or generating any business for any other entity of his or her choosing. The amount of payment may not vary based on the volume or value of any previous or expected referrals to or business otherwise generated for the entity by the physician. The physician must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

The insurance must be a *bona fide* malpractice insurance policy or program. The premium, if any, must be calculated based on a *bona fide* assessment of the liability risk covered under the insurance. This may vary according to full-time and part-time physicians. For physicians who engage in obstetrical practice on a part-time or sporadic basis, the costs must be attributed exclusively to the obstetrical portion of the physician's malpractice insurance. The costs must also be related exclusively to services provided in a primary care HPSA.

(s) *Professional Courtesy.* Professional courtesy is the provision of free or discounted health care items or services to a physician or his or her immediate family members or office staff.¹⁶⁷ When offered by an entity with a formal medical staff to a physician or a physician's immediate family member or office staff, professional courtesy does not constitute a financial relationship if certain conditions are satisfied. First, the professional courtesy must be offered to all physicians on the entity's *bona fide* medical staff or in the entity's local community or service area without regard to the volume or value of referrals or other business generated between the parties. The health care items and services provided must be of a type routinely provided by the entity. The entity must have a professional courtesy policy that is set out in writing and approved in advance by the entity's governing body. The professional courtesy must not be offered to a physician (or immediate family member) who is a Federal health care program beneficiary, unless there has been a good faith showing of financial need. Finally, the arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

(t) *Retention Payments in Underserved Areas.* A hospital may provide remuneration to a physician to persuade the physician to remain at the hospital if certain conditions are met.¹⁶⁸ If the conditions are met, the payment does not constitute a financial relationship under Stark. The physician's current medical practice must be located in a rural area or HPSA or in an area with demonstrated need for the physician as determined by the Secretary. Alternatively, at least 75% of the physician's patients must reside in a MUA or be a member of a MUP.

To be eligible for a retention payment, a physician must have a *bona fide* firm written recruitment offer or offer of employment from a hospital, academic medical

¹⁶⁷ 42 C.F.R. § 411.357(s).

¹⁶⁸ 42 C.F.R. § 411.357(t).

center or physician organization that is not related to the physician's current hospital. The offer must specify the remuneration being offered to the physician. The offer must require the physician to move the location of his or her medical practice at least 25 miles *and* outside of the geographic area served by his or her current hospital. Additionally, the offer must comply with regulatory requirements related to physician recruitment, as discussed above.

The amount of the retention payment is limited to the lower of two metrics. First, the amount cannot exceed the difference between the physician's current income and the income being offered by the other hospital. Alternatively, the amount cannot exceed the reasonable costs that the hospital would incur to replace the physician.

As an alternative to providing a firm offer, a physician may provide a written certification that the physician has a *bona fide* opportunity for future employment by a hospital, academic medical center or physician organization. The opportunity must require the physician to move at least 25 miles and outside the geographic area served by the hospital.

The certification must contain at least five provisions. First, the physician must detail the steps he or she has taken to bring about the employment opportunity. Second, the physician must provide details about the opportunity, including the identity and location of the future employer and the anticipated income. Third, the physician must certify that the future employer is not related to the current hospital. Fourth, the physician must provide the date on which he or she anticipates relocating his or medical practice. Fifth, the physician must provide information sufficient for the hospital to verify the information provided in the written certification.

After receiving the physician's written verification, the hospital must take reasonable steps to verify that the physician has a *bona fide* opportunity. If the physician has a *bona fide* opportunity, then the hospital may make a retention payment. The retention payment may not exceed the lower of two metrics. First, the payment cannot exceed an amount equal to 25 percent of the physician's current income. Alternatively, the retention payment cannot exceed the reasonable costs that the hospital would incur to replace the physician.

The hospital cannot enter into a retention arrangement with a particular referring physician more than once every 5 years. The amount and terms of the payment may not be altered in any manner that takes into account the volume or value of referrals or other business generated by the physician. The arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

If the physician practices in a HPSA or an area with demonstrated need for the physician through an advisory opinion, then the Secretary can waive the relocation requirements so long as all other requirements are met.

The retention payment exception is also available to federally qualified health centers or rural health clinics provided that they meet the above conditions.

(u) *Community-Wide Health Information Systems.* A Stark exception exists for items or services of information technology that are provided by an entity to a physician.¹⁶⁹ Such an arrangement will not constitute a financial relationship if certain conditions are satisfied. First, the technology must provide the physician with access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts and related information for patients served by community providers and practitioners. The purpose of this technology must be to enhance the community's overall health. The items or services must be available as necessary to enable the physician to participate in a community-wide health information system. They must principally be used by the physician as part of the community-wide health system.

The community-wide health information system must be available to all providers, practitioners and residents of the community who wish to participate. The services or items cannot be provided to the physician in any manner that takes into account the volume or value of referrals or other business generated by the physician.

The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

(v) *Electronic prescribing items and services.* A Stark exception exists for items and services necessary and used solely to receive and transmit electronic prescription information.¹⁷⁰ The items and services can include hardware, software or information technology and training services. To qualify for the exception, certain conditions must be satisfied. The items and services may be provided in three different ways. They can be provided by a hospital to a physician who is a member of its medical staff. A group practice can provide these items or services to a physician who is a member of the group. Finally, a prescription drug sponsor or a Medicare Advantage organization can provide them to a prescribing physician.

The items and services must be provided as part of, or used to access, an electronic prescription drug program. The program must meet the applicable standards under Medicare Part D at the time the items and services are provided.

The donor or its representative cannot take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems. The donor must not restrict or take any action to limit the physician's right or ability to use the items or services for any patient. Neither the physician nor the physician's practice can make the receipt of items or services a condition of doing business with the donor. Neither the eligibility of a physician to receive the items or services nor the amount or nature of the items or services can be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties.

¹⁶⁹ 42 C.F.R. § 411.357(u).

¹⁷⁰ 42 C.F.R. § 411.357(v).

The arrangement must be in a written agreement that (1) is signed by the parties (2) specifies the items and services being provided and the donor's cost of the items and services and (3) covers all of the electronic prescribing items and services to be provided by the donor.

Finally, the donor must not have actual knowledge of, and not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor

(w) *Electronic health records items and services.* A Stark exception exists for items and services used to create, maintain, transmit or receive electronic health records when they are provided by an entity to a physician at no cost.¹⁷¹ Certain conditions must be satisfied to qualify for this exception. The software must be interoperable at the time it is provided to the physician. Software is interoperable when it can communicate and exchange data accurately, effectively, securely and consistently with different information technology systems, software applications and networks. Software will be deemed interoperable if a recognized certifying body has certified it no more than 12 months prior to the date it is provided to the physician. The software must also be able to exchange data in a manner that allows the clinical or operational purpose and meaning of the data to be preserved and unaltered. The donor must not limit or restrict the use, compatibility or interoperability of the items or services. The software must have electronic prescribing capability that meets the applicable standards under Medicare Part D at the time the items and services are provided.

The physician must pay 15% of the cost of the items or services prior to receiving them. The donor cannot finance the physician's payment or loan funds to the physician to pay for the items and services. Neither the physician nor the physician's practice can make receipt of the items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

Neither the eligibility of a physician for the items or services nor the amount or nature of the items or services can be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. There are numerous ways to satisfy this condition. The determination can be based on one of the following metrics:

- The total number of prescriptions written by the physician.
- The size of the physician's medical practice.
- The total number of hours that the physician practices medicine.
- The physician's use of automated technology in his or her practice.
- Whether the physician is a member of the donor's medical staff.

¹⁷¹ 42 C.F.R. § 411.357(w).

- The level of uncompensated care provided by the physician.
- Any other reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.

The arrangement must be set forth in a written agreement and signed by both parties. The agreement must specify the items and services to be provided, the donor's costs and the amount of the physician's contribution. The agreement must cover all of the electronic health records items and services to be provided by the donor.

The donor must not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient. The donor must not have actual knowledge of, and not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.

The items and services cannot include staffing of physician offices. They cannot be used primarily to conduct personal business or business unrelated to the physician's medical practice.

The arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

Finally, the transfer of the items or services and compliance with all the above conditions must occur before December 31, 2013.

6. Exceptions to Any Financial Relationship

(a) *Physician Services.* Services that are personally performed by a physician do involve a "referral" and therefore do not implicate the Stark Law. In addition, physician services furnished personally by another physician who is a member of the referring physician's group practice are not subject to the Stark Law's prohibition on referrals.¹⁷² Physician services are also exempt if they are performed under the supervision of another physician who is a member of the referring physician's group practice. For this exception, physician services include those services that are performed "incident" to the physician's services.

(b) *In-Office Ancillary Services.* Certain in-office ancillary services, including some durable medical equipment (DME), are exempt from the referral prohibition.¹⁷³ To qualify for the exception, certain conditions must be satisfied related to (1) who performed the service, (2) where the service was performed and (3) who or what entity billed for the service.

¹⁷² 42 C.F.R. § 411.355(a).

¹⁷³ 42 C.F.R. § 411.355(b).

The services must be furnished personally by (1) the referring physician, (2) a physician who is a member of the same group practice or (3) an individual who is supervised by the referring physician or a member of the physician's group practice.

The services must be performed in accordance with one of the following four sets of location requirements. First, the services can be provided in the "same building" in which the referring physician or his or her group practice has an office that is normally open to patients for at least 35 hours per week. The referring physician or one or more members of his or her group practice must regularly practice medicine and furnish physician services in the same building at least 30 hours per week, including some physician services unrelated to the furnishing of DHS.

Second, the services can be provided in the same building in which the patient usually receives physician services from the referring physician or member of the referring physician's group practice. The referring physician or his or her group practice must own or rent an office in that building that is normally open to patients for medical services at least 8 hours per week and must also regularly practice medicine in that building at least 6 hours per week.

Third, the service can be provided in the same building where the referring physician is present and orders the service during the patient visit. The referring physician or his or her physician's group practice must own or rent an office in that building that is normally open to patients at least 8 hours per week and must regularly practice in that building at least 6 hours per week.

Finally, the services can be furnished in a "centralized building" that is used by the group practice for the provision of clinical laboratory services or for the provision of some or all of the group's DHS.

If the services are provided in a qualifying location, then the services must be billed by one of five specific individuals or entities. First, the physician performing or supervising the service can bill for the service. The group practice of the performing or supervising physician can bill for the service under the group practice's billing number. Third, the group practice may bill for the service under the group practice's billing code if the supervising physician is a physician in the group practice. Fourth, an entity that is owned by the performing or supervising physician or his or her group practice may bill under the physician's or the group practice's billing number. Finally, an independent third party billing company acting as an agent may bill for the services under a billing number assigned to the physician, group practice or entity.

Certain DME are covered by this exception and must comply with additional conditions. Covered DME include canes, crutches, walkers and folding manual wheelchairs. These items are covered if the patient requires the DME to depart from the physician's office. Blood glucose monitors are also covered by the exception if they are furnished by a physician or employee of a physician or group practice that provides outpatient diabetes self-management training.

The DME must be furnished in one of the four types of locations discussed above. The item must be furnished personally by the physician ordering the DME, by another physician in the group practice or by an employee of the physician or group practice. The physician or group practice must meet all DME supplier standards. The arrangement must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

A special rule applies to home care physicians. A home care physician is a physician whose principal practice consists of treating patients in the patient's private home. A private home does not include a nursing, long-term care or other facility or institution unless a patient has a private home at such a facility. Home care physicians will satisfy the same building requirement if the physician provides the service contemporaneously with a physician service that is not a DHS.

A referring physician must make certain disclosures when referring a patient for particular imaging services. Covered imaging services include magnetic resonance imaging, computed tomography and positron emission tomography. When referring for such services, the physician must provide the patient with written notice that imaging services are available from other providers. This notice must be provided at the time the referral is made. The notice must include a list of at least 5 other suppliers that provide the imaging service and are located within a 25 mile radius of the referring physician's office. The notice must be written in plain English. Notice is not required if no alternate providers are in the 25 mile radius.

(c) *Services Furnished by an Organization (or its Contractors or Subcontractors) to Enrollees.* Services furnished by an organization to enrollees of certain prepaid health plans are exempt from the referral prohibition.¹⁷⁴ The following plans are exempt:

- An HMO or a CMP that has entered into a valid contract with CMS authorizing Medicare payments to the HMO or CMP.
- A health care prepayment plan that has entered into a valid written agreement with CMS to participate in the Medicare program.
- An organization that is receiving payments on a prepaid basis for Medicare enrollees through a demonstration project to evaluate payment systems for healthcare services and propose changes to increase the efficacy of the provision of healthcare services.¹⁷⁵
- A HMO that has been authorized to receive Medicare payments.¹⁷⁶

¹⁷⁴ 42 C.F.R. § 411.355(c).

¹⁷⁵ 42 U.S.C. § 1395b-1 and 42 U.S.C. § 1395b-1 note.

¹⁷⁶ Section 1310(d) of the Public Health Service Act.

- A coordinated care plan offered by an organization in accordance with a contract with CMS under the Medicare Advantage Program.
- A MCO contracting with a State.
- A prepaid inpatient health plan or prepaid ambulance health plan contracting with a State to provide services to Medicaid recipients.
- A health insuring organization contracting with a State to perform quality assessment and performance improvement strategies.¹⁷⁷
- An entity operating other demonstration projects under the Act.¹⁷⁸

(d) *Academic Medical Centers.* Services provided by an academic medical center are not subject to the Stark Law’s prohibitions if certain conditions are met.¹⁷⁹

The academic medical center (“AMC”) must be an accredited medical school or academic hospital. The AMC must have one or more faculty practice plans affiliated with the medical school, the affiliated hospital or the accredited academic hospital. An accredited academic hospital is a hospital or health system that sponsors four or more approved medical education programs.

The AMC must also have one or more affiliated hospitals in which a majority of the physicians on the medical staff consists of physicians who are faculty members. A majority of the hospital’s admissions must be made by physicians who are faculty members. A faculty member is a physician who is either on the faculty of the affiliated medical school or on the faculty of one or more of the educational programs at the accredited academic hospital. When determining whether a majority of the hospital admissions are made by faculty members, the AMC may aggregate faculty members from any affiliate medical school or accredited academic hospital education program.

If the entity is a qualified AMC, certain conditions must be satisfied for it to come under the exception. First, the referring physician must be a *bona fide* employee of a component of the academic medical center on a full-time or substantial part-time basis. The referring physician must be licensed to practice medicine in the state. The referring physician must have a *bona fide* faculty appointment at the affiliated medical school or at one or more of the educational programs at the accredited academic hospital. Furthermore, the referring physician must provide either substantial academic services or substantial clinical teaching services and receive compensation from the AMC as part of his or her employment agreement. Substantial means he or she spends at least 20 percent of his or her professional time or 8 hours per week providing academic services or clinical teaching services.

¹⁷⁷ 42 C.F.R. § 438.200(d).

¹⁷⁸ Sections 1115(a), 1915(a), 1915(b), or 1932(a) of the Act.

¹⁷⁹ 42 C.F.R. § 411.355(e).

Second, the compensation paid to the referring physician must satisfy certain conditions. The total compensation must be set in advance and not exceed fair market value for the services provided. The total compensation amount must not take into account the volume or value of any referrals or other business generated by the referring physician within the academic medical center.

Third, payments made by the AMC must also satisfy certain conditions. All transfers of money between components of the academic medical center must directly or indirectly support the missions of teaching, indigent care, research, or community service. The relationship of the components of the academic medical center must be set forth in one or more written agreements or other written documents that have been adopted by the governing body of each component. All money paid to a referring physician for research must be used solely to support *bona fide* research or teaching and must be consistent with the terms and conditions of the grant.

Finally, the referring physician's compensation arrangement must not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

(e) *Implants Furnished by an ASC.* Implants furnished by an ambulatory surgery center (ASC) do not implicate the Stark Law's prohibitions if certain conditions are satisfied.¹⁸⁰ Exempt implants include cochlear implants, intraocular lenses and other implanted prosthetics.

The implant must be implanted by the referring physician or a member of the referring physician's group practice in an ASC. The ASC with which the referring physician has a financial relationship must be certified by Medicare.

The implant must be implanted during a surgical procedure paid by Medicare to the ASC. The arrangement for the furnishing of the implant must not violate the anti-kickback state and all billing and claims submission for the implants must not violate any Federal or State law or regulation governing billing or claims submissions.

This exception does not apply to any financial relationships between the referring physician and any entity other than the ASC in which the implant is furnished or implanted.

(f) *EPO and Other Dialysis-Related Drugs.* The provision of EPO and other dialysis-related drugs do not implicate the Stark Law's prohibitions if certain conditions are satisfied.¹⁸¹ Exempt drugs include outpatient prescription drugs required to ensure the efficacy of dialysis and identified as eligible for this exception on the List of CPT/HCPCS Codes. The drugs must be furnished in or by an end stage renal disease (ESRD) facility. This includes drugs that the ESRD facility dispenses to a patient to use at home.

¹⁸⁰ 42 C.F.R. § 411.355(f).

¹⁸¹ 42 C.F.R. § 411.355(g).

The arrangement must not violate the anti-kickback statute. All billing and claims submission for the EPO and other dialysis-related drugs must not violate any Federal or State law or regulation governing billing or claims submission.

This exception does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.

(g) *Preventive Screening Tests, Immunizations and Vaccines.* The provision of preventive screening tests, immunizations and vaccines do not implicate the Stark Law's prohibitions if certain conditions are satisfied.¹⁸² First, the test, immunization or vaccine must be subject to CMS mandated frequency limits. The arrangement for the provision of the preventive screening tests, immunizations and vaccines must not violate the anti-kickback statute. All billing and claims submission for the preventive screening tests, immunizations and vaccines must not violate any Federal or State law or regulation governing billing or claims submission. The preventive screening tests, immunizations and vaccines must be covered by Medicare and recognized by Medicare as exempt under this exception.

(h) *Eyeglasses and Contact Lenses Following Cataract Surgery.* Eyeglasses and contact lenses that are covered by Medicare when furnished to patients following cataract surgery do not implicate the Stark Law prohibitions so long as the arrangement does not violate the anti-kickback statute.¹⁸³ Additionally, all billing and claims submission for the eyeglasses or contact lenses must not violate any Federal or State law or regulation governing billing or claims submission.

(i) *Intra-Family Rural Referrals.* A physician may refer patients who live in rural areas to the physician's immediate family member or to an entity with which a family member has a financial relationship if certain conditions are satisfied.¹⁸⁴

The patient's medical condition must require timely service. Those services must not be available in a timely manner within 25 miles of, or 45 minutes from, the patient's residence. 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 in the area.

The financial relationship must not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission.

¹⁸² 42 C.F.R. § 411.355(h).

¹⁸³ 42 C.F.R. § 411.355(i).

¹⁸⁴ 42 C.F.R. § 411.355(j).

7. Reporting Requirements

The Stark regulations include a section that requires DHS entities to provide information to CMS or the OIG, upon request, about the entities' financial relationships with physicians. Anyone who fails to report such information when requested and as required by the regulation may be subject to a civil money penalty of up to \$10,000 for each day following the deadline, until the information is submitted.

8. Advisory Opinions

Similar to the OIG advisory opinions for the AKS, discussed above, Section 1877(g)(6) of the Social Security Act requires CMS to issue certain written advisory opinions regarding potential Stark Law violations.¹⁸⁵ These opinions provide guidance on whether a physician's referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship are prohibited under the Medicare program by section 1877 of the Social Security Act.

The purpose of the CMS advisory opinion process is to provide an opinion, binding upon the requestor, concerning application of the Stark Law to specific factual situations. The requestor must be a party to the existing or proposed arrangement and is the only individual or entity that may rely on the advisory opinion. CMS specifically disclaims the ability of third parties to be bound by, or legally rely on, its advisory opinions.

CMS sets forth a specific procedure for submitting advisory opinion requests (format, substantive information, additional information), which can be found at 42 C.F.R. § 411.372. CMS makes its advisory opinions available to the general public through the CMS website.¹⁸⁶ To date, CMS has only published nine advisory opinions.

9. Voluntary Disclosures

Section 6409 of PPACA required HHS to establish a voluntary self-referral disclosure protocol ("SRDP"). The SRDP is separate from the advisory opinion process: it cannot be used to obtain a CMS determination as to whether an actual or potential Stark Law violation occurred. Instead, the SRDP provides a process through which health care providers of services and suppliers may self-disclose actual or potential violations of the Stark Law. It is open to all health care providers of services and suppliers, whether individuals or entities, and is not limited to any particular industry, medical specialty, or type of service.

¹⁸⁵ Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Correcting Amendment, 69 Fed. Reg. 57,226 (Sept. 24, 2004) (to be codified at 42 C.F.R. pt. 411).

¹⁸⁶ CMS Physician Self Referral Advisory Opinions, available at: http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.

The SRDP includes: (1) a listing of the information that a disclosing party should provide CMS to analyze the actual or potential violation (e.g., description of actual or potential violations, financial analysis, a description of the disclosing party's compliance program, etc.); (2) the process for making a self-disclosure submission to CMS; and (3) the factors that CMS may consider in reducing amounts otherwise owed by disclosing parties. The voluntary disclosure submission should separately list each financial arrangement that is relevant to the alleged overpayment obligation, providing the requested information, analysis and overpayment amount for each arrangement.

PPACA also grants the Secretary of HHS the authority to reduce the amount due and owing for all violations of the Stark Law by considering the following:

- The nature and extent of the improper or illegal practice;
- The timeliness of such disclosure;
- The cooperation in providing additional information related to the disclosure;
- The litigation risk associated with the matter disclosed;
- The financial position of the disclosing party; and
- Other such factors as the Secretary of HHS considers appropriate.

Upon submitting a disclosure under the SRDP, PPACA's obligation to return any potential overpayment within 60 days will be suspended until a settlement agreement is entered, the provider of services or supplier withdraws from the SRDP, or CMS removes the provider of services or supplier from the SRDP. While the matter is under CMS inquiry, the disclosing party must refrain from making payment relating to the disclosed matter to federal healthcare programs or their contractors without CMS' prior consent.

CMS will review the circumstances surrounding the matter disclosed to determine an appropriate resolution. As a condition of disclosing a matter pursuant to the SRDP, the disclosing party agrees that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement. The SRDP should not be used if the underlying conduct could give rise to an AKS claim. CMS may refer voluntary disclosures submitted under the SRDP to the OIG and/or DOJ. CMS posts on its website certain information related to select voluntary disclosures resolved under the SRDP.

B. The Georgia Patient Self-Referral Act of 1993

1. In General. The Georgia Patient Self-Referral Act of 1993¹⁸⁷ (the "Georgia Stark Law") prohibits health care providers from referring a patient for the

¹⁸⁷ O.C.G.A. §§ 43-1B-1 to -8.

provision of DHS to an entity in which the health care provider or an immediate family member has an investment interest, unless an exception applies.¹⁸⁸

Health care providers include physicians, chiropractors, podiatrists, optometrists, pharmacists, and physical therapist licensed by the state. The Georgia Stark Law prohibits presenting a claim for payment for a service furnished pursuant to a prohibited referral. No regulations have been promulgated to date for the Georgia Stark Law.

The Georgia Stark Law defines DHS to include: clinical laboratory services, physical therapy services, rehabilitation services, diagnostic imaging services, pharmaceutical services, durable medical equipment, home infusion therapy services (including related pharmaceuticals and equipment), home healthcare services, and outpatient surgical services.

The Georgia Stark Law is broader than the federal Stark Law in that it is not limited to referrals for services payable by federal or state health care programs. However, the Georgia Stark Law does not apply to any health care provider or to any DHS if the financial interest of such health care provider in such DHS is restricted or regulated pursuant to any federal law that is applicable to such health care provider or DHS and that covers private paying patients as well as Medicare or Medicaid patients.

2. Exceptions. The Georgia Act at first appears to be a broad prohibition against self-referrals because of its application to all payers, but there several exceptions that limit its scope significantly. Major exceptions are contained in the definitions of “referral” and “investment interest,” and the Georgia Act also contains exceptions for certain cases of community need, and health services regulated by federal law.

(a) *“Referral” Exceptions.* The Georgia Stark Law prohibits certain referrals. Seven types of orders, recommendations or plans of care do not constitute a referral when they meet certain criteria.

First, a radiologist may refer a patient for diagnostic imaging services.¹⁸⁹

Second, a health care provider specializing in the provision of radiation therapy services may refer a patient for radiation therapy services.¹⁹⁰

Third, a health care provider may refer a patient within the health care provider’s group practice.¹⁹¹

Fourth, a pathologist may refer a patient for diagnostic clinical laboratory tests and pathological examination services.¹⁹² The services must be furnished by or under the

¹⁸⁸ O.C.G.A. § 43-1B-4.

¹⁸⁹ O.C.G.A. § 43-1B-3(10)(C)(i).

¹⁹⁰ O.C.G.A. § 43-1B-3(10)(C)(ii).

¹⁹¹ O.C.G.A. § 43-1B-3(10)(C)(iii).

supervision of the pathologist and the services must be pursuant to a consultation requested by another health care provider.

Fifth, a hospital's staff health care provider may refer a patient to the hospital at which the health care provider has current staff privileges.¹⁹³

Sixth, a health care provider may refer patients to receive items or services if certain conditions are met.¹⁹⁴ The items or services must be provided to the patient by the health care provider or by a member of his or her group practice. The patient must be a patient of the health care provider or of a member of the provider's group. The items or services must be provided or performed at the direction or under the supervision of the health care provider or his or her group practice.

Seventh, a health care provider may refer a patient when the patient is in need of emergency health care services where any delay in treatment could reasonably be expected to jeopardize the life or health of the person affected.¹⁹⁵

(b) *“Investment Interest” Exceptions.* The Georgia Stark Law prohibits covered investors from holding investment interests in any individual, partnership, firm, corporation or other business entity.¹⁹⁶ Covered investors are health care providers or entities owning a legal or beneficial ownership or investment interest, directly or indirectly, including, without limitation, through an immediate family member, trust or another entity related to the investor.¹⁹⁷ The law excepts certain investment interests by a covered investor.

First, an investor may invest in a provider of a designated health service solely in a rural area.¹⁹⁸ “Rural area” means a county with a population density of no greater than 65 persons per square mile, as defined by the United States decennial census of 1990.¹⁹⁹

Second, an investor may acquire an investment interest in an entity that provides designated health services if certain conditions are met.²⁰⁰ The investment interest must be in the form of a debt instrument. The debt instrument must be an integral part of a plan by the entity to acquire the investor's equity investment interest in the entity. The interest rate must be consistent with fair market value. The maturity date of the debt instrument must be no later than July 1, 1996.

¹⁹² O.C.G.A. § 43-1B-3(10)(C)(iv).

¹⁹³ O.C.G.A. § 43-1B-3(10)(C)(v).

¹⁹⁴ O.C.G.A. § 43-1B-3(10)(C)(vi).

¹⁹⁵ O.C.G.A. § 43-1B-3(10)(C)(vii).

¹⁹⁶ O.C.G.A. § 43-1B-3(8).

¹⁹⁷ O.C.G.A. § 43-1B-3(9).

¹⁹⁸ O.C.G.A. § 43-1B-3(8)(A).

¹⁹⁹ O.C.G.A. § 43-1B-3(11).

²⁰⁰ O.C.G.A. § 43-1B-3(8)(B).

Third, an investor may invest in real property that establishes a landlord-tenant relationship between the investor and a health care provider.²⁰¹ The rent must not be determined in a manner that takes into account the business volume or profitability of the tenant or that exceeds fair market value.

The fourth exception allows for certain financial relationships with an educational institution that provides education and training in the health services.²⁰² An educational institution can have a financial relationship with an entity through which its faculty or employees, who are health care providers, provide designated health services.

Fifth, the investor may invest in a publically held corporation with total assets over \$50 million.²⁰³ The shares must be traded on a national exchange or over the counter. The investor must not own more than 1 percent of the corporation. There must not be a special stock class for health care provider investors. No income from the investment interest can be tied to the volume of referrals.

(c) *Exception for Community Need.* A referral that would otherwise be prohibited is excepted if there is no other entity or facility of reasonable quality, price or service in the community that can provide the service to the patient.²⁰⁴ Certain conditions must be satisfied to qualify for this exception. There must not be alternative financing that is reasonably available to finance the entity or facility. A health care provider cannot be required to make referrals or otherwise generate business as a condition for becoming or remaining an investor. All other individuals must be given a bona fide opportunity to invest in the facility on the same terms as a referring health care provider.

The facility must not loan funds or guarantee loans for referring health care providers. The investment income must not be based on the volume of referrals made by the health care provider.

The facility must provide uncompensated health services for indigent or charity patients at a standard which meets or exceeds 3 percent of the facility's gross revenue after provisions for bad debts and third-party adjustment have been deducted. The services offered must be reasonably financially accessible to the residents of the facility's service area.

Prior to making the referral, the health care provide must disclose to the patient the provider's financial interest in the facility. The disclosure must be in writing and approved by the health care provider's respective board.²⁰⁵ The disclosure must include:

²⁰¹ O.C.G.A. § 43-1B-3(8)(C).

²⁰² O.C.G.A. § 43-1B-3(8)(D).

²⁰³ O.C.G.A. § 43-1B-3(8)(E).

²⁰⁴ O.C.G.A. § 43-1B-6.

²⁰⁵ O.C.G.A. § 43-1B-5.

- The existence of the investment interest.
- The name and address of each applicable entity in which the health care provider is an investor.
- The patient's right to obtain the items or services from another facility.

The health care provider must post a copy of this disclosure in a conspicuous public place in the provider's office.

(d) *Exception for Workers' Compensation Claimants.* The Georgia Act used to contain an exception for referrals from a physician²⁰⁶ listed on a valid panel of workers' compensation physicians and treating the referred patient pursuant to Georgia's workers' compensation statutes or the rules of the State Board of Workers' Compensation.²⁰⁷ However, this exception was repealed in 2006.²⁰⁸

(e) *Exception for Health Care Providers with Interest in Health Service Regulated by Federal Law.* The Georgia Stark Law does not apply to the financial relationships of any health care provider or designated health service if those financial relationships are restricted or regulated by any federal law which applies to health care providers or designated health services and which covers private paying patients as well as Medicare or Medicaid patients.²⁰⁹

3. Disclosure of Permitted Self-Referrals

If a provider's referral of a patient to an entity in which he or she has an investment interest is not prohibited by the Georgia Act, then the provider must furnish the patient with a written disclosure form approved by the provider's licensing board informing the patient of the following information: (i) the existence of the investment interest; (ii) the name and address of the entity or entities in which the referring provider is an investor; and (iii) the patient's right to obtain the items or services from another provider or supplier of the patient's choice unless otherwise restricted by law.²¹⁰ The Georgia Act also requires that the provider post a copy of the disclosure form in a conspicuous public place in the care provider's office.²¹¹ Failure to comply with the disclosure requirements is grounds for disciplinary action by the provider's licensing board.²¹²

²⁰⁶ Note that this exception applies only to physicians, and not to all providers subject to the Georgia Act.

²⁰⁷ O.C.G.A. § 43-1B-3(7).

²⁰⁸ O.C.G.A. § 43-1B-7 (repealed by Act No. 696, § 5, 2006 Ga. Laws 676, 678 eff. July 1, 2006).

²⁰⁹ O.C.G.A. § 43-1B-8.

²¹⁰ O.C.G.A. § 43-1B-5(a).

²¹¹ O.C.G.A. § 43-1B-5(b).

²¹² O.C.G.A. § 43-1B-5(c).

4. Penalties

If a health care provider or entity collects any amount billed in violation of the Georgia Stark Law, the health care provider or entity shall timely refund the amount to the payer or individual. The Georgia Stark Law subjects any person who presents or causes to be presented a bill or claim for service that resulted from the prohibited referral to a civil penalty of up to \$15,000 for each service. Moreover, any healthcare provider participating in a “cross-referral” scheme or arrangement is subject to a civil penalty of up to \$50,000 for each scheme or arrangement. Additionally, if a health care provider or entity that divides or agrees to divide fees for DHS with any health care provider or entity based on the prohibited referral, it is subject to a civil penalty of not more than \$15,000 for each service. Finally, violation of the Georgia Stark Law constitutes grounds for disciplinary action by the health care provider’s respective licensing board.

5. Enforcement History. As stated above, the State has not promulgated any regulations related to the Georgia Stark Law. Furthermore, the authors have been unable to identify any cases of enforcement actions that have been pursued or settlement agreements that have been entered into premised on a violation of the Law, although there are a handful of briefs and court filings citing the Law that have been submitted in civil cases.

IV. FALSE CLAIMS, FRAUD, AND MISREPRESENTATION

A. The False Claims Act

1. In General. The federal False Claims Act²¹³ is one of the primary vehicles currently being used to enforce health care fraud and abuse laws, through actions brought directly by the government as well as actions brought by relators under the False Claims Act’s *qui tam* provisions.²¹⁴ The False Claims Act punishes knowing and willful fraudulent claims for payment against the federal government with civil monetary penalties and up to treble damages. The False Claims Act may be violated through any of seven different acts, including:²¹⁵

- Knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval by the federal government;²¹⁶
- Knowingly making or using, or causing to be made or used, a false record or statement to get a false claim paid or approved;²¹⁷

²¹³ 31 U.S.C. §§ 3729 *et seq.*

²¹⁴ 31 U.S.C. § 3730(b).

²¹⁵ 31 U.S.C. § 3729(a)(1)(A) – (G).

²¹⁶ 31 U.S.C. § 3729(a)(1)(A).

²¹⁷ 31 U.S.C. § 3729(a)(1)(B).

- Conspiring to defraud the government by getting a false or fraudulent claim allowed or paid;²¹⁸ or
- Knowingly making, using, or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay money or transmit property to the government.²¹⁹

Violations are punishable by a civil penalty of not less than \$5,500 and no more than \$11,000 per claim, plus three times the damages sustained by the government.²²⁰ In the case of physicians, each claim form listing codes for various services provided (and not each code for services) constitutes a separate claim when submitted.²²¹

In Fiscal Year 2012, the Justice Department recovered nearly \$5 billion in false claims acts cases, including record recoveries of more than \$3 billion for health care fraud.²²² The Attorney General and HHS attributed these record recoveries to the creation of the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”). HEAT is an interagency task force that increases coordination and optimizes criminal and civil enforcement.²²³

2. The Qui Tam Enforcement Mechanism. The False Claims Act contains a unique enforcement mechanism that permits private citizens, referred to as *qui tam* relators, to file suit on behalf of the federal government.²²⁴ *Qui tam* suits are filed under seal, giving the government a chance to investigate the allegations and determine whether to intervene in the suit.²²⁵ If the government elects not to intervene, then the relator may litigate the case on his or her own.²²⁶ If the government intervenes, then the action is conducted by the government from that point forward.²²⁷

²¹⁸ 31 U.S.C. § 3729(a)(1)(C).

²¹⁹ 31 U.S.C. § 3729(a)(1)(G).

²²⁰ 31 U.S.C. § 3729(a). Violators who timely cooperate with the government before a criminal, civil, or administrative action is commenced, and before having knowledge that an investigation exists, are liable for a reduced penalty of no less than twice the damages suffered by the government. 31 U.S.C. § 3729(a)(2).

²²¹ See United States v. Krizek, 111 F.3d 934, 940 (D.C. Cir. 1997) (each HCFA 1500 form, and not each CPT code on form, held to constitute a claim).

²²² See Press Release, U.S. Dep’t of Justice, Office of Public Affairs, Justice Department Recovers Nearly \$5 Billion in False Claims Act Cases in Fiscal Year 2012 (Dec. 4, 2012), available at <http://www.justice.gov/opa/pr/2012/December/12-ag-1439.html>.

²²³ Id.

²²⁴ 31 U.S.C. § 3730(b).

²²⁵ 31 U.S.C. § 3730(b)(2).

²²⁶ 31 U.S.C. § 3730(b)(4)(B).

²²⁷ 31 U.S.C. § 3730(b)(4)(A).

Qui tam relators are generally entitled to receive between 15% and 25% of any recovery obtained as a result of any suit in which the government intervenes.²²⁸ If the government does not intervene, and the relator litigates the action, then the relator is entitled to a share of between 25% and 30% of the recovery.²²⁹ The relator may also recover attorneys' fees and costs.²³⁰

Qui tam relators are often insiders who have access to confidential documents and who may have been involved in the conduct underlying the False Claims Act action. If the relator planned and initiated the fraud, then his or her percentage of the recovery may be reduced or even eliminated.²³¹ A relator convicted of criminal wrongdoing related to the False Claims Act allegations is not entitled to any share of the recovery.²³²

3. Application to the Fraud and Abuse Laws Through Express Certification Theories. Submitting reimbursement claims for health care items and services rendered in violation of the violation of laws or requirements applicable to federal healthcare programs may violate the False Claims Act if the claimant certifies compliance with federal health care laws and regulations in connection with the claim. In United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,²³³ the court held a false certification of compliance with laws and regulations given in connection with submission of a hospital's cost report creates liability under the False Claims Act if the government has conditioned payment upon the certification of compliance.²³⁴ The government has alleged that a false certification of compliance with laws submitted as part of Corporate Integrity Agreement constitutes a False Claims Act violation.²³⁵ When submitting a claim for reimbursement, a physician may incur False Claims Act liability for falsely certifying the medical necessity of services²³⁶ or that he or she was the physician who provided or personally supervised the services.²³⁷

Certain providers who receive reimbursement from government health programs do not file an annual cost report or other document certifying compliance with federal health care laws and regulations. Implied certification is a judicially created doctrine whereby a mere request for payment implicitly represents material compliance with relevant laws regulations and conditions of participation/payment, so that submission of

²²⁸ 31 U.S.C. § 3730(d)(1).

²²⁹ 31 U.S.C. § 3730(d)(2).

²³⁰ 31 U.S.C. § 3730(d)(1)-(2).

²³¹ 31 U.S.C. § 3730(d)(3).

²³² Id.

²³³ 125 F.3d 899 (5th Cir. 1997) (certification of compliance false due to violations of the Anti-Kickback Statute and the Stark Law).

²³⁴ Id. at 902.

²³⁵ United States ex rel. Matheny v. Medco Health Solutions, Inc., 671 F.3d 1217 (11th Cir. 2012).

²³⁶ United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 376 n.6 (5th Cir. 2004).

²³⁷ Peterson v. Weinberger, 508 F.2d 45, 52 (5th Cir. 1975).

claims for services provided in violation of such laws regulations or conditions may violate the False Claims Act.²³⁸

4. Recent Changes to the FCA. Section 1909(b)(1) of the Social Security Act requires states to establish liability for false or fraudulent claims described in the federal FCA with respect to any expenditure described in section 1903(a) of the Social Security Act. The passage of the Fraud Enforcement and Recovery Act of 2009 (“FERA”) brought about the first significant amendment of the FCA since 1986. FERA amended the federal FCA to establish liability for knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval.²³⁹ FERA also amended the federal FCA to establish liability for conspiring to commit a violation of another subsection of section (a)(1) of the federal FCA.²⁴⁰ Section 1909(b)(2) of the Social Security Act requires state false claims acts to contain provisions that are at least as effective in rewarding and facilitating *qui tam* actions for false and fraudulent claims as those described in sections 3730 through 3732 of the federal FCA.

FERA also modified the FCA to include a “reverse false claims provision” by expressly including the retention of an overpayment as an “obligation.” Thus, a basis for FCA liability exists if the recipient knowingly concealed such an overpayment from the federal government or knowingly and improperly avoided or reduced the overpayment.²⁴¹ PPACA further established that Medicare and Medicaid overpayments must be reported and returned “within 60 days after the date on which the overpayment was identified” or the date any corresponding cost report is due, whichever is later.²⁴² An overdue overpayment is considered an “obligation” for the purposes of the FCA’s reverse false claims provision.²⁴³

²³⁸ Courts supporting the theory of implied certification under the Stark Law, the Anti-Kickback Statute, or both, include United States ex rel. Freedman v. Suarez-Hoyos, 781 F. Supp. 2d 1270, 1279 (M.D. Fla. 2011) (implied certification under the Anti-Kickback Statute); United States ex rel. Wilkins v. United Health Group, Inc., 659 F.3d 295 (3d Cir. 2011) (implied certification under the Anti-Kickback Statute); and United States v. Rogan, 459 F. Supp. 2d 692, 728 (N.D. Ill. 2006) aff’d, 517 F.3d 449 (7th Cir. 2008)(implied certification under the Stark Law and the Anti-Kickback Statute); United States ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88, 94 (3d Cir. 2009)(implied certification under the Stark Law and the Anti-Kickback Statute). But see United States ex rel. Perales v. St. Margaret’s Hospital, 243 F. Supp. 2d 843 (C.D. Ill. 2003) (stating lack of consensus among courts on theory of implied certification (citing United States ex rel. Joslin v. Cmty. Home Health of Md., Inc., 984 F. Supp. 374, 384 (D. Md. 1997))); United States ex rel. Obert-Hong v. Advocate Health Care, 211 F. Supp. 2d 1045 (N.D. Ill. 2002)(also stating lack of consensus among courts on theory of implied certification, without citations); United States ex rel. Gross v. AIDS Research Alliance-Chicago, 415 F.3d 601, 605 (7th Cir. 2005) (where an FCA claim is based upon an alleged false certification of regulatory compliance, the certification must be a condition of the government payment in order to be actionable).

²³⁹ 31 U.S.C. § 3729(a).

²⁴⁰ 31 U.S.C. § 3729(a).

²⁴¹ 31 U.S.C. § 3729(b)(3).

²⁴² 42 U.S.C. § 1320a-7k(d).

²⁴³ 42 U.S.C. § 1320a-7k(d)(3).

In 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank”) amended the federal FCA by, among other things, broadening the FCA to cover conduct by persons “associated” with a whistleblower in furtherance of an FCA whistleblower action, expanding the definition of protected conduct to include employees’ lawful efforts to investigate or stop FCA violations, and establishing a three-year statute of limitations for retaliation actions.²⁴⁴

In 2010, PPACA changed the language of the AKS to provide that claims submitted in violation of the AKS automatically constitute false claims for purposes of the FCA. Previously, many courts had found that there was nothing “false” about a claim if it was submitted by an innocent party (i.e., the person who filed the claim with the government had no connection to the unlawful conduct). At times, even when a claimant’s behavior was not innocent, courts held that there was no false claim because the reimbursement claim itself did not expressly state that the claimant had complied with the AKS.²⁴⁵

PPACA also made several changes to the public disclosure bar of the federal FCA (i.e., relators should not be permitted to pursue claims already known to the government and which it was in the process of investigating). Prior to PPACA, the First Circuit had set forth a multi-step analysis to determine whether an action was barred by the public disclosure bar:

(1) Whether there has been public disclosure of the allegations or transactions in the relator’s complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statutes; (3) if so, whether the relator’s suit is “based upon” those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the “original source” exception as defined in § 3730(e)(4)(B).²⁴⁶

While PPACA did not alter steps (1) or (3), it did add procedural changes affecting steps (2) and (4). Post-PPACA, a court must dismiss an action or claim made under the federal FCA (unless opposed by the Government), if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed in the news media or in a congressional, Government Accountability Office, or other Federal report, hearing, audit or investigation.²⁴⁷ In 2011, the Supreme Court offered further guidance on the public disclosure bar, holding that the public disclosure bar prevents qui

²⁴⁴ 31 U.S.C. § 3730(h).

²⁴⁵ See United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010).

²⁴⁶ United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 728 (1st Cir. 2007).

²⁴⁷ 31 U.S.C. § 3730(e)(4)(A). This amendment reversed the Supreme Court’s ruling in Graham County Soil & Water Conservation District v. United States ex rel. Wilson, 130 S. Ct. 1396 (2010), that in the context of a federal statute devoted to combating federal fraud where the terms “congressional” and “Government Accounting Office” related to federal sources, the term “administrative” should be encompass state or local administrative bodies, not just federal ones.

tam actions under the FCA if the fraud has already been disclosed by the government in response to a request under the Freedom of Information Act.²⁴⁸

Notwithstanding a public disclosure, *qui tam* actions may still go forward if the relator is an “original source.” PPACA modified the definition of “original source.” Previously, “original source” was defined as an individual who had “direct and independent knowledge of the information on which the [FCA] allegations are based” and who had “voluntarily provided the information to the Government” before filing an FCA action.²⁴⁹ Post-PPACA, “original source” means an individual who disclosed the information on which the allegations or transactions in the *qui tam* complaint are based before a public disclosure or an individual who “has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions.”²⁵⁰ The changes to the definition of “original source” generally make it easier for relators to survive the public disclosure bar.

PPACA also removed jurisdiction from the public disclosure bar by changing the beginning of 31 U.S.C. § 3730(e)(4) from “No court shall have jurisdiction . . .” to “The court shall dismiss . . . ,” thus changing the public disclosure bar from a jurisdictional defense that could be raised at any level of the proceeding to an affirmative defense. Moreover, PPACA’s addition of the language “unless opposed by the Government” to the affirmative defense language: “[t]he court shall dismiss an action or claim under this section, unless opposed by the Government . . .” gives the government the unilateral right to decide whether or not the public disclosure bar should apply to a case.²⁵¹

The combined effect of the changes FERA, Dodd-Frank and PPACA brought about has been to increase the number of *qui tam* cases. The annual number of *qui tam* cases has increased from the double digits in the late 1980s to more than 630 in 2011.

B. The Georgia Medicaid False Claims Act

The Georgia State False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 through 49-4-168.6 is similar to the federal FCA in that it provides a basis of civil action against any person who, among other things:

- Knowingly presenting or causing to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- Knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

²⁴⁸ Schindler Elevator Corp. v. United States ex rel. Kirk, 131 S.Ct. 1885 (2011).

²⁴⁹ 31 U.S.C. § 3730(e)(4)(B) (2006).

²⁵⁰ 31 U.S.C. § 3730(e)(4)(B).

²⁵¹ 31 U.S.C. § 3730(e)(4)(A).

- Conspiring to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid;
- Knowingly making, using or causing to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia.²⁵²

The Georgia Medicaid FCA only applies to Medicaid claims. It allows for civil penalties ranging from \$5,500 to \$11,000 for each false or fraudulent claim, plus treble damages.²⁵³ Violators may also be liable to the State for all costs of any civil action brought to recover such penalties.²⁵⁴ A Georgia Medicaid FCA claim must be brought within the later of: six years from when the violation occurred or four years after the date when material facts of the violation are or reasonably should have been known by the state official responsible to act under the circumstances. No Georgia Medicaid FCA lawsuit may be filed more than 10 years after the date of the violation that is the subject of the lawsuit.²⁵⁵

The Attorney General of Georgia and private persons, though *qui tam* actions on behalf of the State, may file Georgia Medicaid FCA lawsuits in any state court. In the case of a Georgia Medicaid FCA lawsuit brought by a private person, the Attorney General of Georgia may pursue the matter, settle the matter, or decline to proceed. The private person may collect between 0% and 30% of the judgment or settlement, depending on, among other things, the information provided by the private person, the private person's contribution to the success of the case and whether the Attorney General pursues the matter.²⁵⁶ The Georgia Medicaid FCA also has a whistleblower protection provision that prohibits employers from retaliating against employees who report their employer's potentially false claims or who assist to bring a FCA action.²⁵⁷

Section 6031 of the federal Deficit Reduction Act of 2006 gives states an additional 10 percent share of any FCA settlements tied to joint federal-state programs – like Medicaid – if their false claims laws closely mirror the federal FCA. Accordingly, Georgia made significant revisions to the Georgia State False Medicaid Claims Act in 2012 in an attempt to bring it into compliance with the federal FCA so that Georgia would remain entitled to an additional 10 percent recovery above its share of any Medicaid false claims proceeds.

Like the federal FCA, Georgia's Medicaid FCA has a public disclosure bar providing that a court shall dismiss a civil action brought by a relator if substantially the

²⁵² O.C.G.A. § 49-4-168.1(a).

²⁵³ O.C.G.A. § 49-4-168.1(a).

²⁵⁴ O.C.G.A. § 49-4-168.1(c).

²⁵⁵ O.C.G.A. § 49-4-168.5.

²⁵⁶ O.C.G.A. § 49-4-168.2.

²⁵⁷ O.C.G.A. § 49-4-168.4.

same allegations were already publicly disclosed, unless dismissal is opposed by the government, or unless the relator is an “original source” of the information.²⁵⁸ The 2012 revisions to Georgia’s Medicaid FCA eliminate the requirement for pre-approval by the Attorney General for private whistleblowers to commence a suit.²⁵⁹

The Georgia Medicaid FCA tracks the language of Dodd-Frank providing a three-year statute of limitations for anti-retaliation claims by whistleblowers.²⁶⁰

In April 2013, OIG sent Georgia DCH a letter stating that Georgia’s amended Medicaid False Claims Act is not at least as effective in rewarding and facilitating *qui tam* actions as the federal FCA and thus in order to continue to qualify for the incentive under section 1909 of the Social Security Act, Georgia must amend the Georgia False Medicaid Claims Act to meet the requirements of section 1909 of the Social Security Act.²⁶¹

C. The Georgia Taxpayers Protection False Claims Act

As discussed above, the federal Fraud Enforcement and Recovery Act of 2009 (“FERA”), the Patient Protection and Affordable Care Act of 2010, and the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 enhanced the federal False Claims Act. In 2012, Georgia enacted the Georgia Taxpayers Protection False Claims Act (“GTPFCA”), O.C.G.A. §§ 23-3-120 to -127, in response to a March 21, 2011 letter from the OIG stating that the Georgia State False Medicaid Claims Act no longer meets the requirements of section 1909(b) of the Social Security Act and thus would no longer qualify for an additional 10 percent recovery above its share of any Medicaid false claims proceeds.²⁶² In a follow-up letter dated August 31, 2011, OIG based its analysis on the fact that the Georgia State False Medicaid Claims Act did not provide at least a three-year statute of limitations for retaliation actions and thus was not at least as effective in rewarding and facilitating *qui tam* actions as the federal FCA.²⁶³

The GTPFCA expands the reach of Georgia’s false claims act beyond Medicaid-reimbursable services by creating new and significant liability for all industries doing business with state or local governments in Georgia. Under the GTPFCA, *any* person or entity that knowingly or recklessly submits a false claim to *any* government body in

²⁵⁸ O.C.G.A. § 49-4-168.2(1)(2).

²⁵⁹ O.C.G.A. § 49-4-168.2(b).

²⁶⁰ O.C.G.A. § 49-4-168.4(c).

²⁶¹ Letter from Daniel R. Levinson, Inspector Gen., U.S. Dep’t of Health & Human Servs., to Toni Prine, Office of Inspector Gen. Ga. Dep’t of Cmty. Health (April 3, 2013) (on file with the U.S. Dep’t of Health & Human Servs., Office of Inspector Gen.) [available at http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp](http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp).

²⁶² Letter from Daniel R. Levinson, Inspector Gen., U.S. Dep’t of Health & Human Servs., to Robert M. Finlayson III, Office of Inspector Gen. Ga. Dep’t of Cmty. Health (March 21, 2011).

²⁶³ Letter from Daniel R. Levinson, Inspector Gen., U.S. Dep’t of Health & Human Servs., to Robert M. Finlayson III, Office of Inspector Gen. Ga. Dep’t of Cmty. Health (Aug. 31, 2011), [available at https://oig.hhs.gov/fraud/docs/falseclaimsact/georgia-supplement.pdf](https://oig.hhs.gov/fraud/docs/falseclaimsact/georgia-supplement.pdf).

Georgia has submitted a false claim, regardless of whether the person or entity specifically intended to defraud the government.²⁶⁴

Not only did Georgia broaden what constitutes a violation, it also enacted steep civil penalties ranging from \$5,500 to \$11,000 for *each* false claim, treble damages, costs, expenses, and attorneys' fees.²⁶⁵ Furthermore, the GTPFCA instills new investigatory powers in Georgia's Attorney General and permits the Attorney General to delegate investigative and prosecutorial responsibilities to district attorneys or other appropriate local government officials.²⁶⁶

V. SELECT CIVIL MONETARY PENALTIES

A. The Beneficiary Inducement Statute

1. In General. The federal Civil Monetary Penalties Law (the "CMP Law") imposes CMPs of up to \$10,000 for each wrongful act on a person or entity who offers remuneration to a Medicare or Medicaid beneficiary if the person or entity knows or should know that the remuneration is likely to influence the beneficiary's selection of a health care provider or service for which payment may be made by Medicare or Medicaid ("Beneficiary Inducement Statute").²⁶⁷ The Beneficiary Inducement Statute is an intent based law. For purposes of this law, a person "should know" of information if the person acts in deliberate ignorance or reckless disregard of the truth or falsity of that information.²⁶⁸ While any activities protected under the AKS safe harbors are permitted under the CMP Law, the converse is not true. However, it is generally assumed that, absent unusual circumstances, arrangements that fit within a CMP Law exception would be less likely to be prosecuted under the AKS.

The OIG has issued a 1991 Special Fraud Alert, a 2002 Special Advisory Bulletin and numerous Advisory Opinions regarding the CMP Law and explaining the elements of and exceptions to the law.²⁶⁹ High risk areas include: beneficiary transportation; health fairs/free screenings; patient discounts; and patient gifts and marketing practices.

²⁶⁴ O.C.G.A. §§ 23-3-120 to -121. The GTPFCA allows state false claims liability to reach non-Medicaid claims involving the money or property of state or local government, including counties, cities, towns, school boards, and any "other political subdivision of the state or of such local government." O.C.G.A. § 23-3-120(3). The GTPFCA prohibits current or former public employees or officials from bringing state false claims civil actions where such individual seeks to base allegations on information or records to which he or she had access as a result of his or her public employment or office. O.C.G.A. § 23-3-122(i)-(j).

²⁶⁵ O.C.G.A. § 23-3-121(a),(c).

²⁶⁶ O.C.G.A. § 23-3-122(a).

²⁶⁷ 42 U.S.C. § 1320a-7a(a)(5).

²⁶⁸ 42 U.S.C. § 1320a-7a(i)(7).

²⁶⁹ OIG Special Fraud Alert: *Routine Waiver of Copayments or Deductibles under Medicare Part B* (May 1991), in Publication of OIE Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994); OIG Special Advisory Bulletin: *Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

2. Remuneration. Remuneration includes the waiver of all or any part of a beneficiary's coinsurance or deductible amounts and the transfer of items or services for free or other than for fair market value.²⁷⁰ However, remuneration historically has specifically excluded:

- *Need-based cost-sharing waivers:* The waiver of coinsurance and deductible amounts if the waiver is not offered as part of any advertisement or solicitation, the person does not routinely waive coinsurance or deductible amounts, and the provider:
 - Waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
 - Fails to collect coinsurance or deductible amounts after making reasonable collection efforts;²⁷¹
- *Properly disclosed health plan differentials in copayments or deductibles:* Differentials in coinsurance and deductible amounts as part of a benefit plan design, if disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented, and otherwise meeting regulations promulgated by HHS;²⁷²
- *Preventive care incentives:* Incentives given to individuals to promote the delivery of preventive care services,²⁷³ where the delivery of services is not tied, directly or indirectly, to the provision of other services reimbursed in whole or in part by Medicare or Medicaid;²⁷⁴
- *Waivers of hospital outpatient co-pays in excess of minimum copayment amounts:* Reductions in copayments for Medicare-covered hospital outpatient services under 42 U.S.C. § 1395l(t)(5)(B);²⁷⁵
- *Anti-kickback safe harbor:* Practices permitted by a Safe Harbor under the Medicare Anti-Kickback Statute;²⁷⁶
- *Gifts of nominal value:* The OIG has interpreted the statute to permit the offering of inexpensive gifts (other than cash or cash equivalents) or services to a beneficiary so long as the gift has a retail value of no more

²⁷⁰ 42 U.S.C. § 1320a-7a(i)(6).

²⁷¹ 42 U.S.C. § 1320a-7a(i)(6)(A).

²⁷² 42 U.S.C. § 1320a-7a(i)(6)(C).

²⁷³ 42 U.S.C. § 1320a-7a(i)(6)(D).

²⁷⁴ 42 C.F.R. § 1003.101.

²⁷⁵ 42 U.S.C. § 1320a-7a(i)(6)(D). The exception for certain reductions in copayments for certain hospital outpatient services appears in the second subsection (6)(D).

²⁷⁶ 42 U.S.C. § 1320a-7a(i)(6)(B).

than \$10 to an individual patient, and no more than \$50 in the aggregate annually per patient.²⁷⁷

PPACA added four additional exclusions to the definition of “remuneration”:

- *Additional regulatory exceptions:* Any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs;²⁷⁸
- *Transfer of coupons or rebates from a retailer:* The offer or transfer of items or services for free or less than fair market value by a person, if they:
 - Consist of coupons, rebates, or other rewards from a retailer;
 - Are offered or transferred on equal terms available to the general public, regardless of health insurance status; and
 - Are not tied to the provision of other items or services reimbursed in whole or in part by a federal or state health care program;²⁷⁹
- *Items or services for individuals determined to be in financial need:* The offer or transfer of items or services for free or less than fair market value by a person, if they:
 - Are not offered as part of any advertisement or solicitation;
 - Are not tied to the provision of other services reimbursed in whole or in part by a federal or state health care program;
 - Are reasonably connected to the medical care of the individual; and
 - Are provided after determining in good faith that the individual is in financial need;²⁸⁰ or
- *Waiver of co-pays for covered Part D generic drugs:* Certain waivers of copayments by prescription drug plans for generic drugs.²⁸¹

²⁷⁷ Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From Public Law 104-191, 65 Fed. Reg. 24,400, 24,409-11 (Apr. 26, 2000)(to be codified at 42 C.F.R. pts. 1001, 1003, 1005 and 1006).

²⁷⁸ 42 U.S.C. § 1320a-7a(i)(6)(F).

²⁷⁹ 42 U.S.C. § 1320a-7a(i)(6)(G).

²⁸⁰ 42 U.S.C. § 1320a-7a(i)(6)(H).

²⁸¹ 42 U.S.C. § 1320a-7a(i)(6)(I).

Incentives that are not advertised or otherwise disclosed to a beneficiary before the beneficiary selects a provider do not constitute an inducement for services provided, because an incentive can influence a beneficiary's selection only if the beneficiary knows about the incentive before making his or her choice.²⁸²

B. The Civil Monetary Penalties Law

1. Summary of the Law. The Civil Monetary Penalties Law ("CMP Law")²⁸³ was created by the Medicare and Medicaid Amendments of 1980,²⁸⁴ and amended extensively by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").²⁸⁵ The HHS Secretary is authorized by the Social Security Act to seek CMPs. The Secretary of HHS has delegated many of these CMPs to the OIG. Except as provided below, the penalties apply equally to individuals, organizations, agencies, and other entities.²⁸⁶ Beneficiaries are not subject to the CMP Law.²⁸⁷

The CMP Law provides for the assessment of civil monetary penalties against an entity that engages in activities, including:

(a) Knowingly presenting or causing to be presented, a claim for services not provided as claimed or which is otherwise false or fraudulent in any way, if the claim:

(i) Is for a medical or other item or service that the presenter knows or should know was not provided as claimed (including a pattern or practice of upcoding that the presenter knows or should know will result in greater payment than the proper code);²⁸⁸

(ii) Is known or should be known by the presenter to be false or fraudulent;²⁸⁹

(iii) Is presented for a physician's service (or item or service incident to a physician's service), when the presenter knows or should know that the individual furnishing or supervising the furnishing of the service (i) was not licensed as a physician, (ii) was licensed as a physician through a misrepresentation of material fact or cheating on the licensure examination, or (iii) misrepresented his or her

²⁸² 65 Fed. Reg. at 24,409.

²⁸³ 42 U.S.C. § 1320a-7a.

²⁸⁴ Pub. L. No. 96-499, tit. IX, 94 Stat. 2599, 2609 (codified in scattered sections of U.S.C. tit. 42).

²⁸⁵ Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of U.S.C. tits. 18, 26, 29, and 42).

²⁸⁶ 42 U.S.C. § 1320a-7a(a).

²⁸⁷ Id.

²⁸⁸ 42 U.S.C. § 1320a-7a(a)(1)(A). "Upcoding" is the practice where a patient's diagnosis related group (DRG), evaluation and management (E/M), or other code is inappropriately shifted to yield higher reimbursement from the Medicare or Medicaid system.

²⁸⁹ 42 U.S.C. § 1320a-7a(a)(1)(B).

certification by a medical specialty board to the patient at the time the service was rendered;²⁹⁰

(iv) Is for an item or service rendered during a period when the person providing the item or service was excluded from participation in the program;²⁹¹ or

(v) Is for a pattern of items or services the person knows or should know are not medically necessary.²⁹²

(b) Knowingly giving or causing to be given false or misleading information reasonably expected to influence the decision to discharge a patient;

(c) Knowingly presenting or causing to be presented a claim that is in violation of any of the following:

(i) An assignment of benefits under 42 U.S.C. § 1395u(b)(3) (B)(ii);²⁹³

(ii) An agreement with a state agency not to charge a person for an item or service in excess of the amount permitted to be charged;²⁹⁴

(iii) An agreement to be a participating physician or supplier under 42 U.S.C. § 1395u(h)(1);²⁹⁵ or

(iv) An agreement not to charge an individual for inpatient hospital services for which such individual would be entitled to have payment made under Medicare Part A but for a denial or reduction of payments under 42 U.S.C. § 1395ww(f)(2).²⁹⁶

(d) Offering or giving remuneration to any beneficiary of a federal health care program likely to influence the receipt of reimbursable items or services;

(e) Arranging for reimbursable services with an entity which is excluded from participation from a federal health care program;

(f) Knowingly or willfully soliciting or receiving remuneration for a referral of a federal health care program beneficiary; or

²⁹⁰ 42 U.S.C. § 1320a-7a(a)(1)(C).

²⁹¹ 42 U.S.C. § 1320a-7a(a)(1)(D).

²⁹² 42 U.S.C. § 1320a-7a(a)(1)(E).

²⁹³ 42 U.S.C. § 1320a-7a(a)(2)(A).

²⁹⁴ 42 U.S.C. § 1320a-7a(a)(2)(B).

²⁹⁵ 42 U.S.C. § 1320a-7a(a)(2)(C).

²⁹⁶ 42 U.S.C. § 1320a-7a(a)(2)(D).

(g) Using a payment intended for a federal health care program beneficiary for another use.²⁹⁷

An individual who is excluded from the Medicare program under 42 U.S.C. § 1320a-7 may be individually liable for civil monetary penalties for a violation of the CMP Law by an entity which participates in the Medicare or Medicaid program, if at the time of the violation the individual:

- Knows or should know of his exclusion and retains a direct or indirect ownership or control interest in the entity committing the violation; or
- Is an officer or managing employee of the entity.²⁹⁸

This prohibition applies only to individuals and not to organizations, agencies, or other entities.²⁹⁹

The OIG may also seek CMPs against individuals who violate the AKS or the Stark Law. CMPs are available for violations of the AKS if the individual knowingly and willfully: (1) offers or pays remuneration to induce the referral of Federal health care program business; or (2) solicits or receives remuneration in return for the referral of Federal health care program business.³⁰⁰ CMPs are available for violations of the Stark Law if an individual presents or causes to be presented a claim that the individual knows or should know is for a service for which payment may not be made under 42 U.S.C. § 1395nn.³⁰¹

In addition to any other penalties prescribed by law, violation of the CMP Law is punishable by:

- Civil money penalties of (i) not more than \$10,000 for each item or service or, (ii) in cases of giving false information to influence discharge decisions, not more than \$15,000 for each individual with respect to whom false or misleading information was given, or (iii) in cases of excluded individuals maintaining a prohibited relationship with an entity, not more than \$10,000 for each day the prohibited relationship occurs;³⁰² and

²⁹⁷ 42 U.S.C. § 1320a-7a.

²⁹⁸ 42 U.S.C. § 1320a-7a(a)(4).

²⁹⁹ Id.

³⁰⁰ 42 U.S.C. § 1320a-7a(a)(7).

³⁰¹ 32 U.S.C. § 1395nn(g)(3).

³⁰² 42 U.S.C. § 1320a-7a(a). For violations of the Anti-Kickback Statute, the Civil Monetary Penalties Law provides for civil monetary penalties of not more than \$50,000 for each violation. Id.

- An assessment of up to three times the amount claimed for each such item or service in lieu of damages sustained by the United States or a state agency because of the improper claim.³⁰³

The Secretary of HHS may also exclude the party who violates the CMP Law from all federal health care programs, and may direct the appropriate state health care programs also to exclude the party.³⁰⁴

2. OIG Self-Disclosure Protocol. The OIG offers a Provider Self-Disclosure Protocol (“SDP”) for providers who wish to voluntarily identify, disclose, and resolve self-discovered evidence of potential fraud to OIG. The OIG issued its most recent update to the SDP on April 17, 2013.³⁰⁵ The revised SDP supersedes and replaces the 1998 Federal Register Notice and the three Open Letters to Health Care Providers in 2006, 2008, and 2009 regarding the SDP. The SDP provides guidance on how to investigate instances of potential fraud involving the federal health care programs, quantify damages, and report the conduct to OIG to resolve the provider’s liability under the OIG’s CMP authorities. In addition to listing requirements for all SDP disclosures, the SDP sets forth further specific disclosure requirements conduct involving: false billing; excluded persons; and the AKS and the Stark Law.

The SDP is not available: (1) for matters that do not involve potential violations of federal criminal, civil, or administrative law for which CMPs are authorized (e.g., one exclusively involving overpayments or errors); (2) to request an opinion from OIG regarding whether an actual or potential violation has occurred; (3) for disclosures of arrangements involving only liability under the Stark Law without accompanying potential liability under the AKS for the same arrangement.

Self-disclosure gives providers the opportunity to avoid the costs and disruptions associated with a Government-directed investigation and civil or administrative litigation. While the OIG cannot bind the DOJ or other government agencies, OIG consults with those agencies, as appropriate, regarding the resolution of SDP matters. Consistent with OIG’s statutory authority to impose a penalty of up to \$50,000 for each such transaction, for AKS submissions accepted into the SDP, OIG requires a minimum \$50,000 settlement amount to resolve the matter. For all other matters accepted in to the SDP, OIG requires a minimum \$10,000 settlement. OIG has resolved over 800 disclosures since 1998, resulting in recoveries of more than \$280 million.

³⁰³ Id. For violations of the Anti-Kickback Statute, the Civil Monetary Penalties Law provides for an assessment of damages of up to “3 times the total amount of remuneration offered, paid, solicited, or received, *without regard to whether a portion of the remuneration was offered, paid, solicited, or received for a lawful purpose*” Id. (emphasis added).

³⁰⁴ Id.

³⁰⁵ Updated OIG’s Provider Self-Disclosure Protocol (Apr. 17, 2013), available at <https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>.

VI. COMPLIANCE PROGRAMS

A. Overview

Beginning in 1998, the OIG embarked on a major initiative to engage the private health care community in preventing the submission of erroneous claims and in combatting fraud, waste, and abuse in the federal health care programs through voluntary compliance programs.³⁰⁶ PPACA included provisions that eventually will require all providers and suppliers to have compliance programs as a condition of enrollment in the Medicare and Medicaid programs. Effective January 1, 2011, new mandatory compliance program requirements became effective for Medicare Advantage and Medicare Part D programs. PPACA Section 6102 separately required Medicare skilled nursing facilities and Medicaid nursing facilities to have in place an effective compliance program by March 10, 2013.

A compliance program is a comprehensive strategy to ensure an organization consistently complies with applicable laws and regulations relating to its business activities. The OIG has provided guidance to various sectors of the health care industry about the factors it believes contribute to a successful compliance program, but its guidance is not “one-size-fits-all.”³⁰⁷ Rather, the OIG encourages each provider to identify risk areas that are most relevant to its own business model and to focus its compliance efforts on preventing and mitigating those risks. An effective compliance program can help a company reduce the likelihood of wrongdoing, reduce penalties if wrongdoing occurs, disseminate information on new laws and rules in a systematic way, and decrease the possibility of whistleblower actions by providing an internal reporting structure.

B. Elements of an Effective Compliance Program

In making recommendations to the health care industry about how to develop and implement an effective compliance program, the OIG has focused on seven specific elements. These elements are based on the U.S. Sentencing Guidelines, which allow for a reduction in certain penalties when these compliance elements are present.³⁰⁸ Those seven elements are as follows:

³⁰⁶ The OIG has issued 14 guidance statements related to corporate compliance. See Health and Human Services, Office of the Inspector General, *Compliance Guidance*, available at <http://oig.hhs.gov/fraud/complianceguidance.asp>. Specifically, the OIG has issued compliance program guidance for hospitals, home health agencies, clinical laboratories, third-party medical billing companies, durable medical equipment prosthetics, orthotics, and supply organizations, hospices, Medicare+Choice organizations, nursing facilities, individual and small group physician practices, ambulance suppliers, pharmaceutical manufacturers, and recipients of HHS research grants.

³⁰⁷ See OIG Compliance Program Guidance, available at <http://oig.hhs.gov/compliance/compliance-guidance/index.asp>.

³⁰⁸ U.S. Federal Sentencing Guidelines Manual, § 8B2.1, available at http://www.ussc.gov/Guidelines/2010_guidelines/Manual_HTML/8b2_1.htm.

1. Written Code of Conduct and Policies. The OIG recommends that each health care provider develops standards of conduct for all employees that reflect a clearly delineated commitment to compliance by senior management. The code should be distributed to all employees and should be reviewed regularly and updated as applicable statutes, regulations, and Federal health care program requirements are modified. The OIG recommends the development and distribution of written compliance policies that identify specific areas of risk to the provider and bright line rules and procedures to minimize these risks.

2. Designation of a Compliance Officer and a Compliance Committee. The OIG recommends designating a Compliance Officer to serve as the leader for compliance activities. The Compliance Officer should be a well-qualified, high-level official in the organization with direct access to the governing body and CEO. The Compliance Officer needs sufficient funding and staff to perform his or her responsibilities fully.

The OIG recommends that a Compliance Committee be established to advise the Compliance Officer and assist in the implementation of accompanying programs. The Compliance Committee benefits from having perspectives of individuals with varying responsibilities in the organization; therefore, the Compliance Committee should be comprised of a cross-section representing the company's different areas. The Compliance Committee's role should be: (1) analyzing the organization's industry environment, the legal requirements with which it must comply, and specific risk areas; (2) assessing existing policies and procedures that address risk areas; (3) working with appropriate departments to develop standards of conduct and procedures to promote compliance; (4) recommending and monitoring the development of internal systems; (5) determining the appropriate strategy and approach to promote compliance and detect potential violations; and (6) developing a system to solicit, evaluate, and respond to complaints and problems.

3. Conducting Effective Training. Health care providers should take steps to communicate their standards and procedures to all affected employees and contractors by requiring participation in training programs and disseminating publications that contain specific requirements presented clearly. All levels of employees should be trained, and managers of different departments should assist in identifying areas in which employees could benefit from additional training. Instructors can come from within or from outside the company. New employees should be trained early in their employment about all aspects of the provider's compliance program. Targeted training should be provided to employees involved in billing, coding, and marketing. Providers should retain accurate records of employee training, including attendance logs and materials distributed at training sessions. Training programs should be reviewed annually for effectiveness and for changes in the Federal health care programs, OIG and CMS guidance and advisories, results from internal and external audits and investigations, and trends identified in hotline reports. Other issues to consider include the trainers' qualifications, the length of the sessions, the need for general and specific training, whether the company's governing body has received training on issues related to fraud, waste, and abuse, and the effectiveness of sanctions and incentives to encourage participation in training.

4. Developing Lines of Communication. Open lines of communication facilitate the success of a compliance program. To foster open lines of communication, confidentiality and non-retaliation policies should be written and distributed to all employees. The OIG encourages the use of hotlines (including anonymous hotlines), confidential email reporting systems, written memoranda, newsletters, and other forms of information exchange to maintain open lines of communication. If a hotline is utilized, the number should be distributed and publicized widely. A health care provider should have at least one form of anonymous reporting available. The types of questions and reports received should be documented so that effective and appropriate follow-up can occur. Internal investigations should be shared with the entity's governing body and relevant departments.

5. Enforcing Standards through Well-Publicized Disciplinary Guidelines. Effective compliance programs include guidance on disciplinary actions for all employees, including managers and officers. The OIG suggests that this can be achieved by developing a written policy statement setting forth the degrees of disciplinary actions that may be taken for employees and other personnel who fail to comply with code of conduct or other applicable policies. Sanctions can include verbal warnings, education and retraining, suspension, privilege revocation, financial penalties, termination or other personnel action. Disciplinary standards should be disseminated throughout the company. Furthermore, the consequences of non-compliance should be applied and enforced consistently, and enforcement of disciplinary standards should be well-documented.

6. Auditing and Monitoring. A health care provider should engage in an ongoing evaluation process to ensure that its compliance program is achieving its goals and meeting its standards. Periodic audits by both internal and external auditors are beneficial for any compliance program. Included among the available auditing and monitoring techniques are on-site visits by the Compliance Officer or other reviewers, interviews with personnel, pre-submission audits of claims, and review of written materials prepared by the provider's various departments. The provider should document its auditing and monitoring efforts and generate reports on those efforts to be shared with the senior management and Compliance Committee. A provider should develop a detailed annual audit plan designed to minimize risks associated with improper claims and billing practices. The plan should be reevaluated annually and should take into account findings from previous audits, identified risk areas, and high-volume services. Other areas include an assessment of billing systems and claims accuracy in an attempt to identify causes of billing errors, the qualifications and independence of coding and auditing personnel, trends or improvements in error rates, and review of billing documentation. Providers also should monitor compliance with internal policies. The OIG also recommends an annual review of the compliance program itself for satisfaction of the seven elements.

7. Responding to Detected Offenses and Developing Corrective Actions. By responding to detected offenses, including violations of the compliance program or failure to comply with federal or state law, a provider helps promote the success of its compliance program and also helps to maintain its reputation as a reliable

and honest health care provider Therefore, when a report is made regarding a possible violation, there must be a prompt and timely investigation into the matter to determine whether a violation occurred and, if so, what corrective action needs to be taken. Investigations will vary depending on the reported act. Records of the investigation should be maintained, including a description of the investigative process, a list of the witnesses interviewed, copies of interview notes and key documents, and results of the investigation. Corrective action should be determined on a case-by-case basis. Included among some of the possible corrective actions are education and retraining, employment suspension or termination, referrals to criminal and/or civil law enforcement authorities, the formal development of a corrective action plan, a report to a Medicare Administrative Contractor, and the refund of overpayments.

Nursing facilities have slightly different compliance program requirements set forth under PPACA.³⁰⁹

C. Board Oversight of Compliance Programs

On April 2, 2003, OIG and the American Health Lawyer’s Association (“AHLA”) jointly published Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors.³¹⁰ This document was designed to help Board members ask knowledgeable and appropriate questions related to health care corporate compliance. In July 2004, OIG and AHLA published additional guidance in An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors.³¹¹ This document addresses the roles of the in-house corporate general counsel and an organization’s Chief Compliance Officer in supporting the compliance oversight function of health care organization Boards of Directors. While case law has established a Board’s duty to oversee a compliance program, it has not enumerated a specific

³⁰⁹ The eight core elements for a nursing facility compliance program are:

1. Compliance standards and procedures must be adopted and followed.
2. Specific individuals with authority and sufficient resources must be assigned to oversee compliance.
3. The organization must exercise due care to ensure that the above authority is not delegated to an individual with a propensity to engage in PPACA criminal, civil and administrative violations.
4. The organization must take steps to educate its employees and agents of the compliance program.
5. The organization must take reasonable steps to achieve compliance with its standards.
6. The standards and procedures must be consistently enforced.
7. If an offense is detected, the organization must respond appropriately and prevent similar offenses.
8. The organization must periodically reassess the compliance programs and make changes necessary to reflect changes within the organization.

³¹⁰ Available at <https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRscGuide.pdf>.

³¹¹ Available at <http://oig.hhs.gov/fraud/docs/complianceguidance/Tab%204E%20Appendx-Final.pdf>.

methodology for doing so.³¹² These documents are designed to assist health care organization directors in exercising their duty of oversight.

VII. HIPAA PROVISIONS TO COMBAT HEALTHCARE FRAUD

Although not as well-known as its privacy and security components, the Health Insurance Portability and Accountability Act (“HIPAA”) includes a number of provisions to combat health care fraud. These include:

- Establish and fund a health care fraud and abuse control program within DHHS;³¹³
- Require exclusion from Medicare and Medicaid for felony convictions related to healthcare fraud or controlled substances;³¹⁴
- Create a program encouraging Medicare beneficiaries to report fraud and abuse and to offer suggestions to improve efficiency of the Medicare program;³¹⁵
- Require issuance of advisory opinions, additional safe harbors, and fraud alerts regarding the Medicare Anti-Kickback Statute;³¹⁶
- Expand conditions under which civil monetary penalties and intermediate sanctions can be imposed on health maintenance organizations participating in Medicare;³¹⁷
- Established a database of final adverse actions taken against health care providers;³¹⁸ and
- Made knowing and willful transfer of assets to gain Medicaid eligibility subject to criminal penalties.³¹⁹

³¹² In re Caremark Int’l Inc. Derivative Litig., 698 A.2d 959, 970 (Del. Ch. 1996) (“[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.”); Stone ex rel. AmSouth Bancorporation v. Ritter, 911 A.2d 362 (Del. 2006).

³¹³ Pub. L. No. 104-191, § 201, 110 Stat. at 1992 (codified in 42 U.S.C. § 1320a-7c).

³¹⁴ Id. § 211, 110 Stat. at 2003 (codified in 42 U.S.C. § 1320a-7).

³¹⁵ Id. § 203, 110 Stat. at 1998 (codified in 42 U.S.C. § 1395b-5).

³¹⁶ Id. § 205, 110 Stat. at 2000 (codified in 42 U.S.C. § 1320a-7d).

³¹⁷ Id. § 215, 110 Stat. at 2005 (codified in 42 U.S.C. § 1395mm).

³¹⁸ Id. § 221, 110 Stat. at 2009 (codified in 42 U.S.C. § 1320a-7e).

³¹⁹ Id. § 217, 110 Stat. at 2008 (codified in 42 U.S.C. § 1320a-7b).

HIPAA also created four new federal healthcare fraud offenses. Each of these offenses involves acts against or affecting any health benefit programs, which are defined to include “any public *or private* plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract.”³²⁰ Note that these laws apply to private health benefit programs as well as government health benefits programs.

A. Health Care Fraud Scheme

A person who knowingly and willfully executes or attempts to execute a scheme to defraud a health care benefit program, or to obtain, by means of false or fraudulent pretense, representation, or promises, any money or property owned by or under the custody or control of any health benefit program, in connection with the delivery of or payment for healthcare benefits, items, or services, commits a federal crime punishable by fine, up to ten years imprisonment, or both.³²¹ If the violation results in serious bodily injury, then the term of imprisonment may be up to twenty years, and imprisonment may be up to life if the violation results in serious bodily injury.³²² Actual knowledge or specific intent to commit a violation of 18 U.S.C. § 1347 is not required.³²³

Mere acts taken in furtherance of a scheme to defraud are insufficient to violate this law; instead, there must be an execution or attempted execution of the scheme to defraud.³²⁴

Each submission of a fraudulent claim for payment constitutes illegal execution of a scheme.³²⁵

B. False Statements Relating to Health Care Matters

HIPAA also made it a federal crime under 18 U.S.C. § 1035 to knowingly and willfully (i) falsify, conceal, or cover up a material fact, (ii) make any materially false or fraudulent statement or representation, or (iii) make or use a materially false writing or document knowing that such writing or document contains any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for healthcare benefits, items, or services.³²⁶ 18 U.S.C. § 1035 only applies to matters

³²⁰ 18 U.S.C. § 24(b) (emphasis added).

³²¹ 18 U.S.C. § 1347.

³²² Id.

³²³ Id.

³²⁴ United States v. Hickman, 331 F.3d 439, 446-47 (5th Cir. 2003).

³²⁵ Id.

³²⁶ 18 U.S.C. § 1035.

involving a health care benefit program.³²⁷ Violation is punishable by fine, up to five years imprisonment, or both.³²⁸

C. Theft or Embezzlement in Connection with Health Care Benefit Program

Embezzlement, theft, conversion, or intentional misapplication of “any of the moneys, funds, securities, premiums, credits, property, or other assets” of a health benefit program is punishable by fine, imprisonment of up to ten years, or both.³²⁹ However, if the funds involved do not exceed \$100, then the maximum term of imprisonment is one year.³³⁰

D. Obstruction of Criminal Investigations of Health Care Offenses

Under 18 U.S.C. § 1518(a), any person who willfully prevents, obstructs, misleads, delays, or attempts to prevent, obstruct, mislead, or delay the communication of information or records relating to a violation of a federal health care offense to a criminal investigator may be fined or imprisoned for not more than five years, or both.³³¹

E. Other Federal Health Care Offenses

HIPAA also designated under 18 U.S.C. § 24(a)(2) nine existing federal crimes as federal health care offenses if the crime committed relates to a health benefit program.³³² PPACA further expanded 18 U.S.C. § 24 to include violations of the AKS, Food Drug and Cosmetic Act and certain ERISA provisions. The effect of this is to require exclusion from the Medicare program of an individual convicted of any of these offenses.

³²⁷ Id.

³²⁸ Id.

³²⁹ 18 U.S.C. § 669(a).

³³⁰ 18 U.S.C. § 1669(a).

³³¹ 18 U.S.C. § 1518.

³³² 18 U.S.C. § 24(a)(2).

HEALTHCARE FRAUD AND ABUSE

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