Chapter 1415
Personal Services and Management Agreements

Overview

Healthcare providers—directly or indirectly—enter into contracts under which one party agree to furnish the other party with personal services (such as professional services) or management services. If the party furnishing services to the provider is in a position to refer business reimbursable by a federal health care program, or is in a position to receive such referrals, application of the broadly drafted federal anti-kickback statute is a significant concern for both parties. In calling for compliance, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) has identified many risk areas with respect to such arrangements, and has emphasized the value of structuring such contracts to comply fully with the OIG's personal services and management contracts safe harbor.

This chapter discusses application of the anti-kickback statute to personal services and management agreements and the available safe harbor. Compliance guidance issued by the OIG and related case law and settlement agreements also are discussed. For information on management services devoted to marketing, which have received particular OIG emphasis, see *Chapter 1430, Marketing Practices*. For information on potential penalties for violating the anti-kickback statute, see *Chapter 210, Penalties*.

1415.10 Law and Regulatory Summary

1415.10.10
Application of the Anti-Kickback Statute to Personal Services and Management Agreements

Contracts for the performance of personal or management services pose concerns under the anti-kickback statute if, generally, the:

- party performing the services for a provider is in a position to directly or indirectly refer business reimbursable by a federal health care program, or is in a position to receive such referrals from the other party directly or indirectly;; and
- payments made are in any way meant to induce such referrals—even if those payments also are meant to compensate the party fairly for services rendered.

Agreements, naturally, will be entered into on a mutually beneficial basis, but the arrangements will be suspect if payments vary with the volume of referrals or if financial incentives are offered in exchange for referrals. Also, if those purchasing services from referral sources purchase more services than they actually need, there is a suspicion that they are doing so as a means of inducing referrals.

The conviction of two osteopaths for kickback violations illustrates the concerns potentially posed by agreements for services. Brothers Robert and Ronald LaHue, as principals of a medical group that specialized in treating patients in nursing homes, received substantial annual payments from hospitals as gerontology consultants. Yet the LaHues were found to have provided very little in the way of services, but very much in the way of referrals to the hospitals. A jury found—and a federal court confirmed that the evidence was ample—that the agreements were specifically intended to compensate the LaHues for making referrals.[1]

1415.10.20
Safe Harbor for Personal Services and Management Contracts

Parties can minimize kickback concerns under the anti-kickback statute by structuring arrangements to comply fully with the requirements set forth in the personal services and management contracts safe harbor.[2] Under this safe harbor, an arrangement wherein one party (the "agent") performs services under an agreement with another (the "principal") is excluded from consideration under the anti-kickback statute if it satisfies all of the following seven requirements:

(1) The agreement is in writing and signed by the parties.

(2) The agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies what services the agent will provide.

(3) If it is for periodic, sporadic, or part-time work, the agreement specifies exactly the schedule of intervals in which services will be performed, the

[1] *See United States v. Anderson*, 85 F. Supp. 2d 1084 (D. Kan. 1999).

[2] 42 C.F.R. § 1001.952(d).

ISBN 1-55871-427-8

length of such intervals, and the exact charge for the intervals.

(4) The agreement term is at least one year.

(5) The aggregate compensation paid to the agent is set in advance, consistent with fair market value in arms-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment might be made in whole or in part under Medicare, Medicaid or other federal healthcare program.

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

(7) The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of those services.

The "commercially reasonable business purpose" test, the OIG has explained, "is intended to preclude safe harbor protection for health care providers that surreptitiously pay for referrals—whether because of coercion or by their own initiative—by . . . purchasing more services than they actually need from referral sources."[3]

The safe harbor further clarifies that the agent is any person who performs services for the principal, other than a bona fide employee of the principal.[4]

1415.20 Industry Compliance Guidelines

1415.20.10

Types of Agreements

Contractual arrangements for the provision of specific services to or for the benefit of a healthcare provider should be carefully structured when federal healthcare program-covered business may be generated, directly or indirectly, by one party for the other. Such arrangements are commonly entered into for personal or management services.

Personal Services. The "personal services" category is relevant to many types of services provided in the healthcare industry, except services provided by bona fide employees. For example, professional physician services provided by the physician as an independent contractor are included in this category. Services provided by vendors to healthcare provider customers also may fall within this category. A contract for a physician group to provide medical services to and for the benefit of a hospital or hospital department is a classic example of a personal services arrangement. So is a medical director agreement, in which a physician contracts to provide administrative or supervisory services, other than direct patient care services, to and for the benefit of a hospital or other facility or group.[5] Professional services for which physicians might be retained include, as well, the development of treatment protocols or training programs.

Based on its interpretations in past advisory opinions, the OIG is unlikely to impose administrative sanctions under the anti-kickback or civil monetary penalties law where an arrangement for professional services does not meet a safe harbor, but is unlikely to generate impermissible remuneration, including appreciable new business, and incorporates sufficient safeguards. Advisory Opinion No. 03-15 addresses this situation. There, the OIG analyzed a proposal to reintegrate a medical group and a hospital that originally were a single entity.[6] The hospital and the physician group sought to enter into a 10-year professional agreement under which the group would provide exclusive medical services in a new hospital outpatient clinic and also would provide services in the emergency department.

Analyzing the arrangement for anti-kickback violations, the OIG found that the compensation the group would receive under the personal services agreement would be substantially the same as what they received before the proposed arrangement. Moreover, the amounts were certified by the requestors to be consistent with fair market value in arms'-length transactions. The arrangement was unlikely, therefore, to generate impermissible remuneration from the hospital to the group, especially given the fact that there was offsetting remuneration from the group to the hospital arising from a transfer of the group's assets to the larger entity. The agreement also was unlikely to result in appreciable new business for the group, since the patients were largely the same people the group was currently treating, the OIG said (see *Chapter 1410, Joint Ventures and Acquisitions,* § 1410.20.20.20, for a fuller discussion of the opinion).

The OIG found another arrangement unlikely to generate prohibited remuneration in Advisory Opinion No. 12-15,[7] concerning a hospital's arrangement to pay a per diem fee to specialist physicians for working on-call shifts. Under the proposed arrangement, physicians in a few specialties are required to be present at the hospital while on call, but most specialists are subject to unrestricted call, meaning a physician may be off-site as long as he or she can respond, in person, to a call at the hospital within 30 minutes. The hospital offers the op-

[3] Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,525 (Nov. 19, 1999) (§ II.B.2).

[4] 42 C.F.R. § 1001.952(d).

[5] *See* Centers for Medicare & Medicaid Servs. (CMS), State Operations Manual (Pub. 100-07), App. PP, Tag F501, Medical Director, for a description of the role and duties of medical directors in long term care facilities.

[6] OIG, Advisory Op. No. 03-15 (Dec. 11, 2003).

[7] OIG, Advisory Op. No. 12-15 (Oct. 30, 2012).

ISBN 1-55871-427-8

portunity to participate in the arrangement to all specialists on its staff who are subject to unrestricted call. Participating physicians enter into one-year written agreements containing automatic renewal provisions. Participating physicians who admit emergency patients must provide care to the patients during their inpatient stays and must see the patients for follow-up care in their office practices, regardless of the patient's insurance status or ability to pay.

The hospital determines the per diem rate for each specialty each year based on: (1) the likely number of days per month the specialty would be called; (2) the likely number of patients a specialist would see per call day; and (3) the likely number of patients requiring inpatient care and post-discharge follow-up care in a specialist's office. Specialists on call receive the per diem fee for every call shift, whether they are called or not.

According to the OIG, the key inquiry is whether the compensation is fair market value in an arm's-length transaction for actual and necessary items or services, and not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties. The hospital certified that, based on an independent valuation, the per diem payment amounts are commercially reasonable, within the range of fair market value, without regard to referrals or other business generated between the parties.

The OIG was persuaded that the arrangement has safeguards sufficient to reduce the risk of prohibited remuneration by several factors: the hospital allocates funds for the per diem call payments annually; participating specialists provide actual and necessary services, for which they are not otherwise compensated; the hospital offers the arrangement to all specialists allowed to take unrestricted call; and the arrangement is structured so that the hospital absorbs all costs and none accrue to federal health care programs.

A laboratory's performance of services, including labeling test tubes and specimen collection containers, for dialysis facilities falls within the "personal services" category. The OIG determined one version of this scenario potentially violated the anti-kickback statute because: (1) the services would be provided at no cost to the dialysis facilities; (2) the services would be performed by personnel located in the lab's own facilities, and no personnel of the lab would be stationed in the dialysis facilities; and (3) the lab would retain sole discretion regarding the selection of which dialysis facilities would be offered the labeling services and such selection would be based upon whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility.[8]

Management services. Management services are services other than professional services provided to and for the benefit of a provider or group of providers. Management service organizations, for example, might contract to provide—or arrange for the provision of—management and administrative services necessary for the operation of a provider's business. Typical management services that MSOs provide include, but are not limited to, billing and collection, accounting, marketing,[9] purchasing, managed care contracting, staffing, recruiting, quality assurance, and facilities and personnel management. Agreements by hospitals to manage private medical practices also fall into this category.

Relevant agreements can include risk sharing arrangements, joint research initiatives, or data collection arrangements, though the OIG has warned in the latter two instances that the research to be performed or the data to be collected must have real value to the entity paying for them.[10] Providers also are cautioned against awarding educational grants or honoraria that are really fee-for-service payments and more appropriately classified as personal services agreements.[11]

Referrals of potential concern can flow in either direction in the contractual relationship. In the hospital-physician context, for example, there is the danger that the physician-contractor performing services will be overpaid to reward referrals from the physician to the hospital. There also is the converse danger that a physician-specialist will be underpaid in recognition of the value of referrals from the hospital, or from other specialists practicing there, to the physician.

1415.20.20
Potential Problem Areas

1415.20.20.10
General Areas Identified by the OIG

Almost all of the OIG's industry-specific compliance guidance documents caution that contracts and arrangements with actual or potential referral sources must comply with all applicable statutes and regulations—including, specifically, the anti-kickback statute. The OIG indicates that compliance policies should provide that:[12]

[8] OIG, Advisory Op. No. 16-12 (Nov. 28, 2016).

[9] Marketing arrangements raise particular concerns and are addressed separately at *Chapter 1430, Marketing Practices*.

[10] Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,525-63,526 (§ II.B.2).

[11] Lynn Shapiro Snyder, Epstein Becker & Green P.C., Washington, D.C., at Nov. 1, 2002, Food & Drug Law Institute and American Health Lawyers Association audioconference, *see IG Compliance Guidance Raises Questions for Pharmaceutical Industry*, 6 BNA's Health Care Fraud Report 843 (Nov. 13, 2002).

[12] Compliance Program Guidance for Home Health Agencies, 63 Fed. Reg. 42,410, 42,418 (Aug. 7, 1998) (§ II.A.4); the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36,368, 36,380 (July 6, 1999) (§ II.A.4); and Hospices, 64 Fed. Reg. 54,031, 54,040 (Oct. 5, 1999) (§ II.A.4). In addition, the OIG compliance guidance for hospitals makes the first two of these statements, 63 Fed. Reg. 8987, 8992 (Feb. 23, 1998) (§ II.A.5), and the guidance for nursing facilities includes language akin to the first and third, 65 Fed. Reg. 14,289, 14,297 (Mar. 16, 2000) (§ II.B.2.e).

ISBN 1-55871-427-8

- all of the organization's contracts and arrangements with referral sources must comply with all applicable statutes and regulations;
- the organization will not submit or cause to be submitted to federal health care programs any claims for patients who were referred pursuant to contracts and financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute; and
- the organization will not offer or provide incentives to potential referral sources, including contractors, for the purpose of inducing referrals in violation of the anti-kickback statute.

Several of the OIG documents, in their lists of risk areas, include additional, though brief, references to kickback concerns posed by personal services or management contracts:

- The OIG's original compliance program guidance for hospitals gives "excessive payment for medical directorships" and below-market fees for administrative services as examples of incentives to physicians that might run afoul of the anti-kickback statute.[13] With an eye, also, on the other side of the referral coin—that is, improperly induced referrals from the hospital to physician-specialists—the document also lists as a specific risk area "hospital financial arrangements with hospital-based physicians that compensate physicians for less than the fair market value of services they provide to hospitals or require physicians to pay more than market value for services provided by the hospital"; the OIG points to "token or no payment for Part A supervision and management services" and excessive charges for billing services as examples.[14]
- The OIG's supplemental compliance guidance for hospitals[15] goes into much greater detail about the constraints the anti-kickback statute places on business arrangements related directly or indirectly to items or services reimbursable by a federal health care program such as Medicare. It lists the safe harbors most relevant to hospitals, including that for personal services and management contracts[16] and cautions that, while physicians are the primary referral source for hospitals, hospitals also receive referrals from other health care professionals (e.g., physician assistants and nurse practitioners) and so should examine these relationships also to ensure compliance with the anti-kickback law.[17] The guidance also provides a list of factors hospitals should use to review their physician compensation arrangements for the risk of fraud and abuse[18] and discusses the different considerations that arise when compensation arrangements are made between hospitals and traditional hospital-based physicians.[19] It warns that uncompensated or below-market arrangements will be scrutinized carefully for anti-kickback compliance.[20]
- The documents for home health agencies, DMEPOS suppliers, and hospices list "incentives to actual or potential referral sources" as a specific risk area.[21] The home health document gives, as an example of a problematic arrangement, an agency that provides nursing or administrative services for free or below fair market value to physicians, hospitals, or other potential referral sources. Another example is an agency that either pays a referring physician a salary for services not rendered or pays for services rendered an amount in excess of fair market value.
- The document for nursing facilities identifies "financial arrangements with physicians and outside contractors" as a specific area of potential fraud and abuse to guard against, and "[f]inancial arrangements with physicians, including the facility's medical director" as a specific risk area.[22]

Similarly, an OIG special fraud alert issued in 1994 on hospital incentives to referring physicians included, among its list of suspect activities, "payment for services (which may include consultations at the hospital) that require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services rendered."[23]

A 1991 OIG report focusing on the relationship between a hospital and its hospital-based physicians warned that "contracts which require the hospital-based physicians to split portions of their income with hospitals are suspect, although not per se violations of the statute." In some of the instances it reviewed for the report, the OIG said, "there was little basis to require hospital-based physicians to turn over a percentage of

[13] Compliance Program Guidance for Hospitals, 63 Fed. Reg. at 8990 n.23 (§ II.A.2).

[14] 63 Fed. Reg. at 8990, 8992 (§ II.A.5) (noting that compliance policies should forbid financial arrangements with hospital-based physicians that are designed to provide inappropriate remuneration to the hospital); OIG, Financial Arrangements Between Hospitals and Hospital-Based Physicians (OIG Management Advisory Report No. OEI-09-89-00330, Oct. 1991), http://oig.hhs.gov/oei/reports/oei-09-89-00330.pdf.

[15] Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005).

[16] 70 Fed. Reg. at 4864.

[17] 70 Fed. Reg. at 4865.

[18] 70 Fed. Reg. at 4866.

[19] 70 Fed. Reg. at 4867.

[20] *Id.*

[21] Home Health Agency Compliance Guidance, 63 Fed. Reg. at 42,414 n.25 & accompanying text (§ II.A.2); DMEPOS Compliance Guidance, 64 Fed. Reg. at 36,374 n.58 & accompanying text (§ II.A.2); Compliance Guidance for Hospices, 64 Fed. Reg. at 54,035 n.29 & accompanying text (§ II.A.2).

[22] Nursing Facility Compliance Guidance, 63 Fed. Reg. at 14,291 (§ II.A), 14,298 n.71 & accompanying text (§ II.B.2.e).

[23] OIG Special Fraud Alert: Hospital Incentives to Referring Physicians (May 1992), *reprinted at* 59 Fed. Reg. 65,372, 65,375 (Dec. 19, 1994).

ISBN 1-55871-427-8

their earnings to the hospital," leading the OIG to suspect that the payment was being made for referrals.[24]

An OIG advisory opinion[25] concerning the proposal of a managed care services company to disburse financial incentives on behalf of the state Medicaid program to physicians who agree to participate in a pay-for-performance program by ordering or recommending certain specified services, made clear that the OIG believes that the anti-kickback implications of any arrangement are determined by the substance, not the form, of the transaction.

"Superficial appearances are not controlling," the opinion said. Nonetheless, the OIG found, the arrangement raised the question whether the anti-kickback statute is implicated because of the appearance that the services company was making payments to participating physicians by issuing pay-for-performance program checks drawn on its own bank account. "Ideally, this ostensible problem would be solved by drawing payments from a state bank account," the opinion said, but state law governing the Medicaid program foreclosed that option. As a result, the OIG analyzed the arrangement and decided it would not impose sanctions because of the specific circumstances of the arrangement, including first of all that the payments would not be made with company money, but would be funded by the state.

The OIG further cautioned that physician compensation arrangements may result in significant liability in its Fraud Alert issued in June 2015.[26] The OIG stated that physicians entering into compensation arrangements must ensure that those arrangements reflect fair market value for bona fide services that the physicians actually provide. The OIG acknowledged that many compensation arrangements are legitimate but cautioned that an arrangement may violate the anti-kickback statute even if one purpose of the arrangement is to compensate a physician for his or her past or future referral of patients. The OIG highlighted its effort to crack down on illegitimate compensation arrangements by stating that it has reached settlements with twelve individual physicians who entered into questionable compensation arrangements. The OIG alleged that the compensation took into account the physicians' volume or value of referrals and did not reflect fair market value for services actually performed by the physicians, and that the physicians entered into arrangements in which an affiliated healthcare entity paid the physicians' front office staff, thereby, relieving the physicians of that financial burden and, in turn, constituted improper remuneration.

1415.20.20.20 Marketing or Distribution Arrangements

Contracts or components of contracts under which one party markets the services or distributes the goods of another, where the services or goods are covered by a federal health care program, are always viewed by the OIG as potentially implicating the anti-kickback statute's prohibition against offering or accepting remuneration for the purposes of "arranging for or recommending purchasing, leasing, or ordering" of any program-covered service or item.

For example, in Advisory Opinion No. 11-08,[27] the OIG stated that the anti-kickback law could be implicated in existing and proposed contractual arrangements between a durable medical equipment (DME) supplier and various independent diagnostic testing facilities (IDTFs) where physicians who were in a position to prescribe the DME supplier's products may have had a financial interest in some of the IDTFs, and where IDTF staff had occasion to interact with patients before the patients selected a particular DME supplier. The opinion stated that the arrangements were potentially problematic because they involved direct payments to IDTFs that could closely tie the DME supplier to IDTF staff members and, in some instances, to physicians with financial interests in the IDTF who were in a position to prescribe. According to the OIG, the connection "effectively allows (the DME supplier) to obtain in-person contacts with patients . . . through health care professionals who are in a position of trust" before a patient selects a DME supplier. This could lead to a "risk that the IDTF staff members and, in some instances, physicians with financial interests in the IDTF, could inappropriately influence a beneficiary" to select the DME supplier in question. The OIG acknowledged, however, that a definitive conclusion on a violation of the federal statute would require a determination of the parties' intent.

For detailed discussion of the restrictions organizations must abide by, see *Chapter 1430, Marketing Practices*.

1415.20.20.30 Part-Time Contractual Arrangements

Part-time contractual arrangements between health care providers, the OIG said in explaining the personal services safe harbor, "are especially vulnerable to abuse because they are subject to modification based on changing referral patterns between the parties."[28] Accounting for what it sees as an inherent potential for abuse in business arrangements between parties in actual or potential referral relationships, the OIG has

[24] OEI, Financial Arrangements Between Hospitals and Hospital-Based Physicians (OEI-09-89-00330, Oct. 1991).

[25] OIG Advisory Op. No. 06-15 (Oct. 10, 2006). *See also* OIG, Advisory Op. No. 11-10 (Aug. 1, 2011) (same fact pattern).

[26] OIG, Fraud Alert: Physician Compensation May Result in Significant Liability (June 2015).

[27] OIG, Advisory Op. No. 11-08 (June 14, 2011).

[28] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,974 (July 29, 1991) (§ III.C.2).

ISBN 1-55871-427-8

strictly limited safe harbor protection to contracts that set forth the timing, frequency, and length of services.

The OIG recognizes that in some relationships, the providers for legitimate reasons might be unable to specify the timing or duration of services or the precise compensation involved. "For example," the OIG said, "compensation under a management contract requiring the furnishing of supplies and the hiring of personnel may need to vary depending on the costs of the supplies and number of personnel. Or, a health care provider may contract with an allied health practitioner group (such as a physical therapy group) to pay a specific amount per hour of care provided, without being able to anticipate the scheduling of services in advance." Such relationships are not necessarily illegal, but they would fall outside the safe harbor and would have to be examined on a case-by-case basis to make sure that the parties in no way intended to reflect the value of referrals in any payments made under the agreement.

The OIG also noted that "[m]any periodic contracts of this sort would fall outside the statute because the compensation involved is not linked to referral opportunities. A contract to serve as medical director of a small clinic on a part-time basis, for example, is not likely to involve activities or compensation tied to the referral of patients or to arrangement for services reimbursable under Medicare or Medicaid programs."[29]

Advisory Opinion No. 01-17 [30] addressed medical director compensation in connection with an ASC joint venture between a hospital-affiliated entity and an entity owned indirectly by five ophthalmologists. The joint venture agreement was accompanied by three related ancillary agreements, one of which was a personal services arrangement in which one of the investing ophthalmologists served as medical director for the surgical center three or four hours per week.

In assessing the propriety of the medical director agreement, the OIG found that it met all the requirements of the safe harbor for personal services and management contracts provided on a periodic, sporadic, or part-time basis[31] except for the requirements that 1) the contract specify the exact schedule, precise length, and exact charge for the intervals, and 2) the aggregate compensation paid over the term of the contract be set in advance.

The OIG nonetheless said that it would not subject the arrangement to administrative sanctions in connection with the anti-kickback statute because the agreement presented a low risk of fraud and abuse. This was because the compensation the medical director was receiving was certified to be consistent with fair market value, based upon a specified hourly rate, subject to a monthly payment cap, and paid only upon written documentation of the hours and the services provided, the OIG said.

The OIG reached a similar conclusion in an advisory opinion concerning a hospital district's arrangement for a contractor to provide hemodialysis services.[32]

Under the arrangement, the contractor agreed to provide acute hemodialysis services at the district's hospitals, billable only by the hospital, for a fair value amount per treatment. The contractor also agreed to provide, at its own facilities or at community end-stage renal dialysis facilities, chronic hemodialysis services to certain indigent patients without regard to their ability to pay. Neither the contractor nor the community ESRD facilities would bill the hospital district or the patients for these services, according to the opinion.

In analyzing the proposed arrangement, the OIG observed that its fluctuating fee arrangement made it ineligible for protection under the personal services and management contracts safe harbor. However, the OIG also said that the risk of overutilization or increased costs to the federal programs from acute hemodialysis services is minimal.

Given that observation, the OIG said, its main concern was the fact that the contractor would be providing free chronic hemodialysis services in the case of certain indigent patients. Free services are problematic if the hospital was referring federal health care program business to the contractor in exchange for the free services, which in this case were dialysis services the hospital district might otherwise have to fund.

The OIG found, however, that a number of factors under the proposed arrangement reduced the risk of fraud or abuse and therefore it concluded it would not impose sanctions under the anti-kickback or other laws. These factors were:

- since criteria for requiring chronic hemodialysis are well established and generally sufficient to deter unnecessary services, and Medicare reimbursement for chronic dialysis is set prospectively, federal payment would be approximately the same amount per dialysis service, regardless of the arrangement;
- while it is unclear whether the hospital district would receive any remuneration, to the extent it did receive remuneration (i.e., the district avoided costs for the indigent and uninsured patients), the remuneration would inure to the public, not private, benefit;
- the arrangement has no adverse impact on competition because it is for only a one-year period and the hospital district used an open competitive bidding process consistent with government contracting laws;
- the hospital district's ability to influence dialysis referrals of insured patients is unclear since insured patients generally have the ability to choose their provider; ability to influence referrals is

[29] *Id.*
[30] OIG, Advisory Op. No. 01-17 (Oct. 17, 2001).
[31] 42 C.F.R. § 1001.952(d).
[32] OIG, Advisory Op. No. 03-07 (Mar. 26, 2003).

ISBN 1-55871-427-8

greater for the indigent, who often have little choice; and

- some free dialysis services will be provided by community ESRD facilities not otherwise involved in the arrangement, which could be seen as an effort by them to share responsibility for indigent care.

The OIG found in another advisory opinion that an arrangement in which a company would furnish allergy laboratory services to a physicians' office could violate the anti-kickback statute and be subject to administrative penalties.[33] A laboratory services management company proposed to enter into exclusive contracts with physician practices to provide allergy testing and immunotherapy services within the physicians' medical offices.

Under the proposed arrangement the management company would provide the lab personnel and technicians, equipment, supplies, training, and billing and collection services to the physicians, and would also review patient files to identify candidates for allergy laboratory services. The physicians would provide the office space to operate the lab, administrative staff, office supplies and furniture, liability and malpractice insurance, and physician supervision and interpretation of laboratory results, and would bill federal health care programs and third-party payers for laboratory items and services provided. The physicians would pay the lab a fee of 60 percent of the gross collections from allergy and immunotherapy testing in exchange for the items and services provided by the lab.

The OIG concluded that the arrangement would not qualify for the equipment leases and personal services and management contracts safe harbors from the anti-kickback statute for two reasons: (1) the services would be provided on an as-needed basis rather than on a specified schedule; and (2) the compensation would be a percentage of the collections from allergy and immunotherapy testing, rather than a predetermined amount set in advance. The OIG said that percentage compensation arrangements are "inherently problematic" under the anti-kickback statute, because they relate to the volume and value of business generated between the parties, rather than the fair market value of the services provided. The OIG also pointed out that the lab's review of patient files to identify candidates for allergy testing services would be a suspect marketing activity, and would create a risk of overutilization.

1415.20.20.40
Physician Consulting Arrangements

Advisory Opinion No. 98-19. An advisory opinion in 1998 indicated that the OIG will view physician consulting arrangements with some degree of suspicion.[34] The arrangement before the OIG was a proposed joint venture between an independent physician association and a managed care organization, in which the IPA would assign rights to long-term physician services agreements in a fair market value exchange for stock in the MCO, making the IPA the exclusive provider panel for all managed care plans in which the MCO participated.

The basic joint venture did win the OIG's approval, but the OIG declined to express its view of an ancillary contract for a "medical management program." Under this contract, the IPA would arrange for its shareholder-physicians to help develop credentialing, utilization review, quality improvement, and case management programs and treatment protocols for the MCO's managed care products. The IPA and MCO would negotiate separately the specific compensation for each medical program to be developed, and the agreement would establish a detailed set of guidelines for determining the compensation for each program.

The Medical Management Program Agreement, the OIG said, was not specific enough to allow the OIG to determine whether it would comply with the anti-kickback statute. "For practical purposes," the OIG continued, "it represents an agreement to agree to enter into unspecified future personal services contracts. Because physician consulting arrangements generally represent an area of significant abuse, personal services contracts for consulting services must be subject to careful, individualized scrutiny. In examining such contracts, we need to know, at a minimum, specific information about the compensation, the nature of the services to be performed, the identity of the particular physicians providing the services, and the existence of any other relationships between the parties."

Advisory Opinion No. 04-09.[35] A professional services corporation asked the OIG whether it could employ primary care physicians as consultants to be on call and available for telephone consultation 24 hours per day, seven days a week. The consulting physicians would receive $50 per hour for a maximum number of hours per month based on a number of patients for which the consulting physician agreed to consult. The maximum monthly compensation would be capped at $750 for 15 hours of service provided with respect to 20 or more patients, the corporation said. Furthermore, none of the costs incurred by the corporation for consulting services would be billed to any federal health care program or to any patient or other third-party payer.

The corporation, a group of gerontologists treating nursing home patients, said the arrangement was necessary because it consistently found it difficult to obtain complete and accurate patient histories, including essential information on past treatments, tests, and responses or reactions to medications. It therefore sought to employ the primary care physicians who previously treated the patients as consultants.

The OIG said that, as long as the consulting physicians qualified as bona fide employees under the Inter-

[33] OIG, Advisory Op. No. 11-17 (Nov. 27, 2011).
[34] OIG, Advisory Op. No. 98-19 (Dec. 21, 1998).
[35] OIG, Advisory Op. No. 04-09 (July 22, 2004).

ISBN 1-55871-427-8

nal Revenue Service definition, a determination not within the scope of the anti-kickback advisory opinion process, the proposed arrangement is protected by the statutory exception and regulatory safe harbor for employee compensation. This was because the compensation was to be paid under an employment agreement for the furnishing of covered items and services, the OIG said.

The OIG added that a similar arrangement with independent contractor physicians or other non-employees would not be protected and would raise fraud and abuse concerns, as would any similar payment arrangement with the nursing home. The anti-kickback statute "disfavors payment structures that tie compensation, even for services, to patients referred by the compensated party." However, where such payments are made pursuant to a bona fide employment relationship, the arrangement is protected despite the risk of fraud and abuse it otherwise presents, it said.

Advisory Opinion No. 11-12.[36] A large hospital with a nationally-ranked neuroscience unit and excellent stroke care asked the OIG whether an arrangement to provide stroke and neurological consultations and immediate emergency protocols via telemedicine to community hospitals in the large hospital's service area would violate the anti-kickback statute. Although it noted that the arrangement could "generate prohibited remuneration under the anti-kickback statute if the requisite intent were present," the OIG said it would not impose sanctions on the requesting hospital.

The OIG first determined that the proposed arrangement would not satisfy the safe harbor for personal services and management contracts, because the arrangement lacked a specific schedule of the intervals, length, and charge for the services. In then weighing the facts and circumstances of the proposed arrangement, the OIG was persuaded that the risk that the remuneration under the arrangement could result in improper payments was adequately reduced.

The OIG listed five persuasive factors:

- The arrangement was unlikely to generate increased referrals, and if successful, could reduce the number of transferred patients to the requestor hospital.
- Neither volume nor value of anticipated referrals from community hospitals would be a condition of participation in the arrangement.
- Stroke patients would be the primary beneficiaries of the arrangement; patients in community hospitals could get better care more quickly, without a transfer to the larger hospital, and the large hospital would have more space available for patients needing tertiary care.
- While the arrangement would allow the requestor hospital and participating hospitals to use each other's marks in marketing activities, neither party would be required to do any marketing, and each would have to pay its own marketing costs.
- The arrangement would be unlikely to increase cost to federal health care programs, since few if any of the requesting hospital's consultations would be billable to Medicare.

1415.20.20.50 "Gainsharing" Arrangements

Personal services agreements that call for "gainsharing" between hospitals and physicians have been singled out as problematic. As explained by the OIG in a special advisory bulletin[37] in July 1999, "the term typically refers to an arrangement in which a hospital gives physicians a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physicians' efforts. In most arrangements, in order to receive any payment, the clinical care must not have been adversely affected as measured by selected quality and performance measures. In addition, many plans require a determination by an independent consultant that the payment represents 'fair market value' for the collective physician efforts."

In both the bulletin and in its supplemental compliance guidance for hospitals, the OIG said it recognized that appropriately structured gainsharing arrangements can serve legitimate business and medical purposes, offering significant benefits as long as there is no adverse effect on patient care. However, the OIG also said that gainsharing arrangements affecting services reimbursed under the Medicare or Medicaid fee-for-service programs are foreclosed by the civil money penalties prohibition against inducing the reduction or limitation of services to Medicare or Medicaid patients. Because the OIG focused on the civil monetary penalty (CMP) provisions, it did not analyze gainsharing arrangements in depth under the anti-kickback statute, but the supplemental guidance advised that, whenever possible, hospitals should consider structuring cost-savings arrangments under the personal services safe harbor. The OIG recognized, however, that in many cases this protection is not available because gainsharing arrangements typically involve percentage payments and not aggregate fees set in advance.[38]

The OIG bulletin did not rule out all efforts in personal services agreements to align hospital and physician incentives. It noted, in fact, that "hospitals may align incentives with physicians to achieve cost savings through means that do not violate [the CMP law]. For example, hospitals and physicians may enter into personal services contracts where hospitals pay physicians

[36] OIG, Advisory Op. No. 11-12 (Aug. 20, 2011).

[37] OIG Special Advisory Bulletin on Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985 (July 14, 1999), *relying on* Social Security Act § 1128A(b)(1) [42 U.S.C. § 1320a-7a(b)(1)]. Under certain conditions, such incentive plans are permitted in managed care plans for Medicare and Medicaid patients.

[38] Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. at 4870.

ISBN 1-55871-427-8

based on a fixed fee that is fair market value for services rendered, rather than a percentage of cost savings." But, the OIG added, "Such contracts must meet the requirements of the anti-kickback statute."[39] The OIG also noted that such arrangements may implicate the anti-kickback law and the Stark self-referral limitations.[40]

Advisory Opinion No. 01-1. In a January 2001 advisory opinion,[41] the OIG approved a gainsharing arrangement between a hospital and a group of cardiac surgeons that was not a fixed fee arrangement, providing further guidance on what type of physician cost-savings arrangements might be permissible under the CMP and anti-kickback laws.

The proposed arrangement involved a hospital's paying its cardiac surgeon group a share of the first year cost savings resulting from changes in operating room practices pursuant to a hospital study of practice patterns that identified 19 specific ways to curb the inappropriate use or waste of medical supplies. Fourteen of the 19 recommendations were to open packaged items only as needed during a procedure. Most of these recommendations involved surgical tray or comparable supplies, but one advised not opening disposable components of the cell saver unit until a patient experiences excessive bleeding, a recommendation the hospital said would delay cell saver readiness by not more than two to five minutes and would not adversely affect patient care. Also recommended were: 1) substituting certain less costly items for those currently being used, and 2) limiting the use of Aprotinin—a medication given to many surgical patients to prevent hemorrhaging—to patients at higher risk of hemorrhaging.

The OIG analyzed the proposed arrangement under both the CMP and anti-kickback laws. It found that, because the program had a number of features designed to protect against inappropriate reductions in services, it would not invoke sanctions under either law. Among these features, the opinion said, was the per capita distribution of cost savings to physicians, establishing historical baselines for judging performance, and setting floors for utilization below which no savings would be shared. For example, with respect to the cell saver and substitution recommendations, the hospital would use objective historical and clinical measures to establish a "floor" (current usage) below which no financial benefit would accrue to the surgeon group. Current year costs would be adjusted to account for any inappropriate reductions in use of items below the targets set and the group would be paid 50 percent of the difference between the adjusted current year costs and base year costs.

The OIG found that all the recommendations (except that to open surgical tray items as needed) violated the CMP law's prohibition against inducing the reduction or limitation of care to federal health care program beneficiaries. It found however, that the program as a whole contained seven safeguards that, in combination, led it to conclude sanctions should not be imposed under the CMP. These were:[42]

- The specific cost-saving actions and resulting savings were clearly and separately identified, creating a "transparency" that would allow for public scrutiny and individual physician accountability for any adverse effects.
- The hospital offered credible medical support for the position that implementing the recommendations would not adversely affect patient care.
- Payments under the arrangement were based on all surgeries regardless of the patients' insurance coverage (subject to the cap on payment for federal health care program procedures), were not disproportionately performed on federal health care program beneficiaries, and were calculated based on the hospital's actual out-of-pocket acquisition costs, not an accounting convention.
- The arrangement protected against the risk of inappropriate reductions in services by utilizing accepted objective measures to establish baselines below which no savings would accrue.
- Patients were to receive written disclosures and be provided an opportunity to review the cost savings recommendations prior to their admission (or, where pre-admission consent was impracticable, prior to consenting to surgery).
- Financial incentives were limited in duration (one year) and amount.
- Because the surgeon group's profits were distributed to its members on a per capita basis, the incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

The OIG also found the program could violate the anti-kickback statute. Specifically, it said, the proposed arrangement could encourage surgeons to admit Medicare patients so that the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the hospital's Part A payment, depending on cost savings. The more procedures a surgeon performed, the more money he or she could receive.

The OIG concluded, however, that it would not impose sanctions because the particular circumstances of the arrangement reduced the likelihood that it would be used to attract referring physicians or increase referrals from existing physicians. In particular, the OIG said, the following features of the program reduced the risk of fraud and abuse under the anti-kickback statute:[43]

[39] Gainsharing Arrangements and CMPs for Hospital Payments to Physicians, 64 Fed. Reg. at 37,986-37,987.
[40] 64 Fed. Reg. at 37985 n.1.
[41] OIG, Advisory Op. No. 01-1 (Jan. 18, 2001).
[42] *Id.*
[43] *Id.*

ISBN 1-55871-427-8

- Participation in the arrangement was limited to surgeons already on staff, thus "limiting [its] effectiveness in attracting other surgeons." Furthermore, the incentive to refer was substantially reduced because the contract term was limited to one year, limiting any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payer. Finally, potential savings derived from procedures for federal health care program beneficiaries were capped based on the prior year's admissions of such beneficiaries.
- Since the surgeon group (composed entirely of cardiac surgeons with no cardiologists or other physicians) was the sole participant in the arrangement, the arrangement eliminated the risk it would be used to reward other physicians to refer patients for surgery. Also, within the surgeon group, profits were distributed to members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.
- The program specified clearly the particular changes in operating room practice that would generate savings. Since the preparation of the cell saver and the administration of Aprotinin carried an increased liability risk for the physicians, it was not unreasonable for surgeons to receive increased compensation for making these changes, the OIG said. Moreover, the payments were limited to 50 percent of the projected cost savings identified in the hospital study recommending the changes.

The advisory opinion cautioned that payments of 50 percent of cost savings in other arrangements, "including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result."

Advisory Opinion No. 05-01. In February 2005, the OIG again addressed the issue of physician cost-saving arrangements in an advisory opinion that fine-tuned and expanded on Advisory Opinion No. 01-1, and included the important cost-saving option of standardizing medical devices used by physicians.

This opinion, too, concerned a proposed gainsharing arrangement with a group of cardiac surgeons.[44] Specifically, a hospital wanted to share with the group 50 percent of any first-year savings achieved through a detailed plan that relied on implementation of 24 specific cost-reducing recommendations in four categories, the opinion said. Eighteen of these were "open as needed" items or cheaper equivalents similar to those discussed in the earlier advisory opinion. A third category called for performing blood cross-matching only as needed (all patients would be typed and screened prior to the procedure, with a cross-matching done only when a patient required a transfusion). The fourth category concerned product standardization of certain cardiac devices. The hospital proposed to pay the surgeon group 50 percent of the cost savings achieved by implementing the 24 recommendations for a period of one year.

The OIG analyzed the proposed arrangement in relation to the CMP and the anti-kickback statute.[45] It found that all but one of the "open as needed" recommendations did not implicate the CMP law because the "insubstantial time it takes to open a package of supplies readily available in the operating room" would make "no perceptible reduction or limitation in the provision of items or services to patients." This conclusion did not apply to the recommendation concerning disposable components of the cell saver unit, however.[46] The OIG found the CMP would apply to all the remaining recommendations—cell saver unit components, blood cross-matching, substitution of less costly items, and standardization of cardiac devices. As with the very similar fact pattern in Advisory Opinion No. 01-1, however, the OIG said there were sufficient safeguards to protect patients from the dangers the CMP was designed to prevent and that it would not impose sanctions. These safeguards were the same as those found in the earlier opinion, with the exception of one pertaining to the standardization of devices. Regarding that recommendation, the OIG said, inappropriate reductions in services were protected against by ensuring that physicians would have the same selection of cardiac devices available after implementation of the proposed arrangement as before. The arrangement is "designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices," the opinion said.

The OIG also found the program could violate the anti-kickback statute because it could result in illegal remuneration if the requisite intent to induce referrals were present. Nonetheless, the OIG concluded it would not impose sanctions because of the particular circumstances surrounding the arrangement, each of which was similar to the three mitigating circumstances previously recognized in Advisory Opinion No. 01-1.

Despite the major similarities between the two gainsharing opinions, Kevin G. McAnaney, former chief of the OIG's Industry Guidance Branch, told BNA the more recent opinion giving the green light to the proposal for cardiac standardization could signal a new approach. In the past, the risks of kickback violations in the acquisition and use of high-priced cardiac devices

[44] OIG, Advisory Op. No. 05-01 (Feb. 3, 2005).

[45] While observing that the arrangement also could potentially implicate the Stark self-referral law, the OIG did not discuss this further since that statute falls outside the scope of the OIG's advisory opinion authority.

[46] Because cell saver components are used with a machine that has a built-in startup delay, there would be an additional delay in the cell saver's availability, the OIG said.

ISBN 1-55871-427-8

such as defibrillators and stents led the OIG to be much more strict.[47]

Advisory Opinion Nos. 05-02 to 05-06. McAnaney's assessment was confirmed a short time later when the OIG released several more opinions on essentially similar gainsharing arrangements, including product standardization. In February 2005, the OIG released five additional opinions[48] involving physician cost-saving in cardiac care. Each addressed some combination of 1) opening packaged surgical tray or comparable supplies only as needed or using them only as needed (e.g., certain vascular closure devices); 2) performing blood cross-matching only as needed; 3) substituting less costly items (e.g., slush drapes, reusable head supports); and 4) cardiac device product standardization (e.g., stents, pacemakers, diagnostic devices), and each reached the conclusion that sufficient safeguards exist so the OIG would not impose sanctions.[49]

The chief difference between Advisory Opinion No. 05-01 and the latest group of opinions is their greater specificity, according to D. McCarty Thornton, a former chief counsel to the OIG now with Sonnenschein Nath & Rosenthal LLP in Washington, D.C. No. 05-01 allowed product standardization, but provided few particulars, leaving health care attorneys and advisers to guess how broadly or narrowly they should follow the advice. In the latest opinions, the OIG has approved a broad spectrum of devices that doctors and hospitals can agree to make standard, based on cost efficiency.

In the five recent opinions, hospital practice pattern reports identified areas where cardiology departments could trim costs; the hospital and the physicians would evaluate devices and agree to use, when medically appropriate, items selected largely for cost-efficiency. A fairly broad range of devices was included in arrangements the OIG found acceptable.

"This is the first time the OIG has given approval to a methodology for rewarding physicians for changing their referral practice," Thornton said. It addresses the problem that, while almost all devices and other items used in patient medical care are ordered by doctors, they are paid for by hospitals. The OIG's approval of gainsharing in these opinions finally allows doctors and hospitals to align their financial interest in an important cost center of the hospital, he said. It opens the door, for the first time, for hospitals to play a key role in influencing the prices it will pay, he said. The OIG's allowing the product standardization provisions gives physicians financial incentives to choose clinically equivalent and medically appropriate devices that also are the most cost-efficient. Put another way, product standardization "gives hospitals a weapon to use in price battles" with device manufacturers where they previously had no power to influence choices on increasingly expensive devices, Thornton said.

The key to the OIG's approval of the product standardization elements of the gainsharing arrangements was the safeguards against patient harm, the opinions stated. Most notable was the one-year, 50-percent payout to the groups versus a multi-year plan that would pay non-specific or varying incentives to individual doctors, Thorton said. None of the proposed arrangements would pay cost-saving bonuses beyond the first year, and in all cases the payout would go to the group rather than individuals. The other important limitation in the proposals was the requirement that hospitals would continue to stock a full range of devices, not just those that had been agreed upon as the standard products. Thornton also observed that the doctors, in accepting the gainsharing deals, agreed to give up some flexibility to make autonomous decisions.

The implication of the opinions is that the same methodology could be applied to devices in other areas, such as orthopedics, provided the same or similar safeguards are incorporated into a gainsharing arrangement, he said.

Advisory Opinion No. 12-22. The OIG in a December 2012 advisory opinion[50] approved an arrangement involving a management agreement between a hospital and a physician group that included performance fees as part of the physicians' compensation. The requestor, a large, rural acute-care hospital, operated four cardiac catheterization laboratories on its campus, the only ones within a 50-mile radius. The hospital provided space, certain non-physician staff, equipment, and supplies for the labs. The hospital entered into a three-year management agreement with the only cardiology group in town. The group billed Medicare Part B and other payers for cardiology services rendered by its physicians.

Under the agreement, the group provided management and medical direction services for the labs in exchange for a co-management fee comprised of a guaranteed, fixed annual fee, and a potential annual performance-based fee.

The performance fee was composed of the hospital's employee satisfaction, patient satisfaction, improved quality of care within the labs, and implementing cost-saving measures. The group earned these fees based on meeting certain achievement benchmarks. The hospital engaged an independent third-party firm to annually review data related to the performance fee and the clinical appropriateness of the cardiac catheterization procedures performed at the labs, and annually review

[47] *See also IG OKs Gainsharing Arrangement Between Hospital, Surgeons Group*, 14 BNA's Health Law Rep. 181 (Feb. 10, 2005).

[48] OIG, Advisory Op. Nos. 05-02 (Feb. 17, 2005), 05-03 (Feb. 17, 2005), 05-04 (Feb. 17, 2005), 05-05 (Feb. 25, 2005) and 05-06 (Feb. 25, 2005).

[49] Since advisory opinions are specific to the requestor and, despite similar facts patterns, cannot be relied upon by others, separate requests were submitted by the same requestor—a consulting agency in Georgia on behalf of certain of its hospital clients—for opinions on similar arrangements with various groups of cooperating physicians.

[50] OIG, Advisory Op. No. 12-22 (Dec. 31, 2012).

ISBN 1-55871-427-8

the group's performance to confirm that the arrangement did not adversely impact patient care.

The OIG found that, even though the arrangement implicated the CMP, it would not seek sanctions for several reasons:

- The hospital certified that the arrangement had not adversely affected patient care. The hospital and its Board of Directors, internal auditing staff, and certain hospital staff committees monitored both the performance of the group and its implementation of cost savings measures to protect against inappropriate reductions or limitations in patient care or services.
- The risk that the arrangement would lead the group's physicians to apply a specific cost savings measure in medically inappropriate circumstances was low. The parties structured the benchmarks within the performance fee to allow the cardiologists flexibility to use the most cost-effective clinically appropriate items and supplies.
- The financial incentive tied to the cost savings component was reasonably limited in duration and amount. The performance fee was subject to a maximum annual cap and the term of the arrangement was limited to three years.
- Receipt of any part of the performance fee was conditioned upon the cardiologists neither stinting on care provided to patients, increasing referrals to the hospital, cherry-picking healthy patients or those with desirable insurance, nor accelerating patient discharges.

With regard to the anti-kickback statute, the OIG found that the arrangement would not fall in the safe harbor for personal services and management agreements because the aggregate compensation paid to the cardiology group was not set in advance. The OIG was concerned that the arrangement could disguise remuneration from the hospital to reward or induce referrals by the cardiology group, and could produce illegal remuneration if the requisite intent were present, but it declined to impose sanctions because:

- The compensation paid under the management agreement was fair market value for the services.
- The compensation did not vary with the number of patients treated. Thus, an increase in patient referrals to the hospital did not result in an increase in compensation to the group.
- Because the hospital operated the only cardiac catheterization laboratories within fifty miles, and because the group did not provide such services at any other location, the hospital would be unlikely to offer compensation to the group as an incentive for referrals to the hospital's labs instead of to another lab.
- The specificity of the measures used to determine the performance fee helped ensure that its purpose was to improve quality, rather than reward referrals.
- The agreement was in writing with a limited term.

For more discussion of the OIG's position on gainsharing, see *Chapter 2210, Relationships Between Physicians and Hospitals*, § 2210.20.40.

Advisory Opinion No. 17-09. The OIG in 2017 approved an arrangement involving a group of neurosurgeons who agreed to implement cost-reduction measures in surgical procedures performed at a nonprofit hospital in exchange for a share of the hospital's related cost savings.[51] The group performs all the spinal surgeries at the hospital. The arrangement was structured as follows:

- The hospital, through a subsidiary, would pay the neurosurgeons a share of three years of cost savings attributable to changes the neurosurgeons would make when selecting and using products for spinal fusion surgeries.
- The subsidiary would perform management and administrative services and assist a newly formed committee to oversee and monitor the arrangement.
- Cost savings opportunities would be identified through historical review of the neurosurgeon's spinal fusion surgeries.

The OIG evaluated the methodology the parties used to develop the cost-saving recommendations, the monitoring and documentation safeguards that were implemented, and the methodology used to calculate each performance year's savings, and concluded that they were "reasonable." Therefore, it would not impose sanctions under the gainsharing CMP law.

The OIG then concluded that, although the arrangement could implicate the anti-kickback statute, it presented sufficiently low risk of fraud and abuse because:

- The incentive payments would be distributed to the neurosurgeons on a per capita basis, reducing the risk that there would be an incentive for any particular neurosurgeon to generate disproportionate cost savings.
- The potential savings are capped based on the number of surgeries performed by the neurosurgeons on federal health care program beneficiaries in the relevant base year and tied to the actual, verifiable cost savings attributable to each recommendation.
- The aggregate payment to the neurosurgeons would not exceed 50 percent of the projected cost savings estimated at the beginning of the term.
- The committee collects and reviews data on patient severity, age, and payor for the spinal surgeries covered by the arrangement to confirm a historically consistent selection of patients.
- The group, rather than individual physicians, retains a percentage of the adjusted total perfor-

[51] OIG, Advisory Op. No. 17-09 (Dec. 29, 2017).

ISBN 1-55871-427-8

mance year savings, which can be used only for the group's administrative expenses and recruitment expenses.

- The risk of improper duplicate payments was minimal because of the annual rebasing method, which removes savings from prior years and ensures that the performance year savings are calculated only as compared to the most recent base year.
- The product standardization recommendations were based on review of national guidelines and evidence-based medical review.
- The neurosurgeons have available the same selection of devices and supplies that they had prior to the arrangement and continue to make patient-by-patient determinations as to the most appropriate device or supply.
- No neurosurgeons from other physician groups participate in the arrangement.

In this opinion, the OIG did not analyze the arrangement under the safe harbor for personal services and management agreements because the physicians did not perform those types of services for the hospital. However, the advisory opinion is an integral piece to the overall gainsharing concept, and similar gainsharing arrangements are often integrated into arrangements that do involve personal or management services.

1415.20.20.60
Payments at Greater Than Fair Market Value

The general rule is that if the potential for referrals exists between the parties to a personal services or management contract, payments for the services in question must be at fair market value. Payments that exceed the fair market value of the services provided are always a red flag, for it has long been the OIG's position that an inference can be drawn in such circumstances that the amount by which payments exceed fair market value represents illegal remuneration for referrals.[52] That compensation be consistent with fair market value in arm's-length transactions is one of the requirements of the personal services safe harbor.[53] But even in the case of an arrangement outside the safe harbor, fair market value will still be a key criterion—that is, if payments exceed fair market value, the arrangement will not pass muster with the OIG even if other facts and circumstances can be marshaled in its favor.

Advisory Op. No. 98-15 shows how the OIG will look for fair market value, among other factors, in assessing an arrangement outside the personal services safe harbor.[54] Under the pharmacy services contract in question, "Company B" would dispense anti-hemophilia factor and other outpatient drugs prescribed by a university hemophilia center for certain patients and provide outpatient pharmacy services in connection with a Public Health Service Act drug discounting program for those patients. The outpatient pharmacy services, available on an as-needed basis, would include inventory management, billings, collections, and educational support. The arrangement could not qualify under the safe harbor because the nature of the services provided precluded an exact specification of the schedule for their performance and the aggregate amount of compensation would not be set in advance.

Nonetheless, the arrangement would pose a minimal risk of fraud or abuse, the OIG concluded, because it would implement the congressional intent embodied in the government drug discounting program; Company B would be paid fair market value for services rendered; the agreement would exclude Medicaid fee-for-service patients to avoid problems with certain Medicaid regulations; and patient freedom of choice would be preserved, in that patients would be told about other pharmacy providers and the financial relationship between the university and Company B. With respect to fair market value, the OIG noted that Company B would be paid only for its services, not for the drugs themselves (which would be purchased by the university). Compensation for dispensing anti-hemophilia factor would be based on a fixed amount per unit of factor dispensed, and Company B would have no control over the number of units dispensed. And the parties had represented that Company B's compensation would represent fair market value in an arms-length transaction for the services rendered.

Important though fair market value might be in winning approval of an arrangement outside the personal services safe harbor, and even though the OIG might examine fair market value in the context of an investigation, organizations should note that the OIG, by law, cannot evaluate fair market value in an advisory opinion. That is, the statutory advisory opinion provisions exclude factual questions of fair market value from the scope of an opinion request.[55]

The fact that fair market value is significant does not mean that an arrangement is necessarily home free if fair market value can be established. The "one purpose" test of *United States v. Greber*[56]—that an arrangement violates the anti-kickback statute if one purpose of the remuneration is to obtain money for referral of services

---

[52] *See* OEI, Financial Arrangements Between Hospitals and Hospital-Based Physicians (No. OEI-09-89-00330, Oct. 1991); Letter from D. McCarty Thornton, Associate General Counsel, Inspector General Division, to T.J. Sullivan, Technical Assistant, Office of the Associate Chief Counsel, Internal Revenue Service (Dec. 22, 1992), *both citing United States v. Lipkis*, 770 F.2d 1447, 1449 (9th Cir. 1985); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985); and *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *see also,* Special Fraud Alert: Hospital Incentives to Referring Physicians (May 1992), *reprinted at* 59 Fed. Reg. 65,372, 65,375 (suspect list includes "payment for services in excess of the fair market value of services rendered").

[53] 42 C.F.R. § 1001.952(d)(5).

[54] OIG, Advisory Op. No. 98-15 (Nov. 10, 1998).

[55] Social Security Act § 1128D(b)(3) [42 U.S.C. § 1320a-7d(b)(3)].

[56] *Greber,* 760 F.2d at 71.

ISBN 1-55871-427-8

or to induce referrals—has been understood to mean that payments even at fair market value are illegal if they are intended to reward or induce referrals. As noted below,[57] one argument posed by the defendant osteopath in *United States v. Neufeld* was that the anti-kickback statute could not be applied to him because, rather than being paid in return for referring patients, he did perform substantial services in connection with the consulting agreements in question. Rejecting this argument, and citing *Greber* and *United States v. Kats*,[58] the federal district court said, "Numerous courts have interpreted the 'in return for' language [of the anti-kickback statute] to encompass situations where only one of multiple purposes of payment was to refer patients."[59]

Nor is the government required, in order to establish an anti-kickback violation, to prove that services were paid for at more than fair market value. The defendants in the LaHue prosecution, for example,[60] argued that the government had not established that payments for consulting services were made in excess of fair market value. But the government's case, the court noted, was not based solely on a disparity of value between remuneration paid and services rendered. "The government was not . . . required to prove anything about value," the court said. "The government was required to prove that remuneration was offered, paid, solicited, or received to induce or in return for patient referrals."[61]

1415.20.20.70
Payments at Less Than Fair Market Value

Paying less than fair market value under a personal services agreement can be just as problematic as paying more than fair market value.[62] The issue has arisen in the context of financial arrangements between hospitals and such specialists as anesthesiologists, pathologists, and radiologists—practitioners who might be dependent on their position at a hospital to obtain referrals from other specialists practicing there. Although the OIG, in a 1991 report, focused mostly on the potential for kickback violations if specialists paid too much for services provided by the hospitals, the OIG also saw dangers in hospitals providing no reimbursement, or token reimbursement, to specialists. In the latter scenario, in the OIG's view, the specialists providing services at less than fair market value would in fact be "paying" for the potential for referrals.[63]

In very limited circumstances, payments at less than fair market value might be acceptable. In Advisory Op. No. 15-10,[64] for example, the OIG was asked about an agreement under which a hospital system proposed to lease non-clinician employees and operational and management services to a psychiatric hospital in its integrated health network for an amount equal to the system's "fully loaded" costs, plus an administrative fee.

The OIG determined that the proposal implicated the anti-kickback statute by charging the psychiatric hospital, a potential referral source, an amount possibly below fair market value, and that it did not qualify for the personal services and management contracts safe harbor. Nevertheless, the proposal presented a low risk of fraud and abuse because: (1) it was structured to comply with the Medicare cost reporting rules, which consider only payments between related parties for services that do not exceed costs allowable; (2) it achieved cost efficiencies and reduced labor and operational costs, which indirectly benefited the federal healthcare programs; and (3) there was no evidence to suggest it was intended to induce referrals.

In Advisory Op. No. 99-11,[65] the OIG was asked about an arrangement under which residents from local teaching facilities would donate their time and services to a nonprofit coalition; the coalition would thus be able to offer psycho-dynamically oriented psychotherapy services for free or at reduced prices, and the residents would gain an opportunity for supervised training in this type of therapy. The potentially problematic referral potential lay in the fact that patients who were found not to be suitable for therapy (such as those needing hospitalization or treatment for drug or alcohol addiction) would be given a list of alternative providers, and the list might include the participating teaching facilities if the patient was originally referred to the coalition from one of those facilities.

The OIG said, "The Arrangement raises concerns under the anti-kickback statute to the extent that the Participating Institutions may be providing free clinical services to the Coalition as a means of generating referrals of alternative treatment mental health business that they can bill to a Federal health care program." But sanctions would not be imposed under the circumstances stated, the OIG found, given the small number of patients, the limited number of referrals that would be made from the program, the fact that no federal health care program would be billed for the coalition's services, the teaching facilities' legitimate business purpose for participating, and the significant community benefit offered.[66]

---

[57] *See United States v. Neufeld (1995)*.

[58] *Kats*, 871 F.2d at 108.

[59] *Neufeld*, 908 F. Supp. at 497.

[60] *See The LaHue Prosecution (United States v. Anderson (1999))*.

[61] *United States v. Anderson*, 85 F. Supp.2d 1047, 1069 (D. Kan. 1999).

[62] *See also Chapter 1420, Discounts and Free Items*.

[63] Financial Arrangements Between Hospitals and Hospital-Based Physicians, *supra* n.10; *see also* Compliance Program Guidance for Hospitals, 63 Fed. Reg. at 8990 n.25 (§ II.A.2).

[64] OIG, Advisory Op. No. 15-10 (July 20, 2015).

[65] OIG, Advisory Op. No. 99-11 (Nov. 1, 1999).

[66] For an advisory opinion in which donated services were seen as potential kickback violations, on the other hand, *see* OIG, Advisory Op. No. 98-16 (Nov. 10, 1998) (proposed service agree-

ISBN 1-55871-427-8

In contrast, in Advisory Opinion No. 13-15[67] the OIG declined to approve an anesthesia services provider's proposal to contract with a psychiatry practice group to provide anesthesia services on a part-time, as-needed basis. The psychiatry practice group would bill for the services and pay the anesthesia services provider a fixed, per diem rate below fair market value and below what it would receive if it billed for the services directly.

Noting its long-standing view that the opportunity to generate a fee can constitute illegal remuneration even if no payment is made for a referral, the OIG first concluded that the anesthesia services provider gave the practice group the opportunity to generate a fee equal to the difference between the amount the group billed and collected and the amount it paid to the anesthesia services provider. The OIG then determined that the amount paid to the anesthesia provider did not meet the safe harbor for personal services and management contracts because:

- the aggregate compensation to be paid over the term of the contract was neither set in advance, nor consistent with fair market value; and
- the safe harbors do not apply to amounts paid by a principal to an agent.

Because the arrangement seemed to be designed to allow the group receive to compensation—the portion of the anesthesia services provider's revenues—in exchange for its referrals to the anesthesia services provider, the OIG concluded that it posed a significant risk of fraud and abuse under the anti-kickback statute.

In Advisory Opinion No. 08-06,[68] the OIG found that the anti-kickback statute safe harbor for personal services and management contracts potentially could have applied to a laboratory company's proposal to label test tubes and specimen collection containers at no cost to dialysis facilities. However, the OIG said, the safe harbor did not apply because the dialysis facilities would have paid nothing for labeling services performed by the lab, which is hardly their fair market value.

While the absence of a safe harbor is not fatal to an arrangement, the opinion said, the OIG also determined that the lab's proposal appeared to offer nonmonetary discounts to certain dialysis facilities for Medicare-covered composite rate tests to induce referrals for more lucrative noncomposite rate testing services. Further, it said, "it appears possible that the selected dialysis facilities are soliciting improper nonmonetary 'discounts' on business for which they bear risk in exchange for referrals of business for which they bear no risk."

Indeed, the opinion continued, the proposed arrangement posed a significant risk of improper swapping of business, especially in light of the lab's representation that its competitors also were offering such "discounts," the OIG continued. "These competitor 'discount' arrangements may similarly run afoul of the anti-kickback statute," it said, concluding the arrangement could risk kickback sanctions.

1415.20.20.80
Per Patient, Per Click, Per Order Payment Arrangements

In Advisory Op. No. 03-8,[69] the OIG was asked about a proposal under which a company would develop and manage distinct part inpatient rehabilitation units in general acute care hospitals. The arrangement required the management company to provide all patient care personnel, other than nurses, and a leadership team consisting of a program director, a community outreach coordinator, and a medical director. For these services, each participating hospital would pay the company a monthly management fee calculated on a per patient per day basis.

The arrangement did not fall within the personal services and management contracts safe harbor because the aggregate compensation paid by each hospital would not be set in advance, the OIG said. The OIG also decided that the risk of fraud and abuse by the parties was sufficient that, if the intent to induce or reward referrals was present, anti-kickback penalties could be imposed. The arrangement also could be grounds for exclusion from federal health care programs and imposition of civil monetary penalties, the opinion said.

Per patient, per procedure ("per click"), per order, and similar payment arrangements with parties in a position to refer or recommend items or services payable by a federal health care program are disfavored under the anti-kickback statute, the OIG said in its legal analysis. The concern is that such arrangements can promote overutilization and unnecessarily lengthy stays. Use of such a payment mechanism is not automatically fatal, however, since even arrangements that fall outside a safe harbor do not necessarily violate the anti-kickback statute, but must be evaluated on a case-by-case basis. [70]

In the arrangement at issue in Advisory Op. No. 03-08, the following features of the proposed arrangement were problematic, the OIG said:

- the Medicare inpatient rehabilitation facility PPS payment methodology could offset concerns about excessive lengths of stay, but would not reduce the risk of overuse, since the company and the hospitals have an identical incentive to fill all beds;
- although 75 percent of a unit's patients must have at least one of 10 specified conditions in order for the unit to qualify as an inpatient rehabilitation

ments under which a pharmacy company would place licensed pharmacists in hospital transplant centers to facilitate patients' post-transplant care, secure insurance coverage for pharmaceuticals and services provided by the company, and process prescriptions through the company's distribution center).

[67] OIG, Advisory Op. No. 13-15 (Nov. 12, 2013).

[68] OIG, Advisory Op. No. 08-06 (May 9, 2008).

[69] OIG, Advisory Op. No. 03-08 (Apr. 10, 2003).

[70] *See, e.g.,* Remark to this effect by the OIG in Advisory Op. No. 05-08 (June 13, 2006).

ISBN 1-55871-427-8

facility,[71] the other 25 percent could have diffuse symptoms or conditions and the OIG could not determine how malleable the criteria were for establishing each of the 10 conditions;

- although the nurses performing the pre-admission screenings would not be the company's employees, as workers in the unit they would share with the company the common goal of making the unit a financial success;
- the units would be under the medical direction of a physician in a position to generate patient referrals for the unit;
- the requesting company would be performing community outreach, including marketing; and
- while the per patient per day fee may be reflective of the actual costs incurred, it could also simply cloak a success fee.

Two OIG opinions issued on the same day showed how an arrangement that does not qualify for a safe harbor nonetheless may be protected against sanction if it has sufficient safeguards against fraud and abuse. In Advisory Opinion No. 10-23,[72] the OIG found that an arrangement in which a provider of sleep disorder diagnostic testing would provide equipment, staff, and marketing to a hospital on a per-test fee basis for a hospital-owned sleep-testing facility could generate prohibited remuneration under the anti-kickback statute and consequently lead to administrative sanctions.

The opinion said that the anti-kickback safe harbors for equipment rental and for personal services and management contracts,[73] while potentially applicable, did not apply because the aggregate compensation paid by the hospital was not set in advance, a condition of both safe harbors.

The OIG also rejected a claim that the arrangement did not violate the anti-kickback statute because it was in full compliance with Medicare regulations applicable to services secured by hospitals under arrangements. [74] It was still necessary to analyze an arrangement even if a provider was in compliance with relevant coverage and payment rules because such an arrangement still could run afoul of the anti-kickback statute, the OIG said in an advisory opinion. In a list that the OIG said was not exclusive, an "under arrangements" transaction might implicate the anti-kickback statute if, for example:

- A hospital pays above-market rates for the arranged-for services to influence referrals.
- An under-arrangements entity agrees to accept below-market rates to secure referrals from a hospital to the under-arrangements entity, its direct or indirect owners, or its affiliates, including affiliated providers and suppliers.
- A hospital owns an interest in an under-arrangements entity such that the hospital receives remuneration in the form of returns on investment in exchange for referrals to the under-arrangements entity or to an affiliate of the under-arrangements entity (such as an affiliate that furnishes ancillary services or equipment).
- A referral source for the hospital, such as a physician or physician group, owns an interest in the under-arrangements entity. Even if the under-arrangements services are provided at fair market value, the referral source might have an incentive to condition its referrals to the hospital on the hospital's use of its under-arrangements entity or supplier.
- The putative under-arrangements transaction includes the furnishing of items and services ancillary or additional to the services being furnished under arrangements or includes, directly or indirectly, the furnishing of items and services to patients who are not hospital inpatients or outpatients (e.g., patients who have been discharged from the hospital).

In sum, the OIG said, a violation of the anti-kickback statute can occur when an entity receives compensation for providing referrals that are payable under a federal health care program. In the case of this arrangement, the provision of marketing services by the sleep-testing provider placed it in a position to generate referrals for the hospital. The fact that the provider would receive a fee for each referral generated raises the level of potential abuse by providing a financial incentive to recommend the hospital's testing facility. While the provider claimed that the per-test fee would not take into account the volume or value of any referrals, the OIG said that this safeguard could not offset the risk of abuse based on generating referrals for a financial incentive.

The OIG also said that sleep-testing services are often prone to over-use, and that a per-test fee structure can often lead to a higher volume of service.

In a companion opinion released the same day,[75] the OIG said neither administrative sanctions nor civil monetary penalties for kickback violations would be imposed in connection with another proposed arrangement involving a sleep-testing entity that would provide equipment, staff, and marketing services to a hospital-owned facility. In this case, however, the sleep-testing provider and hospital would enter into a written agreement with a term of at least one year that would include an annual fixed fee for the use of the provider's equipment, a second annual fixed fee for the marketing services, and a third annual fixed fee for other services and

[71] 42 C.F.R. § 412.23(b).

[72] OIG, Advisory Op. No. 10-23 (Nov. 4, 2010).

[73] 42 C.F.R. § 1001.952(c) and (d), respectively.

[74] Social Security Act § 1861(s) expressly states that diagnostic services ordinarily furnished by a hospital (or others under such arrangements) to its outpatients for the purpose of diagnostic study are considered to be "medical and other health services" reimbursable under the act.

[75] OIG, Advisory Op. No. 10-24 (Nov. 4, 2010).

ISBN 1-55871-427-8

supplies. None of the fixed fees would take into account the volume or value of services provided.

In its analysis, the OIG said that the agreement memorializing the proposed arrangement incorporated many key safeguards enumerated in the equipment lease and personal services and management contracts safe harbors although it did not in fact qualify for either of the safe harbors. Among these safeguards were the use of aggregate, fixed fees consistent with fair market value in arm's-length transactions that did not take into account the volume or value of federal health care program business. It found that while payments for marketing services could lead to financial incentives to generate unnecessary referrals, in this case the presence of a fixed fee not connected to volume or value mitigated this possibility. It also determined that since the fees in the proposed arrangement would be set in advance, they would be payable regardless of whether the hospital was able to successfully bill a patient or third-party payer, and would remain constant no matter the volume of patient referrals. In addition, the OIG said, physicians interpreting the results of a sleep study would have no financial relationship with the sleep-testing provider and therefore no incentive to gain referrals from the provider. As a result, no administrative sanctions would be imposed for proceeding with the arrangement.

The OIG once again expressed its concern with this type of arrangement in Advisory Opinion No. 14-06,[76] in which it declined to approve a specialty pharmacy's proposal to pay a fee to retail pharmacies that refer patients whose prescriptions for specialty drugs they are unable to fill to the specialty pharmacy. According to the specialty pharmacy, the fee would be paid "per fill"—that is, upon receipt of the initial prescription and upon each subsequent refill throughout the course of the patient's therapy, and it would be based on the fair market value of the retail pharmacy providing certain support services, including services related to accepting new patients, gathering and recording information, counseling patients, obtaining consent to transfer prescriptions to the specialty pharmacy, and transmitting prescriptions to the specialty pharmacy.

The OIG first determined that this arrangement implicated the anti-kickback statute because the specialty pharmacy would pay the fee to the retail pharmacies each time the services resulted in the referral of a patient, including federal health care program beneficiaries, to the speciality pharmacy. The OIG then concluded that the arrangement posed more than a minimal risk of fraud and abuse because, although the support services could benefit patients by providing coordination of care services, the amount of per-fill fees the retail pharmacies would receive would be directly tied to the number of patients that they refer to the specialty pharmacies.

1415.20.20.90
No- or Low-Risk Arrangements

In a December 2004 advisory opinion,[77] the OIG rejected a proposed arrangement for the provision of pathology services because it was very similar to a problematic arrangement described in its Special Advisory Bulletin of April 2003.[78]

The request for the opinion was made by a company in the business of arranging for the provision of pathology laboratory services. It proposed to enter into a series of contracts with physician group practices to operate pathology labs for each group in an off-site location. The requestor proposed to furnish all necessary management and administrative services; technical, professional, and supervisory pathology services; equipment leasing; premises subleasing; and, if requested, billing services for each physician group to operate its own path lab (see *Chapter 1410, Joint Ventures and Acquisitions,* § 1410.20.10.20, at n.76 for a fuller discussion of the opinion).

The OIG found the physician group would be expanding into a related line of business—pathology services—that would be dependent on referrals from the physician group, which, on the whole, would commit almost nothing in the way of financial, capital, or human resources to the path lab and so would assume no or very little real business risk. Thus, the group easily could control the amount of business it sent to the labs and, by making substantial referrals, easily ensure the business generated would meet or exceed the monthly fee owed to the company that set up the arrangement. The per specimen and percentage billing fees also would create virtually no financial risk for the physicians since the fees would be based on actual utilization and billing of services.

The OIG concluded it would potentially impose administrative sanctions if it determined that the parties to the proposed arrangement had an intent to violate the anti-kickback law.

1415.20.30
Safe Harbor Compliance

1415.20.30.10
In General

The surest way to avoid kickback concerns, if one party is in a position to refer federal health care program-covered goods or services to the other, is to structure personal services and management contracts to meet all of the requirements of the safe harbor discussed above (see *Safe Harbor for Personal Services and Management Contracts*, § 1415.10.20). If business realities preclude meeting all of the requirements, then meeting as many of the requirements as possible will increase the chances that the arrangement will be viewed as nonabusive, as long as there is no underlying

[76] OIG, Advisory Op. No. 14-06 (Aug. 15, 2014).
[77] OIG, Advisory Op. No. 04-17 (Dec. 17, 2004).
[78] OIG Special Advisory Bulletin: Contractual Joint Ventures (April 2003), *reprinted in* 68 Fed. Reg. 23,148 (April 30, 2003).

ISBN 1-55871-427-8

purpose to induce or reward referrals of business reimbursed under federal health care programs.

1415.20.30.20
"Aggregate Compensation" and "Schedule of Intervals" Requirements

Many common types of independent contractor arrangements, in fact, will fall outside the safe harbor. Because arrangements for periodic or part-time work often are based not on time expended but on completion of a job, they might not be able to fulfill the safe harbor requirement that the agreement specify with precision the schedule of intervals in which services will be performed, the length of such intervals, and the applicable charge. And arrangements that incorporate performance-based incentives will not be eligible for safe harbor treatment because of the requirement that aggregate compensation over the term of the agreement be set in advance. Such arrangements, though outside the safe harbor, do not necessarily violate the anti-kickback statute, but whether they are allowable would have to be determined by the OIG on a case-by-case basis.

Percentage-based payments will not render a non-safe-harbored agreement per se illegal. "We recognize that legitimate considerations . . . could result in some part of the payment [being] based on a percentage . . . payment arrangement without these payments influencing or being influenced by Medicare or Medicaid referrals," the OIG said in 1991 when it issued the safe harbor. "However, the more the payments appear to reflect the volume of referrals from the financially-interested party, the more suspect the arrangement becomes and the more likely we will need to examine it carefully."[79]

Indeed, the OIG reaffirmed both the "aggregate compensation" and "specific schedule of intervals" requirements in commentary to its 1999 safe harbor additions and modifications:

> We recognize that these requirements may raise practical problems for certain providers seeking safe harbor protection for part-time or as-needed arrangements. Nevertheless, we are aware of many instances of abuse in these types of arrangements; therefore, for purposes of granting protection from prosecution, we believe it is appropriate to protect only those arrangements that can meet the safe harbor's strict standards. However, as we have stated numerous times, safe harbors do not define the scope of legal activities under the anti-kickback statute. Part-time, as-needed, and other similar arrangements that cannot fit within the safe harbor may be lawful, if no payments are made, directly or indirectly, to induce referrals of Federal health care program business.[80]

The OIG, in its 1991 commentary, did give some examples of compensation arrangements that would not satisfy the safe harbor but still could be acceptable under a case-by-case analysis (given, of course, the lack of any intent to induce or reward referrals):

> We recognize that health care providers, for various reasons, may be unable to specify the timing or duration of business arrangements, or the precise compensation involved. For example, compensation under a management contract requiring the furnishing of supplies and the hiring of personnel may need to vary depending on the costs of the supplies and number of personnel. Or, a health care provider may contract with an allied health practitioner group (such as a physical therapy group) to pay a specific amount per hour of care provided, without being able to anticipate the scheduling of services in advance.[81]

Even if an independent contractor arrangement, for such reasons, cannot be as specific as the safe harbor would require, it is well-advised to evidence good faith by tying down compensation and scheduling as much as possible. For example, the personal services agreement might include a compensation cap or formula for determining compensation.

1415.20.30.30
"One Year" Requirement; Early Termination

A safe harbor condition that caused a lot of concern when it was proposed was the one-year requirement. Many professional services for which a provider might contract—including medical or surgical consulting services or peer review functions—involve activities that require less than one year to complete, commenters emphasized. The OIG stood by its one-year requirement, reiterating its concern that abuse could result from "periodic renegotiation of ostensibly short term agreements, in response to changes in referral patterns." But it added that the one-year requirement "restricts the period within which contract terms may not be changed, and not the time within which services under a contract may be performed." Thus, the OIG advised, "So long as contract terms are not altered within a one year period, an agreement that is performed in less than one year's time will meet the one year requirement in the safe harbor provision."[82]

The one-year requirement also has raised questions about the propriety of early termination clauses. Clauses allowing a party to terminate the agreement for "good cause" certainly are common in business agreements, and usually serve legitimate business purposes—but they can, in fact, cause problems for safe harbor compliance. A general statement allowing termination "for good cause" or just "for cause," without

---

[79] OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,973 (§ III.C.2).

[80] Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63,526 (Nov. 19, 1999) (§ II.B.2).

[81] OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,974 (§ III.C.2).

[82] *Id.*

ISBN 1-55871-427-8

elaboration, will undercut the one-year requirement in the OIG's view and will not satisfy the safe harbor. (And a clause that allows termination without cause certainly will be unacceptable.) There are two concerns. One is that such provisions could be used as a cover where the real intent is to renegotiate terms to account for referrals. A second is that parties with ill intent could disguise payments for referrals by arranging for payments up front and then terminating the agreement before performance of any services. To separate potentially abusive clauses from those that serve legitimate business purposes, the OIG has stated that a clause in a one-year agreement allowing early termination "for cause" would be allowable if it:

- specified the conditions that would justify termination for cause, and
- was operated in conjunction with an absolute prohibition on any renegotiation of the lease or contract or further financial arrangements between the parties for the duration of the original one-year term.[83]

An example of an early termination clause that normally would not jeopardize safe harbor status is a clause drafted to comply with Internal Revenue Service guidelines governing advance determinations of tax-exempt status. Under these guidelines, facilities seeking tax exemption must be able to terminate, on 90 days' notice, contracts with nonexempt persons if compensation is based on fees charged for services furnished by the nonexempt persons.[84]

1415.20.30.40
Multiple, Overlapping Contracts Precluded

The OIG became concerned, after the safe harbor had been in effect for several years, that some providers were circumventing its intent by entering into multiple, overlapping one-year agreements for different slices of the services to be provided, with the terms of the later agreements based in part on the volume of business being generated between the parties under existing agreements. The OIG gave this example: "a one year personal services contract between a hospital and a high-volume referring physician is created for the physician to perform certain services. The next month a new one year contract is created for a slightly different service, with the amount of payment influenced by the previous months referrals."[85] In the 1999 safe harbor modifications, the OIG added language to expressly preclude such arrangements. This language is in condition number two of the safe harbor, that the agreement must cover all of the services the agent provides to the principal for the term of the agreement and specify what services the agent will provide.

1415.20.30.50
"Reasonable Business Purpose" Requirement

The OIG had specific concerns that providers could use personal services contracts, even those that seemed to satisfy the safe harbor conditions as stated in 1991, to purchase more services than they actually needed as a means of paying for referrals. To close what it saw as a potential loophole, the OIG in 1999 also added the requirement that the "aggregate services contracted for must not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of those services." Thus, the purchase, the OIG explained, "must be of . . . services that the lessee or purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives."[86]

An example of an arrangement that seemed not to fill a commercially reasonable business purpose was discussed in Advisory Op. No. 06-02.[87] This involved a proposal by a DME manufacturer and supplier to consign its products to physician practices while, under a separate personal services agreement, leasing the services of a trained technician to the physicians for a fixed monthly fee. Although certifying that the personal services agreement satisfied the safe harbor, the company was unable to explain to the OIG's satisfaction why a physician practice would pay a DME supplier to lease a technician to fulfill what appeared to be supplier obligations (e.g., fitting federal and non-federal patients for orthotics and DME, completing in-home set-up of equipment, instructing patients on the use of the products, monitoring patient progress, obtaining payer precertification, managing product inventory).

Despite the fact that intent to involve referrals is not part of safe harbor analysis, the OIG considered the possibility the leased technician services agreement "may have purposes not revealed on the face of the contract or through the advisory opinion request submissions." It therefore was unwilling to conclude the agreement would satisfy the safe harbor requirements for arms'-length fair market value payments for services actually needed and rendered. What may have been technical compliance with safe harbor requirements was not sufficient to entitle the arrangement to protection, the OIG concluded. It saw no apparent business rationale for the DME company to maintain a physical presence in the practice's office or administrative presence in the practice's business other than the potential for generating business.

The OIG also used Advisory Op. No. 06-02 to reiterate its position that arrangements in which manufacturers and suppliers furnish physician practices with management or other similar services related to their prod-

[83] Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,526 (§ II.B.2).

[84] OIG Anti-Kickback Provisions, 56 Fed. Reg. at 35,973-35,974 (§ III.C.2).

[85] *See also* OIG, Advisory Op. No. 04-08 (June 30, 2004), where the OIG found the overlapping, as-needed aspect of proposed leases would make it difficult to monitor, assess, and document fair market value.

[86] Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,525 (§ II.B.2).

[87] OIG, Advisory Op. No. 06-02 (Mar. 28, 2006).

ISBN 1-55871-427-8

ucts warrant "close scrutiny under the fraud and abuse laws," adding:

> These arrangements may provide the manufacturer or supplier with a physical presence in the physician practice's office or an administrative presence in the physician practice's business, creating additional opportunities to influence and reward referrals. No apparent business rationale would appear to exist for a manufacturer or supplier to forge these ties to physician practices, apart from the potential for generating additional business.[88]

1415.30 Enforcement

1415.30.10
Settlement Agreements

Settlement	Alleged Misconduct	Resolution/Penalties
United States ex rel. Emanuele v. Medicor Assocs., No. 10-cv-245 (W.D. Pa. settled Mar. 5, 2018).	A hospital paid a cardiology group up to $2 million per year under twelve physician and administrative services arrangements that were created to secure Medicare patient referrals. The hospital allegedly had no legitimate need for the services contracted for, and in some instances the services either were duplicative or were not performed.	The hospital agreed to pay $20.75 million to settle the allegations. See *Hospital, Physician Group Settle Fraud Charges for $20.8M*, BNA's Health Care Fraud Rep. (Nov. 22, 2017).
United States ex rel. Ameer v. Philips Elec. North America, No. 2:14-cv-2077-PMD (D.S.C. settled Mar. 19, 2016).	A medical device manufacturer paid for call center services provided to DME suppliers that purchased its CPAP equipment, but charged DME suppliers for the service if they sold competing CPAP equipment. The call service consisted of automated messages sent to CPAP customers to remind them to replenish their CPAP supplies.	The manufacturer agreed to pay $34.8 million and entered into a five-year corporate integrity agreement to settle the allegations. See *Sleep Device Maker Respironics Settles FCA Case for $35M* BNA's Health Care Fraud Rep. (Mar. 2, 2016).
United States ex rel. Beaujon v. Hebrew Homes Health Network, Inc., et al., No. 12-20951 (S.D. Fla. settled June 16, 2015).	A SNF hired numerous physicians as medical directors, who under their contracts had numerous job duties and hourly requirements. However, the physicians did not perform these duties, and instead, were paid by the SNF for patient referrals, which increased substantially after the medical directors were added to the payroll.	The SNF agreed to pay $17 million to settle the allegations and entered into a corporate integrity agreement. This is the largest settlement involving alleged violations of the anti-kickback statute by SNFs in the United States. See 116 *BNA's Health Care Daily Rep.* (June 17, 2015).
United States ex rel. Fragoules v. Daiichi Sankyo, Inc., No. 10-10420 (D. Mass. settled Jan. 9, 2015).	A pharmaceutical company paid physicians in the form of speaker fees. The payments were made even when physician participants were speaking on duplicative topics over company-paid dinners. The physicians only spoke to members of their own staff, and the associated dinners' costs exceeded the company's own internal cost limitation.	The company agreed to pay $39 million to settle the allegations and entered into a corporate integrity agreement. See 7 *BNA's Health Care Daily Rep.* (Jan. 12, 2015).

[88] *Id.* at 9.

ISBN 1-55871-427-8

Settlement	Alleged Misconduct	Resolution/Penalties
United States ex rel. Health Dimensions Rehabilitation, Inc. v. RehabCare Group, Inc., No. 4:12-cv-00848-AGF (E.D. Mo. settled Jan. 17, 2014).	A nursing home rehab services company disclosed a "therapist recruiting fee" in a public earnings conference call, prompting a competitor's CEO to file a whistle-blower lawsuit. The company paid kickbacks to another company in the form of a $600,000 initial payment and between 10 percent and 15 percent of subsequent profits to provide rehabilitation services to nursing homes managed by a third company and formerly serviced by the second company's therapists.	The three companies agreed to pay $30 million to settle the allegations. The settlement terms require that the companies to restructure their contract arrangements, in addition to the $30 million settlement payment. The relator's share was $700,000. See 18 *BNA's Health Care Fraud Rep.* 78 (Jan. 22, 2014).
United States ex rel. Hutcheson v. Blackstone Medical Inc., No. 06-11771-WGY (D. Mass., settlement announced Nov. 2, 2012).	A whistleblower alleged that a medical device company paid kickbacks to spinal surgeons, including sham consulting agreements, sham royalty arrangements, sham research grants, and travel and entertainment.	The company agreed to pay $30 million to settle the allegations and entered into a Corporate Integrity Agreement (CIA). (16 *BNA's Health Care Fraud Rep.* 900, Nov. 14, 2012).
United States v. Zimmer Inc., D.N.J., No. 2:07-mj-08130-MCA, Deferred Prosecution Agreement Between the United States (U.S. Attorney for the District of New Jersey) and Zimmer Inc. (agreement filed Sept. 27, 2007).	Five U.S. manufacturers of hip and knee surgical implants violated the anti-kickback law by using consulting agreements with orthopedic surgeons as inducements for the surgeons to use a particular company's artificial knee and hip replacement and reconstruction products. Surgeons typically received tens of thousands to hundreds of thousands of dollars yearly under the consulting arrangements, and some physicians did little or no work for the compensation they received as consultants but agreed to use the paying company's product exclusively.	Zimmer and three other companies agreed to corporate reforms and federal monitoring for 18 months to avoid criminal prosecution. The fifth company entered into a nonprosecution agreement that requires it to implement the same reforms as the other four companies, including 18 months of federal monitoring.
Medtronic Inc., (Western District of Tennessee, July 19, 2006).	Medical device manufacturer violated the anti-kickback statute and False Claims Act because one of its divisions allegedly paid kickbacks to doctors in the form of sham consulting and royalty agreements as well as expensive luxury trips. The kickbacks were paid in exchange for the doctors' use of the company's spinal products.	The company agreed to pay $40 million to settle the civil allegations. It also entered into a five-year CIA with the OIG. 10 *BNA's Health Care Fraud Rep.* 552 (July 19, 2006).

ISBN 1-55871-427-8

Settlement	Alleged Misconduct	Resolution/Penalties
United States ex rel. Reilly v. Catskill Regional Medical Center f/k/a Community General Hospital of Sullivan County, No. 00 Civ. 7906 (S.D.N.Y. settlement approved Sept. 13, 2005).	Two affiliated consulting firms illegally referred Medicaid patients to three hospitals, causing the hospitals to file false reimbursement claims for millions of dollars. Under the guise of administrative services agreements for alcohol and substance abuse treatment and detoxification units, the hospitals paid the companies between $50,000 and $73,000 per month for Medicaid patient referrals.The consultants made inpatient alcohol detoxification referrals to Mount Vernon Hospital, knowing that the hospital was not licensed by the state to provide such services.	The consulting firms agreed to pay the government $2.75 million to settle the charges.

ISBN 1-55871-427-8

1415.30.20
Court Rulings

Facts	Outcome
The former medical director of a health center entered into an agreement with a diagnostic imaging center, wherein the facility paid her a set amount of cash for each MRI, CAT scan, ultrasound, echocardiogram and DEXA scan she referred. The medical director referred more than 1,000 tests during the nearly three-year scheme.	The medical director was sentenced to six months in federal prison and five months of home confinement. She was also fined $30,000, ordered to forfeit $51,200, and serve two years of supervised release. *United States v. Siripurapu,* No. 13-cr-394-CCC (D. N.J. sentencing Oct. 24, 2013).
A former medical director of a hospice provider entered into a written contract with a co-owner of the hospice to make it appear that all payments to the medical director received from the hospice provider were for services he rendered in his capacity as medical director, when in fact most of the payments were illegal kickbacks for referring Medicare and Medicaid patients to the hospice provider.	The medical director was sentenced to 51 months in prison, fined $300,000, and ordered to serve three years of supervised release. The former medical director faces mandatory exclusion from participation in any federal health-care program. *United States v. Goldman,* No. 12-cr-305 (E.D. Pa. sentencing Oct. 23, 2013).
The Justice Department accused five U.S. manufacturers of hip and knee surgical implants of violating the anti-kickback law by using consulting agreements with orthopedic surgeons as inducements for the surgeons to use a particular company's artificial knee and hip replacement and reconstruction products. The companies accounted for 95 percent of the market for such implants. According to the government, surgeons typically received tens of thousands to hundreds of thousands of dollars yearly under the consulting arrangements. Some physicians did little or no work for the compensation they received as consultants but agreed to use the paying company's product exclusively, DOJ said. The surgeons also failed to disclose their financial relationships with the device manufacturers to their patients or to the hospitals where they performed their surgeries.	Four of the five companies agreed to corporate reforms and federal monitoring for 18 months to avoid criminal prosecution. The fifth company, which was the first to cooperate with federal prosecutors, entered into a nonprosecution agreement that requires it to implement the same reforms as the other four companies, including 18 months of federal monitoring. The four companies also agreed to pay a total of $311 million to settle government claims under the anti-kickback statute and the civil False Claims Act. Each company's settlement amount is based on its market share and other related business factors during the period from 2002 through 2006. In addition, the four implant makers entered into five-year corporate integrity agreements that require additional reforms and monitoring under OIG supervision. *Deferred Prosecution Agreement Between the United States (U.S. Attorney for the District of New Jersey) and Zimmer Inc., United States v. Zimmer Inc.,* D.N.J., No. 2:07-mj-08130-MCA (agreement filed Sept. 27, 2007).
Kickback violations were found in agreements with six hospitals under which the osteopaths were to provide gerontology consulting services. From 1984 through 1994, first as "Co-Directors of Gerontology" and then as consultants, the osteopaths each received $75,000 per year from one hospital. Also convicted were the president and chief executive officer and the senior vice president and chief operating officer of one of the hospitals. As soon as the relationship with the hospital began, the osteopaths' referrals to another hospital dropped dramatically, with a corresponding increase in referrals to the first hospital. According to the court, "Witness after witness testified that the LaHues performed very few actual services in return for the substantial annual sum they were paid."	The osteopaths were sentenced as follows: Robert LaHue, 70 months, a $75,000 fine, and $142,040 in restitution; Ronald LaHue, 37 months and a $25,000 fine. The hospital president, Anderson, was sentenced to 51 months and a $75,000 fine. *United States v. Anderson*, 85 F. Supp.2d 1047 (D. Kan. 1999). *LaHues, Hospital Executive Sentenced, Fines Imposed in Fraud, Kickback Case*, 3 BNA's Health Care Fraud Rep. 970 (Nov. 3, 1999). The hospital agreed to pay $17.5 million to settle fraud allegations stemming from the relationship with the LaHues. *Missouri Hospital to Pay $17.5 Million to Settle Medicare Kickback Allegations*, 1 BNA's Health Care Fraud Rep. 630 (Sept. 24, 1997). In March 2004, a federal district court agreed it was appropriate for the government to exclude Anderson from participating in federal health care programs for 15 years. *Anderson v. Thompson,* No. 02-2312-JAR, (D. Kan.March 10, 2004).

ISBN 1-55871-427-8

Facts	Outcome
Three clinical laboratories operated by physician-owned limited partnerships entered into laboratory management agreements with a unit of a large clinical laboratory company. The three laboratories were required to provide facilities and equipment necessary for the operation of the clinical labs, and repair and maintain lab space and pay utility charges. The company had a duty to staff, operate, and supervise the labs, and conduct all billing and collection activities on their behalf. The company was to receive a fee of 76 percent of the labs' net revenues, while the labs received 24 percent. The labs did very little testing of their own; 85 percent to 90 percent of tests physicians ordered from the labs were performed at the company's facilities. The OIG charged that through these agreements, officials of the labs actually were soliciting and receiving payments from the company in return for referrals of lab tests.	The Ninth Circuit disagreed with the OIG and found for the defendant labs. *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995).
An osteopath who focused his practice on AIDS patients was paid to assist in the development of treatment and educational programs for a home infusion company's staff and patients. An indictment charged that the agreements were part of a kickback conspiracy in which the osteopath solicited remuneration in return for referring patients to the company for home infusion therapy, and a federal court refused to dismiss the indictment.	The district court rejected the osteopath's vagueness challenge, saying that soliciting payment for referrals is an "inherently wrongful activity and one of which a physician should particularly be aware." *United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995). The 6th Circuit Court of Appeals affirmed the district court's denial of the defense's motion to dismiss. *United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995).
An osteopath who headed a company providing physicians with diagnostic services billed Medicare for services for monitoring devices that recorded cardiac activity. When payment was received, the company forwarded 40 percent, not to exceed $65 per patient, to the referring physician. The osteopath was charged with offering illegal remuneration to the referring physicians. The company called the payments "interpretation fees" for the referring physicians' consultations as well as for the physicians' explaining the test results to patients. However, the interpretations actually were performed by the osteopath and the payments to referring physicians exceeded what Medicare would have paid for such services. The government introduced testimony the osteopath had given in an earlier civil proceeding, in which he testified that "if the doctor didn't get his consulting fee, he wouldn't be using our service. So the doctor got a consulting fee."	The 3rd Circuit Court of Appeals upheld the jury conviction. "If the payments were intended to induce the physician to use Cardio-Med's services," the court said, "the statute was violated, even if the payments were also intended to compensate for professional services." *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985).

ISBN 1-55871-427-8

Facts	Outcome
A jury found kickbacks in an arrangement for laboratory specimen collection and handling services where the payments were at less than fair market value. Mobile Medical Industries, whose president was the named defendant, provided management services for a medical group. Specifically, MMI agreed to refer lab work to Automated Laboratory Services in exchange for payments of approximately 20 percent of the revenue that ALS derived from MMI's business.	The company president was convicted of offenses including receiving kickbacks and conspiracy to defraud the United States. The U.S. Court of Appeals for the Ninth Circuit recounted that "[t]o account for the kickback payments," MMI collected specimens, spun down blood, supplied forms and stickers, and carried insurance, but, the court said, "[t]he fair market value of these services was substantially less than the compensation MMI received from ALS, and there is no question that ALS was paying for the referrals as well as the described services." The OIG has subsequently cited this dictum as support for the notion that when payments are made between parties in a potential referral relationship, amounts that exceed fair market value of the goods or services in question can be inferred to be payments for referrals. *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985)

ISBN 1-55871-427-8