Enforcement actions involving physicians are increasingly common, particularly in the areas of financial relationships with hospitals and financial relationships with pharmaceutical and device manufacturers. Although some of the physicians involved may have the intent to violate a law or regulation, physicians often find themselves in trouble because of mistake, inattention, or a failure to understand the risks. Unfortunately, it is seldom that “mistake, inattention or failure to understand the risks” amounts to a cognizable legal defense.

Fortunately, in recent years the Office of the Inspector General (“OIG”) has undertaken to publicly identify and discuss the major areas of enforcement risks for health care providers, including physicians. It is no surprise that many of these risk areas involve physician conduct, given that Medicare is structured to pay for (1) physician services, and (2) other items and services that are ordered by a physician, such as hospitalization, diagnostic testing, home health services, etc. Fundamentally, physicians control access to the Medicare Trust Funds.

This outline identifies and summarizes the major risk areas for conduct involving physicians, and relies principally on OIG primary source guidance, such as in the
Compliance Program Guidance for Small Group Physician Practices, the Compliance Program Guidance for Pharmaceutical Manufacturers, and the OIG’s Draft Supplemental Program Compliance Guidance for Hospitals. This paper also provides basic suggestions designed to assist providers, and physicians in particular, stay out of trouble.

I. **Anti-Kickback Risk Areas**

A. **General Rule**

Under the Federal health care program Anti-Kickback Law, it is illegal for any individual or entity “knowingly and willfully” to offer or pay “remuneration” – directly or indirectly, overtly or covertly, in cash or in kind – to “induce” a person to:

- “refer” an individual to a person for the furnishing (or arranging for the furnishing) of any item or service “for which payment may be made” under a Federal health care program;
- “purchase” or “order” such an item or service; or
- “arrange for or recommend” purchasing or ordering such an item or service.²

It also is illegal under the Anti-Kickback Law to “solicit” or “receive” remuneration for such purposes.³

---


² 42 U.S.C. § 1320a-7b(b)(2). In contrast to the Stark law, the Anti-Kickback Law covers Federally-funded health care programs other than Medicare and Medicaid.
The policy objectives behind the Anti-Kickback Law are: (1) preventing the corruption of medical judgment; (2) preventing the over utilization of items or services covered by a Federal health program (and the concomitant increase in program costs); and (3) preventing unfair competition. Understanding the policy objectives behind the law is helpful for providers because they offer guidance as to where enforcement priorities lie.

Where the Anti-Kickback Law has been violated, the government may proceed criminally or administratively. If the government proceeds criminally, a violation of the statute is a felony punishable by up to five years imprisonment, a fine of up to $25,000 and mandatory exclusion from participation in all Federal health care programs. If the government proceeds administratively, it may impose a civil monetary penalty of $50,000 per violation and an assessment of not more than three times the total amount of “remuneration” involved. Additionally, it may exclude the offering or receiving parties from participation in all Federal health care programs. The government has also recently pursued Anti-Kickback Law violations civilly through False Claims Act cases brought by the Department of Justice. False Claims Act violations can result in significant penalties (up to $11,000 per false claim), treble damages, as well as possible exclusion from Federal health care programs.

---

3 Id. § 1320a-7b(b)(1).
4 See, e.g., OIG Advisory Opinion 98-3 (April 6, 1998).
5 42 U.S.C. §§ 1320a-7b(b) and 1320a-7a(a)(7).
Recognizing that the Anti-Kickback Law “is so broadly written as to encompass many harmless or efficient arrangements,”\textsuperscript{6} Congress and HHS have created a series of statutory “exceptions”\textsuperscript{7} and regulatory “safe harbors.”\textsuperscript{8} An arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, even if the arrangement would otherwise violate the statute. Importantly, such protection is afforded only to those arrangements that “precisely meet” all of the often numerous conditions set forth in an exception or safe harbor.\textsuperscript{9} “Material” or “substantial” compliance with an exception or safe harbor is insufficient.\textsuperscript{10} Additionally, in 1996 Congress authorized the OIG to issue advisory opinions concerning whether an existing or contemplated arrangement violates the Anti-Kickback Law.\textsuperscript{11}

As emphasized strongly by the OIG in its recent Supplemental Compliance Program Guidance for Hospitals and its Compliance Program Guidance for Pharmaceutical Manufacturers, physicians face significant exposure to Anti-Kickback Law based on financial relationships with other health care parties. The following are among the Anti-Kickback risk areas highlighted by the government in these Guidances as well as other pertinent Guidances and Advisories.

\textsuperscript{7} 42 U.S.C. § 1320a-7b(b)(3).
\textsuperscript{8} 42 C.F.R. § 1001.952. The statute specifically authorizes HHS to develop such safe harbors. 42 U.S.C. § 1320a-7(b)(3)(E).
\textsuperscript{9} OIG Advisory Opinion 98-5 (April 24, 1998).
\textsuperscript{10} Id.
\textsuperscript{11} 42 U.S.C. § 1320a-7d(b).
B. Financial Relationships with Hospitals

Issue: Recruitment and Relocation Arrangements

It is not uncommon for hospitals to provide incentives to recruit physicians and other health care professionals to join the hospitals’ medical staff and provide services to the surrounding communities. However, such arrangements can also have significant fraud and abuse implications. The government’s position is that, if a recruited physician establishes a private practice, instead of becoming an employee of the hospital, the Anti-Kickback Law could be implicated if one purpose of the recruitment is to induce referrals to the recruiting hospital. Although safe harbor protection is available, it is limited to recruitments to officially designated health professional shortage areas.\(^\text{12}\)

Basic Considerations

When assessing the degree of risk associated with recruitment arrangements, parties should consider the following:

- *The need for the recruitment.* Community need, not hospital business need, is the fundamental justification for recruitment and relocation packages. Demonstrating a legitimate community need largely depends on the specialty and the hospital service area where the physician is being recruited.

\(^{12}\) 42 C.F.R. § 411.357(e).
• *The size and value of the recruitment benefit.* The parties need to weigh whether the payment is limited to that reasonably necessary, considering the difficulty in attracting physicians to that community.

• *The duration of payout for the recruitment benefit.* In instances where the total benefit payout period extends longer than three years from the initial recruitment agreement, increased risk exists.

• *The existing practice of the physician.* If the physician is coming from a significant distance, there is less risk that the arrangement would be perceived as being for referrals.\(^{13}\)

Underwriting a doctor joining a group practice raises particularly difficult issues. Under the Stark Law (explicitly) and the Anti-Kickback Law (implicitly), only the marginal costs attributable to the new doctor joining a practice may be paid to the group. For example, marginal costs include the costs associated with renting new space to accommodate a new physician, but if no new space is necessary (*i.e.*, there was an empty office) there would be no additional marginal costs for space. Another example: Marginal costs would not include the new physician’s share of the current office assistant’s salary.

**Issue: Compensation Arrangements with Physicians**

A classic area of Anti-Kickback Law concern is compensation arrangements between a hospital and physician where the physician is providing items or services to, or on behalf of, the hospital or where the hospital is providing items or services to the

\(^{13}\) 69 Fed. Reg. at 32022.
physician. Included among the compensation relationships at risk for violating the Anti-Kickback Law are: medical directorship agreements, personal or management services agreements, and space or equipment leases and agreements for the provision of billing, nursing, or other staff services.

**Basic Considerations**

In order to curb the risk of a potential Anti-Kickback Law violation resulting from a compensation arrangement, physician compensation arrangements should be reviewed and assessed for the following risks:

- Is the remuneration between the physician(s) and the hospital fair market value based on an arm’s length transaction that does not take into account the volume or value of any past or future referrals or other business generated between the parties?

- Are the items and services obtained from the physician legitimate, commercially reasonable and necessary to achieve a legitimate business purpose of the hospital? Assuming that the hospital needs the items and services, does the hospital have multiple arrangements with different physicians, so that in the aggregate the items or services provided by all physicians exceed the hospital’s actual needs?

- Is the arrangement properly and fully documented in writing and is there additional documentation evidencing that the physician provided the services and that the hospital monitored the services?
• Are safeguards in place to ensure that physicians do not use hospital outpatient space, equipment, or personnel to conduct their private practice and that they bill using the appropriate site-of-service modifier?\textsuperscript{14}

Hospitals and physicians should also try to structure compensation arrangements to fit within a safe harbor, or come close to fitting within a safe harbor, if possible. At a minimum, hospitals should develop policies and procedures requiring physicians to document, and the hospital to monitor, the services or items provided under any kind of personal services arrangements, and ensure that payments are set at fair market value.

**Issue: Joint Ventures**

Hospital/physician joint ventures appear to be on the rise. However, the OIG has long had concerns regarding the propriety of joint venture arrangements between physicians and those providing items and services reimbursable by Federal health care programs. The OIG’s primary concern is remuneration, resulting from a joint venture, which might be a disguised payment for past or future referrals to the joint venture or to one or more of its participants. Examples of suspect remuneration include dividends, profit distributions and general economic benefits received under the terms of the related contracts. As evidenced in the OIG’s 2003 Special Advisory Bulletin on Joint Ventures,\textsuperscript{15} contractual joint ventures pose the same kinds of risks as equity joint ventures and should be analyzed in the same manner.

\textsuperscript{14} Id.

Basic Considerations

In order to reduce the risks associated with joint venture agreements, parties to the agreements should consider the following:

- **The manner in which joint venture participants are selected and retained.**
  Refrain from selecting participants in a manner that takes into account, directly or indirectly, the volume or value of referrals.

- **The manner in which the investments are financed and profits are distributed.** Joint ventures cannot be a vehicle to disguise direct or indirect payment for referrals. The following are signs that it may be such a vehicle:
  
  1. participants are offered investment shares for a nominal or no capital contribution;
  2. participant investment capital is disproportionately small, and the returns on the investment is disproportionately large, when compared to a typical investment in a new business enterprise;
  3. participants are permitted to borrow their capital investments from another participant or from the joint venture, and to pay back the loan through deductions from profit distribution, thus eliminating the need to contribute cash;
  4. participants are paid extraordinary returns on the investment in comparison to the risk involved; or
5. a substantial portion of the gross revenues of the venture are derived from participant-driven referrals.

- *Manner in which the line of service was selected.* In instances of contractual joint ventures, a health care provider seeking to expand into a new line of service, and joining with a would-be competitor of the new line of business, present fraud and abuse concerns.

- *Relationship between the parties.* The existence of a non-compete agreement between the joint venture entities could be problematic.\textsuperscript{16}

Of course, parties to a joint venture can reduce their risk of violating the Anti-Kickback Law by structuring the venture to fit within a safe harbor. Among the applicable safe harbors available to physicians and hospitals entering into joint ventures include the “small entity” investment safe harbor (which is difficult to meet); the safe harbor for investment interests in an entity located in an underserved area; and the hospital-physician ambulatory surgical center safe harbor.\textsuperscript{17}

**Issue: Medical Staff Credentialing**

Depending on how a hospital structures its medical staff credentialing, there is a risk of implicating the Anti-Kickback Law. For example, conditioning privileges on a particular number of referrals or requiring the performance of a particular number of procedures, beyond the volume necessary to ensure clinical proficiency, potentially raises risks under the Anti-Kickback Law. Nonetheless, according to OIG, a credentialing policy that categorically refuses privileges to physicians with significant

\textsuperscript{16} Id.; 69 Fed. Reg. at 32020.

\textsuperscript{17} Id.
conflicts of interest with the hospital would not appear to implicate the Anti-Kickback Law.\textsuperscript{18}

**Basic Considerations**

Hospitals should examine their credentialing policies and practices to ensure that the provisions and practices are in compliance with the Anti-Kickback Law.\textsuperscript{19}

**Issue: Malpractice Insurance Subsidies**

If a hospital subsidizes or pays for the malpractice insurance premiums of a potential referral source (\textit{e.g.}, physician), then such a payment could be considered suspect under the Anti-Kickback Law.

**Basic Considerations**

The government is aware of the current issues involving the increasing costs of malpractice insurance, and has offered limited guidance to relieve the problem.\textsuperscript{20} According to the OIG’s limited guidance, the factors that should be considered when offering malpractice insurance, in order to reduce risk, include whether: the subsidy is being provided on an interim basis for a fixed period in a state or states experiencing severe access or affordability problems; the subsidy is being offered only to limited physicians or physicians with established referral bases; the criteria for receiving a subsidy is related to the volume or value of referrals or other business generated by the physician; physicians are required to perform services equal to the value of the subsidy; and whether the insurance is available regardless of the location at which the physician

\textsuperscript{18} 69 Fed. Reg. at 32023.

\textsuperscript{19} \textit{Id}.

\textsuperscript{20} The Anti-Kickback Law contains an obstetrical malpractice exception; however, it is limited to certain underserved areas of the country. 42 C.F.R. § 411.357(r).
provides services.\footnote{69 Fed. Reg. at 32023-32024.} Despite the above guidance on the Anti-Kickback Law, it is entirely unclear how malpractice subsidies could fit within any of the exceptions to the Stark Law. Some hospitals in malpractice crisis states are simply employing certain physicians to avoid legal difficulties associated with malpractice premium support.

**Issue: Gainsharing Arrangements**

Since the 1999 Special Advisory Bulletin\footnote{Office of Inspector General, Special Advisory Bulletin, Gainsharing Arrangements and CMPs for Hospital Physicians to Reduce or Limit Services to Beneficiaries (July 1999).} addressing gainsharing arrangements and the OIG's civil monetary penalty ("CMP") authorities, government policy in this area has become clear, albeit very narrow. As noted in the Special Advisory Bulletin, under the CMP statute, a hospital is prohibited from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries under the physician's direct care. As long as the hospital knows that the payment may influence the physician to reduce or limit services to patients, then the CMP may be violated. Additionally, these same arrangements can violate the Anti-Kickback Law if the cost-saving measures are used to influence referrals, \emph{e.g.}, if the physician is influenced to cherry pick healthier patients for the hospital offering the gainsharing payments.\footnote{Id. and 65 Fed. Reg. 59434, 59446-59447 (October 5, 2000) (OIG Compliance Program Guidance for Individual and Small Group Physician Practices).}
Basic Considerations

Hospitals should be very leery of gainsharing and incentive arrangements, as the OIG’s view of the controlling legal authority remains narrow, at best.24

C. Financial Relationships with Pharmaceutical and Device Manufacturers

Physicians should identify remunerative relationships with any entity with whom they are in a position to generate Federal healthcare business. As evidenced by the OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers, many physician relationships with pharmaceutical manufacturers risk violating the Anti-Kickback Law. Most of the same risks apply to physician relationships with device manufacturers.

Basic Considerations

Physicians should scrutinize any potential arrangements with pharmaceutical companies to make sure they do not violate the Anti-Kickback Law. Reflecting on the purposes of the Anti-kickback Law, the OIG Compliance Program Guidance to Pharmaceutical Manufacturers provided some helpful questions physicians should use to evaluate their relationships with manufacturers. These questions include:

- Does the arrangement have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement have a potential to increase costs to the Federal health care programs, beneficiaries, or enrollees?

24 Id. and 42 C.F.R. § 411.357(d); see also Advisory Opinion No. 01-1 (January 18, 2001).
• Does it have the potential to be a disguised discount to circumvent the Medicaid Drug Rebate Program Best Price calculation?

• Does it have a potential to increase risk of over-utilization or inappropriate utilization?

• Does it raise patient safety or quality of care concerns?25

**Issue: Gifts and Gratuities, Meals and Entertainment**

Although pharmaceutical manufacturers may provide physicians with certain reasonable gifts in limited contexts, those gifts should always be focused on “informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.” Otherwise, they risk violating the Anti-Kickback Law.26

**Basic Considerations**

The OIG’s Guidance for Pharmaceutical Manufacturer’s discussion of gifts and gratuities to physicians heavily references the recommendations contained in the Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Providers (“PhRMA Code”). According to the PhRMA Code, pharmaceutical companies may provide physicians with meals that are part of informational presentations and discussions as long as they: (a) are modest as judged by local standards; (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. If the venue is not appropriate for

---


26 PhRMA Code on Interactions with Healthcare Professionals
communication, for example, a loud restaurant where no presentation can be given, the meal should not be paid for by the pharmaceutical representative. Meals may not be provided for physicians’ spouses and the company representative must be present at the meal. 27 Likewise, physicians who provide consulting services may be given reasonable compensation and may be reimbursed for reasonable travel, lodging, and meal expenses incurred as part of providing consulting services, but only as part of a bona fide consulting arrangement. 28

Additionally, items or gifts that primarily benefit patients may be offered to healthcare professionals if they are valued at $100 or less, but may only be offered occasionally. Items of minimal value may be offered if they are primarily associated with a healthcare professional’s practice, such as pens and notepads with the company logo. Items for the personal benefit of the healthcare provider are not permitted. 29 While stethoscopes are an acceptable gift because they primarily benefit patients, items such as golf balls or CD players bearing the drug company’s name are not acceptable, regardless of how nominal their value. In all cases, nothing may be provided to a physician if it might interfere with the physician’s independent decision-making regarding his or her prescribing practices. 30

Although the PhRMA Code is not law or authoritative, the fact that it is referenced approvingly by the OIG provides incentive for physicians and those they interact with to

27 Id. at 7.
28 Id. at 11.
29 Id. at 17.
30 Id. at 19.
pay careful attention to its provisions. Additionally, many pharmaceutical companies have voluntarily adopted the PhRMA Code.

**Issue: Research Services and Educational Funding**

Payments to physicians for research services and educational funding by pharmaceutical companies also create potential Anti-Kickback risks. The concern is that these programs will be used to induce or reward purchase of the manufacturer’s product.\(^\text{31}\)

**Basic Considerations**

Companies may provide financial support for physician continuing medical education (“CME”) or other scientific and educational conferences or professional meetings sponsored by third party organizations. However, any money for these events should be given to a conference’s sponsor to reduce the overall cost of registration for attendants – the money may not be given directly to physicians. Drug manufacturers and other entities that bill Federal health care programs should not underwrite the costs of travel, lodging or other personal expenses of non-faculty physicians attending CME or other third party educational conferences, nor should they compensate physicians for their time spent at these events.

Physicians should be careful when these arrangements appear to induce the physician to use a company’s products. Certain characteristics of an arrangement that will raise red flags to OIG include:

1. post-marketing research activities;

2. funding conditioned on the purchase or use of the drug manufacturer’s product; and
3. the research contract originates with the pharmaceutical manufacturer’s marketing and sales department.

In addition to these concerns, physicians should make sure that payment for research services is fair market value for legitimate, reasonable and necessary services.\textsuperscript{32}

\textbf{Issue: Discounts from Pharmaceutical Manufacturers}

The government’s position is that discounts or other inducements that are offered to doctors for products that are reimbursable, in part or in whole, by any of the Federal healthcare programs may violate the Anti-Kickback Law if one purpose of the discounts is to influence referrals.\textsuperscript{33}

\textbf{Basic Considerations}

There is an exception in the Anti-Kickback Law for discounts. However, the discount must be disclosed and accurately reported. Additionally, the discount must be in the form of a reduction in the price of a good or service based on an arms-length transaction. The discount must be either given or at least set at the time of sale.\textsuperscript{34} However, in light of how physicians claim reimbursement for Medicare services (CMS-1500 form), there is no obvious way to report discounts (unlike hospitals which can do so on cost report forms).

\textsuperscript{32} \textit{Id.}
\textsuperscript{33} 68 Fed. Reg. at 23735.
\textsuperscript{34} \textit{Id.}
II. Stark Law Issues

A. General Rule

Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn (commonly known as the “Stark Law”), prohibits a physician from making referrals of Medicare or Medicaid patients for certain designated health services to any entity with which the physician has a “financial relationship,” unless the arrangement qualifies for one of the statutory or regulatory exceptions. A physician is considered to have a financial relationship with an entity if the physician has, directly or indirectly, an “ownership or investment interest” in the entity or a “compensation arrangement” with the entity. An ownership or investment interest can be through debt, equity or other means. A compensation arrangement includes any relationship involving any remuneration between a physician and an entity.

Entities that submit claims for services provided as a result of prohibited referrals are subject to payment denial and obligations to refund. For knowing violations, providers of designated health services, as well as the referring physicians are subject to substantial penalties. The statute permits little leeway because its terms are mandatory. In this regard, the Stark Law is often referred to as a “strict liability” statute without fault.

35 The Stark Law extends the referral prohibition to Medicaid in an indirect manner. Rather than prohibit physician self-referrals, the Medicaid prohibition applies to the states by denying Federal matching payment for services provided as a result of prohibited referrals.


37 42 C.F.R. § 411.354(a)-(c).
since, unlike the Anti-Kickback Law, the intent of the parties is not relevant for purposes of determining whether a violation of the law has occurred. The Stark Law applies to referrals involving the following services (defined in the statute as “designated health services”):

1. clinical laboratory services;
2. physical therapy services;
3. occupational therapy services;
4. radiology services, including MRI, CT scan, and ultrasound services;
5. radiation therapy services and supplies;
6. durable medical equipment (“DME”) and supplies;
7. parenteral and enteral nutrients, equipment, and supplies;
8. prosthetics, orthotics, and prosthetic devices and supplies;
9. home health services;
10. outpatient prescription drugs; and
11. inpatient and outpatient hospital services.\(^38\)

The statute defines “referral” very broadly. According to 42 U.S.C. § 1395nn(h)(5), a physician makes a referral whenever he or she requests the provision of an item or service that is covered under Part B of the Medicare program or requests a plan of care which includes the provision of a designated health service. Indeed, even a

\(^{38}\) 42 U.S.C. § 1395nn(h)(6).
request for a service that will be provided within the physician's own office can constitute a “referral” for purposes of the Stark Law.

The Stark Law establishes various exceptions to the self-referral prohibition. Some exceptions apply exclusively to ownership interests, some exceptions apply exclusively to compensation arrangements, and some exceptions apply to both ownership interests and compensation arrangements. If a physician (or immediate family member) has a prohibited financial arrangement with an entity that furnishes designated health services, his or her financial arrangement must fall into one of the exceptions to the self-referral prohibition or the physician will be precluded from referring patients to that entity, and the entity will be precluded from billing anyone for services resulting from the referral.

B. Stark Law Risk Areas

The same Anti-Kickback risk areas (discussed above) that involve physician financial relationships with hospitals and other health care entities should also be analyzed for compliance with the Stark Law. As emphasized by the Supplemental Compliance Program Guidance for Hospitals, providers should implement systems to ensure that all conditions in the exceptions upon which they rely are fully satisfied.\footnote{69 Fed. Reg. at 32018.} For example, many of the Stark Law regulatory exceptions require agreements to be written, signed and be for an amount that is fair market value. Further, providers need to be mindful that although the recent Stark II, Phase II regulations contain exceptions for inadvertent noncompliance, these exceptions are not broad and should not be used as a replacement to careful implementation of procedures and policies. Some other
areas of potential risk (in addition to those discussed previously in the first part of this paper) include medical staff incidental benefits and professional courtesies (non-monetary compensation).

**Issue: Non-Monetary Compensation and Medical Staff Incidental Benefits**

Unless structured to fit within the confines of a Stark Law exception, providing or receiving medical staff benefits and many business courtesies, including social events, gifts, parking, meals, etc., may violate the Stark Law. The provision of such benefits could be seen as remuneration for referrals to hospital for DHS.⁴₀

**Basic Considerations**

Hospitals should create detailed hospital policies governing the provision of such benefits and should carefully monitor the provision of benefits in connection with the applicable Stark Law exceptions. In particular, the parties should ensure that such benefits fall within the requirements of the Stark Law medical staff incidental benefits or other applicable exceptions including the professional courtesy exception.⁴¹

Additionally, detailed policies and procedures should be drafted and implemented to address non-monetary compensation (both acceptance and the providing of) and incidental benefits. Such compensation and benefits should be monitored to ensure compliance with law and policies and procedures. In so doing, physicians and hospitals can reduce the risks of appearing to inappropriately provide or accept remuneration in exchange for referrals.

---

⁴₀ *Id.*

⁴¹ *Id.;* 42 C.F.R. § 411.357(m).
**Issue: Professional Courtesy**

Although “professional courtesy” at one time referred to the practice of physicians waiving the entire professional fee for other physicians, the term has taken on an expanded meaning and includes a varied assortment of accommodations to a wide-range of persons including family members and staff, or “insurance only billing.” Hospital-sponsored professional courtesies may implicate the fraud and abuse laws, both Anti-Kickback and Stark, if the courtesy is considered to be an inducement for referrals to the hospital.

42

**Basic Considerations**

If a hospital chooses to sponsor professional courtesy to physicians, their family or office staff, it must make sure for Stark Law purposes that it fits within the newly created professional courtesy exception.

43

**III. Quality of Care Issues**

Quality of care issues are gaining increased attention from government enforcement agencies. Substandard or unnecessary care is a malpractice liability risk, and it is also potentially grounds for exclusion of an individual or entity from participation in Federal health care programs. Specifically, the OIG has authority to exclude a provider if the individual or entity provides unnecessary items or services (i.e. items or services substantially in excess of the needs of a patient) or substandard items or services (i.e., items or services of a quality which fails to meet professionally recognized standards of health care). Exclusion can be based upon any unnecessary or

---


43 *Id.*
substandard items or services, regardless of whether the patient is a Medicare or Medicaid beneficiary. Further, neither knowledge nor intent is required for exclusion.\(^{44}\) In addition, the government has invoked the civil False Claims Act in matters involving quality issues, where it believes it can show that a provider “knowingly” billed for substandard or unnecessary services. It should be noted that to date, OIG has rarely pursued exclusion actions for substandard or unnecessary care that was not flagrant.

**Basic Considerations**

Hospitals and physicians need to be diligent in reviewing the quality of care provided by the hospital and the physicians providing care in the hospital. Hospitals need to take an active role in monitoring quality of care by appropriately overseeing the credentialing and peer review of its medical staffs. Hospitals also should be diligent in meeting their conditions of participation (“CoPs”). In particular, they should be careful to pay attention to the CoPs pertaining to quality assessment and performance. Further, hospitals should consider the benefits of developing and implementing policies and procedures to address quality of care review and a method to evaluate compliance with the policies and procedures.\(^{45}\) Understandably, this is easier said than done. Often times, there is an inherent tension between independent peer review and hospital oversight. Independent peer review is run by the medical staff, not the hospital. As such, the ultimate issues and cases reviewed by the committee are chosen by the committee, in compliance with applicable laws and policies. Despite this tension, it

---


\(^{45}\) Id.
remains in the best interest of both parties to implement effective methods to monitor quality of care.

**Issue: Unnecessary Independent Services**

Hospitals and physicians face increasing risk with the OIG when they perform unnecessary services on Medicare beneficiaries.  

**Basic Considerations**

Hospital peer review bodies should review not only bad outcomes, but also consider sampling practitioners who are providing a relatively large number of the same procedure for possible unnecessary care being rendered. Similarly, claims of unnecessary or low quality care should be referred to the peer review body whenever reported, regardless of whether it is reported by staff, patients or other practitioners.

**IV. Other Issues**

**Issue: Physician Coding and Billing**

As emphasized in the Compliance Program Guidance for Small Group Physician Practices, physicians need to be vigilant in ensuring their coding and billing practices are in compliance with Federal and state requirements and that they do not fall within with the following coding and billing fraud and abuse risk areas:

1. billing for items and services not rendered or not provided as claimed;

2. submitting claims for equipment, medical supplies and services that are not reasonable and necessary;

---

3. double billing resulting in duplicate payment;
4. billing for non-covered services as if covered;
5. knowing misuses of provider identification numbers, which results in improper billing;
6. unbundling (billing for each component of the service instead of billing or using an appropriate all-inclusive code);
7. failure to properly use coding modifiers;
8. clustering; and
9. upcoding the level of service provided.\footnote{65 Fed. Reg. at 59439.}

**Basic Considerations**

Although it is not possible to prevent all coding and claim submission errors, the OIG advises that providers can reduce the risks by implementing written standards and procedures that address proper coding and billing. Providers need to ensure that such policies reflect the current reimbursement principles and coding guidelines, and that staff receives training appropriate for any duties related to billing and coding. Providers should also consider implementing procedures to audit claims, on a sample basis, and before they are submitted for payment, to ensure that they are accurate and are correctly coded.\footnote{Id.}
Issue: Documentation

Lack of appropriate documentation can result in a host of fraud and abuse claims against a provider. For example, insufficient documentation can result in a billed service being considered unnecessary. As discussed at length in the Compliance Program Guidance for Small Group Physician Practices, lack of appropriate documentation can result in a Stark Law violation, for example, a lease agreement that does not specify the timing of the lease or the services to be provided there under. 49

Basic Considerations

Providers need to implement policies and procedures addressing proper documentation. Additionally, sample audits to ensure that proper documentation is occurring can help assure that services rendered or items ordered are appropriate.

Issue: Concierge Medicine

A physician conditioning the availability of his or her services for payment of a premium, otherwise known as “concierge” medicine, has raised eyebrows within the government, especially in cases involving patients who are beneficiaries of Federal health care programs. Asking Medicare beneficiaries for payment of certain items or services already considered to be a Medicare covered benefit could result in the provider being charged with a substantial penalty, or even exclusion from Medicare and other Federal health care programs. 50

49 65 Fed. Reg. at 59438.
Basic Considerations

A physician should avoid requiring any generalized payments for the physician’s services that could be characterized as partially going toward services covered by Medicare. For example, one physician made his patients pay an annual fee of $600 for a “personal healthcare contract.” The physician claimed that the services to be provided under the contract were not covered by Medicare. The OIG found that at least some of the contracted services, such as “coordination of care with other providers,” “a comprehensive assessment and plan for optimum health,” and “extra time” spent on patient care, were already covered services. The physician settled with OIG for a penalty and agreed to stop presenting the contracts to his patients.51

Issue: Provider Gifts to Beneficiaries

Physicians are not permitted to offer gifts to Medicare beneficiaries that will influence their choice of Medicare provider.52 The government’s position is that offering gifts could give providers an incentive to offset the cost of the gifts by providing cheaper or lower-quality services.53 Gifts include waiver of co-payments and deductibles and transfer of items or services. Nominal gifts are permissible for free or less than fair market value.54

51 Id.
53 Section 1128A(a)(5) of the Social Security Act.
54 Office of Inspector General, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries, August 2002. The OIG has interpreted nominal gifts to be those with a retail value in excess of $10 in one instance or $50 per patient per year.
Basic Considerations

In instances where physicians want to provide gifts to beneficiaries, they should ensure such gifts fall within provided exceptions to the inducements to beneficiaries prohibition. There are five exceptions to this prohibition: (1) waivers of cost-sharing amounts based on financial need; (2) properly disclosed co-payment differentials in health plans; (3) incentives to promote the delivery of certain preventive care services; (4) any practice permitted under the Federal Anti-Kickback Law; or (5) waivers of hospital outpatient co-payments in excess of the minimum co-payment amounts.\footnote{Id.} In addition to the exceptions, valuable services or other remuneration can be provided to financially needy beneficiaries so long as the determination of need is made by an independent entity, such as a patient advocacy group.\footnote{Id.} In certain limited circumstances, complimentary local transportation may also be permissible.