

A Roadmap for New Physicians

Avoiding Medicare and Medicaid Fraud and Abuse



U.S. Department of Health & Human Services
Office of Inspector General

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Introduction

Most physicians strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Society places enormous trust in physicians, and rightly so. Trust is at the core of the physician-patient relationship. When our health is at its most vulnerable, we rely on physicians to use their expert medical training to put us on the road to a healthy recovery.

The Federal Government also places enormous trust in physicians. Medicare, Medicaid, and other Federal health care programs rely on physicians' medical judgment to treat beneficiaries with appropriate services. When reimbursing physicians and hospitals for services provided to program beneficiaries, the Federal Government relies on physicians to submit accurate and truthful claims information.



The presence of some dishonest health care providers who exploit the health care system for illegal personal gain has created the need for laws that combat fraud and abuse and ensure appropriate quality medical care. This brochure assists physicians in understanding how to comply with these Federal laws by identifying “red flags” that could lead to potential liability in law enforcement and administrative actions. The information is organized around three types of relationships that physicians frequently encounter in their careers:

- I. Relationships with payers,
- II. Relationships with fellow physicians and other providers, and
- III. Relationships with vendors.

The key issues addressed in this brochure are relevant to all physicians, regardless of specialty or practice setting.



Fraud and Abuse Laws

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.



False Claims Act [31 U.S.C. §§ 3729–3733]

The civil FCA protects the Government from being overcharged or sold shoddy goods or services. **It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.** Filing false claims may result in fines of up to three times the programs' loss plus \$11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law.

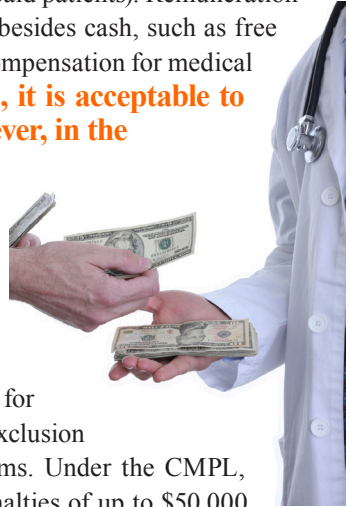
Under the civil FCA, no specific intent to defraud is required. The civil FCA defines “knowing” to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Further, the civil FCA contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any recoveries. Whistleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors.

There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines. Physicians have gone to prison for submitting false health care claims. OIG also may impose administrative civil monetary penalties for false or fraudulent claims, as discussed below.



Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of “remuneration” to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. **In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime.** The statute covers the payers of kickbacks—those who offer or pay remuneration—as well as the recipients of kickbacks—those who solicit or receive remuneration. Each party’s intent is a key element of their liability under the AKS.



Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to *bona fide* employees.

 For additional information on safe harbors, see “OIG’s Safe Harbor Regulations” available at <http://oig.hhs.gov/fraud/safeharborregulations.asp>.

As a physician, you are an attractive target for kickback schemes because you can be a source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.

Many people and companies want your patients' business and would pay you to send that business their way. Just as it is illegal for you to take money from providers and suppliers in return for the referral of your Medicare and Medicaid patients, it is illegal for you to pay others to refer their Medicare and Medicaid patients to you.

Kickbacks in health care can lead to:

- ▼ Overutilization
- ▼ Increased program costs
- ▼ Corruption of medical decisionmaking
- ▼ Patient steering
- ▼ Unfair competition



The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients. Routinely waiving these copays could implicate the AKS and you may not advertise that you will forgive copayments. However, you are free to waive a copayment if you make an individual determination that the patient cannot afford to pay or if your reasonable collection efforts fail. **It is also legal to provide free or discounted services to uninsured people.**

Besides the AKS, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the AKS. A physician can be guilty of violating the AKS even if the physician actually rendered the service and the service was medically necessary. **Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug or ordered that wheelchair even without a kickback.**



Physician Self-Referral Law [42 U.S.C. § 1395nn]

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.

“Designated health services” are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.



The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law’s restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in the Federal health care programs.



For more information, see CMS’s Stark law Web site available at <http://www.cms.gov/physicianselfreferral/>.




Exclusion Statute [42 U.S.C. § 1320a-7]

OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations.

If you are excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that you furnish, order, or prescribe.

Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice. In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program.



 For more information, see OIG’s Special Advisory Bulletin entitled “The Effect of Exclusion From Participation in Federal Health Care Programs” available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>.

You are responsible for ensuring that you do not employ or contract with excluded individuals or entities, whether in a physician practice, a clinic, or in any capacity or setting in which Federal health care programs may reimburse for the items or services furnished by those employees or contractors. This responsibility requires screening all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities. This online database can be accessed from OIG's Exclusion Web site. If you employ or contract with an excluded individual or entity and Federal health care program payment is made for items or services that person or entity furnishes, whether directly or indirectly, you may be subject to a civil monetary penalty and/or an obligation to repay any amounts attributable to the services of the excluded individual or entity.



For more information, see OIG's exclusion Web site available at <http://oig.hhs.gov/fraud/exclusions.asp>.



Civil Monetary Penalties Law [42 U.S.C. § 1320a-7a]

OIG may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue. Penalties range from \$10,000 to \$50,000 per violation. Some examples of CMPL violations include:

- ▼ presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- ▼ presenting a claim that the person knows or should know is for an item or service for which payment may not be made;
- ▼ violating the AKS;
- ▼ violating Medicare assignment provisions;
- ▼ violating the Medicare physician agreement;
- ▼ providing false or misleading information expected to influence a decision to discharge;
- ▼ failing to provide an adequate medical screening examination for patients who present to a hospital emergency department with an emergency medical condition or in labor; and
- ▼ making false statements or misrepresentations on applications or contracts to participate in the Federal health care programs.

I. Physician Relationships With Payers

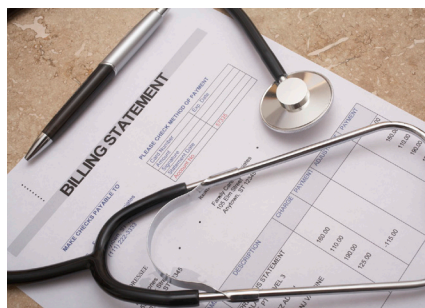
During residency, you probably are not focused on who pays for your patients' care. Once you start practicing, it is important to understand who the payers are. The U.S. health care system relies heavily on third-party payers, and, therefore, your patients often are not the ones who pay most of their medical bills. Third-party payers include commercial insurers and the Federal and State governments. **When the Federal Government covers items or services rendered to Medicare and Medicaid beneficiaries, the Federal fraud and abuse laws apply.** Many States also have adopted similar laws that apply to your provision of care under State-financed programs and to private-pay patients. Consequently, you should recognize that the issues discussed here may apply to your care of all insured patients.



Accurate Coding and Billing

Payers trust you, as a physician, to provide necessary, cost-effective, and quality care. You exert significant influence over what services your patients receive, you control the documentation describing what services they actually received, and your documentation serves as the basis for bills sent to insurers for services you provided. The Government's payment of claims is generally based solely on your representations in the claims documents.

Because the Government invests so much trust in physicians on the front end, Congress provided powerful criminal, civil, and administrative enforcement tools for instances when unscrupulous providers abuse that trust. The Government has broad capabilities to audit claims and investigate providers when it has a reason to suspect fraud. Suspicion of fraud and abuse may be raised by irregular billing patterns or reports from others, including your staff, competitors, and patients.



When you submit a claim for services performed for a Medicare or Medicaid beneficiary, you are filing a bill with the Federal Government and certifying that you have earned the payment requested and complied with the billing requirements. If you knew or should have known that the submitted claim was false, then the attempt to collect unearned money constitutes a violation. A common type of false claim is “upcoding,” which refers to using billing codes that reflect a more severe illness than actually existed or a more expensive treatment than was provided. Additional examples of improper claims include:

- ▽ billing for services that you did not actually render;
- ▽ billing for services that were not medically necessary;
- ▽ billing for services that were performed by an improperly supervised or unqualified employee;
- ▽ billing for services that were performed by an employee who has been excluded from participation in the Federal health care programs;
- ▽ billing for services of such low quality that they are virtually worthless; and
- ▽ billing separately for services already included in a global fee, like billing for an evaluation and management service the day after surgery.

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Upcoding

Medicare pays for many physician services using Evaluation and Management (commonly referred to as “E&M”) codes. New patient visits generally require more time than follow-up visits for established patients, and therefore E&M codes for new patients command higher reimbursement rates than E&M codes for established patients. An example of upcoding is an instance when you provide a follow-up office visit or follow-up inpatient consultation but bill using a higher level E&M code as if you had provided a comprehensive new patient office visit or an initial inpatient consultation.

Another example of upcoding related to E&M codes is misuse of Modifier 25. Modifier 25 allows additional payment for a separate E&M service rendered on the same day as a procedure. Upcoding occurs if a provider uses Modifier 25 to claim payment for an E&M service when the patient care rendered was not significant, was not separately identifiable, and was not above and beyond the care usually associated with the procedure.

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Case Examples of Fraudulent Billing



- A psychiatrist was fined \$400,000 and permanently excluded from participating in the Federal health care programs for misrepresenting that he provided therapy sessions requiring 30 or 60 minutes of face-to-face time with the patient, when he had provided only medication checks for 15 minutes or less. The psychiatrist also misrepresented that he provided therapy sessions when in fact a non-licensed individual conducted the sessions.
- A dermatologist was sentenced to 2 years of probation and 6 months of home confinement and ordered to pay \$2.9 million after he pled guilty to one count of obstruction of a criminal health care fraud investigation. The dermatologist admitted to falsifying lab tests and backdating letters to referring physicians to substantiate false diagnoses to make the documentation appear that his patients had Medicare-covered conditions when they did not.
- A cardiologist paid the Government \$435,000 and entered into a 5-year Integrity Agreement with OIG to settle allegations that he knowingly submitted claims for consultation services that were not supported by patient medical records and did not meet the criteria for a consultation. The physician also allegedly knowingly submitted false claims for E&M services when he had already received payment for such services in connection with previous claims for nuclear stress testing.
- An endocrinologist billed routine blood draws as critical care blood draws. He paid \$447,000 to settle allegations of upcoding and other billing violations.





Physician Documentation

Physicians should maintain accurate and complete medical records and documentation of the services they provide. Physicians also should ensure that the claims they submit for payment are supported by the documentation. The Medicare and Medicaid programs may review beneficiaries' medical records. **Good documentation practice helps ensure that your patients receive appropriate care from you and other providers who may rely on your records for patients' past medical histories.** It also helps you address challenges raised against the integrity of your bills. You may have heard the saying regarding malpractice litigation: "If you didn't document it, it's the same as if you didn't do it." The same can be said for Medicare and Medicaid billing.



For more information on physician documentation, see CMS's Documentation Guidelines for Evaluation and Management Services available at http://www.cms.gov/MLNEdWebGuide/25_EMDOC.asp.



Enrolling as a Medicare and Medicaid Provider With CMS

CMS is the Federal agency that administers the Medicare program and monitors the Medicaid programs run by each State. To obtain reimbursement from the Government for services provided to Federal health care program beneficiaries, you must:

1. **Obtain a National Provider Identifier (NPI).** An NPI is a unique health identifier for health care providers. You may apply for your NPI at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>.
2. **Complete the appropriate Medicare Enrollment Application.** During the enrollment process, CMS collects information to ensure that you are qualified and eligible to enroll in the Medicare Program. Information about Medicare provider enrollment is available at <http://www.cms.gov/MedicareProviderSupEnroll/>.
3. **Complete your State-specific Medicaid Enrollment Application.** Information about Medicaid provider enrollment is available from your State Medicaid agency.

Once you become a Medicare and/or Medicaid provider, you are responsible for ensuring that claims submitted under your number are true and correct.



For tips you can share with your patients on how they can protect themselves from medical identity theft, see OIG's brochure entitled "Tips to Avoid Medical ID Theft" available at

http://oig.hhs.gov/fraud/IDTheft/OIG_Medical_Identity_Theft_Brochure.pdf.



Prescription Authority

The Drug Enforcement Administration (DEA) is a Department of Justice agency responsible for enforcing the Controlled Substances Act. When you prepare to enter practice, you probably will apply for a DEA number that authorizes you to write prescriptions for controlled substances. You also will apply for your State medical license and any additional credentials your State requires for you to write prescriptions. You must ensure that you write prescriptions only for lawful purposes.



Case Examples of Misuse of Physician Provider and Prescription Numbers

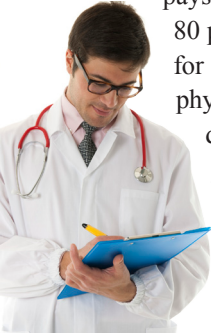
- A physician was ordered to pay \$50,000 in restitution to the Government for falsely indicating on his provider number application that he was running his own practice when, in fact, a neurophysiologist was operating the practice and paying the physician a salary for the use of his number.
- An osteopathic physician was sentenced to 10 years in prison and ordered to pay \$7.9 million in restitution after she accepted cash payments for signing preprinted prescriptions and Certificates of Medical Necessity for motorized wheelchairs for beneficiaries she never examined. More than 60 DME companies received Medicare and Medicaid payments based on her fraudulent prescriptions.
- An internal medicine physician pled guilty to Medicare fraud and to conspiring to dispense oxycodone, morphine, hydrocodone, and alprazolam. The physician allowed unauthorized and non-medical employees at his pain center to prescribe drugs using his pre-signed blank prescription forms. Prescriptions were issued in his name without adequate physical exams, proper diagnoses, or consideration of alternative treatment options. He paid \$317,000 in restitution to the Government.





Assignment Issues in Medicare Reimbursement

Most physicians bill Medicare as participating providers, which is referred to as “accepting assignment.” Each year, Medicare promulgates a fee schedule setting the reimbursement for each physician service. Once beneficiaries satisfy their annual deductible, Medicare pays 80 percent of the fee schedule amount and the beneficiary pays 20 percent. Participating providers receive the Medicare program’s 80 percent directly from the Medicare program and bill the beneficiary for the remaining 20 percent. Accepting assignment means that the physician accepts the Medicare payment plus any copayment or deductible Medicare requires the patient to pay *as the full payment for the physician’s services and that the physician will not seek any extra payment* (beyond the copayment or deductible) from the patient. Medicare participating physicians may not bill Medicare patients extra for services that are already covered by Medicare. Doing so is a violation of a physician’s assignment agreement and can lead to penalties.



The second, less common, way to obtain Medicare reimbursement is to bill as a non-participating provider. Non-participating providers do not receive direct payment from the Medicare program. Rather, they bill their patients and the patients seek reimbursement from Medicare. Although non-participating providers are not subject to the assignment rules, they still must limit the dollar amount of their charges to Medicare patients. Generally, non-participating providers may not charge Medicare beneficiaries more than 15 percent in excess of the Medicare fee schedule amount. It is illegal to charge patients more than the limiting charge established for physicians’ services.



Excluded providers may not receive Medicare payment either as participating or non-participating providers.

You may see advertisements offering to help you convert your practice into a “boutique,” “concierge,” or “retainer” practice. Many such solicitations promise to help you work less, yet earn more money. **If you are a participating or non-participating physician, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid.** It is legal to charge patients for services that are not covered by Medicare. However, charging an “access fee” or “administrative fee” that simply allows them to obtain Medicare-covered services from your practice constitutes double billing.

Case Example of a Physician Violating an Assignment Agreement by Charging Beneficiaries Extra Fees

- A physician paid \$107,000 to resolve potential liability for charging patients, including Medicare beneficiaries, an annual fee. In exchange for the fee, the physician offered: (1) an annual physical; (2) same- or next-day appointments; (3) dedicated support personnel; (4) around-the-clock physician availability; (5) prescription facilitation; (6) expedited and coordinated referrals; and (7) other amenities at the physician's discretion. The physician's activities allegedly violated the assignment agreement because some of the services outlined in the annual fee were already covered by Medicare.



II. Physician Relationships With Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc.

Any time a health care business offers something to you for free or at below fair market value, you always should ask yourself, “*Why?*” For example, if a DME supplier offers to give you cash or to pay for your summer vacation, you should suspect that the supplier is trying to induce you to refer your patients to that vendor. If a laboratory offers to decorate your patient waiting room, you should suspect that it is trying to induce you to send your lab business its way.



For more information on physician relationships with:

fellow providers, see OIG’s “Compliance Program Guidance for Individual and Small Group Physician Practices” available at <http://oig.hhs.gov/authorities/docs/physician.pdf>;

hospitals, see OIG’s “Supplemental Compliance Program Guidance for Hospitals” available at <http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>; and

nursing homes, see OIG’s “Supplemental Compliance Program Guidance for Nursing Facilities” available at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf.



Physician Investments in Health Care Business Ventures

Some have observed that physicians who invest in health care business ventures with outside parties (e.g., imaging centers, labs, equipment vendors, or physical therapy clinics) refer more patients for the services provided by those parties than physicians who do not invest. Maybe this disproportionate utilization partly reflects the physicians’ belief in the value of the services or technology, prompting the investments in the first place. However, there also is a risk that the physicians’ belief in the value of the services or technology is less a cause than an effect of the investment interest. The physician investors’ disproportionate utilization may be motivated partly by the physicians’ ability to profit from the use of the ancillary services. These business relationships can sometimes unduly influence or distort physician decisionmaking and result in the improper steering of a patient to a particular therapy or source of services in which a physician has a financial interest. **Excessive and medically unnecessary referrals waste Government and beneficiary money and**

can expose beneficiaries to harm from unnecessary services. Many of these investment relationships have serious legal risks under the AKS and Stark law.

If you are invited to invest in a health care business whose products you might order or to which you might refer your patients, you should ask the following questions. If the answer is “yes” to any of them, you should consider carefully whether you are investing for legitimate reasons.

- ? Are you being offered an investment interest for a nominal capital contribution?
- ? Will your ownership share be larger than your share of the aggregate capital contributions made to the venture?
- ? Is the venture promising you high rates of return for little or no financial risk?
- ? Is the venture or any potential business partner offering to loan you the money to make your capital contribution?
- ? Are you being asked to promise or guarantee that you will refer patients or order items or services from the venture?
- ? Do you believe you will be more likely to refer more patients for the items and services provided by the venture if you make the investment?
- ? Do you believe you will be more likely to refer to the venture just because you made the investment?
- ? Will the venture have sufficient capital from other sources to fund its ongoing operations?





For more information on physician investments, see:

OIG's Special Fraud Alert entitled "Joint Venture Arrangements" available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>;

OIG's Special Advisory Bulletin on contractual joint ventures available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf>; and

OIG's "Supplemental Compliance Program Guidance for Hospitals" available at <http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>.

Case Examples Involving Kickbacks for Referrals and Self-Referrals

- Nine cardiologists paid the Government over \$3.2 million for allegedly engaging in a kickback scheme. The cardiologists received salaries under clinical faculty services agreements with a hospital under which, the Government alleged, they did not provide some or any of the services.



In exchange, the cardiologists referred their patients to the hospital for cardiology services. Two of the physicians also pled guilty to criminal embezzlement charges involving the same conduct.

- A physician paid the Government \$203,000 to settle allegations that he violated the physician self-referral prohibition in the Stark law for routinely referring Medicare patients to an oxygen supply company he owned.





Physician Recruitment

A hospital will sometimes provide a physician with a recruitment incentive to induce the physician to relocate to the hospital's geographic area, become a member of its medical staff, and establish a practice that helps serve that community's medical needs. Often, such recruitment efforts are legitimately designed to fill a "clinical gap" in a medically underserved area to which it may be difficult to attract physicians in the absence of financial incentives. However, as you begin planning your professional future and perhaps receiving recruitment offers, you need to be aware that in some communities, especially ones with multiple hospitals, the competition for patients can be fierce. Some hospitals may offer illegal inducements to you, or to the established physician practice you join in the hospital's community, to gain referrals. This means that the competition for your loyalty can cross the line into illegal arrangements for which *both you and the hospital* can be liable.

Recruitment arrangements are of special interest to graduating residents and fellows. Within very specific parameters specified in the Stark law and subject to compliance with the AKS, hospitals may provide relocation assistance and practice support under a properly structured recruitment arrangement to assist you in establishing a practice in the hospital's community. Alternatively, a hospital may pay you a fair market value salary as an employee or pay you fair market value for specific services you render to the hospital as an independent contractor. However, the hospital may not offer you money, provide you free or below-market rent for your medical office, or engage in similar activities designed to influence your referral decisions. **You should admit your patients to the hospital best suited to care for their particular medical conditions or to the hospital your patient selects based on his or her preference or insurance coverage.** As noted, if a hospital or physician practice separately or jointly is recruiting you as a new physician to the community, you may be offered a recruitment package. But, you may not negotiate for benefits in exchange for a promise—implicit or explicit—that you will admit your patients to a specific hospital or practice setting unless you are a hospital employee. You should seek knowledgeable legal counsel if someone with whom you are entering into a relationship requires you to admit patients to a specific hospital or practice group.





Tips for Medical Directors

If you choose to accept a medical directorship at a nursing home or other facility, you must be prepared to assume substantial professional responsibility for the care delivered at the facility. As medical director, patients (both your own patients and the patients of other attending physicians) and their families count on you, and State and Federal authorities may hold you accountable as well. To do this job well, you should:

- actively oversee clinical care in the facility;
- lead the medical staff to meet the standard of care;
- ensure proper training, education, and oversight for physicians, nurses, and other staff members; and
- identify and address quality problems.

Case Examples of Medical Directorship Issues

- A physician group practice paid the Government \$1 million and entered into a 5-year Corporate Integrity Agreement to settle alleged violations of the AKS, FCA, and Stark law related to medical directorships with a medical center. Allegedly, the agreements were not in writing, the physicians were paid more than fair market value for the services they rendered, and the payment amounts were based on the value of referrals the physicians sent to the medical center.
- Two orthopedic surgeons paid \$450,000 and \$250,000 to settle allegations related to improper medical directorships with a company that operated a diagnostic imaging center, a rehabilitation facility, and an ambulatory surgery center. The company allegedly provided the physicians with valuable compensation, including free use of the corporate jet, under the medical directorship agreements, which required the physicians to render limited services in return. The agreements with the physicians allegedly called for redundant services and served to encourage the physicians to refer their patients to the facilities operated by the company.



III. Physician Relationships With Vendors



Free Samples

Some physicians welcome visits from pharmaceutical salespeople, while other physicians prefer not to directly engage with industry representatives. If you decide to make your practice accessible to salespeople, you probably will be offered product samples. Many drug and biologic companies provide physicians with free samples that the physicians may give to patients free of charge. **It is legal to give these samples to your patients for free, but it is illegal to sell the samples.**



The Government has prosecuted physicians for billing Medicare for free samples. Opinions differ on whether sampling practices ultimately increase or decrease patients' long-term drug costs. If you choose to accept samples, you will need reliable systems in place to safely store the samples and ensure that samples are not commingled with your commercial stock.

Case Example Involving Drug Samples

- Several urologists pled guilty to charges of conspiracy, paid restitution in the tens of thousands of dollars, and received sanctions against their medical licenses for billing Medicare for injectable prostate cancer drugs they received for free from two pharmaceutical companies. The pharmaceutical companies paid \$1.4 billion for their part of the alleged scheme to give urologists free samples and encourage them to bill Medicare at an inflated price. The pharmaceutical companies also provided urologists with additional inducements to use their drugs over the competitor's products, including drug rebates, education grants, volume discounts, free goods, and debt forgiveness.





Relationships With the Pharmaceutical and Medical Device Industries

Physician-industry collaboration can produce important medical advances. However, some pharmaceutical and device companies have used sham consulting agreements and other arrangements to buy physician loyalty to their products. Such illegal arrangements induce physicians to prescribe or use products on the basis of that loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient.



As a practicing physician, you may have opportunities to work as a consultant or promotional speaker for the drug or device industry. For every financial relationship offered to you, evaluate the link between the services you can provide and the compensation you will receive. Test the propriety of any proposed relationship by asking yourself the following questions:

- ? Does the company *really* need *my* particular expertise or input?
- ? Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
- ? Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?



A good discussion that assists in distinguishing between legitimate and questionable industry relationships is located in the OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" available at <http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf>.

If your contribution is your time and effort or your ability to generate useful ideas and the payment you receive is fair market value compensation for your services without regard to referrals, then, depending on the circumstances, you may legitimately serve as a *bona fide* consultant. **If your contribution is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.**

For example, if a drug company offers to pay you and a hundred other “thought leaders” to attend a conference in the Bahamas without requiring preparatory work on your part or information about your expertise in the field (other than the fact that you are a licensed physician), you should be suspicious that the company is attempting to influence you to prescribe its drug.



Case Example of Kickbacks in the Device Industry

- Four orthopedic device manufacturers paid \$311 million to settle kickback and false claims allegations that the companies bribed surgeons to recommend their hip and knee surgical implant products. The companies allegedly would award physicians with vacations, gifts, and annual “consulting fees” as high as \$200,000 in return for the physicians’ endorsements of their implants or use of them in operations. Many of the individual orthopedic surgeons at the receiving end of the kickbacks are the subject of ongoing investigations by the Government. One orthopedic surgeon recently paid \$650,000 to resolve allegations that the surgeon accepted payments from device manufacturers to use their hip and knee implants.





Transparency in Physician-Industry Relationships

Although some physicians believe that free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows that these types of perquisites can influence prescribing practices. Recent pharmaceutical company settlements with the Department of Justice and OIG require “transparency” in physician-industry relationships, whether by requiring the pharmaceutical company to provide the Government with a list of physicians whom the company paid and/or by requiring ongoing public disclosure by the company of physician payments. **The public will soon know what gifts and payments a physician receives from industry.** The Patient Protection and Affordable Care Act of 2010 requires drug, device, and biologic companies to publicly report nearly all gifts or payments they make to physicians beginning in 2013.

Academic institutions also may impose various restrictions on the interactions their faculty members or affiliated physicians have with industry. These and other considerations may factor into your decision about whether you want to conduct industry-sponsored research; serve as a consultant or director for a drug, biologic, or device company; apply for industry-sponsored educational or research grants; or engage in other relationships with industry.



Both the pharmaceutical industry (through PhRMA) and the medical device industry (through AdvaMed) have adopted codes of ethics for their respective industries regarding relationships with health care professionals. Both codes are available online.



Conflict-of-Interest Disclosures

Many of the relationships discussed in this brochure are subject to conflict-of-interest disclosure policies. Even if the relationships are legal, you may have an obligation to disclose their existence. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders, such as States, universities, and the National Institutes of Health, and from the Food and Drug Administration (FDA) when data are submitted to support marketing approval for new drugs, devices, or biologics. To “manage” your conflicts of interest, consider the conflicts policies that affect your professional activities, candidly disclose any industry money subject to these policies, and adhere to restrictions on your activities. If you are uncertain whether a conflict exists, ask someone. You always can apply the “newspaper test” and ask yourself whether you would want the arrangement to appear on the front page of your local newspaper.



Continuing Medical Education



After finishing your formal graduate medical training, you will assume greater responsibility for your continuing medical education (CME) to maintain State licensure, hospital privileges, and board certification. Drug and device manufacturers sponsor many educational opportunities for physicians. **It is important to distinguish between CME sessions that are educational in nature and sessions that constitute marketing by a drug or device manufacturer.** Industry satellite programs that occur concurrently with a society meeting are generally promotional, even if the primary speaker is a physician who is well known in the field. You should be circumspect about a discussion that focuses on a particular brand drug or device, as opposed to all the treatment alternatives for a specific condition.

For example, if speakers recommend use of a drug to treat conditions for which there is no FDA approval or use of a drug by children when FDA has approved only adult use, you should independently seek out the empirical data that support these recommendations. **Note that although physicians may prescribe drugs for off-label uses, it is illegal under the Federal Food, Drug, and Cosmetic Act for drug manufacturers to promote off-label uses of drugs.**



Advertisements and other promotional materials for drugs, biologics, and medical devices must be truthful, not misleading, and limited to approved uses. FDA is requesting physicians' assistance in identifying misleading advertisements through its Bad Ad Program. If you spot advertising violations, you should report them to FDA by calling 877-RX-DDMAC (877-793-3622) or by emailing badad@fda.gov.

If you are invited to serve as faculty for industry-sponsored CME, ask yourself the following questions:

- ? Does the sponsor *really* need *my* particular expertise or input?
- ? Does the amount of money the sponsor is offering seem fair and appropriate for the educational value I will add to the presentation?
- ? Is it possible the sponsor is paying me for my loyalty so that I will prescribe its drugs or use its devices?
- ? Does the sponsor prepare a slide deck and speaker notes, or am I free to set the content of the lecture?

Compliance Programs for Physicians

Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims. The following seven components provide a solid basis upon which a physician practice can create a voluntary compliance program:

1. Conduct internal monitoring and auditing.
2. Implement compliance and practice standards.
3. Designate a compliance officer or contact.
4. Conduct appropriate training and education.
5. Respond appropriately to detected offenses and develop corrective action.
6. Develop open lines of communication with employees.
7. Enforce disciplinary standards through well-publicized guidelines.

With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.



For more information on compliance programs for physicians, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at <http://oig.hhs.gov/authorities/docs/physician.pdf>.

Where To Go for Help

When you are considering whether or not to engage in a particular billing practice; enter into a particular business venture; or pursue an employment, consulting, or other personal services relationship, it is prudent to evaluate the arrangement for potential compliance problems. The following is a list of possible resources that can help you.

- ➔ Experienced health care lawyers can analyze your issues and provide a legal evaluation and risk analysis of the proposed venture, relationship, or arrangement.

- ➔ The Bar Association in your State may have a directory of attorneys in your area who practice in the health care field.
- ➔ Your State or local medical society may be a good resource for issues affecting physicians and may have listings of health care lawyers in your area.
- ➔ Your specialty society may have information on additional risk areas specific to your type of practice.
- ➔ CMS’s local contractor medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices. The contact information for local contractors is available at http://www.cms.gov/MLNGenInfo/30_contactus.asp.
- ➔ CMS’s “Medicare Physician Guide: A Resource for Residents, Practicing Physicians, and Other Health Care Professionals” available at <http://www.cms.gov/MLNProducts/downloads/physicianguide.pdf>, provides an overview of the Medicare program and information on Medicare reimbursement and payment policies.
- ➔ The OIG’s Web site, available at <http://oig.hhs.gov>, provides substantial fraud and abuse guidance.
- ➔ As discussed above, OIG issues Compliance Program Guidance documents that include compliance recommendations and discussions of fraud and abuse risk areas. These guidance documents are available at <http://oig.hhs.gov/fraud/complianceguidance.asp>.
- ➔ OIG issues advisory opinions to parties who seek advice on the application of the AKS, CMPL, and Exclusion Authorities. Information on how to request an OIG advisory opinion and links to previously published OIG advisory opinions are available at <http://oig.hhs.gov/fraud/advisoryopinions.asp>.
- ➔ CMS issues advisory opinions to parties who seek advice on the Stark law. Information on how to request a CMS advisory opinion and links to previously published CMS advisory opinions are available at http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp.

What To Do If You Think You Have a Problem

If you are engaged in a relationship you think is problematic or have been following billing practices you now realize were wrong:

- ➔ Immediately cease filing the problematic bills.
- ➔ Seek knowledgeable legal counsel.
- ➔ Determine what money you collected in error from your patients and from the Federal health care programs and report and return overpayments.
- ➔ Unwind the problematic investment.
- ➔ Disentangle yourself from the suspicious relationship.
- ➔ Consider using OIG's or CMS's self-disclosure protocols.

OIG Provider Self-Disclosure Protocol

The OIG Provider Self-Disclosure Protocol is a vehicle for physicians to voluntarily disclose self-discovered evidence of potential fraud. The protocol allows providers to work with the Government to avoid the costs and disruptions entailed in a Government-directed investigation. For more information on the OIG Provider Self-Disclosure Protocol, see <http://oig.hhs.gov/fraud/selfdisclosure.asp>.

Case Examples of Physician Liabilities Resolved Under the OIG Provider Self-Disclosure Protocol

- A Minneapolis physician paid \$53,400 and resolved liability for violating his Medicare assignment agreement by charging patients a yearly fee for services, some of which were covered by Medicare.
- A Florida physician paid \$100,000 and resolved liability related to referring patients to a lab owned by his brother.
- A neurosurgery practice paid \$10,000 and resolved liability for employing an individual who was excluded from participation in the Federal health care programs.



What To Do If You Have Information About Fraud and Abuse Against Federal Health Care Programs

If you have information about fraud and abuse against Federal health care programs, use the OIG Fraud Hotline to report that information to the appropriate authorities. The Hotline allows the option of reporting anonymously.

Phone: 1-800-HHS-TIPS (1-800-447-8477)
Fax: 1-800-223-8164
Email: HHSTIPS@oig.hhs.gov
TTY: 1-800-377-4950
Mail: Office of Inspector General
Department of Health & Human Services
Attn: HOTLINE
P.O. Box 23489
Washington, DC 20026



For additional information about the Hotline, visit the OIG Web site at <http://oig.hhs.gov/fraud/hotline/>.



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