FEDERAL ANTI-KICKBACK STATUTE PRIMER

Robert G. Homchick[1]
Davis Wright Tremaine LLP
206 757-8063
roberthomchick@dwt.com

I. ANTI-KICKBACK STATUTE

A. General Prohibition.

The federal anti-kickback statute[2] prohibits the knowing and willful solicitation, offer, payment or acceptance of any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind: (1) for referring an individual for a service or item covered by a federal health care program, or (2) for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item reimbursable under a federal health care program.

Breaking the statute down into elements:

1. No "remuneration, in cash or kind"

2. May be solicited, offered, accepted or received, directly or indirectly,

3. Knowingly and willfully

4. To induce or provide:

a. The referral of patients or business; or

b. The purchase, lease, order or arranging for the purchase, lease, or order of any good, facility, service or item

5. For which payment may be made in whole or in part under a federal health care benefit program (including Medicare and Medicaid)

B. Penalties.

Violation of the law is a felony, punishable with up to five years imprisonment and/or $25,000 fine. In addition, violation can result in exclusion from federal health care programs, including Medicare and Medicaid, and parallel loss of state licensure, hospital privileges and participation in managed care contracts.

[1]The author would like to acknowledge the significant contributions of Christina Asavareungchai, Esq. to this paper.
[2]42 U.S.C. § 1320a-7b(b).

C. Overview.

The language of the anti-kickback statute is very broad and the scope of its prohibitions has been the subject of considerable debate. Congress has repeatedly recognized the potential for unfair application of the statute. First, in 1980, Congress amended the anti-kickback statute to add a requirement that the government establish that the defendant's conduct be "knowing and willful."[3] In enacting this amendment, Congress noted the concern that "criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent. Accordingly, the section clarifies current law to assure that only persons who knowingly and willfully engage in the proscribed conduct could be subject to criminal sanctions."[4] In 1987 Congress again acknowledged potential problems with the breadth of the statute's prohibition and directed the Secretary of HHS to create safe harbors.[5] Congress stated: "the breadth of…statutory language [in the anti-kickback statute] has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. The Committee bill therefore directs the Secretary, in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be subject to criminal prosecution…and that will not provide a basis for exclusion from participation in Medicare or the State health care programs…."[6]

The anti-kickback safe harbors, however, have not provided the level of certainty that Congress envisioned. The safe harbors (discussed below) are narrowly drafted and many include highly technical requirements. The Office of Inspector General (OIG) within the Department of Health and Human Services acknowledges that "safe harbor protection is afforded only to those arrangements that *precisely* meet all of the conditions set forth in the safe harbor"[7] and further, "a payment practice that does not fall within the ambit of a safe harbor does not necessarily violate the anti-kickback statute."[8]

In 1996, in response to continued complaints from the industry regarding the lack of clarity surrounding the scope of conduct subject to the anti-kickback prohibitions, Congress authorized the OIG to issue advisory opinions as to whether certain transactions violate the statute.[9] The legislative history explains Congress' motives for establishing the advisory opinion process: "Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them. These providers should be able to receive guidance from the government regarding financial arrangements. Little or no guidance is currently provided because there are no regulations and only insufficient safe harbors. Without this ability, a chilling effect is placed on legitimate arrangements…."[10]

---

[3]Omnibus Reconciliation Act of 1980, H.R. Rep. No. 96-1167, 96th Cong., 2d Sess. 59, reprinted in 1980 U.S.C.C. A.N. 5526, 5572.
[4]*Id*.
[5]42 U.S.C. § 1320a-7B(b)(3)(E).
[6]S. Rep. No. 100-109, 100th Cong., 1st Sess. 27, reprinted in 1987 U.S.C.C.A.N. 682, 707-708.
[7]OIG Advisory Opinion No. 07-10 (issued September 20, 2007)(*Italics added*).
[8]Letter from Lewis Morris, Chief Counsel to the Inspector Gen., Dep't of Health and Hum. Servs., to [name redacted] (Jan. 15, 2003), at http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf.
[9]42 U.S.C. § 1320a-7d(b).
[10]H.R. Rep. No. 104-496, at 84-85 (1996), reprinted in 1996 U.S.C.C.A.N. 1865, 1884-5.

D. Statutory Exceptions.

The anti-kickback statute has statutory exceptions for:

1. Bona fide payments to W-2 employees

2. Discounts

3. Payments to purchasing agents

4. Certain transactions that fit within "safe harbors" established by the Secretary (see below)

5. Specified risk-sharing arrangements

6. Prescription drug discounts for certain beneficiaries in the "coverage gap" or doughnut hole

E. Intent.

The anti-kickback statute requires the "*knowing and willful*" solicitation, acceptance, payment or receipt of remuneration to induce the referral or ordering of items or services to be paid for by a federal health care benefit program. There are at least two aspects to the standard of intent under the anti-kickback statute that have been the subject of judicial interpretation. First, courts have held that to establish a kickback violation either the primary purpose or one purpose of a payment must be to induce an illegal referral even if other, legitimate purposes exist. In *United States v. Greber*,[11] the Third Circuit adopted the "one purpose" test, holding that a payment is illegal under the anti-kickback statute where one purpose of the payment is to wrongfully induce referrals. This test has been adopted by several other courts.[12]

The "one purpose" test articulated by the *Greber* court, however, must be applied in keeping with this criminal statute's underlying requirement that the defendant's conduct be *knowing and willful*. This second component of the intent analysis under the anti-kickback statute focuses on the degree to which the government must prove that the defendant acted with the intent to violate the law. In *Hanlester Network vs. Shalala*[13] the Ninth Circuit held that the government must demonstrate that the defendant knew that its conduct violated the anti-kickback statute and engaged in the conduct with the specific intent to violate the anti-kickback statute. The *Hanlester* specific intent requirement was not adopted by other federal circuit courts but remained binding precedent in the Ninth Circuit until Congress amended the statute in the Affordable Care Act (ACA). The ACA amendment to the anti-kickback statute provides that "a person need not have actual knowledge of [the anti-kickback statute] or specific intent to commit a violation of [the

[11] 760 F.2d 68, 72 (3d Cir. 1985).
[12] *See United States v. Davis,* 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Kats,* 871 F.2d 105,108 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000), *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011).
[13] 51 F.3d 1390 (9th Cir. 1995).

anti-kickback statute]."[14] While speaking before a Senate Subcommittee on the Department of Justice's efforts to combat health care fraud through criminal prosecution, Acting Deputy Assistant Attorney General Greg Andres stated that "This is an important clarification that effectively abrogates judicial constructions of the phrase 'knowingly and willfully'… that had made it harder for the government to prove health care fraud violations."[15] It is noteworthy that the ACA amendment, however, did not eliminate the requirement that to violate the anti-kickback statute a defendant must *knowingly and willfully* intend to provide remuneration in exchange for patient referrals.

As interpreted by the United States Supreme Court in *Bryan v. U.S.*[16], the requirement of "willful" conduct to establish a violation of a criminal law requires that a person know what he/she is doing is a violation of the law. In the wake of the ACA amendment, it seems clear that the prosecution does not have burden of proving either that the defendant knew the details of the anti-kickback statute or that he/she engaged in conduct with the specific intent to violate that statute. Nonetheless, given the requirement that conduct be "knowing and willful," the government must still prove that the defendant provided remuneration in exchange for patient referrals knowing that that conduct was illegal.[17]

Considering both aspects of the intent requirement under the anti-kickback statute, a violation can be established if the prosecution proves that *one purpose* of the payment is to *unlawfully* induce the referral of items of services to be paid for by a federal health care benefit program.

F. Anti-Kickback Regulatory Safe Harbors.

As noted above, in passing the Medicare and Medicaid Patient and Program Protection Act of 1987 (pub. Law 100-93), Congress expressed concern that the anti-kickback

---

[14] 42 U.S.C. § 1320a-7b(h).

[15] "Statement of Acting Deputy Assistant Attorney General Greg Andres of the Criminal Division Before the Senate Committee on Homeland Security and Governmental Affairs, Washington, D.C. ~ Wednesday, March 9, 2011," *United States Department of Justice*, available at http://www.justice.gov/criminal/pr/testimony/2011/crm-testimony-110309.html (last accessed August 22, 2012).

[16] 524 U.S. 184 (1998). The *Bryan* opinion states: "the willfulness requirement of [the statute] does not carve out an exception to the traditional rule that ignorance of the law is no excuse; knowledge that the conduct is unlawful is all that is required." *Id*. at 196. The Supreme Court cited *Bryan* in *Safeco Ins. Co. v. Burr*, 551 U.S. 47 (2007). The *Burr* opinion interprets "willfulness" when the term is used in a criminal statute and concludes: "[t]hus we have consistently held that a defendant cannot harbor such criminal intent unless he 'acted with knowledge that his conduct was unlawful.'" *Id*. (*quoting Bryan*, 524 U.S. at 193). The Supreme Court also referenced *Bryan* in *Dixon v. United States*, 548 U.S. 1 (2006). The *Dixon* opinion quoted *Bryan* and stated that the term "willfully" in the relevant sentencing provision "requires a defendant to have 'acted with knowledge that his conduct was unlawful'". *Id.* at 5. The court then concluded that the government had to prove beyond a reasonable doubt that petitioner knew she was making false statements and knew that she was breaking the law when she committed the act at issue (specifically, acquiring a firearm while under indictment).

[17] Prosecutors may argue that the term "willful" only refers to consciousness of the act but not to consciousness that that act is unlawful. If this interpretation were accepted then the government could obtain a felony conviction if it could prove that the defendant purposely, and not by accident, paid or received remuneration with the intent to induce referrals, but not that the defendant knew that his/her acts were illegal or otherwise wrongful. No court has adopted this construction of the term "willfully" as used in the anti-kickback statute and at least one court has expressly rejected it. *See United States v. Jain*, 93 F.3d 436, 440 (8th Cir. 1996). Moreover, this interpretation is directly at odds with the Supreme Court's opinions in *Bryan* and *Safeco Ins. v. Burr*, cited above.

statute was overly broad and that its application might render legitimate health care businesses illegal. Congress ordered the Office of Inspector General of HHS (the "OIG") to promulgate safe harbor regulations to shelter business relationships that would not be prosecuted under the statute. Starting in 1991, the OIG has promulgated a series of regulatory safe harbors.

1. **Safe Harbors Are Not Mandatory.** Full safe harbor protection is secured only when an arrangement completely complies with all safe harbor elements. However, there is no legal requirement that transactions between referral sources fit within a safe harbor. The OIG interprets failure to comply fully with a safe harbor as meaning one of three things:

   a. The arrangement does not fall within the ambit of the statute, and is not intended to induce the referral of business reimbursable under Medicare or Medicaid.

   b. The arrangement could be a clear statutory violation.

   c. The arrangement may violate the statute in a less serious manner with the degree of risk depending on a fact-specific inquiry, including whether the parties made a good-faith effort to comply; the arrangement is innocuous, or there is no applicable safe harbor. In these circumstances, the OIG may review the arrangement on a case-by-case basis to determine whether, based upon the totality of facts and circumstances, it poses a risk of fraud and abuse under the statute.

   See 56 Fed. Reg. 35952 (July 29, 1991).

2. **List of Safe Harbors.** The following safe harbors and required elements are found at 42 C.F.R. 1001.952 *et seq*.

   a. Investment interests in large publicly traded entities or certain small entities;

   b. Space rentals

   c. Equipment rentals;

   d. Personal services and management contracts;

   e. Sale of practice;

   f. Referral services;

   g. Warranties;

   h. Discounts;

   i. Employees;

   j. Group purchasing organizations;

k. Certain Medicare Part A waivers of coinsurance and deductibles;

l. Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by certain health plans (managed care);

m. Price reductions offered to certain health plans (managed care);

n. Investment interests in Underserved Areas;

o. Investment interests in surgeon-owned single-specialty, multi-specialty and hospital/physician ambulatory surgical centers ("ASCs");

p. Investment interests in group practices composed exclusively of active investors who are licensed health care professionals;

q. Rural practitioner recruitment incentives;

r. Obstetrical malpractice insurance subsidies;

s. Referral agreements for specialty services;

t. Cooperative hospital service organizations;

u. Ambulance replenishment arrangements;

v. Electronic prescribing and electronic medical records; and

w. Federally qualified health centers.

G. Anti-Kickback Statute and the False Claims Act.

Generally, the federal False Claims Act (FCA), 31 U.S.C. § 3729 *et seq*., prohibits the presentation of a false or fraudulent claim that may be paid in whole or in part by the federal government. For many years, both litigants and the courts have debated whether a violation of the anti-kickback statute was an adequate predicate for asserting that related claims submitted to federal health care programs were actionable under the False Claims Act. Congress in the ACA directly addressed this question by amending the statute to provide that "claims that include items or services resulting from a violation of the AKS also constitute a false or fraudulent claims for purposes of the False Claims Act." 42 U.S.C. § 1320(a)-7b(g).

Some commentators have read this amendment as implying that kickback violations necessarily result in FCA violations. The correct analysis, however, is more complicated. To determine whether a kickback violation creates FCA liability one must determine if the claim "results from" a kickback. How close or related the kickback activities must be to the claim to establish such a causal connection is not clear. "Up the chain" kickbacks – kickbacks which perhaps the claimant did not participate in or even know about – seem unlikely to "result in" a false claim. In addition to these vexing issues, it is also essential

to be mindful that in order that a claim "result from" a kickback, the latter must be proven to have occurred in the first place.

H. Illustrative Case Law.

1. ***United States ex rel. Singh v. Bradford Regional Medical Center, et al.,* No. 1:04-cv-00186-MBC (W.D. Penn., 2010).** This is a lawsuit filed under the False Claims Act's whistleblower provisions, based on alleged violations of the Stark law and anti-kickback statute. Two of the defendants were internal medicine physicians ("Defendant Physicians"), who were formerly employed at Bradford Regional Medical Center ("Hospital"). In 2000, the Defendant Physicians purchased their practice from Hospital and formed V&S Medical Associates, LLC ("V&S").

   V&S decided to lease a nuclear camera and install the camera its own office, allowing V&S to perform nuclear imaging tests in-house rather than referring such tests to Hospital. Because the Defendant Physicians were a major referral source to Hospital, Hospital was allegedly worried about the negative impact of V&S's nuclear camera on Hospital's attempt to establish a cardiology program. Hospital and Defendant Physicians later entered into an arrangement under which Hospital would sublease the camera from V&S, in exchange for compensation to V&S and an additional payment for a covenant not to compete. Plaintiffs charged that this arrangement was designed for Hospital to obtain patient referrals from V&S and Defendant Physicians, in return for illegal kickbacks.

   The court pointed out that unlike the Stark Act which does not look at the parties' intent, the anti-kickback statute does require proof of intent. The court concluded that "much of the evidence in support of establishing the requisite intent of Defendants implicates credibility decisions that are the province of the fact-finder at trial." The court went on to state that the defendants will have a difficult challenge to prove to the fact-finder that they lacked the requisite intent, because the fact-finder will take into account among other items: (a) assessments of the arrangement, demonstrating that the value of the non-competition agreement was roughly equal to the amount of business V&S could generate for Hospital; (b) the fact that after the arrangement was entered, the Defendant Physicians did refer their patients to Hospital; and (c) the question of whether Defendant Physicians, as a practical matter, had any real choice as to where they made referrals due to the rural nature of the area that limited the number of facilities available for referrals from the Defendant Physicians.

2. ***United States ex rel. Lee v. ELA Medical, Inc.*, No. 06-21230-Civ-Jordan (S.D. Florida) (settled in October 2010).** This case involved charges that ELA Medical, Inc. ("ELA") violated the False Claims Act as a result of providing kickbacks to medical providers for the use of ELA's cardiac devices in violation of the anti-kickback statute. Specifically, from 2004 to 2007, the kickbacks were allegedly paid by an independent contractor of ELA to physicians and/or their professional practices who performed pacemaker and defibrillator implant procedures in hospitals located in three Florida counties. The kickbacks included gifts, meals and entertainment, tickets to sporting events, travel to medical conferences and other destinations, fishing and

boating trips, cash payments to a foundation owned by physicians, and travel expenses for physician spouses. Under the terms of a Settlement Agreement, ELA agreed to pay the United States nearly $9.2 million dollars and enter into a Corporate Integrity Agreement.

3. ***United States v. Weinbaum et al*., No. 03-CR-1587-MJL (S.D. Calif.) (mistrial declared Feb. 17, 2005 and April 4, 2006).** In 2003, prosecutors indicted Alvarado Hospital Medical Center in San Diego, its CEO, and others for alleged violations of the anti-kickback statute relating to physician recruitment practices. The hospital's assistant administrator pled guilty to conspiracy, while both the first and second trials for the hospital and CEO ended with the judge declaring mistrials after the juries deadlocked on a verdict. Prosecutors alleged that the hospital used physician relocation agreements to funnel money to physicians who then referred patients in federally funded programs to the hospital.

4. ***McClatchey v. United States*, No. 98-CR-20030-06-JWL (D. Kan. Jan. 16, 2003) 217 F.3d 823 (10th Cir. 2000), cert, denied 531 U.S. 1015 (2000), *on remand* 160 F. Supp. 2d 1254 (D. Kan. 2001).** This case was based on claims that Baptist Medical Center in Kansas City (Baptist) paid doctors Robert and Ronald LaHue to refer patients to Baptist in violation of the anti-kickback statute. During the pertinent period, McClatchey served as Chief Operating Officer and Senior Vice President of Baptist, and then as a Senior Vice President at Health Midwest, which was Baptist's parent corporation at the time. The LaHues were the principals of a medical practice called Blue Valley Medical Group (BVMG), which provided care to patients in nursing homes and similar facilities. In January 1985, Baptist entered into a one-year contract with the LaHues, paying the doctors a total of $150,000 to serve as "Co-Directors of Gerontology Services" at Baptist. Baptist's Chief Financial Officer testified that the negotiations for the 1985 contract had been "backwards," in that the parties first set the fee and only then agreed to the services which the LaHues would provide in return. After the contract was executed, the LaHues began referring large numbers of their patients to Baptist. In June of 1986, after the 1985 contract had expired, Baptist entered into a second one-year agreement with the LaHues, providing that Baptist would pay the doctors a combined $150,000 to perform specified services. Then, despite expiration of the 1986 contract, Baptist continued to pay the LaHues $150,000 each year through 1993, with the exception of 1990, when each doctor received $68,750. The LaHues performed only "minimal" services for Baptist. McClatchey was indicted on July 15, 1998, for conspiring to violate the anti-kickback statute and for a substantive violation of the statute. The jury returned guilty verdicts on both charges. Following the verdict, the district court granted McClatchey's motion for acquittal, which the 10th Circuit reversed. In November 2000, the U.S. Supreme Court denied McClatchey's appeal to stay his conviction. After the district court sentenced McClatchey to three years probation, with home detention of six months under electronic monitoring, and a $30,000 fine and related costs, the 10th Circuit affirmed the district court's calculation of the offense level, reversed the district court's downward departure, and remanded for resentencing. The trial court's charge to the jury is instructive on several key criteria for finding a violation of the anti-kickback statute:

> In order to sustain its burden of proof against the hospital executives for the crime of violating the Anti-Kickback statute, the government must prove beyond a reasonable doubt that the defendant under consideration offered or paid remuneration with the specific criminal intent "to induce" referrals. To offer or pay remuneration to induce referrals means to offer or pay remuneration with the intent to gain influence over the reason or judgment of a person making referral decisions. The intent to gain such influence must, at least in part, have been the reason the remuneration was offered or paid.
>
> On the other hand, defendants Anderson, Keel, and McClatchey cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the creation of an attractive place to which patients can be referred does not induce, as I have just defined it. (emphasis added)

5. ***Kosenske v. Carlisle HMA*, 2009 WL 120888 (3d Cir. 1/21/09).** While the *Kosenske* case involved the application of the Stark Law and its exceptions, the case addressed fair market value issues at length and may have an impact on the interpretation of fair market value issues under the anti-kickback law. See discussion, Section IV.

I. Special Fraud Alerts, Advisory Bulletins and Other Guidance.

The OIG issues Special Fraud Alerts based on information that it acquires regarding certain fraudulent and abusive practices within the health care industry. The has OIG described the purpose of such fraud alerts as follows: "These Special Fraud Alerts provide the OIG with a means of notifying the industry that we have become aware of certain abusive practices which we plan to pursue and prosecute, or bring civil and administrative action, as appropriate. The alerts also serve as a powerful tool to encourage industry compliance by giving providers an opportunity to examine their own practices."[18] The Special Fraud Alerts address a variety of topics, including the following:

- Joint Venture Relationships
- Routine Waiver of Copayments or Deductibles under Medicare Part B
- Hospital Incentives to Referring Physicians
- Prescription Drug Marketing Schemes
- Arrangements for the Provision of Clinical Laboratory Services
- Home Health Fraud
- Fraud and Abuse in the Provision of Medical Services in Nursing Facilities
- Fraud and Abuse in Nursing Home Arrangements with Hospices
- Fraud and Abuse in the Provision of Services in Nursing Facilities
- Physician Liability in Certification of Medical Equipment and Supplies and Home Health Services

[18] 60 F.R. 40847 (August 10, 1995).

- Rental of Office Space in Physicians' Offices
- Telemarketing by Durable Medical Equipment Companies[19]

In addition, the OIG provides ongoing guidance on its interpretation and enforcement of the anti-kickback statute through Special Advisory Bulletins and additional guidance on various topics, both available on its website.[20]

J. Advisory Opinions.

As noted above, in 1996, Congress authorized the OIG to issue advisory opinions as to whether certain transactions violate the anti-kickback statute.[21] The OIG may issue an advisory opinion upon the specific request of a person or organization involved in an actual or anticipated transaction that may be subject to either the anti-kickback statute or civil money penalty ("CMP") law.

Generally, an advisory opinion request must: (1) identify the requestor (no anonymity between the OIG and the requestor); (2) involve an actual set of facts or a seriously proposed transaction that will be implemented should the advisory opinion be favorable; (3) include a complete and specific description of all relevant information pertaining to the arrangement and the circumstances of the conduct, including among other items background information, operative documents if available and otherwise descriptions of proposed terms for proposed arrangements; (4) request advice as to application of the anti-kickback statute or the CMP law to a particular set of facts; and (5) include a signed certification from the requestors, stating that the information provided is true and correct. If the request relates to a proposed arrangement, the request must also include a statement that the requestors plan to undertake the arrangement in good faith (plans may be contingent on the OIG's issuance of a favorable opinion).[22] If the OIG needs additional information prior to rendering an advisory opinion, it may request additional documents or information that it deems necessary.[23] The requestor of an advisory opinion may choose to withdraw the request by providing written notice prior to the issuance of a formal advisory opinion by the OIG.[24]

For informational purposes, the OIG has included resources describing the advisory opinion process on its website. For example, the Preliminary Checklist for Advisory Opinion Requests contains a list of technical requirements; information to include which describes the issues and arrangements; and required certifications. The OIG website also

---

[19]"Special Fraud Alerts," *Office of Inspector General: U.S. Department of Health and Human Services*, available at http://oig.hhs.gov/compliance/alerts/index.asp (last accessed August 22, 2012).

[20]"Special Advisory Bulletins," *Office of Inspector General: U.S. Department of Health and Human Services*, available at http://oig.hhs.gov/compliance/alerts/bulletins/index.asp (last accessed August 22, 2012); "Other Guidance," *Office of Inspector General: U.S. Department of Health and Human Services*, available at http://oig.hhs.gov/compliance/alerts/guidance/index.asp (last accessed August 22, 2012).

[21]42 U.S.C. § 1320a-7d(b).

[22]42 C.F.R. § 1008.37.

[23]42 C.F.R. § 1008.39.

[24]42 C.F.R. § 1008.40.

includes suggested (but not required) questions for requestors to answer based upon the subject matter of the advisory opinion request. [25]

The OIG will not opine as to whether remuneration reflects fair market value or whether a person is a bona fide employee.[26] As a legal matter, an advisory opinion is binding only on HHS and the party requesting the opinion. The official guidance notes that advisory opinions cannot be relied upon by any other party. As a practical matter, however, if a party seeks to ensure compliance with the law by following the guidance provided by the OIG in an advisory opinion it seems unlikely that the government would be able to establish that he or she knowingly and willfully violated the statute. The OIG's website includes a library of advisory opinions. *See* www.oig.hhs.gov.

K. Self Disclosure Protocol.

1. **Background.** The OIG Provider Self-Disclosure Protocol (SDP), introduced in 1998, is intended as a " ... vehicle under which the provider community can voluntarily disclose self-discovered evidence of potential fraud in an attempt to avoid the costs and disruptions that may be associated with a Government directed investigation and with civil or administrative litigation." 63 Fed. Reg. 58399 (10/20/98). The OIG issued an Open Letter to Providers in April 24, 2006, encouraging self disclosure under the SDP and committing generally to settle liability in those situations under the OIG's authority for an amount near the lower end of the continuum for damages arising out of anti-kickback violations (based upon the number and dollar value of improper payments or remuneration) to those damages arising out of Stark Law violations (based upon the number and dollar value of improper claims).

2. **April 15, 2008 Open Letter.** On April 15, 2008, the OIG issued another Open Letter to Providers. In the 2008 Open Letter, the OIG states that it generally will not require a corporate integrity agreement or certificate of compliance agreement when negotiating administrative monetary and permissive exclusion in exchange for payment under the SDP. The OIG cautions that "mere billing errors or overpayments" rather than potential fraud against federal programs are not intended to be addressed by SDP. Rather, providers should submit these matters directly to claims-processing entity. Resources on the SDP can be found at http://www.oig.hhs.gov/fraud/selfdisclosure.asp.

   In the 2008 Open Letter, the OIG provides that an SDP initial submission must include the following elements, in addition to the basic information required under the SDP:

   (1) A complete description of conduct being disclosed.

   (2) A description of internal investigation that the provider has completed or that it commits to complete.

[25] "Advisory Opinions," *Office of Inspector General,* available at http://oig.hhs.gov/compliance/advisory-opinions/index.asp (last accessed August 22, 2012).
[26] 42 C.F.R. § 1008.5(b).

(3) An estimate of damages to federal programs and the methodology used to determine those estimated damages, or a commitment on when the provider will complete the estimate.

(4) A statement of laws potentially violated by the conduct.

The provider must commit to complete the investigation and estimate within three of being accepted into the SDP.

The OIG indicates in the 2008 Open Letter that it has streamlined its internal processes under the SDP in order to provide for an expedited process. In return, the OIG expects "full cooperation from disclosing providers during the verification of the matter disclosed," and will remove providers from SDP participation unless they make timely and good faith disclosures in response to OIG requests for additional information.

3. **March 24. 2009 Open Letter**. On March 24, 2009, the OIG issued a new Open Letter to Healthcare Providers narrowing the SDP's scope with respect to the Stark Law and establishing minimum settlement amounts for submissions. In this Open Letter, the OIG states that:

> ... it will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation. We will continue to accept providers into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law. (emphasis added)

In addition, the OIG establishes a minimum settlement amount of $50,000 for anti-kickback issues accepted into the SDP following the Open Letter's publication date of March 24, 2009. The OIG confirms that it will "continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice, stated in the 2006 open letter, of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred."