

## Chapter 1805

# Hospital Incentives to Physicians

---

### Overview

---

Hospitals and physicians enter into a variety of financial relationships that can include some form of incentive compensation flowing from hospital to physician. Incentives can be based on various types of performance criteria, such as productivity, clinical outcomes or other quality-of-care data, or patient satisfaction data. These incentives can be offered in the context of employment, independent contractor relationships, or physician recruitment or retention arrangements. In all of these contexts, compliance with the anti-kickback statute is necessary. To facilitate compliance, there are several regulatory safe harbors that might apply to protect incentives. Furthermore, the Department of Health & Human Services Office of Inspector General (OIG) has retreated somewhat from its earlier stance prohibiting any gainsharing arrangement that would induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under his or her direct care.

This chapter focuses primarily on implications under the anti-kickback statute of hospital incentives to physicians. However, legal standards arising under two other areas of the Social Security Act, in addition to the anti-kickback statute, are equally significant in structuring proper financial relationships between hospitals and physicians. See *Chapter 2210, Relationships Between Physicians and Hospitals*, for treatment of the Stark law provisions addressing referrals between physicians and hospitals and civil money penalties provisions prohibiting incentives to reduce or limit services. In addition, several of the anti-kickback safe harbors relevant to hospital incentives to physicians, while mentioned in this chapter, are treated in more detail in *Tab 1400, Anti-Kickback—General Risk Areas*. Penalties for anti-kickback violations are covered in *Chapter 210, Penalties*.

Although this chapter focuses on hospital remuneration flowing to physicians, another aspect of hospital-physician financial relationships that warrants compliance attention under the anti-kickback statute—the flow of remuneration from hospital-based physicians to hospitals that are their source of business—is discussed in *Chapter 1415, Personal Services and Management Agreements*, §§ 1415.20.20.60, 1415.20.20.70.

Finally, tax-exempt hospitals should take special note that physician incentive compensation, especially for purposes of recruitment or retention, raises significant issues for the preservation of tax-exempt status. Incentives can run afoul of the tax-exemption requirements that charitable organizations be organized and operated so that no part of their net earnings inure to the benefit of any private entity or individual, and any benefit to a private entity or individual must be no more than incidental to the organization's exempt purposes. While beyond the scope of this guide, these issues bear close scrutiny by tax-exempt organizations.

---

## 1805.10 Law and Regulatory Summary

---

### 1805.10.10

#### Anti-Kickback Statute and Incentives to Physicians

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.<sup>1</sup> For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any

arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.<sup>2</sup>

In 2010, the Patient Protection and Affordable Care Act (ACA) clarified the intent that one must have to violate the anti-kickback statute. Prior to this act, the courts were split on whether one may violate this criminal statute if a defendant was not aware that his/her actions violated the law. However, the ACA amended the anti-kickback statute to state that a “person need not have actual knowledge of this section or specific

<sup>1</sup> 42 U.S.C. 1320a-7b(b).

<sup>2</sup> See, e.g., *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011); *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000); *United*

*States v. Davis*, 132 F.3d 1092 (5th Cir. 1998); *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

intent to commit a violation of this section.”<sup>3</sup> Therefore, one may be subject to the criminal and civil penalties under this act without knowing that one’s activities violated the law. The ACA also amended the anti-kickback statute to clarify that claims submitted to the federal government resulting from a violation of the statute (i.e., kickbacks) are deemed “false and fraudulent claims” and thus subject to the strict penalties of the False Claims Act (FCA).<sup>4</sup>

Patient referrals are basic to the relationship between hospitals and physicians, for the largest proportion of hospital patients are there because they were referred by treating physicians. Thus, it is no surprise that the anti-kickback statute, a major goal of which is to restrain improper incentives for referrals (see *Chapter 1405, Key Concepts and Terms*, § 1405.10.10), is implicated by financial relationships between hospitals and physicians in which some type of remuneration is exchanged.

Hospitals and physicians enter into a variety of financial relationships that can include some form of financial incentive, including:

- employment relationships;
- independent contractor relationships, including medical directorships and professional service agreements;
- physician recruitment arrangements; and
- physician retention arrangements.

Obviously, physicians should be paid fairly for their professional services. But whenever hospitals extend to physicians incentives that go beyond fair payment for professional services and federal health care program-reimbursed business is involved, the question arises whether one reason for the extra compensation is to induce referrals (see *Chapter 1405, Key Concepts and Terms*, § 1405.10.60).

Under the Medicare prospective payment system, hospitals receive a fixed reimbursement rate for each inpatient, based on the type and severity of the medical problem. To remain financially viable, a hospital must maintain a large patient base and operate at full capacity as much of the time as possible. A hospital’s need for increased business under the prospective payment system—and physicians’ ability to fulfill that need—escalate the potential for kickback violations.

In the case of employment and independent contractor relationships, the touchstones for anti-kickback statute compliance are the regulatory safe harbors for employment and personal services and management contracts (see *Applicable Safe Harbors*, § 1805.10.20).

In 1999 the OIG adopted a recruitment safe harbor (see *Practitioner Recruitment*, § 1805.10.20.30), which

applies to recruitment by hospitals in medically underserved areas (MUAs).<sup>5</sup> The safe harbor does not extend to physician retention programs; the OIG views retention programs with some suspicion (see *Retention Incentives*, § 1805.20.20.20), although it has allowed retention incentives in one limited context (see *Obstetrical Malpractice Insurance Subsidies*, § 1805.10.20.40).

In 2006, in order to advance the use of arrangements for items and services needed to help implement Medicare’s new prescription drug benefit and to improve health care quality and efficiency, the OIG adopted safe harbors for electronic prescribing and electronic health records (see *Electronic Prescribing Systems*, § 1805.10.20.50, and *Electronic Health Records Technology*, § 1805.10.20.60).

In addition to the changes resulting from the ACA that modified the text of the anti-kickback statute, this 2010 law also established Shared Savings Programs and encouraged the establishment of Accountable Care Organizations (ACOs).<sup>6</sup> Under the Shared Savings Program, “ACO participants and ACO providers/suppliers will continue to receive fee-for-service payments, and...the ACO legal entity may choose how it distributes shared savings or allocates risk among its ACO participants and its ACO providers/suppliers.”<sup>7</sup>

However, this incentive program would have created potential violations of the previous anti-kickback regulations. Therefore, the Department of Health and Human Services (HHS) created a Waiver Design Notice that would allow incentives from these programs to be distributed to physicians. Under this waiver program, HHS allows certain:

distributions of shared savings received by an ACO from CMS under the Medicare Shared Savings Program: (1) To or among ACO participants, ACO providers/suppliers, and individuals and entities that were ACO participants or ACO providers/suppliers during the year in which the shared savings were earned by the ACO; or (2) for activities necessary for and directly related to the ACO’s participation in and operations under the Shared Savings Program. [HHS] also proposed to waive certain provisions of the Federal anti-kickback statute with respect to any financial relationship between or among the ACO, ACO participants, and ACO providers/suppliers necessary for and directly related to the ACO’s participation in and operations under the Medicare Shared Savings Program that implicates the Physician Self-Referral Law and fully complies with an exceptions (to the general referral prohibitions contained in 42 C.F.R. §§ 411.355 through 411.357).<sup>8</sup>

<sup>3</sup> Pub. L. No. 111-148, § 6402(f)(2), 124 Stat 119 (2010); 42 U.S.C. 1320a-7b(h).

<sup>4</sup> 31 U.S.C. §§ 3721 et seq.

<sup>5</sup> Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (Nov. 19, 1999).

<sup>6</sup> Section 1899 of the Social Security Act, 42 U.S.C. 1395jjj.

<sup>7</sup> 76 Fed. Reg. 67,992, 67,994 (Nov. 2, 2011).

<sup>8</sup> 76 Fed. Reg. at 67,995.

**1805.10.20****Applicable Safe Harbors**

Failure to comply with an anti-kickback safe harbor does not automatically result in a violation of the anti-kickback statute. If an arrangement does not qualify for all of the elements of a safe harbor, the OIG will evaluate the facts and circumstances of the transaction to determine whether the arrangements involve improper intent or are otherwise abusive. However, to ensure compliance with the statute, the OIG has established several safe harbors.

**1805.10.20.10****Employment**

Payments by an employer to bona fide employees are protected from anti-kickback liability by a statutory exception for employment relationships.<sup>9</sup> Under the exception, “employee” includes all persons considered employees for federal employment tax purposes. Payments to bona fide physician-employees, including commissions or other bonuses for business generation, fall within this employment exception (see *Chapter 1430, Marketing Practices*, §§ 1430.10.20.20, 1430.20.20.20).

An arrangement that complies with the employee safe harbor of the anti-kickback statute is described in OIG Advisory Opinion No. 08-22.<sup>10</sup>

**1805.10.20.20****Personal Services and Management Contracts**

As independent contractors, physicians routinely interact with hospitals in a variety of arrangements (see *Chapter 1415, Personal Services and Management Agreements*, § 1415.20.10). The best way to avoid kickback concerns in independent contractor arrangements between hospitals and physicians is to comply fully with the requirements set forth in the personal services and management contracts safe harbor. To satisfy this safe harbor the agreement must meet the following standards:

- the agency agreement is set out in writing and signed by the parties;
- the agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent;
- if the agency agreement is intended to provide for the services of the agent on a periodic, sporadic, or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement must specify exactly the schedule of such intervals, their precise length, and the exact charge for such intervals;

- the term of the agreement is for not less than one year;
- the aggregate compensation paid to the agent over the term of the agreement is set in advance, is 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 may be made in whole or in part under Medicare, Medicaid, or other federal health care programs;
- the services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law; and
- the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.<sup>11</sup>

The standard that requires the aggregate compensation be “set in advance” rules out the payment of incentives based on performance. However, as previously mentioned, failing to comply with a safe harbor does not mean that performance-based incentives are *per se* illegal under the anti-kickback statute, but it does mean that arrangements must be evaluated carefully for anti-kickback statute compliance on a case-by-case basis (see *Chapter 1405, Key Concepts and Terms*, § 1405.20.30). The mere appearance that payments vary with the volume of program-covered referrals makes an arrangement suspect (see *Chapter 1415, Personal Services and Management Agreements*, § 1415.20).

The Stark law also has a personal services exception that requires compensation to be set in advance, but has no “aggregate compensation set in advance” requirement. This provides the ability to make payments on a “per unit” basis (e.g., hourly) so long as they are not based on the volume or value of referrals. The personal services exception excludes some physician incentive plans from the “volume or value” limitation.

**1805.10.20.30****Practitioner Recruitment**

As part of the OIG’s 1999 safe harbor revisions,<sup>12</sup> a safe harbor for practitioner recruitment was created to address the difficulties some communities have attracting physicians.<sup>13</sup> This safe harbor was designed to encourage practitioner relocation to underserved areas without protecting abusive arrangements intended to channel federal program beneficiaries to recruiting hospitals and other entities.<sup>14</sup> Thus, the safe harbor applies only to recruitment of practitioners whose primary

<sup>9</sup> Social Security Act § 1128B(b)(3)(B) [42 U.S.C. § 1320a-7b(b)(3)(B)]; 42 C.F.R. § 1001.952(i).

<sup>10</sup> OIG, Advisory Op. No. 08-22 (Dec. 15, 2008).

<sup>11</sup> 42 C.F.R. § 1001.952(d).

<sup>12</sup> 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 (Nov. 19, 1999).

<sup>13</sup> 42 C.F.R. § 1001.952(m).

<sup>14</sup> Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. at 63,541.

place of practice will be located in an area, whether urban or rural, that is designated a Health Professional Shortage Area (HPSA) for the physician's specialty area by the Health Resources and Services Administration in accordance with 42 C.F.R. pt. 5. Currently HHS only recognizes HPSAs for the specialty areas of primary health care, dental health care, and mental health care. As a result, recruitment incentives for any other physician practicing in a different specialty area will not fall completely within the protection of this safe harbor.

As a general rule, the OIG noted, "remuneration to physicians, including recruitment, should be consistent with fair market value for necessary services rendered by the physician." The safe harbor, the OIG said, "protects certain payment practices that may depart from this general rule if particular criteria established by the safe harbor are met."<sup>15</sup> The payment practices in question are not enumerated in the safe harbor; the rule simply exempts "any payment or exchange of anything of value" when nine specific standards are met. The safe harbor is available to any type of health care entity, not just hospitals.

For discussion of the standards set forth in the safe harbor and the compliance issues involved, see *Practitioner Recruitment*, § 1805.20.30.10.

#### 1805.10.20.40

##### **Obstetrical Malpractice Insurance Subsidies**

Another safe harbor protects malpractice insurance subsidies offered to physicians or certified nurse-midwives who routinely practice obstetrics in a primary care Health Professional Shortage Area.<sup>16</sup> To protect such subsidies paid by hospitals and other entities from the reach of the anti-kickback statute, this safe harbor requires that the:<sup>17</sup>

- payment agreement be in writing;
- practitioner certify that, for the initial coverage period (not exceeding one year), he or she has a reasonable basis to believe that at least 75 percent of the patients treated under coverage of the malpractice policy will reside in a defined HPSA (or Medically Underserved Area or be part of a Medically Underserved Population, as defined by HHS regulations);
- benefits not be conditioned on the practitioner's generating business for the entity paying the subsidy;
- practitioner not be restricted from establishing staff privileges at, or making referrals to, any other entity of his or her choosing;

- amount of the subsidy payment not vary based on the volume or value of referrals of federal or state health care business;
- practitioner not unfairly discriminate against or among federal health care program beneficiaries; and
- insurance be a bona fide malpractice insurance policy or program, and the premium, if any, must be calculated based on a bona fide assessment of the liability risk.

CMS's 2009 Final Hospital Inpatient Prospective Payment Systems rule added 42 C.F.R. § 411.357(r)(2), an alternative to the Stark law exception at 42 C.F.R. § 411.357(r)(1). Under this alternative method of compliance, hospitals, federally qualified health centers, and rural health clinics may qualify for a compensation arrangement for obstetrical malpractice insurance subsidies without meeting conditions set forth in the comparable anti-kickback safe harbor, as 42 C.F.R. § 411.357(r)(1) requires. Subsection (r)(2), however, places strict parameters on provision of the subsidies.

#### 1805.10.20.50

##### **Electronic Prescribing Systems**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a prescription drug benefit in the Medicare program and directed the OIG to promulgate an anti-kickback safe harbor to protect arrangements for electronic prescribing items and services needed to help implement this benefit.<sup>18</sup> The MMA also directed the Centers for Medicare & Medicaid Services to promulgate a comparable exception to the physician self-referral statute (Stark law) (see *Chapter 2210, Physician Financial Relationships*, § 2210..20.10.110). The goal of these protections, effective Oct. 10, 2006, is to enable providers to receive and transmit electronic prescription information in accordance with standards established for the Medicare Part D drug program.

In promulgating the mandated safe harbor, the OIG said in the preamble to the regulation that it did not believe Congress "intended to suggest that a new safe harbor is needed for all or even most arrangements involving the provision of electronic prescribing items and services."<sup>19</sup> The OIG noted that arm's-length, fair-market value arrangements that do not take referrals into account and are not intended to generate federal health care program business should not raise kickback concerns. It also stated that many arrangements can be structured to fit within other safe harbors, including the safe harbors for remuneration offered to employees and

<sup>15</sup> 64 Fed. Reg. at 63,545.

<sup>16</sup> "Certified nurse-midwife," as defined in Social Security Act § 1861(gg)(2) [42 U.S.C. § 1395x], is a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the secretary of the Department of Health & Human Services (HHS), or has been certified by an organization recognized by the secretary.

<sup>17</sup> 42 C.F.R. § 1001.952(o).

<sup>18</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101, enacting Social Security Act § 1860D-4(e)(6) [42 U.S.C. § 1395w-104(e)(6)].

<sup>19</sup> Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45,110, 45,111 (Aug. 8, 2006).

discounts (see *Employment*, § 1805.10.20.10, and *Chapter 1420, Discounts and Free Items*).<sup>20</sup>

In drafting the regulations, the OIG and CMS said they endeavored “to ensure as much consistency as possible” between the anti-kickback safe harbor and the corresponding Stark exception, given the differences in the underlying statutes.<sup>21</sup> The resulting anti-kickback safe harbor and Stark exception impose virtually identical conditions for protection.

The safe harbor protects “nonmonetary remuneration” (items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information provided by: 1) a hospital to a physician who is a member of its medical staff; 2) a group practice to a prescribing health care professional who is a member of the group practice; or 3) a prescription drug program sponsor or Medicare Advantage organization to its participating pharmacists and pharmacies and prescribing health care professionals.<sup>22</sup>

For a discussion of the standards set forth in the safe harbor and the compliance issues involved, see *Safe Harbor Compliance Electronic Prescribing Systems*, § 1805.20.30.40.

Technology to be covered includes broadband and wireless internet connectivity, training, information technology support services, as well as other items and services used in connection with the transmission or receipt of electronic prescribing information. Thus, licenses, rights of use, intellectual property, upgrades, and educational and support services (including, e.g., help desk and maintenance services), as well as patches designed to link the donor’s existing electronic prescribing system to the recipient’s existing electronic prescribing system and software necessary for the hardware to operate may qualify for safe harbor protection. However, billing, scheduling, administrative, and other general office software, as well as technology for personal, non-medical purposes and the provision of office staff, do not.<sup>23</sup>

The OIG also adopted a broad definition of qualifying “prescription information.” Because “prescription information” means “information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription,”<sup>24</sup> technology used to transmit prescriptions for certain non-drug items and services, e.g., durable medical equipment or laboratory tests, may be covered technology, it said.<sup>25</sup>

The statutory requirement that the items and services be “used solely to receive and transmit electronic prescription information” is strictly interpreted to safeguard against abusive arrangements in which donated

technology might have additional value attributable to uses other than electronic prescribing that might be a payment for referrals, the OIG said.<sup>26</sup> Therefore, software that bundles general office management, billing, scheduling, electronic health records, or other functions with the electronic prescribing features would not meet the “used solely” requirement and would not be protected.

The OIG also noted that the provision of bundled software may be eligible for the electronic health records safe harbor (see *Electronic Health Records Technology*, § 1805.10.20.60).

The MMA specifically provided for preemption of state law by the federal electronic prescribing standards, but contained no similar mandate for preemption by the safe harbor for the donation of electronic prescribing technology.<sup>27</sup>

### 1805.10.20.60

#### *Electronic Health Records Technology*

Concurrently with its publication of a final rule on the electronic prescribing safe harbor, the OIG promulgated rules for an anti-kickback safe harbor for arrangements involving the provision of interoperable electronic health records technology and training services. Such protection is needed to promote the use of EHR technology to improve quality of care, patient safety, and health care efficiency, despite the substantial fraud and abuse risks associated with gifts of valuable goods and services to referral sources, the OIG said.<sup>28</sup>

The EHR anti-kickback safe harbor protects non-monetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records provided to an individual or entity engaged in the delivery of health care.<sup>29</sup> The EHR safe harbor applies a “used predominately” standard instead of the “used solely” standard the MMA mandated for the electronic prescribing safe harbor.

Another significant difference between the safe harbors is that the EHR safe harbor extends protection to a broader range of donors and recipients, protecting any health plan donor and any individual or entity donor “that provides services covered by a federal health care program and submits claims or requests for payment, either directly or through reassignment, to the federal health care program.”<sup>30</sup> The OIG said it views this approach as a bright line test focused on individuals and entities in the best position to advance the implementation of EHR adoption through participation in interoperable EHR systems.

<sup>20</sup> *Id.* at 45113.

<sup>21</sup> 71 Fed. Reg. at 45140.

<sup>22</sup> 42 C.F.R. § 1001.952(x)(1).

<sup>23</sup> Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. at 45,116-45,117.

<sup>24</sup> 42 C.F.R. § 1001.952(x), note.

<sup>25</sup> Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. at 45,117.

<sup>26</sup> 71 Fed. Reg. at 45,115.

<sup>27</sup> 71 Fed. Reg. at 45,114.

<sup>28</sup> 71 Fed. Reg. at 45,133.

<sup>29</sup> 42 C.F.R. § 1001.952(y)(1).

<sup>30</sup> *Id.*

In developing the rule, the OIG said it attempted to craft an approach as consistent as possible with that taken by CMS in drafting the comparable Stark law exception, starting with basic definitions used in both the anti-kickback and Stark protections for electronic prescribing and EHR arrangements.

“Electronic health record” means a “repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.”<sup>31</sup> The broad definition is consistent with the government’s goal of encouraging widespread adoption of EHR technology.<sup>32</sup>

“Interoperable” means “able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.”<sup>33</sup>

On October 6, 2015, the OIG released a policy reminder regarding the conditions that must be met for the EHR anti-kickback safe harbor to apply and emphasized their commitment to investigating potentially abusive arrangements that do not actually meet the requirements of the EHR safe harbor.<sup>34</sup>

---

## 1805.20 Industry Compliance Guidelines

---

### 1805.20.10

#### General Principles

There are certain principles concerning hospital payments to physicians that reflect the demands of the anti-kickback statute, and also are consistent with Stark law requirements and Internal Revenue Code tax-exemption criteria. These principles should be applied as an initial step in determining the compliance of any existing or proposed financial relationship between hospitals and physicians, including hospital incentive arrangements with physicians.

In general, any financial relationships between hospitals and physicians should be assessed against the following criteria:

- *Fair Market Value.* Does the amount of compensation reflect the fair market value for services rendered? Fair market value is the amount for which a property or service would change hands between a willing buyer and seller, neither being under any compulsion to buy or sell and both having reasonable knowledge of the facts.
- *Reasonable Compensation.* Is the amount of compensation commercially reasonable based on relationships between similarly situated parties?
- *Compensation Not Related to Referrals.* Is the amount of compensation totally unrelated to the volume or value of referrals or any other form of business generated between the parties?

In evaluating hospital incentives to physicians, these basic guidelines can be used as a litmus test to make a preliminary determination of the legality of the existing or proposed arrangement. A “yes” answer to all three questions goes a long way toward assuring legal compliance, although, where an anti-kickback safe harbor is concerned, complete compliance with the safe harbor’s terms is the safest approach. If the answer to any of the

questions is “no,” or is at all difficult to ascertain, the arrangement warrants careful scrutiny by legal counsel.

### 1805.20.20

#### Suspect Practices Identified by the OIG

##### 1805.20.20.10

#### *Recruitment Incentives*

In May 1992, the OIG published a special fraud alert that addressed hospital recruitment incentives to physicians. The alert reported that a variety of arrangements, resulting either in reductions in the physician’s professional expenses or an increase in his or her revenues, were being used to compensate physicians for patient referrals. The OIG expressed concern over the negative impact such conduct could have on the quality of patient care:

These incentive programs can interfere with the physician’s judgment of what is the most appropriate care for the patient. They can inflate costs to the Medicare program by causing physicians to overuse inappropriately the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute care facility) offering the best or most appropriate care for that patient.<sup>35</sup>

According to the alert, a hospital engages in suspect incentive practices if it offers or provides a physician:<sup>36</sup>

- payment of any sort for each patient referred to the hospital;
- free or significantly discounted office space or equipment;

<sup>31</sup> 42 C.F.R. § 1001.952(y), note.

<sup>32</sup> Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. at 45,122.

<sup>33</sup> 42 C.F.R. § 1001.952(y), note.

<sup>34</sup> OIG Policy Reminder: Information Blocking and the Federal Anti-Kickback Statute

<sup>35</sup> OIG Special Fraud Alert: Hospital Incentives to Physicians (May 1992), reprinted at 59 Fed. Reg. 65,372, 65,375 (Jan. 19, 1994).

<sup>36</sup> 59 Fed. Reg. 65,376.

- free or significantly discounted billing, nursing, or other staff services;
- free training for the physician's office staff;
- a guarantee that, if the physician's income fails to reach a predetermined level, the hospital will supplement the remainder;
- low-interest or interest-free loans, or loans that can be forgiven if a physician refers patients to the hospital;
- payment of the cost of the physician's travel and expenses for conferences;
- payment for the physician's continuing education courses; or
- coverage under the hospital's group health insurance plans at an inappropriately low cost.

Financial incentive packages that incorporate these or similar features might be subject to prosecution under the anti-kickback statute if one purpose is to influence the physician's medical decision as to where to refer patients for treatment.

The concern expressed in the fraud alert has not lessened over time. When the safe harbor for physician recruitment in medically underserved areas was issued in 1999, the OIG was not prepared to expand the safe harbor by protecting practitioner recruitment across the board. Experience "over the past few years has shown that practitioner recruitment is an area frequently subject to abusive practices," the OIG said.<sup>37</sup>

A number of judicial proceedings between private parties have identified serious anti-kickback issues in physician recruitment arrangements (see *Court Rulings*, § 1805.30.30).

One such case, *Feldstein v. Nash Community Health Services*,<sup>38</sup> raises an important caveat, in that the recruitment agreement there expressly denied that there was any obligation to refer patients, yet the language was found to be potentially problematic anyway. The agreement stated that "the compensation which you are to receive is not conditional on the use of any item or service offered by the Hospital." Nonetheless, the court held that whether the contract violated the anti-kickback statute was an issue of fact to be decided by a jury. The court's ruling was based on its finding of ambiguity in the contract language that directly preceded the clause denying a referral obligation, which stated, "You [the physician] recognize that Hospital is a convenient acute care medical facility for the majority of patients likely to utilize your services for medical treatment and . . . has excellent facilities and treatment capabilities." The case sends a signal that recruitment

agreement language, to avoid trouble, should not even indirectly encourage referrals.

### 1805.20.20.20

#### **Retention Incentives**

In addition to attracting new physicians, hospitals often persuade employed physicians or physicians who regularly admit patients to continue their existing relationship with the hospital. Retention incentives must be approached with particular caution, since the physician recruitment safe harbor does not extend to such arrangements. The OIG warned in its 1999 preamble to the safe harbor that "[b]ecause of the increased risk of kickbacks [in an ongoing relationship where referrals are already occurring], payments for retention purposes require closer scrutiny than initial recruitment payments." However, the OIG has protected retention incentives in one limited context (see *Obstetrical Malpractice Insurance Subsidies*, § 1805.10.20.40). In addition, a general physician retention safe harbor might be the subject of future rulemaking, the OIG said.<sup>39</sup>

In addition, the OIG has indicated that hospitals may, under certain limited circumstances, provide for loan forgiveness of an income guarantee provided through a recruitment incentive, if the physician continues to remain in a certain geographic area for a period of three years.<sup>40</sup>

### 1805.20.20.30

#### **Gainsharing**

The OIG has historically applied a strict prohibition on "gainsharing" agreements in the context of personal services and management contracts. Under such an agreement, a hospital might give independent contractor-physicians providing clinical services to hospital patients a share of the cost savings attributable to the physicians' efforts. Such arrangements—when they affect services delivered to Medicare or Medicaid patients on a fee-for-service basis—are unlawful under the civil money penalties (CMP) provisions that proscribe inducements to limit or withhold health care services, according to the OIG.<sup>41</sup>

However, the OIG's apparent position is that the CMP provisions in question would not apply to incentives paid to physicians who function in a management or supervisory capacity with respect to the operation of a hospital department, provided that the purpose is to encourage departmental efficiency. The OIG, in commenting on proposed rules in 1994, cited Congress' belief that such incentives were allowable from a CMP perspective if they encouraged efficiency in the operation of a specific department and did not affect direct

<sup>37</sup> 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, 63,543 (Nov. 19, 1999) (§ II.C.4).

<sup>38</sup> *Feldstein v. Nash Community Health Servs.*, No. 5:97-CV-522-BR-3 (E.D.N.C. memorandum and order March 16, 1999).

<sup>39</sup> Safe Harbor Clarifications and Additions, 64 Fed. Reg. at 63,543 (§ II.C.4).

<sup>40</sup> OIG, Advisory Op. No. 01-04 (May 3, 2001).

<sup>41</sup> 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), *interpreting* Social Security Act § 1128A(b) [42 U.S.C. § 1320a-7a(b)].

patient care responsibilities. “We believe, for example, there may be certain types of hospital incentive plans to physicians, such as those designated to reward the timely review and completion of medical records which do not impact on direct patient care responsibilities or do not affect patient referral patterns, that may be acceptable and therefore not be subject to civil money penalties under this provision,” the OIG said.<sup>42</sup>

Furthermore, in a January 2001 advisory opinion, the OIG appeared to reverse a long-standing position that gainsharing arrangements “contain common elements” that make them uniformly unacceptable, finding that a proposed gainsharing arrangement between a hospital and a group of cardiac surgeons would not trigger administrative sanctions.<sup>43</sup> In addition, the OIG indicated a willingness to exercise discretion and protect some such arrangements, if it finds them “medically appropriate” after applying its own standards and review process.<sup>44</sup>

In February 2005, the OIG again addressed the issue of physician cost-saving arrangements in a series of opinions that fine-tuned and expanded on its 2001 advisory opinion (No. 01-01), approving the important cost-saving option of standardizing medical devices used by physicians.<sup>45</sup> In these opinions, the OIG determined that certain arrangements would not be subject to sanctions if they include features that safeguard against fraud and abuse. In addition, in 2008 the OIG released two more opinions that again allowed gainsharing arrangements between a hospital and a group of cardiac surgeons and anesthesiologists that had exclusive relationships with the hospitals.<sup>46</sup> As a result of this and similar opinions (see *Physician Cost-Sharing*, § 1805.20.40.30), obtaining a favorable OIG determination through the advisory opinion process before implementing a gainsharing program seems essential.

After a hiatus from addressing the gainsharing issue, in January 2018, the OIG discussed the issue of physician cost-saving arrangements in an advisory opinion<sup>47</sup> approving an arrangement under which a group of neurosurgeons agreed to implement cost-reduction measures in designated surgical procedures performed at a medical center in exchange for the medical center sharing a percentage of its subsequent savings. The OIG determined that the protocol used to develop the cost-saving recommendations, the monitoring and documentation safeguards, and the methodology used to calculate each performance year’s savings seemed reasonable. It concluded that these features, taken together, reduce the risk that payments made by the medical

center to the surgeons would induce the surgeons to reduce or limit medically necessary services to their Medicare or Medicaid patients.

The OIG emphasized that gainsharing arrangements often encourage physicians to admit patients to participating hospitals because the physicians may receive a share of the cost-savings. Here, however, the OIG concluded that the safeguards put in place mitigate any incentives that the surgeons would have to refer patients to the medical center. The OIG elaborated on several other safeguards the arrangement has in place to reduce the risk of violation of the anti-kickback statute, including annual rebasing and limitation to a single physician group.

For a full discussion of gainsharing, see *Chapter 2210, Relationships Between Physicians and Hospitals*, § 2210.20.40.

### 1805.20.30

#### Safe Harbor Compliance

##### 1805.20.30.10

#### *Practitioner Recruitment*

Protection by the anti-kickback safe harbor for physician recruitment arrangements depends on careful adherence to its requirements and recognition that it is limited in many respects.<sup>48</sup> To achieve safe harbor protection, a recruitment arrangement must satisfy nine express conditions enumerated in the safe harbor regulation. These are as follows:

- *Written Agreement.* The arrangement must be set forth in a written, signed agreement that specifies the benefits and obligations involved.
- *Practitioners Affected.* The safe harbor addresses incentives for a new practitioner (one who has been practicing in the specialty for less than one year) or a relocating practitioner, and thus does not extend to retention incentives.
- *Specialty Areas.* A major limitation is that a practitioner can be induced to locate or relocate only into an area designated as a Health Professional Shortage Area for his or her specialty. HPSAs currently are designated by HHS only for the specialties of primary care, dentistry, and mental health.<sup>49</sup> Thus, protection is denied to recruiting arrangements that involve specialists such as neurologists, gastroenterologists, or cardiovascular surgeons.
- *Referrals.* A recruitment arrangement cannot require that the recruited practitioner generate

<sup>42</sup> Civil Money Penalties for Hospital Physician Incentive Plans, 59 Fed. Reg. 61,571, 61,573 (Dec. 1, 1994) (§ I.I.B.2).

<sup>43</sup> OIG, Advisory Op. No. 01-01 (Jan. 18, 2001).

<sup>44</sup> Inspector General Opens the Door to Hospital Gainsharing Arrangements, 5 *BNA’s Health Care Fraud Rep.* 135 (Feb. 7, 2001).

<sup>45</sup> OIG, Advisory Op. Nos. 05-01 (Feb. 4, 2005), 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).

<sup>46</sup> OIG, Advisory Op. Nos. 07-21 and 07-22, (Jan. 7, 2008).

<sup>47</sup> OIG, Advisory Op. No. 17-09 (Dec. 29, 2017).

<sup>48</sup> 42 C.F.R. § 1001.952(n). For the OIG’s commentary, see *Safe Harbor Clarifications and Additions*, 64 Fed. Reg. at 63,541-63,545 (§ I.I.C.4).

<sup>49</sup> *Safe Harbor Clarifications and Additions*, 64 Fed. Reg. at 63,531 (§ I.I.C.1).

business for the recruiting entity, and the amount or value of benefits provided cannot vary, be adjusted, or be renegotiated in any manner based on volume or value of expected referrals. However, the OIG said that income guarantees, a form of recruitment incentive, do not offend these requirements if the maximum guarantee amount and formula for determining payment are set in advance, formula is not tied to volume or value of referrals, and guarantee is not subject to renegotiation.

- *Staff Privileges.* The recruiting entity can require that a practitioner maintain staff privileges, but cannot restrict the practitioner from establishing staff privileges at (or making referrals to) any other entity of his or her choosing. The OIG elaborated, “A hospital may not condition recruitment payments on aggregate admissions by the practitioner, nor may it require a recruited practitioner to admit a proportionate share of his or her patients to the hospital. A hospital may impose conditions intended to ensure quality of patient care, such as requiring that a physician have performed a minimum number of a particular type of procedure before performing the procedure at the hospital.”
- *Patients Served.* At least 75 percent of the new practice revenues must be generated from patients residing in a HPSA or Medically Underserved Area, or who are members of a Medically Underserved Population (as defined in HHS regulations). In addition, if the practitioner is leaving an established practice, at least 75 percent of the new practice revenues also must be generated from patients not previously served by the practitioner. The OIG said that parties to recruitment arrangements can use any reasonable method to calculate the percentages, provided they use the same principles consistently over time and avoid manipulating data to obscure noncompliance.
- *Three-Year Term.* Recruitment incentives under the safe harbor can be provided for a period of not more than three years, as long as the terms of the agreement are not renegotiated during that period in any substantial aspect, such as payments or benefits promised to recruited practitioners. (If the HPSA into which the practitioner was recruited ceases to be a HPSA during this period, the recruitment arrangement will not lose its safe harbor protection.) The OIG did not extend protection for an unlimited duration because, “[t]he risk of kickbacks is mitigated when payments are made to new or relocating physicians who do not have established referrals streams that can be locked up through inappropriate incentives and loyalties.”

- *Joint Recruiting Efforts.* The safe harbor extends no specific protection to joint recruiting arrangements—involving, for example, payments from hospitals to group practices or solo practitioners to assist the group practice or solo practitioner in recruiting a new physician. While recognizing potential benefits of joint recruiting efforts, the OIG also said that “these arrangements can be used to disguise payments for referrals from the group practice or solo practice to the hospital.” The OIG concluded, “joint recruitment arrangements are not necessarily illegal and must be evaluated on a case-by-case basis”—through an advisory opinion, if the parties wish. Parties considering joint recruiting must comply with the requirement that the payment or exchange of anything of value not directly or indirectly benefit any entity or person (other than the practitioner being recruited) in a position to make or influence referrals of program-related business to the recruiting entity. This test clearly denies safe harbor protection to a hospital that provides a group practice or an employer-physician with an incentive to recruit a physician, such as guaranteeing a level of income with respect to the new physician.
- *Nondiscrimination Requirement.* The safe harbor requires that the recruited practitioner “agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.” According to the OIG, this test does not require recruited practitioners to become participating providers in the Medicare and Medicaid programs. “However, if they participate in any federal health care program, they must treat all program beneficiaries in a nondiscriminatory manner,” the OIG said.

#### 1805.20.30.20

##### ***Obstetrical Malpractice Insurance Subsidies***

The safe harbor protecting obstetrical malpractice insurance subsidies in underserved areas in large part tracks the requirements of the practitioner recruitment safe harbor.<sup>50</sup>

The subsidy safe harbor protects practitioners who provide substantial and regular obstetrical services; it does not protect subsidies for those who practice obstetrics only occasionally. A practitioner does not have to be a full-time obstetrician or certified nurse-midwife, though, and a practitioner can practice part-time in a HPSA (spending, for example, several days in an inner-city clinic) and part-time elsewhere. The safe harbor covers subsidies for that portion of an insurance premium that is reasonably allocable to obstetrical services provided in a HPSA.

A group practice that provides obstetrical malpractice insurance subsidies can qualify as an “entity” for

<sup>50</sup> 42 C.F.R. § 1001.952(o). For the OIG’s commentary, see 64 Fed. Reg. at 63,545 (§ ILC.5).

safe harbor purposes if the subsidy agreement satisfies all safe harbor criteria, the OIG said.

The OIG said the safe harbor should not be interpreted as calling into question the legality of other types of malpractice insurance subsidies, which might qualify for protection under the practitioner recruitment, personal services contracts, or employment safe harbors. For example, the OIG has allowed subsidies for malpractice insurance for physicians practicing in specialties other than obstetrics.<sup>51</sup> At the same time, the OIG said, malpractice insurance subsidies paid to or on behalf of potential referral sources outside of a safe harbor might be suspect and should be evaluated on a case-by-case basis.

### 1805.20.30.30

#### *Malpractice Insurance Premium Subsidies*

In a Jan. 15, 2003, letter,<sup>52</sup> the OIG responded to a hospital association's request for its views regarding a medical malpractice insurance assistance program. The hospital association was proposing to provide temporary assistance in obtaining professional liability insurance to physicians on its hospitals' medical staffs in Florida, Nevada, Texas, and West Virginia, arrangements the association said were necessary to forestall disruption in the provision of medical services in these states.

The OIG advised the association to request an advisory opinion, however, it also provided some guidance. It cited the subsidy safe harbor for practitioners who provide substantial and regular obstetrical services (see *Obstetrical Malpractice Insurance Subsidies*, § 1805.10.20.40), and said that, depending on the circumstances, malpractice premium support also could fit into the employee or physician recruitment safe harbors at 42 C.F.R. §§ 1001.952(i), (n). It also reminded the association that payment practices that do not fall within the ambit of a safe harbor do not necessarily violate the anti-kickback statute.

The OIG added that, being well aware of the current disruption in the medical malpractice liability insurance markets in some states, it certainly would exercise its enforcement discretion to take the problem into account in evaluating temporary financial arrangements designed to help assure continued access to care for federal health care beneficiaries.

Addressing the specifics of the association's proposal, the OIG said the arrangement exhibited a number of safeguards:

- it would be provided on an interim basis for a fixed period (although it could be extended if economic conditions required it) in states experiencing severe access or affordability problems;
- only current active medical staff (or physicians joining the medical staff who are new to the local-

ity or have been in practice for less than one year) would be eligible;

- criteria for receiving assistance would not be related to the volume or value of referrals or other business generated;
- physicians receiving assistance would pay at least as much as they currently pay for malpractice insurance;
- participating physicians would be required to perform services for the hospital association and give up certain litigation rights and the value of such services and relinquished rights would be equal to the fair market value of the insurance assistance; and
- assistance would be available regardless of the location at which the physicians provide services, including, but not limited to, other hospitals.

Finally, the OIG reminded the association that it has only limited jurisdiction with respect to the anti-kickback and the Stark II statutes since the Department of Justice has independent anti-kickback jurisdiction and the Centers for Medicare and Medicaid Services has primary jurisdiction over Stark II. Accordingly, it said the association should contact them directly to solicit their views.

### 1805.20.30.40

#### *Electronic Prescribing Systems*

Under this anti-kickback safe harbor, hospitals and other permissible donors may give electronic prescribing items and services to certain physicians and other health care providers provided the following conditions are met:<sup>53</sup>

- The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.
- The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems.
- For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.
- Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.

<sup>51</sup> See OIG, Advisory Op. No. 04-19, (Jan. 6, 2005) (allowing an insurance subsidy arrangement between a hospital and two neurosurgeons.)

<sup>52</sup> Letter from Lewis Morris, chief counsel, OIG, to [recipient redacted] (posted Jan. 16, 2003).

<sup>53</sup> 42 C.F.R. § 1001.952(x).

- Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties (see *Selecting Recipients* below).
- The arrangement is set forth in a written agreement that: 1) is signed by the parties, 2) specifies the items and services being provided and the donor's cost of the items and services, and 3) covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). This requirement is met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by HHS upon request. The master list should be maintained in a manner that preserves the historical record of agreements.
- The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.

In discussing the requirement that the recipient not already possess “equivalent” items and services, the OIG reiterated its view that providing such redundant items and services poses a heightened risk of abuse, adding, “we do not believe items and services are ‘necessary’ for electronic prescribing if the recipient already possesses equivalent items or services.”<sup>54</sup> Because donors who provide technology knowing a recipient already has equivalent technology, or who act in deliberate disregard of that fact, will not be protected by the safe harbor, the OIG cautioned that “prudent donors may want to make reasonable inquiries of potential recipients and document the communications.”

#### 1805.20.30.50

##### *Electronic Health Records Technology*

In the preamble to the rule establishing the EHR safe harbor, the OIG provided guidance on the scope of its protection by giving various examples.<sup>55</sup>

**Donors.** Provisions of the safe harbor establish that all technology donations made to physicians be provided by entities furnishing designated health services and certain other specified entities.

*Examples of protected donors:* Hospitals, group practices, physicians, nursing and other facilities, pharmacies, laboratories, oncology centers, community health centers, federally qualified health centers, dialysis facilities, health plans,<sup>56</sup> and ancillary services providers and suppliers.

*Examples of donors not protected:* Pharmaceutical, device, or durable medical equipment manufacturers, or other manufacturers or vendors that indirectly furnish items and services used in the care of patients.

**Recipients.** Protected recipients are any “individual or entity engaged in the delivery of health care.” The final rule permits donations without regard to whether the recipient is on a medical staff, is a member of a group practice, or is in a network of a PDP sponsor or MA organization. Protected recipients include practitioners, providers, and suppliers that furnish services directly to federal health care program beneficiaries and health plan enrollees.

*Examples of protected recipients:* Physicians, group practices, physician assistants, nurse practitioners, nurses, therapists, audiologists, pharmacists, nursing and other facilities, federally qualified health centers and community health centers, laboratories and other suppliers, and pharmacies.<sup>57</sup>

*Selecting Recipients:* The EHR safe harbor allows donors to use selective criteria for choosing recipients, provided that neither the eligibility of a recipient, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. This contrasts with other anti-kickback safe harbors due to what the OIG called the “unique public policy considerations”<sup>58</sup> surrounding EHR and the government’s desire to encourage the adopting of interoperable systems.

The safe harbor deems certain selection criteria “not to directly take into account the volume or value of referrals or other business generated between the parties.” Donations are protected if the selection of the recipient is determined based on:<sup>59</sup>

- total number of prescriptions written by a recipient (but not the number or value of prescriptions dispensed or paid by the donor, or billed to a federal program);
- size of the recipient’s medical practice (e.g., total patients, patient encounters, or relative value units);
- total number of hours the recipient practices medicine;
- recipient’s overall use of automated technology in the medical practice (without specific reference to use of technology in connection with referrals to the donor);
- whether the recipient is a member of the donor’s medical staff; or
- level of uncompensated care the recipient provides.

<sup>54</sup> 71 Fed. Reg. at 45,116. Upgrades of equipment or software may meet the “necessary” standard.

<sup>55</sup> 71 Fed. Reg. at 45,128.

<sup>56</sup> Including health plans defined in 42 C.F.R. § 1001.952(l)(2), the existing safe harbor for certain managed care arrangements.

<sup>57</sup> Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. at 45,129.

<sup>58</sup> 71 Fed. Reg. at 45,130.

<sup>59</sup> 42 C.F.R. §§ 1001.952(y)(5)(i)-(vi).

**Technology.** To ensure that the safe harbor is available only for software, information technology, and training services closely related to EHR, the OIG drafted the safe harbor to require that: 1) EHR functions be predominant; 2) the core functionality of the technology is the creation, maintenance, transmission, or receipt of individual patients' EHR; and 3) donated technology include an electronic prescribing component.<sup>60</sup> The safe harbor also protects arrangements involving software packages that include other functionality related to the care and treatment of individual patients (e.g., patient administration, scheduling functions, billing, and clinical support), reflecting the fact that it is common in the marketplace for EHR software to be integrated with other features.

There is no limit on the value of protected technology that may be donated, but software must be interoperable at the time it is donated<sup>61</sup> and the recipient of the technology must pay at least 15 percent of the donor's cost for the items and services before receiving the technology.<sup>62</sup> All donated software and health information technology and training services are subject to the cost-sharing requirement. Upgrades included in the initial purchase price of the technology do not trigger additional cost-sharing responsibilities when the recipients receive them. To ensure the legitimacy of the cost-sharing obligation, the safe harbor rule prohibits the donor (or any affiliated individual or entity) from financing the recipient's costs through payments or loans.

The OIG said that, depending on the circumstances, a differential in the amount of cost sharing a donor imposes on various recipients might give rise to an inference that an arrangement is directly related to the volume or value of referrals or other business generated between the parties, thus rendering the arrangement ineligible for safe harbor protection. Therefore, the reason and basis for the differential should be closely scrutinized.<sup>63</sup>

The OIG also offered a caution related to the donation of internally developed software and add-on modules, advising donors to use a "reasonable and verifiable method" for allocating costs and maintain contemporaneous and accurate documentation.<sup>64</sup> The OIG stated it will scrutinize cost allocation methods to ensure they do not inappropriately shift costs in a manner that provides an excess benefit to the recipient or result in the recipient's effectively paying less than 15 percent of the donor's true cost of the technology.

*Examples of protected technology:* Interface and translation software; rights, licenses, and intellectual property related to electronic health records software; connectivity services, including broadband and wireless internet services; clinical support and information services related to patient care (but not separate research

or marketing support services); maintenance services; secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging); training and support services (such as access to help desk services); and all forms of connectivity services.<sup>65</sup>

*Examples of technology not protected:* Hardware (and operating software that makes the hardware function); storage devices; software with core functionality other than electronic health records (e.g., human resources or payroll software or software packages focused primarily on practice management or billing); items or services used by a recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations; and the provision of staff to recipients or their offices (e.g., provision of staff to transfer paper records to the electronic format).

## 1805.20.40

### Advisory Opinions

#### 1805.20.40.10

#### Physician Recruitment

In Advisory Opinion No. 01-4,<sup>66</sup> the OIG decided that a hospital's proposal to provide remuneration (i.e., a loan subject to favorable terms, together with conditional loan forgiveness) to a physician to relocate would not be subject to sanctions. The county the hospital is in is not a designated HPSA, but that county and all others in the hospital's service area are designated as MUAs in which there is a shortage of the physician's specialties, otolaryngology and head and neck surgery.

Under the proposal, the hospital would loan the physician annually during the five years of his residency training an amount equal to the aggregate monthly payments that the physician is required to make on his medical school loans, plus an additional amount each year to be used for any other educational expenses. Interest on the loan would be the prime rate plus 1 percent, with the rate being adjusted semi-annually.

In exchange, upon completion of his residency training, but not later than August 1, 2005, the physician would relocate to the city in which the hospital is located and maintain a full-time private otolaryngology and head and neck surgical practice there. This arrangement would continue for three consecutive years, during which time the physician would agree to repay the loan and interest in three equal annual payments. However, the hospital would incrementally forgive this obligation by forgiving one-third of the physician's payment obligations for each year that the physician fulfills his obligations to the hospital. If the physician defaulted, the outstanding balance would become immediately due and payable.

<sup>60</sup> 71 Fed. Reg. at 45,124.

<sup>61</sup> 42 C.F.R. § 1001.952(y)(2).

<sup>62</sup> 42 C.F.R. § 1001.952(y)(11).

<sup>63</sup> 71 Fed. Reg. at 45,132.

<sup>64</sup> 71 Fed. Reg. at 45,133.

<sup>65</sup> 71 Fed. Reg. at 45,125.

<sup>66</sup> OIG, Advisory Op. No. 01-04 (May 3, 2001).

The hospital certified:

- the arrangement would not be renegotiated in any substantial aspect during its term;
- the arrangement would not be conditioned upon the generation of business for the hospital;
- the physician would not be restricted from establishing staff privileges at or generating any business for any other entity of his choosing;
- the amount or value of the remuneration provided under the proposed arrangement would not vary in any manner based on the volume or value of any expected referrals of business for which payment might be made in whole or in part under any federal health care program;
- at least 75 percent of the revenues of the physician's new practice will be generated from patients residing in a HPSA or a MUA or who are part of a Medically Underserved Population as defined in CMS regulations; and
- the arrangement would not directly or indirectly benefit any person (other than the physician and his patients) or entity in a position to make or influence referrals to the hospital of items or services payable by a federal health care program.

The OIG concluded that the arrangement implicates the anti-kickback statute, but that it would not subject the hospital to administrative sanctions. It said that while the arrangement can not qualify for the physician recruitment safe harbor because the physician is not relocating to a HPSA (HPSA designations are available only for certain primary care specialties) and the benefit is not limited to three years (see *Practitioner Recruitment*, § 1805.20.30.10), analysis of the facts convinced the OIG that the risk of health care fraud and abuse was minimal.

Specifically, the OIG said that in evaluating such arrangements on a case-by-case basis it would ask, at a minimum, the following questions:

- whether there is documented evidence of an objective need for the practitioner's services (even an area not designated as a HPSA may be deficient with respect to a particular specialty);
- whether the practitioner has an existing stream of referrals within the recruiting entity's service area (risk of kickbacks is mitigated when payments are made to new or relocating practitioners who do not have established referral streams that can be locked up through inappropriate incentives and loyalties);
- whether the benefit is narrowly tailored so that it does not exceed that which is reasonably necessary to recruit a practitioner; and
- whether the remuneration directly or indirectly benefits other referral sources.

In this case, the OIG concluded that the facts and the hospital's certifications indicated sufficient safeguards against referral fraud and abuse and showed that the arrangement would benefit the public by increasing access to health care services in a medically underserved area.

#### **1805.20.40.20**

##### ***Merger of Existing Business***

Advisory Opinion No. 03-15<sup>67</sup> shows the importance of analyzing a transaction from every perspective in determining whether illegal remuneration is being paid.

The opinion concerned a proposal between a hospital and an incorporated, multi-specialty group practice. Formerly, the hospital and the medical practice were one combined entity, but the medical practice split off when the hospital was donated to a non-profit corporation. The transaction was proposed when the group outgrew its current space and found it would incur substantial costs in acquiring new space. It then proposed to transfer all its assets to the hospital, including nursing and technical support staff, in exchange for the hospital's satisfying all encumbrances related to the transferred assets, up to a preset cap.

In analyzing the arrangement for kickback violations, the OIG recognized that "the most obvious remuneration—the transfer of the group's assets to the hospital—flows in the same direction as the most obvious referral pattern—the physicians' referrals of their patients to the hospital." Having determined that the transfer, being essentially a restructuring and merger of existing businesses, would not result in appreciable new hospital referrals, it said that unless there also is a referral of business from the hospital to the group in exchange for either the group's assets or the group members' referrals to the hospital, the arrangement would not present a kickback problem. To be certain of an arrangement's legality, however, all possible inducements or rewards for the purchase or referral of federal health care program business must be examined. The OIG said it therefore would focus its analysis on transactions ancillary to the asset transfer and on other possible referral opportunities.

One ancillary arrangement was a 10-year professional services agreement (PSA) under which the group would provide exclusive professional services in a new hospital outpatient clinic and also would provide services in the hospital's emergency department, while the hospital would bill patients and their third-party payers for such services and pay the group a fee. The hospital also would purchase the group's office building, providing space for the group in the hospital's clinic, and enter into an administrative and support services agreement by which the hospital would provide the group with administrative and billing services for accounts receivable that the group generated prior to the proposed arrangement.

<sup>67</sup> OIG, Advisory Op. No. 03-15 (Dec. 18, 2003).

The OIG determined that the group's compensation under the PSA would be substantially the same as the compensation they received before the proposed arrangement. Moreover, these amounts, what the group would pay under the administrative services agreement, and what the hospital would pay for the group's building all 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 offsetting remuneration from the group to the hospital arising from the transfer of the group's assets, the OIG concluded.

### 1805.20.40.30

#### *Physician Cost-Saving*

In 2005, after a long hiatus, the OIG produced several opinions concerning hospital gainsharing arrangements with physicians. It has continued to develop its position on the subject in recent years.

*Advisory Opinion No. 05-01.* A hospital sought the OIG's opinion on whether it could share with a group of cardiac surgeons 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, including product standardization.<sup>68</sup> The OIG analyzed the proposed arrangement in relation to the CMP provisions and the anti-kickback statute and found that all but one of them violated the CMP law's prohibition against inducing the reduction or limitation of care to federal health care program beneficiaries.<sup>69</sup> 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 provisions.

The OIG also found the program could potentially violate the anti-kickback statute but said it would not impose sanctions. Kevin G. McAnaney, former chief of the OIG's Industry Guidance Branch, told BNA that the OIG's approval of the arrangement could signal a change from the days when the risks of kickback violations in the acquisition and use of high-priced cardiac devices such as defibrillators and stents led the OIG to be much more strict.<sup>70</sup>

*Advisory Opinion Nos. 05-02 to 05-06.* McAnaney's assessment was confirmed a short time later when the OIG released five more opinions approving essentially similar gainsharing arrangements.<sup>71</sup> These opinions do not mean that the OIG now will allow most such ar-

rangements, however. "Absent a change in law, it is not currently possible for gainsharing arrangements to be structured without implicating the fraud and abuse laws," OIG Chief Counsel Lewis Morris told the House Ways and Means Health Subcommittee in 2005.<sup>72</sup>

While some arrangements can be narrowly targeted to induce doctors to reduce the use of specific medical devices and supplies or to adopt particular clinical practices that reduce costs, others are more problematic, offering physician payments to reduce total average costs per case below specific dollar amounts, Morris testified. Providers with proposals they believe provide sufficient protection from abuse should seek a favorable ruling from the OIG before instituting any gainsharing plan, McAnaney told Bloomberg Law.<sup>73</sup>

*Advisory Opinion Nos. 07-21 and 07-22.* The OIG's increasing focus on quality in assessing the legality of gainsharing arrangements is seen in two advisory opinions involving cardiac surgery at an acute care hospital that it approved in January 2008. One concerned a hospital's agreement to share cost savings with a cardiac surgeon group and the other involved a similar arrangement with an anesthesiologist group.<sup>74</sup>

In approving the arrangements, which involved the hospital administrator's recommendations to surgeons and anesthesiologists for reducing spending associated with cardiac procedures, the OIG emphasized the requestors' submission of credible medical evidence to determine that use of the cost-saving measures would not adversely affect patient care. Furthermore, the OIG noted favorably the requestors' statement that they periodically reviewed the arrangements for any adverse effects on clinical care.

*Advisory Opinion Nos. 08-09, 08-15, 08-16, 08-21.* In these advisory opinions, the OIG continued its loosening of restrictions on gainsharing for particular cost-sharing arrangements in clinical areas where physicians control the majority of costs, such as cardiac catheterization procedures and open heart surgery. In Advisory Opinion 08-09,<sup>75</sup> its first approval for a project involving orthopedic surgeons and neurosurgeons (other areas in which physicians control most costs), the OIG considered an arrangement whereby a medical center agreed to pay the orthopedic surgery and neurosurgery groups a share of the first-year cost savings directly attributable to specific changes made in the groups' operating room practices during certain spine fusion surgery procedures. In designing the program, a medical center

<sup>68</sup> OIG, Advisory Op. No. 05-01 (Feb. 3, 2005). See *Chapter 1415, Personal Services and Management Agreements*, § 1415.20.20.50, for details of the specific gainsharing plans.

<sup>69</sup> The Stark law also could be implicated, but this self-referral prohibition falls outside the scope of the OIG's advisory authority, the opinion said. Advisory opinions on Stark are issued by CMS.

<sup>70</sup> See also *IG OKs Gainsharing Arrangement Between Hospital, Surgeons Group*, 9 BNA's Health Care Fraud Rep. 134 (Feb. 16, 2005).

<sup>71</sup> OIG, Advisory Op. Nos. 05-02 (Feb. 17, 2005), 05-03 (Feb. 17, 2005), 05-04 (Feb. 17, 2005), 05-05 and 05-06 (Feb. 25, 2005). For

details of these proposals, see *Chapter 1415, Personal Services and Management Agreements*, § 1415.20.20.50.

<sup>72</sup> See *Gainsharing Deals Should Be Evaluated Individually, HHS OIG Tells House Hearing*, 9 BNA's Health Care Fraud Rep. 766 (Oct. 12, 2005).

<sup>73</sup> Telephone interview with Kevin G. McAnaney, Former Chief of the OIG Industry Guidance Branch (Nov. 3, 2005).

<sup>74</sup> OIG, Advisory Op. Nos. 07-21 (Jan. 14, 2008) and 07-22 (Jan. 14, 2008).

<sup>75</sup> OIG, Advisory Op. No. 08-09 (Aug. 7, 2008).

administrator studied the groups' historic practices and identified 36 specific cost-saving opportunities in two categories: the use of bone morphogenetic protein on a "use as needed" basis and 35 product standardization recommendations for certain spine fusion devices and supplies.

The arrangement implicates the CMP for reductions of or limitations on direct patient care services provided to federal health care program beneficiaries, the OIG said. Nonetheless, it said, the OIG would not impose civil penalties because "the specific cost-saving actions and resulting savings were clearly and separately identified and the transparency of the arrangement allowed for public scrutiny and individual physician accountability for any adverse effects, including any difference in treatment among patients based on nonclinical indicators." The OIG also found several other mitigating factors, including the facts that the financial incentives were reasonably limited in duration and amount and that, because the surgeon groups would distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was lessened.

The opinion said that the arrangement also could implicate the anti-kickback law. However, the OIG found, certain circumstances and safeguards of the arrangement reduced the likelihood that the arrangement could be used to attract referring physicians or increase referrals from existing physicians. Specifically, participation was limited to surgeons already on the medical staff who perform spine fusion surgery and the arrangement's structure eliminated the risk that it might be used to reward surgeons or other physicians who refer patients to the surgeon groups. Finally, the OIG said, the change in operating room practice resulting from the recommendations increased surgeons' liability exposure, making it not unreasonable that they receive compensation for the increased risk.

In Advisory Opinions 08-15 and 08-16, the OIG broke new ground. In the former, it approved for the first time a gainsharing arrangement with a term greater than one year and in the latter it approved, again for the first time, a pay-for-performance arrangement between a hospital and its staff physicians.<sup>76</sup>

In the gainsharing opinion, the OIG approved an existing multiple-year arrangement in which a hospital shared with groups of cardiologists a percentage of three years of the hospital's cost savings arising directly from the physicians' implementation of a number of cost reduction measures in certain procedures, most of which involved standardizing medical devices and supplies and reducing their inappropriate use during certain cardiac catheterizations. The hospital proposed to pay each physician group a share of the cost savings it achieved over a three-year period; the groups, in turn,

would distribute this amount on a per capita basis to their members.

In the opinion on the P4P arrangement, another form of gainsharing, a hospital solicited the OIG's position on collecting, and sharing with its physicians, bonus compensation from a private insurer for achieving certain quality/efficiency standards. The OIG approved (for an initial term of three years) the hospital's sharing the incentive payments with a newly formed physician entity. The private insurer would not be a party to the arrangement and any qualified physician on the hospital's medical staff for a minimum of a year would be eligible to participate. The arrangement required the hospital to track quality measures (relating in 2008 to six conditions or procedures) and outcomes for all patients. Each quality target was a measure described in a joint effort of CMS and the Joint Commission to establish a uniform set of national hospital quality measures.

In each opinion, the OIG concluded it would not impose sanctions under the after being satisfied that sufficient safeguards existed to prevent adverse effects on quality of care or physicians' referral patterns.

Advisory Opinion No. 08-21<sup>77</sup> was the 13th gainsharing sharing arrangement approved by the OIG since 2001, all of which have been based on a gainsharing model developed by Goodroe Healthcare Solutions LLC in Norcross, Georgia. Under the arrangement, the hospital agreed to share cost savings over a two-year period with four cardiology groups and one radiology group resulting from changes the groups' doctors made to cardiac catheterization procedures performed at the hospital in the past two years, according to the advisory opinion. The changes were based on a total of 27 recommendations for improved efficiency that included the standardization of medical devices and supplies used in cardiac catheterization procedures and curbing the inappropriate use or waste of medical devices and supplies, the OIG said.

The OIG said that the arrangement had the potential to result in illegal kickbacks to doctors and be grounds for civil monetary penalties, but the arrangement contained sufficient safeguards to mitigate unlawful activity.

*Advisory Opinion Nos. 17-09.* After a hiatus from addressing the issue, the OIG once again reviewed a gainsharing proposal in 2017.<sup>78</sup> This time, it approved an arrangement under which a group of neurosurgeons agreed to implement cost-reduction measures in certain procedures performed at a medical center in exchange for a percentage of the medical center's resulting savings. The OIG determined that the protocol used to develop the cost-saving recommendations, the monitoring and documentation safeguards, and the methodology used to calculate each performance year's savings seemed reasonable. These features, taken together, reduced the risk that payments from the medical center to

<sup>76</sup> OIG, Advisory Op. Nos. 08-15 (Aug. 14, 2008) and 08-16 (Aug. 14, 2008).

<sup>77</sup> OIG, Advisory Op. No. 08-21 (Dec. 8, 2008).

<sup>78</sup> OIG, Advisory Op. No. 17-09 (Dec. 29, 2017).

the surgeons would induce the surgeons to reduce or limit medically necessary services to Medicare and Medicaid patients.

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

#### 1805.20.40.40

##### *Paying for On-Call Coverage*

On-call payment arrangements raise anti-kickback concerns because the payments could be misused to entice doctors to generate referrals to the hospital making the payments, the OIG has said.<sup>79</sup> For example, the OIG said in a September 2007 advisory opinion, on-call compensation arrangements that reimburse physicians for “lost opportunity” but do not reflect bona fide lost income, or those that compensate doctors where no identifiable services were provided, are especially suspect. Other problematic arrangements, the opinion said, are those that pay doctors disproportionately higher aggregate on-call payments than their regular medical practice income and payment structures that compensate physicians for services that insurers or patients also reimburse.

The OIG nonetheless said there is a legitimate need for hospitals to pay physicians for on-call coverage to meet Emergency Medical Treatment and Labor Act requirements and to encourage physicians to take call in markets where there are shortages of certain specialists. The OIG therefore approved an existing arrangement at a not-for-profit medical center that pays physicians for care provided to uninsured and underinsured patients who present to the emergency department and for the follow-up care of those subsequently admitted as inpatients.<sup>80</sup>

In requesting the opinion, the hospital told the OIG that it developed the arrangement because of the growing unwillingness among certain specialists to provide on-call coverage without being compensated for the care provided. “The Medical Center consequently had to transfer ED patients to other medical facilities both for emergency treatment and necessary inpatient care that might have been handled more conveniently and efficiently at the Medical Center,” according to facts presented in the advisory opinion. “Given the special role of the ED in caring for the underinsured and uninsured, the shortage of available physicians hindered the Medical Center in fulfilling its charitable mission,” the hospital said.

The OIG agreed the arrangement provides “an obvious public benefit” and also concluded that the arrangement has numerous safeguards. Despite its concerns about the potential kickback risks, the OIG found that, in contrast to many troublesome on-call arrangements, the medical center based physician payments on certified fair market values for actual services, without re-

gard to the volume or value of referrals or business generated by a physician. The per diem rates were based on the severity of illness a specialist would be likely to encounter in treating a patient that came to the hospital's emergency department, the likelihood a particular specialist would have to respond when on call, the likelihood a particular specialist would have to respond to a request for inpatient consultation for an uninsured patient when on call, and the degree of inpatient care required by a specific specialist for patients that first present in the emergency department.

The arrangement further required that participating physicians be available for monthly on-call rotation that was divided among other department or division specialists as equally as possible, provided inpatient care through discharge to any patient (regardless of ability to pay) seen in the emergency department while the physician was on call who was admitted to the hospital, participated in the hospital's risk management and quality initiatives, and maintained medical records for patients seen under the on-call arrangement.

While such arrangements possibly could be covered under the anti-kickback safe harbor for personal services and management contracts, the OIG said the program did not meet the condition that payments be set in advance because daily payments to doctors could vary month-to-month.

In deciding not to impose administrative sanctions on the medical center, the OIG took into consideration that, because the program addressed a real need to meet on-call coverage and uncompensated care needs, the risk was low that the arrangement was “instituted as a way to funnel unlawful remuneration to physicians for referrals.”

The program minimized the risk for fraud and abuse by offering on-call compensation to all relevant specialties, instituting a monthly call schedule that was divided among physicians equitably, and requiring physicians to provide follow-up care to patients they saw in the emergency department who were then admitted as inpatients. “This obligation applies regardless of the patient's ability to pay for care and lessens the risk that physicians might ‘cherry-pick’ only those emergency room patients that are likely to be lucrative,” the OIG said in its analysis. The OIG also took into account that the arrangement was structured so that the hospital absorbs the costs of the on-call program rather than shifting them to federal health programs.

The issue of on-call payments to physicians was again addressed by the OIG in 2009.<sup>81</sup> In Advisory Opinion No. 09-05, the OIG addressed the hospitals compensating on-call physicians who rendered services to uninsured patients. Under the proposed arrangement, physicians who rendered services to uninsured patients while on-call would receive a flat fee paid by the hospital (ranging from \$100 to \$350 depending on services ren-

<sup>79</sup> OIG, Advisory Op. No. 07-10 (Sept. 27, 2007).

<sup>80</sup> *Id.*

<sup>81</sup> OIG, Advisory Op. No. 09-05 (May 14, 2009).

dered). The fees would be paid only if the patient was not eligible for Medicaid but qualified for funding under a separate state program. No reimbursement would be made to physicians if the patient was covered by any other third party payer, and physicians would be required to waive all billing and collection rights against any third party payer or patient for the services rendered.

In deciding not to impose administrative sanctions on the medical center, the OIG stated that such an arrangement would be acceptable because:

- the payments were within the range of fair market value for services rendered and reimbursement was only for services actually rendered by the physicians;
- the shortage of on-call physicians suggested that the hospital had a legitimate rationale for revising its on-call coverage policy;
- the proposal would be offered to all physicians and impose tangible responsibilities on them; and
- the arrangement provided an equitable mechanism for the hospital to compensate physicians who actually provided care that the hospital must furnish to be eligible for state program funding.

In October 2012, the OIG again signaled its acceptance of hospitals providing compensation, under certain circumstances, for on-call physicians.<sup>82</sup> The design of the proposed program was similar to the program in Advisory Opinion 07-10, in that it provided a per diem reimbursement for on-call physicians regardless of whether the physician's services were utilized. While this opinion did not add much in the form of new law to the prior two opinions, it did outline the five features that made this program a low risk of fraud and abuse:

- The per diem payment amount was commercially reasonable, within the range of fair market value of actual and necessary services provided without regard to referrals or other business generated between the parties.
- The hospital allocated funds for call coverage for each participating specialty and calculates the per diem annually.
- Participating physicians provided actual and necessary services, for which they were not otherwise compensated, even though the physicians could collect the per diem payment as well as receive separate reimbursement from the patient or insurer.
- The hospital offered the opportunity to participate in the program to all specialists on its staff who were required by its bylaws to take unrestricted call.
- The program was structured so that the hospital absorbed all costs and none accrued to federal health care programs.

#### 1805.20.40.50

##### *Providing Insurance Pre-authorization Services*

The provision of free or below-market goods or services to actual or potential referral sources has long been viewed by the OIG as potentially violating the anti-kickback statute. In 2005, the OIG issued Supplemental Compliance Program Guidance for Hospitals, which states that “[t]he general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value...Arrangement under which hospitals...provide physicians with items or services free or less than fair market value...[or] relieve physicians of financial obligations that they would otherwise incur...pose significant risk.”<sup>83</sup> Therefore, when a party who is in a position to benefit from referrals provides free administrative services to an referral source, there is a risk that at least one if its purposes is to influence referrals. However, in 2010 the OIG, in Advisory Opinion No. 10-13, acknowledged that in limited circumstances, a hospital may provide insurance pre-authorization service free of charge for physicians and not be in violation of the anti-kickback statute.<sup>84</sup>

In this opinion, a hospital attested that many payers are now requiring pre-authorization for certain diagnostic imaging services, and that a pre-authorization number must be used to obtain reimbursement for claims. Furthermore, the hospital stated that it regularly received incorrect pre-authorization numbers from a referring physician's office, and that because the physician's reimbursement was not tied to obtaining the correct number, they had no incentive to provide the hospital with the correct information. Therefore, the hospital proposed making a pre-authorization service available on an equal basis to all patients and referring physicians using the hospital's diagnostic services without regard to any physician's overall volume or value of expected or past referrals.

The OIG cited four reasons why would it not impose administrative sanctions in connection with the proposal:

- The arrangement would not target any particular physician.
- The hospital would not make payments under the proposed arrangement, and it had no ancillary agreement with referring physicians that would otherwise reward referrals to the hospital.
- The hospital's personnel obtaining the pre-authorizations would operate transparently by identifying themselves to insurers as employees of the hospital, and would provide each physician with a copy of all the information it submitted to insurers to obtain the pre-authorization for that physician's patients.
- Since only the hospital's reimbursement for its services was at stake if the pre-authorization num-

<sup>82</sup> OIG, Advisory Op. No. 12-15 (Oct. 23, 2012).

<sup>83</sup> 70 Fed. Reg. 4858, 4866 (Jan. 31, 2005).

<sup>84</sup> OIG, Advisory Op. No. 10-13 (Aug. 24, 2010).

ber was incorrect, the hospital had a legitimate business interest in offering uniform pre-authorization services.

**1805.20.40.60**

**Free Electronic Interface**

The OIG declined to impose sanctions on an arrangement proposed by a hospital to provide physicians with free access to an online interface that would allow physicians to place orders for laboratory and diagnostic testing at the hospital, and allow the hospital to communicate the results back to the physicians, in Advisory

Opinion No. 12-20.<sup>85</sup> The hospital would offer the service to any community physicians or physician practices that requested access. The hospital would also provide support services to maintain and update the software. Participating physicians would still be responsible for their own electronic health records systems.

The OIG determined that the arrangement would not constitute remuneration under the anti-kickback statute because the interface would not have independent value to the physicians apart from the services the hospital would provide, and thus, would not implicate the anti-kickback statute.

**1805.30 Enforcement**

**1805.30.10**

**Settlement Agreements**

| Settlement  | Alleged Misconduct   | Resolution/Penalties  |
|---|--|---|
| Mercy Health (settlement announced Sept. 13, 2017).   | A hospital group self-disclosed that it discovered through an internal audit that it may have directly or indirectly provided excessive compensation to six physicians over the course of three years.   | The hospital group agreed to pay \$14.25 million to settle the allegations. See <i>DOJ, Ohio Hospital Settle False Claims Act Allegations</i> , BNA's Health Law Reporter (May 17, 2018).   |
| <i>United States ex rel. Mason v. Health Management Associates</i> , No. 1:14-cv-579, (D.D.C., settlement announced Dec. 19, 2017). | From 2008 through 2012, a physician group received remuneration from a hospital group in exchange for recommending patients be admitted to those hospitals on an inpatient basis when they should have been treated on an outpatient basis.  | The hospital agreed to pay \$7.5 million to settle the allegations. See <i>Doctor Groups Pay \$33M to Settle Kickback Claims</i> , BNA's Health Care Fraud Report (Jan. 3, 2018).           |
| <i>United States ex rel. Scott v. Pine Creek Med. Ctr., LLC</i> , No. 3:14-cv-3065, (N.D. Tex., settlement announced Dec. 4, 2017). | Between 2009 and 2014, a hospital engaged in an illegal kickback scheme under which physicians referred their patient to the hospital in exchange for the hospital paying for marketing and advertising services on the physicians' behalf.  | The hospital agreed to pay \$7.5 million to settle the allegations. See <i>Texas Hospital to Pay \$7.5M to Settle Kickback Allegations</i> , BNA's Health Care Fraud Report (Dec. 6, 2017). |
| <i>United States ex rel. Emanuele v. Medicor Assocs.</i> , No. 10-cv-245 (E.D. Pa., settlement announced Nov. 13, 2017).            | A hospital paid a cardiology group up to \$2.0 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, and some were either duplicative or not performed. | The hospital agreed to pay \$20.7 million to settle the allegations. See <i>Hospital, Physician Group Settle Fraud Charges for \$20.8M</i> , BNA's Health Law Reporter (Nov. 22, 2017).     |
| MediSys Health Network Inc. (settlement announced Sept. 13, 2017).  | The owner and operator of two hospitals provided referring physicians with excessive compensation and free office space in exchange for tens of thousands of referrals.  | The owner and operator agreed to pay \$4 million to settle the allegations. See <i>177 BNA's Health Care Daily Report</i> (Sept. 14, 2017).   |

<sup>85</sup> OIG, Advisory Op. No. 12-20 (Dec. 19, 2012).

| Settlement  | Alleged Misconduct   | Resolution/Penalties  |
|---|--|---|
| Lexington Medical Center (settlement announced July 28, 2016).  | A medical center entered into asset purchase agreements with 28 physicians that were tied to patient referrals, were not commercially reasonable, or provided compensation in excess of fair market value, all in violation of the Stark Law.  | The medical center agreed to pay \$17 million to settle the allegations. See 146 <i>BNA's Health Care Daily Report</i> (July 29, 2016).   |
| Adventist Healthcare (settlement announced Sept. 21, 2015).   | A healthcare organization billed Medicare and Medicaid for services rendered to patients referred by physicians who received bonuses that took into account the value of the referrals and billed Medicare for physicians' services with improper coding modifiers, which allowed the organization to receive greater reimbursement amounts than it was entitled.  | The healthcare organization agreed to pay \$115 million to settle the allegations. See 184 <i>BNA's Health Care Daily Report</i> (Sept. 23, 2015).  |
| Columbus Regional Healthcare System and Dr. Andrew Pippas (settlement announced Sept. 4, 2015).                     | A hospital paid and the physician accepted an excessive salary and directorship payments in violation of the Stark Law. The hospital also submitted claims to Medicare for radiation therapy at higher levels than what was actually provided.   | The hospital agreed to pay \$25 million, plus additional contingent payments not to exceed \$10 million and entered into a five-year corporate integrity agreement, and the physician agreed to pay \$425,000 to settle the allegations. See 174 <i>BNA's Health Care Daily Report</i> (Sept. 9, 2015). |
| Mercy Health Springfield Communities and Mercy Clinic Springfield Communities (settlement announced Aug. 13, 2015). | Two healthcare providers submitted claims to Medicare for services provided to patients referred by physicians who received bonuses based on a formula that took into account the value of the physicians' referrals of patients to the providers.   | The providers agreed to pay \$5.5 million to settle the allegations. See 158 <i>BNA's Health Care Daily Report</i> (Aug. 17, 2015).   |
| Citizen's Medical Center (settlement announced Apr. 21, 2015).  | A hospital provided compensation to cardiologists that exceeded the fair market value of their services and also paid bonuses to emergency room physicians that improperly took into account their cardiologist referrals.   | The hospital agreed to pay \$21.75 million to settle the allegations. See 79 <i>BNA's Health Care Daily Report</i> (Apr. 24, 2015).   |
| Family Dermatology P.C. (settlement announced Apr. 21, 2015).   | An owner and operator of a dermatopathology lab and a number of dermatology practices engaged in improper financial relationships with a number of physicians who were employed as independent contractors. The owner, Family Dermatology, P.C., required or financially incentivized the physicians to use the in-house pathology lab for pathology services. The services by the lab, which were provided as a result of improper referrals, were then billed to Medicare, | The owner and operator agreed to pay \$3,247,835 to settle the allegations. See 78 <i>BNA's Health Care Daily Report</i> (Apr. 23, 2015).   |

| Settlement  | Alleged Misconduct   | Resolution/Penalties  |
|---|--|---|
| Robinson Health System Inc. (settlement announced Mar. 31, 2015).   | A hospital paid kickbacks to a number of referring physicians and also engaged in management agreements with two physician groups where the physicians did not provide the type of management services to have justified the payments they received.   | The hospital agreed to pay \$10 million to settle the allegations. See 62 <i>BNA's Health Care Daily Report</i> (Apr. 1, 2015).   |
| Ashland Hospital Corporation d/b/a King's Daughters Medical Center (E.D. Ky. settlement announced May 28, 2014).              | A hospital paid unreasonably high salaries that were in excess of fair market value to several cardiologists who referred cardiovascular services to the hospital, which billed Medicare and Medicaid for the referred services.   | To settle the allegations, the hospital agreed to pay \$40.9 million and entered into a five-year corporate integrity agreement. See 103 <i>BNA's Health Care Daily Report</i> (May 29, 2014).  |
| St. Mary Medical Center (E.D. Pa. settlement announced Jan. 6, 2014).   | A hospital failed to properly administer the terms of recruitment contracts, resulting in net overpayments by federally funded health programs to recruited physicians. The hospital voluntarily disclosed that it had failed to recover Medicare and Medicaid overpayments that accrued while income guarantee agreements with 15 physicians were in effect, as required under the terms of the agreements. | The hospital agreed to pay \$2.3 million to settle the allegation. Separate settlement agreements cover the periods between April 2007 and June 2010, when the hospital had income guarantee agreements with 10 physicians, and between January 2005 and August 2010, when the hospital had agreements with five physicians. See 05 <i>BNA's Health Care Daily Report</i> , (Jan. 8, 2014). |
| Settlement Agreement Between the United States and Pacific Health Corporation (C.D. Cal. settlement announced Aug. 24, 2012). | Three hospitals allegedly paid recruiters to deliver homeless Medicare and Medi-Cal beneficiaries by ambulance from the "Skid Row" area in Los Angeles to the hospitals for treatment that was often medically unnecessary.  | The health care corporation agreed to pay the federal government and California \$16.5 million to resolve the civil charges against the hospitals. In addition, one subsidiary agreed to plead guilty to federal conspiracy charges arising out of the kickback scheme, and another related facility agreed to enter into a corporate integrity agreement (CIA) with the OIG.               |

1805.30.20

Court Rulings

| Facts  | Outcome   |
|--|---|
| An assistant hospital administrator allegedly caused more than \$116 million worth of fraudulent claims to be submitted to Medicare. The scheme involved paying kickbacks to patient recruiters and owners of assisted living facilities and group care homes in exchange for the recruiters and owners sending Medicare beneficiaries to the hospital's partial hospitalization program. The hospital would then bill for services that were not medically necessary or never provided. | The administrator pleaded guilty to one count of conspiracy to commit healthcare fraud, one count of conspiracy to defraud the United States and to pay and receive illegal health care kickbacks, and five counts of paying or offering to pay health care kickbacks. He faces a maximum of 10 years in prison for the conspiracy to commit health care fraud, five years for conspiracy to defraud the United States, and five years for each health care kickback count. <i>United States v. Khan</i> , (S.D. Tex. guilty plea entered Feb. 22, 2012). <i>Hospital Official Pleads Guilty in Scheme To Bill Medicare for Mental Health Services</i> , 16 <i>BNA's Health Care Fraud Rep.</i> 193, Mar. 7, 2012). |

| Facts  | Outcome   |
|--|---|
| <p>This breach of contract lawsuit was brought by a physician who entered into a recruitment agreement with a hospital in which he agreed to relocate his family and practice to Rocky Mount, N.C. In exchange, the hospital agreed to provide him with the following benefits for the term of the one-year contract: a guarantee that his cash collections would not be less than \$20,000 during each full month for the term of the agreement; medical office space, valued at \$1,667 per month; office employee assistance, valued at \$3,333 per month; practice establishment and marketing assistance to expedite efficient practice startup; assistance in obtaining medical office furniture and equipment; moving and relocation expenses in the amount of \$15,000; health benefits for him and his family; medical malpractice insurance; and reimbursement of professional fees and expenses. After the physician had relocated but before he had gained admitting privileges at the hospital, the hospital was purchased by another company and subsequently closed. The acquiring company refused to pay the physician the guaranteed cash collections allegedly due under the recruitment and relocation agreement.</p> | <p>The company defended on the grounds that the contract was void because it violated the anti-kickback statute. Both parties moved for summary judgment. The court denied both motions for summary judgment, holding that whether the agreement violated the anti-kickback statute was an issue of fact to be decided by a jury. <i>Feldstein v. Nash Community Health Servs.</i>, No. 5:97-CV-522-BR-3 (E.D.N.C. memorandum and order Mar. 16, 1999).</p> |
| <p>A hospital advanced money to a physician under a recruitment agreement. Under the terms of the one-year contract, the hospital agreed to provide the physician a guarantee of gross cash receipts of \$8,500 per month, an interest-free loan, free office space, rent and utility subsidies, and reimbursement for malpractice insurance. The agreement stipulated that the physician would: “utilize Hospital for his patients who require hospitalization, unless ... the use of another medical facility is necessary or desirable in order to provide proper and appropriate treatment and care to such patient.” Pursuant to the agreement, the physician was advanced more than \$36,000, which he did not repay under the terms of the contract. The hospital sued to recover the advance, and the physician argued in defense that the contract was void because it violated the anti-kickback statute.</p>  | <p>The court found that the contract violated the anti-kickback statute and therefore was void and unenforceable. The hospital’s suit was dismissed. <i>Polk County Memorial Hospital v. Peters</i>, 800 F. Supp. 1451 (E.D. Tex. 1992).</p>  |

