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Fundamentals of Health Law Fraud and Abuse

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Developing ways to identify and ferret out health care fraud continues to be a significant focus for both federal and state governments. By way of example, the National Health Care Fraud and Abuse Control Program (HCFAC)¹ was responsible in FY 2016 for returning \$2.5 billion in fraudulent and misspent funds. Moreover, more than \$31.0 billion has been returned to the Medicare Trust Fund since its creation in 1997.² In fact, the return on investment for the HCFAC program over the last three years is \$5.00 returned for every \$1.00 expended.³ As another example, since its inception in 2007, the Medicare Fraud Strike Force⁴ (Strike Force) has resulted in the charging of over 3,018 defendants, with 2,041 defendants pleading guilty and 275 convicted in jury trials.⁵

In addition to federal and state governments, private organizations and individuals also play a big role in combating fraud. In FY 2016, *qui tam* relators received over \$5.26 million. Also, in 2012, the Healthcare Fraud and Prevention Partnership (HFPP) was formed between the federal government, state officials, law enforcement, private health insurance plans and associations, and health care anti-fraud associations. “The purpose of the partnership is to exchange data and information between the partners to help improve capabilities to fight fraud, waste and abuse in the health care industry.”⁶

As health care fraud enforcers are targeting a wide array of business arrangements and payment practices as potentially constituting fraud, this Chapter addresses the fundamental legal underpinnings of the broad spectrum of health care fraud and abuse laws. In particular, this Chapter provides a brief overview of the federal laws and regulations, particularly the Anti-Kickback Statute, the physician

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¹ The HCFAC was established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The HCFAC is under the joint direction of the Attorney General for the Department of Justice (DOJ) and the Secretary of the Department of Health and Human Services (HHS), acting through the Inspector General, and is designed to coordinate Federal, state and local law enforcement activities with respect to health care fraud and abuse. *See* Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

² The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2016, January 2017, *available at* <https://oig.hhs.gov/publications/docs/hcfac/FY2016-hcfac.pdf>.

³ *Id.*

⁴ The Strike Force is comprised of interagency teams made up of investigators and prosecutors “that focus on the worst offenders in regions with the highest known concentration of fraudulent activities.” *See Id.*

⁵ *Id.*

⁶ *See* HFPP website at <https://hfpp.cms.gov/>.

self-referral law (known as the Stark Law for its chief legislative architect), and the prohibitions against false claims and fraudulent billing practices. This Chapter also examines the importance of establishing a corporate compliance program.

5.1 The Federal Health Care Program’s Anti-Kickback Statute

5.1.1 Statutory Prohibition

The federal health care program’s Anti-Kickback Statute makes it a felony to knowingly and willfully solicit or receive remuneration “in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service” or “in return for purchasing, leasing, ordering, or arranging for or recommending 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.”⁷ The Anti-Kickback Statute also prohibits a person from knowingly and willfully offering or paying remuneration to any person to induce that person to refer or purchase, lease, order, or arrange for or recommend the purchasing, leasing, or ordering of items or services for which payment may be made by a federal health care program. Although the Anti-Kickback Statute originally applied to Medicare and Medicaid only, over the years it has been broadened to apply to any “Federal health care program,” defined as “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 Benefit Program.⁸

Each offense under the Anti-Kickback Statute is punishable by a fine of up to \$25,000 and imprisonment for up to five years. Violators of the Anti-Kickback Statute also are subject to exclusion from participation in the federal health care programs, as well as imposition of civil monetary penalties for each violation of (i) up to \$50,000, and (ii) three times the amount of the remuneration in question. In addition, as part of the Patient Protection and Affordable Care Act of 2010 along with the Health Care Education Affordability Reconciliation Act of 2010 (referred to collectively as the Affordable Care Act or ACA), Congress established conclusively that a violation of the Anti-Kickback Statute is a false claim for purposes of the federal False Claims Act.⁹

In recognition of the breadth of the prohibition contained in the Anti-Kickback Statute, Congress has enacted several exceptions over the years for certain financial arrangements. Specifically, there are exceptions for:

⁷ 42 U.S.C. § 1320a-7b(b).

⁸ 42 U.S.C. § 1320a-7(g). Examples of federal health care programs include, but are not limited to: Medicare (Title XVIII of the Social Security Act); Medicaid (Title XIX of the Social Security Act); Department of Defense health care programs (*i.e.*, CHAMPUS and TRICARE, Chapter 55 of Title 10, United States Code); programs funded by Maternal and Child Health Block Grants (Title V of the Social Security Act); programs funded by Social Services Block Grants (Title XX of the Social Security Act); a medical care program of the Indian Health Service or of a tribal organization; and a health benefit plan under § 5(e) of the Peace Corps Act.

⁹ See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 § 6402(f)(1) (2010) (codified at 42 U.S.C. § 1320a-7b(g)). Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) [hereinafter ACA].

1. discounts that are properly disclosed and reflected in the costs claimed or charges made by the provider;
2. payments by an employer to an employee for bona fide employment in the provision of covered items and services;
3. amounts paid by providers to a group purchasing organization (GPO) where a written agreement is made between the providers and the GPO specifying the fee and the GPO discloses the amount of the administrative fee to providers purchasing from the GPO;
4. waivers of coinsurance amounts in connection with certain Federally Qualified Healthcare Centers (FQHC);
5. activities protected by the safe harbor regulations (which will be described in the following section);
6. certain risk-sharing arrangements;
7. certain arrangements involving FQHCs;
8. waivers of certain cost sharing amounts under Medicare Part D; and
9. certain discounts made under the Medicare coverage gap discount program.¹⁰

5.1.2 Judicial Interpretation

5.1.2.1 *The First 25 Years of Case Law under the Statute: Pre-Hanlester*

*United States v. Greber*¹¹ is the landmark case on the scope of the Anti-Kickback Statute. In this case, the Third Circuit Court of Appeals adopted the “one-purpose” test. Dr. Greber, an osteopathic physician who was board-certified in cardiology, was president of Cardio-Med, Inc., an organization that provided diagnostic services for cardiac patients. When Cardio-Med performed a test at the request of a referring physician, Cardio-Med also forwarded a portion of the Medicare reimbursement it received to the referring physician. This fee was purportedly for “interpretations” by the referring physician. Evidence was introduced, however, that physicians received these interpretation fees even though Dr. Greber evaluated the tests. In addition, the amount paid to the physicians was more than Medicare allowed for such services. Hence, Dr. Greber was convicted of, among other transgressions, tendering kickbacks in violation of the Anti-Kickback Statute. In upholding his conviction, the Third Circuit Court of Appeals held that “if one purpose of the payment was to induce future referrals, the [Anti-Kickback Statute] has been violated.”

After the *Greber* case, the issue confronting the health care industry was whether the broad “one-purpose” test was applicable merely to the egregious facts presented, or whether the test would be generally applicable to *all* kickback cases. For several years, no other kickback cases considered this issue until 1989, when two separate circuit courts considered the *Greber* “one-purpose” test.

¹⁰ See 42 U.S.C. § 1320a-7b(b)(3); see also 42 U.S.C. § 1395w-104(e).

¹¹ *United States v. Greber*, 760 F.2d 68 (3rd Cir.1985), cert. denied, 474 U.S. 988 (1985).

In *United States v. Kats*,¹² a physician owned a 25% interest in Community Clinic, which collected blood and urine specimens and forwarded the specimens to Tech-Lab. Tech-Lab billed Community Clinic, which in turn billed the California Medicaid and Medicare programs. According to the court's description of the facts, 50% of the laboratory payments were "kicked back" to Community Clinic. The Ninth Circuit Court of Appeals followed the *Greber* holding, and upheld a jury instruction allowing conviction unless the payment was "wholly and not incidentally attributable to the delivery of goods and services." The Ninth Circuit stated that it is not a defense to claim that other purposes are behind the payment as long as one of the material purposes is to induce referrals.

*United States v. Bay State Ambulance and Hospital Rental, Inc.*¹³ concerned the award of a hospital ambulance contract. Allegedly, the ambulance company made illegal payments to a hospital official who sat on the bid committee. Such payments consisted of a management-consulting contract, loans, and other consideration including automobiles and cash. The court cited with approval *Greber's* holding that any amount of inducement is illegal under the Anti-Kickback Statute, but stopped short of explicitly adopting the Third Circuit's broad "one-purpose" test. The district court had instructed the jury that, in order to obtain a conviction under the Anti-Kickback Statute, the *primary* purpose (as opposed to an incidental or minor purpose) of the payments must be improper, and thus the less-favorable *Greber* standard was not directly challenged on appeal. The court in *Bay State Ambulance* also noted that the government was not required to prove that payments received were not reasonable for the work performed, because "the gravamen of Medicare fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient."

5.1.2.2 The Hanlester Decision

On April 6, 1995, the U.S. Court of Appeals for the Ninth Circuit issued a decision in *Hanlester Network v. Shalala*,¹⁴ the first case in which the OIG asserted its civil-sanction authority under the Anti-Kickback Statute. Significantly, the Ninth Circuit determined that the appellants should not be excluded under the statute.

This case involved a network of three clinical laboratories that had been established as physician joint ventures by the Hanlester Network of Santa Ana, California. The joint ventures established by the Hanlester Network were organized as limited partnerships with more than 100 physicians participating as investors. The investment arrangement basically consisted of physicians as limited partners who owned between three and seven shares at \$500 per share. Although no express requirement was made that physician investors refer to the laboratory, physician investors were required to sell back their shares if they retired, lost their medical license, or relocated outside the laboratory's service area. In addition, each joint-venture laboratory was operated under a management agreement with SmithKline Beecham Clinical Laboratories (SBCL). The management agreement provided the payment to SBCL of either \$15,000 per month or 76% of the revenues generated by the joint-venture laboratory, whichever was greater.

¹² *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

¹³ *United States v. Bay State Ambulance and Hospital Rental, Inc.*, 874 F.2d 20 (1st Cir. 1989).

¹⁴ *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), *reh'g en banc denied*, No. 93-55351 (9th Cir. Nov. 15, 1995).

In 1989, the OIG issued notices of proposed program exclusion to five individuals and five entities involved in the joint ventures.¹⁵ The individuals and entities subject to the exclusion action requested an administrative hearing to challenge their proposed program exclusion. Initially, the Administrative Law Judge (ALJ) held that the Anti-Kickback Statute was not violated unless the government demonstrated that there was an actual agreement or *quid pro quo*, whereby the referral of patients to the entity was a condition imposed on physician investors for maintaining their investment interest in the entity. Then, upon initial appeal, the Departmental Appeals Board (DAB) held that the term “inducement” contained in the Anti-Kickback Statute meant something more than “encourage,” but something less than “require”—that is, “an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” The DAB subsequently remanded the case to the ALJ, who concluded that permissive exclusions were necessary for some but not all of the appellants. The defendants then appealed the DAB’s decision to the U.S. District Court for the Central District of California, which affirmed the DAB’s decision,¹⁶ and then to the Ninth Circuit Court of Appeals.¹⁷

Although the Ninth Circuit agreed with the DAB’s definition of the term “inducement,” it reversed the exclusions against the appellants, apparently based on the particular facts of the case. The Ninth Circuit found that “the fact that a large number of referrals resulted in the potential for a high return on investment, or that the practical effect of low referral rates was failure for the labs, is insufficient to prove that appellants offered or paid remuneration to induce referrals” in violation of the Anti-Kickback Statute. The court noted that limited partners were paid dividends based on their ownership share, not the volume of their referrals, and that payments were made to limited partners regardless of whether they referred business to the joint venture.

The Ninth Circuit did find, however, that the Hanlester Network’s Marketing Director, Patricia Hitchcock, had made representations to prospective investors that were indeed in violation of the Anti-Kickback Statute. Thus, Ms. Hitchcock apparently “crossed the line” into illegality by linking a physician-investor’s personal referral pattern to his or her participation in the joint venture.

As a result of Ms. Hitchcock’s conduct, the Court of Appeals further held that the Hanlester Network and joint-venture laboratories’ organizational entities could be held vicariously liable under the Anti-Kickback Statute for Ms. Hitchcock’s actions, regardless of the fact that Ms. Hitchcock acted in a manner contrary to the organizations’ stated policies. Nevertheless, the Court of Appeals found that no remedial purpose would be served by excluding organizational entities of either the Hanlester Network’ or the joint-venture laboratories’ from the Medicare or Medicaid programs, because their vicarious liability arose entirely from the conduct of Ms. Hitchcock, who was no longer associated with the organizations.

The court additionally held that vicarious liability cannot extend to the individual partners in the organizational entities, and that they did not act with the requisite intent in order to constitute an independent violation of the statute. Citing U.S. Supreme Court precedent,¹⁸ the Ninth Circuit

¹⁵ Simultaneously, the OIG announced the settlement of charges against SBCL for \$1.5 million.

¹⁶ *Hanlester v. Sullivan*, CCH Medicare and Medicaid Guide ¶41,076, CV-92-4552 (C.D. Cal. Feb. 10, 1993).

¹⁷ *Hanlester Network v. Shalala*, *supra*.

¹⁸ See *Ratzlaf v. United States*, 114 S. Ct. 655, 657, 126 L. Ed. 2d 615 (1994).

concluded that a party may violate the Anti-Kickback Statute's *mens rea* requirement (i.e., knowingly and willfully) *only* if he or she *knows* that the Anti-Kickback Statute prohibits offering or paying remuneration to induce referrals *and* engages in the prohibited conduct with the *specific intent* to disobey the law. Although Ms. Hitchcock's conduct was sufficiently egregious to infer the requisite intent to violate the Anti-Kickback Statute, the Ninth Circuit found that the other partners displayed no such conduct.

Significantly, the positions held by the Ninth Circuit in the *Hanlester* case were not universally adopted by other courts.¹⁹ Then, in 2010 as part of the ACA, the Anti-Kickback Statute was amended to provide that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section."²⁰

5.1.2.3 *United States ex rel. Jamison v. McKesson*

On September 28, 2012, a Mississippi district court ruled for defendants finding that the government had failed to prove the requisite scienter necessary to violate the Anti-Kickback Statute. The relator, Jamison, claimed that the defendants defrauded the government by forming improper joint ventures, failing to satisfy DME supplier standards, and submitting fraudulent Medicaid cost reports. Under the joint ventures, medical supply companies created DME suppliers within nursing homes that allowed the nursing homes to seek reimbursement under their own DME supplier numbers. Jamison alleged that the monies derived from these joint ventures were kickbacks, and therefore, all claims submitted by the DME suppliers violated the False Claims Act. The government sought \$895 million in damages and penalties.

Asserting an "express false certification" theory of liability, the government claimed that because the defendants had violated the Anti-Kickback Statute, all of the claims submitted also violated the False Claims Act. However, the court ultimately held that there was no violation of the FCA because there was no underlying violation of the Anti-Kickback Statute. In its decision, the court took the position that the government had the burden of establishing fair market value and had failed to prove that the defendants offered its services below fair market value, below actual costs, or at a discount, and therefore failed to prove the inducement required for a violation under the Anti-Kickback Statute. In addition, the court held that the government must provide the Anti-Kickback Statute's knowing and willful standard to meet the scienter requirement.

5.1.3 Special Fraud Alerts

Whereas the safe harbors describe conduct that is explicitly permissible, the OIG also has published various issuances over the past several years that describe conduct that the OIG views as

¹⁹ See, e.g., *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998); *United States v. Jain*, 93 F.3d 436 (8th Cir. 1996), *cert. denied*, 520 U.S. 1273 (1997); *United States v. Neufeld*, 908 F. Supp. 491, 497 (S.D. Ohio 1995); *Med. Dev. Network, Inc. v. Prof. Respiratory Care/Home Medical Equip. Servs., Inc.*, 673 S.2d 565 (Fla. Dist. App. 1996); *United States v. Mittal*, 2002 U.S. App. LEXIS 11220 (2d Cir. 2002); see also *United States v. Starks*, 157 F.3d 833 (11th Cir. 1998); *United States v. Anderson*, 85 F. Supp.2d 1047, 1065–68 (D. Kan. 1999), *rev'd sub nom.*; *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United States v. Shaw*, 106 F. Supp.2d 103 (D. Mass. 2000); *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011).

²⁰ See ACA, § 6402(f)(2) (2010) (codified at 42 U.S.C. § 1320a–7b(h)).

impermissible. Specifically, the OIG issues fraud alerts as a vehicle for identifying fraudulent and abusive practices within the health care industry.

Although the majority of the OIG's fraud alerts are disseminated internally within the government, the OIG has issued several "Special Fraud Alerts" that are distributed directly to members of the health care provider community. To date, the OIG has issued Special Fraud Alerts that address the following:

- joint venture arrangements;
- routine waiver of copayments or deductibles under Medicare Part B;
- hospital incentives to physicians;
- prescription drug marketing schemes;
- arrangements for the provision of clinical lab services;
- home health fraud;
- fraud and abuse in the provision of medical supplies to nursing facilities;
- fraud and abuse in nursing home arrangements with hospices;
- fraud and abuse in the provision of services in nursing facilities;
- rental of space in physician offices by persons or entities to which physicians refer;
- telemarketing by durable medical equipment suppliers;
- physician-owned distributors; and
- laboratory payments to referring physicians.²¹

5.1.4 Advisory Opinions

In 1996, as part of HIPAA, Congress authorized DHHS to issue, upon request, advisory opinions on the applicability of the Anti-Kickback Statute, the safe harbor regulations, and other OIG health care fraud and abuse provisions to either a proposed or an existing financial arrangement.²²

In order to obtain an advisory opinion, the requesting party must submit to the OIG detailed information on the circumstances of the transaction, including all background information, copies of all existing or proposed operative documents, and detailed statements of all collateral or oral understandings. In disclosing this information to the government, the OIG has confirmed that documents submitted in connection with an advisory-opinion request are subject to the Freedom of Information Act (FOIA).

²¹ Copies of these Special Fraud Alerts can be found on the OIG's Internet site at <https://oig.hhs.gov/compliance/alerts/index.asp>. In addition to the Special Fraud Alerts that are listed and address arrangements that may violate the Anti-Kickback Statute, the OIG also has published other types of Special Bulletins and Special Alerts related to other issues (e.g., in 1999, the OIG issued a "Special Bulletin" related to gainsharing arrangements, in 2003 issued a Special Advisory Bulletin entitled "Contractual Joint Ventures", and in 2005 issued a Special Advisory Bulletin entitled "Patient Assistance Programs for Medicare Part D Enrollees").

²² 42 U.S.C. § 1320a-7d; *see also* 42 C.F.R. pt. 1008; 62 Fed. Reg. 7350 (1997); 63 Fed. Reg. 38311 (1998). Copies of all advisory opinions can be found on the OIG's Internet site at <https://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

In addition to the time and costs associated with the requesting party or its representatives preparing the request for an advisory opinion, the requesting party is responsible for reimbursing the OIG for costs in processing the advisory-opinion request.

In July 2008, HHS issued a Final Rule amending its policies relating to the collection and payment by individuals requesting an Advisory Opinion.²³ Under the July 2008 Rule, parties no longer are required to deposit \$250 to the U.S. Treasury upon requesting an OIG Advisory Opinion. According to the OIG, this policy change eliminates the resource demands that arise when a party rescinds its request for an advisory opinion and seeks to recoup its initial deposit. The April 2008 rule also sets forth that parties can no longer pay the U.S. Treasury by way of check or money order but instead must pay for these charges directly through wire or electronic funds transfer.

The OIG is required to issue an advisory opinion within 60 days of receipt of an “accepted” request. The 60-day period does not begin until the OIG deems the request to be complete, but it may be tolled at various times.

5.2 Federal Anti-Kickback Safe Harbor Regulations

Congress established a statutory exception for certain payment practices that the Secretary of the Department of Health and Human Services (DHHS) specifies as being “safe harbored” and therefore not subject to the Anti-Kickback Statute. An arrangement that meets the criteria of a safe harbor is fully protected from criminal and civil liabilities under the Anti-Kickback Statute; it is important to note, however, that failure to fall squarely within the terms of a safe harbor does not necessarily mean that the arrangement is illegal or that it will be investigated or prosecuted. Indeed, the OIG has stated that

[c]ommenters should not infer that because a safe harbor provision does not specifically refer to a particular arrangement or activity, it is unlawful. Nor should [one] interpret that lack of a safe harbor to mean that the [] activit[y] will be subjected to heightened scrutiny. Moreover, safe harbors do not create affirmative obligations on individuals or entities since *compliance with the [] safe harbors is purely voluntary*. The failure to comply with a safe harbor means only that the practice or arrangement does not have absolute assurance of protection from anti-kickback liability.²⁴

Thus, conduct outside the safe harbors must be analyzed based on its particular facts and circumstances to determine whether a violation exists under the Anti-Kickback Statute.

In 1991, the OIG promulgated the first set of final “safe harbor” regulations, which set forth permissible payment practices in the following 11 areas:

1. investment interests;
2. space rental;
3. equipment rental;

²³ 73 Fed. Reg. 40982 (July 17, 2008); 42 C.F.R. § 1008.31(b); 42 C.F.R. § 1008.36(b); 42 C.F.R. § 1008.43(d).

²⁴ 61 Fed. Reg. 2122, 2124 (1996) (emphasis added).

4. personal services and management contracts;
5. sale of a practice;
6. referral services;
7. warranties;
8. discounts;
9. employees;
10. GPOs; and
11. waiver of beneficiary coinsurance and deductible amounts for Part A inpatient hospital services and certain federally qualified and federally funded health centers and health care facilities.²⁵

Although these 11 safe harbors were published as a “final” list, the OIG published “clarifications” to several of these safe harbors in 1999.²⁶

With respect to the applicability of the Anti-Kickback Statute to certain managed-care activities, the OIG has confirmed that the Anti-Kickback Statute does, in fact, apply by adopting several managed-care safe harbors. In particular, in 1996, the OIG not only modified the safe harbor for waivers of inpatient and deductible amounts so as to include Medicare “SELECT PPOs,” but also adopted safe harbors for incentives offered to beneficiaries in order to encourage the use of the preferred provider network and provider discounts offered to managed-care plans.²⁷ Then, in 1999, the OIG issued as an interim final rule two safe harbors related to the shared-risk exception that was added to the Anti-Kickback Statute as part of HIPAA.²⁸

Also in 1999, the OIG finalized additional safe harbors for several different categories of ambulatory surgery centers (ASCs), for group practices, for referral arrangements for specialty services, and for cooperative hospital service organizations. The OIG also adopted several safe harbors related to financial relationships entered into by and with health care entities located in medically underserved areas (MUAs). Specifically, safe harbors were established for investment interests held in health care entities located in MUAs, for remuneration paid as part of a recruitment package in order to attract professionals to an MUA, and for obstetrical malpractice-insurance subsidies paid to a practitioner who is primarily engaged in an obstetrical practice in a designated Health Professional Shortage Area (HPSA).²⁹

In 2001, the OIG established a safe harbor for ambulance arrangements with hospitals and other receiving facilities that replenish drugs and medical supplies used by the ambulance provider when transporting patients to the hospitals or receiving facilities.³⁰

²⁵ 42 C.F.R. § 1001.952(a)–(k); *see also* 56 Fed. Reg. 35952 (1991).

²⁶ *See* 64 Fed. Reg. 63518 (1999); *see also* 59 Fed. Reg. 37202 (1994).

²⁷ 42 C.F.R. § 1001.952 (k)–(m); *see* 61 Fed. Reg. 2122, (Jan. 25, 1996); *see also* 57 Fed. Reg. 51723 (1992).

²⁸ 42 C.F.R. § 1001.952(t)–(u); *see* 64 Fed. Reg. 63504 (1999).

²⁹ 42 C.F.R. § 1001.952(n)–(s); *see* 64 Fed. Reg. 63518 (1999); *see also* 58 Fed. Reg. 49008 (1993).

³⁰ 42 C.F.R. § 1001.952(v); *see* 66 Fed. Reg. 62979 (2001); *see also* 65 Fed. Reg. 32060 (2000).

In August 2006, the OIG issued regulations creating two safe harbors for non-monetary remunerations involving certain electronic prescribing and electronic health records arrangements,³¹ and in October 2007, the OIG published a safe harbor in order to enable FQHCs to more easily provide medical care to underserved populations.³²

In October 2014, the OIG published a proposed rule³³ to add new safe harbors (Proposed Rule). The Proposed Rule sets forth a number of provisions that codify into the regulations certain exceptions and modifications to the laws that Congress has adopted over the last decade. The Proposed Rule addressed the following:

- Part D cost sharing waivers by pharmacies;
- Cost-sharing waivers for emergency ambulance services;
- FQHCs and Medicare Advantage organizations;
- Medicare coverage gap discount programs; and
- Free or discounted local transportation services.

On December 7, 2016, the OIG issued a Final Rule finalizing all of the safe harbors that were proposed, with certain modifications (2016 Safe Harbor Final Rule).³⁴ In the 2016 Safe Harbor Final Rule, OIG stated, “Congress intended the safe harbors to evolve with changes in the health care system, and we believe this final rule balances additional flexibility for industry stakeholders to provide efficient, well-coordinated, patient-centered care with protections against fraud and abuse.”³⁵ The OIG acknowledged that the 2016 Safe Harbor Final Rule takes into account the changes in payment and delivery of health care items and services, advances the needs of providers and patients in rural areas, and recognizes the transition from volume to value-based and patient-centered care.

5.2.1 Investment Interest Safe Harbors

The final safe harbor regulations published in 1991 contained two separate sets of criteria for investment interests: (1) investment interests in large, publicly held companies; and (2) investment interests held in smaller health care companies. In 1999, the OIG adopted a third set of criteria related to investment interests held in health care entities that are located in MUAs.³⁶

5.2.1.1 *Large Investment Interests*

Under this safe harbor, a large publicly traded company must have at least \$50 million in undepreciated net tangible assets related to the furnishing of health care items or services. Moreover, equity securities must be registered with the Securities and Exchange Commission, and the invest-

³¹ 42 C.F.R. § 1001.952(x)–(y); *see* 71 Fed. Reg. 45110 (2006).

³² 42 C.F.R. § 1001.952(w); *see* 72 Fed. Reg. 56632 (2007).

³³ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59717 (proposed Oct. 3, 2014).

³⁴ Medicare and State Health Care Programs; Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016).

³⁵ *Id.* at 88370.

³⁶ 42 C.F.R. § 1001.952(a).

ment interest must be obtained “on terms equally available to the public” through trading on a registered national-securities exchange. As a result of the clarifications adopted by the OIG in 1999, language was added to this safe harbor to “clarify” that the investment interest (1) may not be subject to restrictions or limits on transferability that are not applicable to an investment held by members of the public and (2) must be obtained for the same price available to the general public.

Additional requirements under this safe harbor include that neither the entity nor any investor (nor other individual acting on behalf of the entity or any investor in the entity) may make loans or loan guarantees to investors who may be in a position to refer business to the entity. Further, dividends to investors must be in proportion to the amount of the investment, and the entity may not market or furnish its services differently to passive investors than it does to non-investors.

5.2.1.2 *Small Investment Interests*

With respect to the small entity safe harbor, each of the following eight standards must be satisfied.

1. *“60/40” Investor Rule.* No more than 40% of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12-month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for, the entity. In 1999, the OIG added language to this requirement explaining that equivalent classes of equity investments may be combined.
2. *Terms of Investment.* The terms on which an investment interest is offered to a passive investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be no different than the terms offered to other passive investors.
3. *Investment Not Related to Referrals.* The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items, or services furnished, or the amount of business otherwise generated, by that investor to the entity.
4. *No Requirement to Generate Referrals.* No requirement may be made that a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.
5. *Marketing Efforts.* Neither the entity nor any investor may market or furnish the entity’s items or services (or those of another entity as part of cross-referral agreement) to passive investors differently than to non-investors.
6. *“60/40” Revenue Rule.* No more than 40% of the gross revenue of the entity in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.
7. *Prohibition on Loans.* Neither the entity nor any investor (nor other individual or entity acting on behalf of the entity or any investor in the entity) may loan funds to or guarantee a loan for an investor who is in a position to make or influence referrals to, furnish items or

services to, or otherwise generate business for the entity if the investor uses any part of such loan to obtain the investment interest.

8. *Investment Return.* The amount of payment to an investor in return for the investment interest must be directly proportional to the amount of the capital investment of that investor.

5.2.1.3 *Investments in Entities in MUAs*

In contrast to the OIG's proposal in 1993 to adopt a safe harbor for investments held in entities that are located in "rural" areas, in 1999 the OIG expanded the scope of this safe harbor so as to apply to MUAs, which can be located in either a rural or urban area. Although many of the requirements for this safe harbor are similar to the small investment safe harbor, this safe harbor eliminates the 60/40 Revenue Rule, and modifies the 60/40 Investor Rule to a 50/50 Investor Rule (i.e., no more than 50% of the value of the investment interest of each class of investments may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity). In addition, the OIG has included a requirement that at least 75% of the business in the previous fiscal year or previous 12-month period be derived from services furnished to persons in an MUA or who are members of a medically underserved population (MUP).

5.2.2 *Space and Equipment Rental, and Personal Services and Management Contracts*

The OIG created three separate safe harbors for certain contracts related to space rental, equipment rental, and personal services and management contracts. Nevertheless, all three of these safe harbors share common requirements.³⁷ For example, all three safe harbors require that a written agreement be executed for a term of at least one year that specifies the aggregate payment amount, as well as the premises, equipment, or services covered. If the agreement does not contemplate full-time services, then the agreement must also specify the schedule of intervals, their precise length, and the exact charge for such intervals.

As part of the "clarifications" adopted by the OIG in 1999 and in order to "preclude schemes involving the use of multiple overlapping contracts to circumvent the one-year requirement," the OIG has added a requirement to all three safe harbors that the agreement cover *all* space, equipment, or services for the term of the agreement.

These three safe harbors also require that the payments must be based upon fair market value, and not vary on the volume or value of any Medicare-covered or state health care program-covered referrals or business generated between the parties. For purposes of space rental, fair market value means the value of the rental property for general commercial purposes. For purposes of equipment rental, fair market value means the value of the equipment when obtained from a manufacturer or professional distributor. The assessment of "fair market value" for space and equipment leases, however, may not include additional value for location or convenience to sources of Medicare and/or state health care program business. An additional requirement for personal services and management contracts is that the services performed under the agreement must not involve the counseling or promotion of a business arrangement or other activity that violates any State or federal law.

³⁷ 42 C.F.R. § 1001.952(b)–(d).

5.2.3 Sale of Practice

Although the “sale of practice” safe harbor originally only covered sales between practitioners, the OIG expanded this safe harbor in 1999 to include the sale of a practice by a practitioner in an underserved area to a hospital.³⁸

With respect to the sale of a physician’s practice to another practitioner, the sale must be completed within one year, and the selling practitioner cannot remain in a position to generate business for the purchasing practitioner beyond the one-year period. Thus, the safe harbor would not protect any situation in which the physician who sells the practice is retained on its staff for any significant period of time following the purchase.

With respect to payments made to a practitioner by a hospital or other entity to purchase the practitioner’s practice, the safe harbor requires that: (1) the sale be completed within three years; (2) after the sale is completed, the practitioner not be in a position to make referrals to or generate business for the purchasing entity; (3) the practice be located in a HPSA for the practitioner’s specialty; and (4) the purchasing entity must, in good faith, engage in recruitment activities to find a new practitioner to take over the acquired practice.

5.2.4 Referral Services

The final sale-harbor regulations include a safe harbor for payments to “referral services.”³⁹ Under this safe harbor, a referral service may not exclude any person or entity that meets participation qualifications. Although the safe harbor does not require inclusion of *all* physicians in a particular geographic area, the safe harbor requires that, if the referral service qualifies physicians based upon certain criteria, then such criteria must be applied equally to all participants. In addition, the referral service must disclose to persons seeking referrals how individual participants are chosen, whether a fee is paid, the relationship between the participant and the service, and any restrictions that would exclude a participant.

5.2.5 Warranties

The safe harbors protect payments or exchanges of value under certain manufacturer or supplier warranties.⁴⁰ In order to qualify for safe harbor protection, the buyer and the manufacturer or supplier alike must comply with specified reporting standards. The buyer must report any price reduction or free item obtained as part of the warranty in its cost report or claim for payment. The supplier or manufacturer, in turn, must report such price reductions or free items on the buyer’s invoice (or, if the amount is unknown, the existence of the warranty and the full documentation when known), and inform the buyer of its reporting obligations. The buyer also must furnish the invoice information to the Medicare or relevant state health care program on request. Additionally, the warranty can only be for the item itself, and cannot include payment to an individual or entity other than a beneficiary for any medical, surgical, or hospital expenses incurred by a beneficiary. Finally, the safe harbor not

³⁸ 42 C.F.R. § 1001.952(e).

³⁹ 42 C.F.R. § 1001.952(f).

⁴⁰ 42 C.F.R. § 1001.952(g).

only defines the term “warranty” under the Magnuson-Moss Warranty-Federal Trade Commission Improvement Act’s definition of “written warranty” at 15 U.S.C. § 2301(6) governing the sale and warranty of consumer products, but it also includes one manufacturer’s or supplier’s agreement to replace another manufacturer’s or supplier’s defective item (which is covered by a “written warranty” under that act) on terms equal to the original written warranty.

5.2.6 Discounts

The Anti-Kickback Statute includes several statutory exceptions, including an exception for “a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity...”⁴¹ Despite the existence of a statutory exception, the OIG has adopted safe harbors related to the statutory exceptions as it has taken the position that its role is “to define innocuous arrangements that should not be prosecuted, including the statutory exceptions.”⁴²

In contrast to the statute, which only requires that the discount be “properly disclosed and appropriately reflected” in the entity’s Medicare and Medicaid costs or charges, the safe harbor sets forth a restrictive definition of the term “discount,” excluding such typical discount arrangements as discounts not applicable to Medicare or Medicaid, and those discounts given directly to beneficiaries (e.g., coinsurance waivers).⁴³ In addition, although the safe harbor originally excluded from the definition of “discount” the provision of discounted or free items or services in exchange for the purchase of different items or services, the OIG “clarified” this exclusion so as to allow this type of discount arrangement if the goods and services are reimbursed by the same federal health care program using the same methodology.

The protection provided under the discount safe harbor is categorized based upon the type of party involved in the transaction (buyers, sellers, and offerors) with the safe harbor placing different requirements on the respective parties. Specifically, the safe harbor provides protection to buyers that are Medicare+Choice plans and/or Medicaid risk contractors without imposing any reporting requirements; by contrast, cost-reporting entities not only must report the discount on the cost report, but also must earn the discount within a single fiscal year and claim the benefit of the discount in that or the following fiscal year. All other purchasers, such as Part B suppliers, can only take advantage of discounts made at the time of the original sale, or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service.

With respect to sellers, the safe harbor provides protection for discounts given to cost-reporting entities as long as the seller reports the discount on the purchaser’s invoice and reasonably notifies the buyer of its obligations to report such discount. For cost-reporting entities, the safe harbor also provides that, if the value of the discount is unknown at the time of the sale, the seller can disclose the existence of the discount program on the invoice and furnish the additional documentation later.

⁴¹ 42 U.S.C. § 1320a-7b(3)(A).

⁴² 56 Fed. Reg. 35952, 35957 (1991).

⁴³ 42 C.F.R. § 1001.952(h).

For all other entities, the seller's obligations depend on whether the seller submits a claim or request for payment on behalf of the buyer, or whether the buyer instead submits such claims on its own behalf.

In addition to buyers and sellers, the safe harbor includes protection for offerors, who are individuals or entities who are not sellers but who promote the purchase of an item or service by a buyer at a reduced price. Similar to sellers, the ability of an offeror to qualify for safe harbor protection depends on the offeror satisfying certain requirements that are based upon the type of purchaser.

5.2.7 Employees

The Anti-Kickback Statute includes a statutory exception for “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.”⁴⁴ Despite the significant legislative history that surrounded the enactment of this exception, in which Congress explained its intention to include a broad meaning for the term “employee,” this position was rejected by the OIG as the OIG defined the term “employee” pursuant to the “usual common law rules.”⁴⁵ Therefore, independent-contractor arrangements fall outside the employee safe harbor protection, unless they otherwise qualify for the safe harbor governing personal services and management contracts described earlier.

5.2.8 Group Purchasing Organizations

The Anti-Kickback Statute includes a statutory exception for amounts paid by a vendor to a GPO as long as two conditions are satisfied:

1. the person has a written contract with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract; and
2. in the case of an entity that is a provider of services (as defined in § 1861(u)), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity.⁴⁶

Within the safe harbors, the OIG narrowed the scope of the protection offered to GPOs by excluding GPOs that are part of the same corporate family as the entities for whom the GPOs are purchasing.⁴⁷ On the other hand, although the statute requires that the agreement specify the amount the vendor pays the GPO, irrespective of the amount, the safe harbor permits the agreement to state that vendors will pay the GPO a fee of 3% or less of the purchase price of the vendor's goods. If the fee is more than 3%, the agreement must specify the amount (or, if unknown, the maximum amount) of the GPO payment by each vendor.

⁴⁴ 42 U.S.C. § 1320a-7b(b)(3)(B).

⁴⁵ 42 C.F.R. § 1001.952(i).

⁴⁶ 42 U.S.C. § 1320a-7b(b)(3)(C).

⁴⁷ 42 C.F.R. § 1001.952(j). *See* 81 Fed. Reg. 88368 (2016).

5.2.9 Coinsurance and Deductible Waivers

Under the 2016 Safe Harbor Final Rule, the OIG expanded the safe harbor for waivers of coinsurance and deductible amounts to protect waivers under all federal health care programs, where applicable.⁴⁸ Under the expanded safe harbor, remuneration does not include any reduction or waiver of a beneficiary's obligation to pay copayment, coinsurance, or deductible amounts as long as all the standards are met within one of the following health care providers, if the cost-sharing amounts are owed:

- (1) to a hospital for inpatient hospital services for which a federal health care program pays under the prospective payment system;
- (2) by an individual who qualifies for subsidized services under a provision of the Public Health Services Act or under Titles V or XIX of the Act;
- (3) to a federally qualified health care center or other health care facility under any Public Health Services Act grant program or under Title V of the Act;
- (4) to a pharmacy for cost-sharing imposed under a federal health care program; or
- (5) to an ambulance provider or supplier for emergency ambulance services for which a federal health care program pays under a fee-for-service payment system.

5.2.10 Beneficiary Incentives Offered by Managed-Care Organizations

The safe harbor for beneficiary incentives offered by health plans (e.g., differentials in coinsurance and deductible amounts) applies only to Medicare and Medicaid contracting health plans.⁴⁹ The term "health plan" has been defined in the safe harbor to apply to a managed care entity that:

1. has a formal contract with the Medicare or Medicaid programs;
2. charges a premium regulated by a state insurance statute or existing state statute governing health maintenance organizations (HMOs) or preferred provider organizations (PPOs);
3. is an Employee Retirement Income Security Act (ERISA) or self-funded/self-insured employer or union plan that contracts directly with health care providers or insurance companies; and
4. acts as an intermediary between contract health care providers and employers, union welfare funds, and/or insurance companies such as PPOs.

Nevertheless, no safe harbor protection exists for commercial managed-care plans that furnish coverage to Medicare eligibles on a fee-for-service basis.

Plans that qualify under the definition of a "health plan" and that have a formal Medicare or Medicaid contract also must meet other requirements, such as not discriminating in offering incentives to all potential enrollees. Consequently, these health plans must offer the same incentives to all Medicare or state health care program enrollees, unless otherwise approved by the federal or state

⁴⁸ *Id.* § 1001.952(k).

⁴⁹ *Id.* § 1001.952(l).

program. Moreover, health plans paid on a reasonable cost or similar basis cannot claim the cost of the incentive as a bad debt, or otherwise make additional claims to the federal or state health care program to pay for the incentive.

5.2.11 Price Reductions Offered to Group Health Plans

The managed-care safe harbors also protect price reductions that providers offer to health plans under certain circumstances.⁵⁰ Unlike the beneficiary incentive safe harbor, which applies only to Medicare and Medicaid contracting health plans, the price reduction safe harbor enables non-contracting health plans to qualify for safe harbor protection, albeit based on different safe harbor criteria.

First, for all health plans, a contract must be created between the provider and the health plan, and such contract must be for the sole purpose of furnishing covered items and services to health plan enrollees. Thus, contracts for utilization-review or enrollment-screening services would not qualify for safe harbor protection unless they otherwise meet the employment or personal services contracts safe harbor previously issued.

Second, the health plan must meet certain standards, depending on whether the health plan's relationship with the Medicare and Medicaid programs falls under one of the following categories:

1. risk-based health plans with formal program contracts;
2. cost-based health plans with formal program contracts cost contractors;
3. non-contracting health plans that do not pay providers on an at-risk capitated basis; and
4. health plans making capitated payments to providers.

5.2.12 Practitioner Recruitment

In 1999, the OIG added a safe harbor for physician recruitment activities paid to a physician in order to induce the physician who has been practicing her specialty for less than one year to locate her primary practice to a HPSA for such physician's specialty as long as the following nine requirements are satisfied.⁵¹

1. *Written Agreement.* The arrangement must be set out in writing, specifying the recruitment benefits being provided and the respective parties' obligations.
2. *75% Revenue from New Patients.* If a practitioner is leaving an established practice, at least 75% of the revenues of the new practice must be generated from new patients.
3. *Three-Year Limitation.* The period of the agreement cannot exceed three years, and the terms of the agreement cannot be renegotiated during such three-year period.
4. *No Requirement to Refer.* There may not be any requirement that the physician make referrals to or otherwise generate business for the entity, although the entity may require physician to maintain staff privileges.

⁵⁰ *Id.* § 1001.952(m).

⁵¹ *Id.* § 1001.952(n).

5. *No Restrictions on Staff Privileges.* The practitioner may not be restricted with respect to where the practitioner may maintain staff privileges.
6. *Amount of Benefits.* The amount of benefits provided to the physician may not vary in any manner based on the volume or volume of any expected referrals to or business generated for the entity.
7. *Agreement to Treat.* The practitioner must agree to treat patients receiving Medicare benefits or assistance from a Federal health care program in a nondiscriminatory manner.
8. *75% of Revenues Generated from Underserved Area.* At least 75% of the revenues of the new practice must be generated from patients who reside in a HPSA or a MUA or who are part of a MUP.
9. *Benefits Only Paid to Practitioner.* Except for the practitioner who is being recruited, no payment or exchange of anything of value given to a person or entity in a position to make or influence referrals may be made.

5.2.13 Obstetrical Malpractice-Insurance Subsidies

This safe harbor protects malpractice subsidies for obstetrical care paid by a hospital or other entity where such payment is for a practitioner (including a certified nurse-midwife) who engages in obstetrical practice as a routine part of her medical practice in a primary care HPSA.⁵² Included among the criteria for this safe harbor is a requirement that at least 75% of the practitioner's obstetrical patients, who are treated under the coverage policy, reside in a HPSA or MUA or be part of a MUP. In addition, for practitioners who are not full-time obstetricians or certified nurse-midwives, the safe harbor only protects payments related to obstetrical malpractice insurance.

5.2.14 Investments in Group Practices

The OIG has adopted a safe harbor that protects returns on investments made to a solo or group practitioner investing in her own practice, as long as certain requirements are satisfied. In light of the fact that much of the day-to-day management of most physician groups is given to one physician or a practice manager, the OIG deleted its proposal to require that the group practice be composed of "active investors," and instead merely requires that the group practice be comprised of licensed professionals who practice as part of the group.

Among the other requirements are that the physician's equity interest be held in the group practice itself and not a subdivision of the group, that the group satisfy the Stark Law's requirements for being a "group practice," and that revenues from ancillary services be derived from "in-office ancillary services" that meet the applicable definition under the Stark Law. Moreover, the OIG has required that the group practice be organized "as 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."⁵³

⁵² *Id.* § 1001.952(o).

⁵³ *Id.* § 1001.952(p).

5.2.15 Cooperative Hospital-Services Organizations

This safe harbor protects most cooperative hospital-service organizations (CHSOs) that qualify under § 501(c)(3) of the Internal Revenue Code (IRC), which operate by distributing earnings to members in accordance with the volume of services used by the member hospital.⁵⁴ The safe harbor requires that if the patron-hospital makes a payment to the CHSO, the payment must be for *bona fide* operating expenses of the CHSO. On the other hand, if the CHSO makes a payment to the patron-hospital, the payment must be for the purpose of paying a distribution of net earnings required to be made under IRC § 501(e)(2).

5.2.16 ASCs

In 1993, the OIG proposed adding a safe harbor protecting payments to surgeon-investors in ASCs who refer patients directly to the ASC and perform the surgery themselves on those patients. In contrast to other investment interest safe harbors that limit investment by individuals in a position to refer, the proposed ASC safe harbor would have only protected entities whose investment interests were held entirely by such individuals. After the OIG received a great volume of comments on this proposed safe harbor, however, the OIG significantly revised it in 1999.

In the final regulations, the OIG created four different categories of ASC safe harbors: surgeon-owned ASCs; single-specialty ASCs; multi-specialty ASCs (e.g., a mix of surgeons and specialists); and hospital/physician-owned ASCs. In addition to the surgeons, physicians, and/or a hospital that can have an ownership interest in the entity, certain other “non-tainted” investors can own an investment interest as long as they: (1) do not provide items or services to the ASC or its investors; (2) are not employed by the ASC or any investor; and (3) are not in a position to refer patients directly or indirectly to, or generate business for, the ASC or any of its investors.⁵⁵

Applicable to all four categories of ASCs are requirements that the ASC be Medicare certified, that the ASC’s operating and recovery room space be dedicated exclusively to the ASC (i.e., if the ASC is located in a hospital, the ASC space must be dedicated exclusively to the ASC and not used by the hospital for the treatment of the hospital’s inpatients or outpatients), and that all patients who are referred to the ASC by an investor must receive information about the investor’s investment interest. In addition, all four categories include a requirement that all ancillary services be directly and integrally related to primary procedures performed at the ASC, and that none may be separately billed to Medicare or other federal health care programs.

With respect to the first three categories of ASC safe harbors (i.e., surgeon-owned ASCs, single-specialty ASCs, and multi-specialty ASCs), each requires that physician investors satisfy the “One-Third Practice Income Test,” which requires that each physician investor derive at least one-third of her medical practice income for the previous 12-month period from her own performance of procedures that require an ASC or hospital surgical setting. Moreover, a physician investor in the third category of ASC (i.e., a multi-specialty ASC) must satisfy another standard whereby at least

⁵⁴ *Id.* § 1001.952(q).

⁵⁵ *Id.* § 1001.952(r).

one-third of the physician's procedures that require an ASC or hospital surgical setting be performed at the ASC in which she is investing (known as the "One-Third/One-Third Test").

With respect to the fourth category (i.e., a hospital/physician ASC), the OIG has included a requirement that the hospital not be in a position to make or influence referrals directly or indirectly to the ASC or to any of its physician investors—a development which, from a practical perspective, may preclude many hospital/physician ASC joint ventures from qualifying for safe harbor protection.

5.2.17 Referral Agreements for Specialty Services

This safe harbor excludes from the purview of the Anti-Kickback Statute any "exchange of value" among individuals or entities where one party "agrees to refer a patient to other party for the provision of a specialty services" in return for an agreement that the other party will "refer that patient back at a mutually agreed upon time or circumstance" as long as certain requirements are met.⁵⁶ In particular, the safe harbor requires that the timing and circumstances for the referral back to the originating physician or entity be "clinically appropriate," that the service for which the referral is made not be within the expertise of the referring individual or entity, and that the parties neither receive any payment from each other for the referral nor share or split a global fee in connection with the referred patient. Finally, unless the parties to the agreement belong to the same group practice, the only permitted "exchange of value" is the remuneration the respective parties receive from the third-party payer or the patient for the services furnished to the patient.

5.2.18 Ambulance Replenishing/Restocking

In 2001, the OIG adopted a final regulation establishing safe harbor protection for ambulance "restocking" or "replenishing" arrangements.⁵⁷ As described in the preamble to the safe harbor, ambulance "restocking" is the practice of hospitals, or other receiving facilities, restocking ambulance providers with drugs or supplies used during the transport of a patient to the hospital or receiving facility. Operationally, this is done to ensure that, when the ambulance departs the hospital, it is, as the OIG points out, ready for the next emergency call, fully stocked with current medications, sanitary linens, and a full complement of appropriate medications and supplies, and helps to ensure that supplies, such as intravenous tubing and catheters, are compatible with equipment used in local emergency rooms so as to expedite the transfer of critically ill or injured patients to emergency room systems.⁵⁸

The final regulations address three categories of restocking: general restocking (either for free or for a charge); fair-market-value restocking; and government-mandated restocking. Common to all three categories of safe harbors are the following four conditions:

⁵⁶ *Id.* § 1001.952(s).

⁵⁷ *Id.* § 1001.952(v); *see* 66 Fed. Reg. 62979 (2001); *see also* 65 Fed. Reg. 32060 (2000).

⁵⁸ 66 Fed. Reg. 62979 (2001). In the preamble, the OIG also explains that, although "restocking" is the term commonly used, the OIG uses the word "replenishing" to make clear that "the safe harbor only applies to the gifting or transfer of drugs and supplies that replace comparable drugs and supplies administered," and that the safe harbor is not applicable to "general stocking of the inventories of ambulance providers." *Id.*

1. under no circumstances may both the ambulance provider and the receiving facility bill for the same replenished drug or supply, and all billing or claims submission for the replenished drugs must comply with all federal health care program payment and coverage rules;
2. one of the parties will maintain records of the replenished drugs and medical supplies;
3. no ties to referrals, and
4. all parties will ensure compliance with all other federal, state, and local laws regulating ambulance services.

5.2.19 Federally Qualified Health Centers

In 2003, Congress amended the Anti-Kickback Statute and include a statutory requirement that the OIG develop a safe harbor for certain agreements involving FQHCs. On October 4, 2007, the OIG published a final rule establishing a safe harbor for FQHCs for certain goods, items, services, donations, and loans provided by individuals and entities to certain health centers funded under Section 330 of the Public Health Service Act, which is a health center program designed to assist individuals living in medically underserved areas and populations with limited access to health care resources.⁵⁹

The safe harbor excludes remuneration between a health center and an individual or entity providing goods, items, services, donations, loans, or a combination of these to the health center pursuant to a contract, lease, grant, loan, or other agreement, provided that the agreement contributes to the health center's ability to maintain or increase its services to the medically underserved. The remuneration must be "medical or clinical in nature or relate directly to patient services" such as billing services, administrative support services, technology support and the like.

5.2.20 Risk-Sharing Arrangements

In 1999, the OIG issued two safe harbors for shared-risk arrangements.⁶⁰ The first safe harbor protects price reductions that are offered to "eligible managed care organizations" (EMCOs), which are defined to include HMOs and competitive medical plans (CMPs) with a risk- or cost-based contract; Medicare+Choice organizations that receive capitation payments; certain Medicaid managed care organizations (MCOs), Programs for the All Inclusive Care For the Elderly, and federally qualified HMOs.

This safe harbor is divided into two categories of requirements. The first category sets out standards for arrangements between EMCOs and any individual or entity that contracts directly with the EMCO (referred to as a "first tier" contractor). Among this safe harbor's requirements is the requirement that the EMCO and the first-tier contractor have an agreement that is set out in writing, is for a term of at least one year, specifies the items and services covered under the agreement, and specifies that the first-tier contractor cannot claim payment in any form from a federal health care program for items or services covered under the agreement, except for (1) HMOs and CMPs that have cost-based

⁵⁹ 42 C.F.R. § 1001.952(w); *see* 72 Fed. Reg. 56632 (2007).

⁶⁰ 42 C.F.R. § 1001.952(t)-(u); *see also* 64 Fed. Reg. 63504 (1999).