DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Avoiding Medicare Fraud & Abuse: A Roadmap for Physicians

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I. Introduction

Most physicians strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Trust is at the core of the physician-patient relationship. The Federal Government also places enormous trust in physicians. Medicare and other Federal health care programs rely on physicians' medical judgment to treat patients with appropriate services. When reimbursing physicians and hospitals for services provided to program patients, 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 document 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 document are relevant to all physicians, regardless of specialty or practice setting.

II. 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, the Physician Self-Referral Law (Stark Law), the Social Security Act, and the U.S. Criminal Code. Violations of these laws may result in nonpayment of claims, Civil Monetary Penalties (CMPs), exclusion from the Medicare Program, and criminal and civil liability.

Government agencies, including the Department of Justice (DOJ), 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.

More Information on: Fraud and Abuse in Medicare Part C and Part D and Medicaid

The fraudulent conduct addressed by these laws is also prohibited in Medicare Part C and Part D and in Medicaid, including fraud and abuse related to "dual eligibles." "Dual eligibles" refers to individuals who are entitled to or enrolled in Medicare Part A or enrolled in Part B, and who are eligible for Medicaid. For more information, refer to "Medicare Parts C and D Fraud, Waste, and Abuse Training" available at http://www.cms.gov/MLNProducts/45_ProviderCompliance.asp on the CMS website.

The FCA protects the Federal Government from being overcharged or sold substandard goods or services. The FCA imposes civil liability on any person who knowingly submits, or causes to be submitted, a false or fraudulent claim to the Federal Government. The "knowing" standard includes acting in deliberate ignorance or reckless disregard of the truth related to the claim. An example may be a physician who submits claims to Medicare for medical services he or she knows were not provided. Civil penalties for violating the FCA may include fines and up to 3 times the amount of damages sustained by the Government as a result

of the false claims. There also is a criminal FCA. Criminal penalties for submitting false claims may include fines, imprisonment, or both.

For more information on fraud, visit http://oig.hhs.gov/fraud on the Internet. To view the civil FCA (31 United States Code [U.S.C.] Sections 3729-3733), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title31/pdf/USCODE-2010-title31-subtitleIII-chap37-subchapIII.pdf on the Internet. To view the criminal FCA (18 U.S.C. Section 287), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title18/pdf/USCODE-2010-title18-partI-chap15-sec287.pdf on the Internet.

The Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. Where remuneration is paid, received, offered, or solicited purposefully to induce or reward referrals of items or services payable by a Federal health care program, the Anti-Kickback Statute is violated. If an arrangement satisfies certain regulatory safe harbors, it is not treated as an offense under the statute. The safe harbor regulations are set forth at 42 Code of Federal Regulations (CFR) Section 1001.952. Criminal penalties for violating the Anti-Kickback Statute may include fines, imprisonment, or both.

For more information, visit http://oig.hhs.gov/compliance/safe-harbor-regulations on the Internet. To view the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA.pdf on the Internet.

The Physician Self-Referral Law (Stark Law) prohibits a physician from making a referral for certain designated health services to an entity in which the physician (or an immediate member of his or her family) has an ownership/investment interest or with which he or she has a compensation arrangement, unless an exception applies. Penalties for physicians who violate the Physician Self-Referral Law (Stark Law) include fines as well as exclusion from participation in all Federal health care programs.

For more information, visit http://www.cms.gov/PhysicianSelfReferral on the CMS website. To view the Physician Self-Referral Law (Stark Law) (42 U.S.C. Section 1395nn), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXVIII-partE-sec1395nn.pdf on the Internet.

The Criminal Health Care Fraud Statute (18 U.S.C. Section 1347) prohibits knowingly and willfully executing, or attempting to execute, a scheme or artifice:

- To defraud any health care benefit program; or
- To obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program;

in connection with the delivery of or payment for health care benefits, items, or services. Proof of actual knowledge or specific intent to violate the law is **not** required. Penalties for violating the Criminal Health Care Fraud Statute may include fines, imprisonment, or both.

Under the **Exclusion Statute**, OIG is required to impose exclusions from participation in all Federal health care programs on health care providers and suppliers who have been convicted of:

1. Medicare fraud, as well as any other offenses related to the delivery of items or services under Medicare;
2. Patient abuse or neglect;
3. Felony convictions for other health care-related fraud, theft, or other financial misconduct; or
4. Felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances.

More Information on:
Exclusion from Participation in All Federal Health Care Programs

Exclusion means that, for a designated period, Medicare, Medicaid, and other Federal health care programs will not pay the provider for services performed or for services ordered by the excluded party. For information on OIG's Special Advisory Bulletin titled "The Effect of Exclusion From Participation in Federal Health Care Programs," refer to http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm on the OIG website.

OIG has discretion to impose permissive exclusions on a number of other grounds. To view the Exclusion Statute (42 U.S.C. Section 1320a-7), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7.pdf on the Internet.

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

Under the **Civil Monetary Penalties (CMP) Law**, CMPs may be imposed for a variety of conduct, and different amounts of penalties and assessments may be authorized based on the type of violation at issue. Penalties range from up to $10,000 to $50,000 per violation. CMPs can also include an assessment of up to 3 times the amount claimed for each item or service, or up to 3 times the amount of remuneration offered, paid, solicited, or received. To view the CMP Law (42 U.S.C. Section 1320a-7a), visit http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap7-subchapXI-partA-sec1320a-7a.pdf on the Internet.

III. Physician Relationships With Payers

The United States (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 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. 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 Federal Government's payment of claims is generally based solely on your representations in the claims documents.

When you submit a claim for services performed for a Medicare patient, 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. 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.

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 subsequent hospital visit but bill using a higher level E/M code as if you had provided a comprehensive new patient office visit or an initial hospital visit.

Another example of upcoding related to E/M codes is the 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.

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 Program 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 billing.

More Information on: Physician Documentation

For more information on physician documentation, refer to the "Documentation Guidelines for Evaluation and Management Services" available at http://www.cms.gov/MLNEdWebGuide/25_EMDOC.asp on the CMS website.

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IV. Physician Relationships With Fellow Providers

Any time a health care business offers something to you for free or at below fair market value, you always should ask yourself, "**Why**?"

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, laboratories, 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, these business relationships can sometimes unduly influence or distort physician decision-making 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 cost Federal Government and Medicare beneficiary money and can expose the beneficiaries to harm from unnecessary services**. Many of these investment relationships have serious legal risks under the Anti-Kickback Statute and the Physician Self-Referral Law (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?

More Information on: Physician Investments

For more information on physician investments, refer to OIG's Special Fraud Alert entitled "Joint Venture Arrangements" available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html on the OIG website;

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

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

More Information on: Physician Relationships

For more information on physician relationships with:

Fellow providers, refer to the OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf on the OIG website;

Hospitals, refer to the OIG's "Supplemental Compliance Program Guidance for Hospitals" available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf on the OIG website; and

Nursing homes, refer to the OIG's "Supplemental Compliance Program Guidance for Nursing Facilities" available at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf on the OIG website.

- 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?

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, 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.

Medical Identity Theft

For information on medical identity theft, refer to OIG's brochure titled "Medical Identity Theft & Medicare Fraud" available at http://oig.hhs.gov/fraud/medical-id-theft/OIG_Medical_Identity_Theft_Brochure.pdf on the OIG website.

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 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.

V. Physician Relationships With Vendors

Free 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 Federal Government has prosecuted physicians for billing Medicare for free samples. 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.

Relationships with the Pharmaceutical and Medical Device Industries

Some pharmaceutical and device companies have used sham consulting agreements and other arrangements to buy physician loyalty to their products. 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:

> **More Information on: Industry Relationships**
>
> For more information on distinguishing between legitimate and questionable industry relationships, refer to the OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf on the OIG website.

- 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?

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.**

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. **The public will soon know what gifts and payments a physician receives from industry.** The Affordable Care Act 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.

> **Pharmaceutical and Medical Device Industries Codes of Ethics**
>
> Both the pharmaceutical industry through the Pharmaceutical Research and Manufacturers of America (PhRMA) and the medical device industry through the Advanced Medical Technology Association (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 document 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. 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

You are responsible 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.** 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.**

FDA Bad Ad Program

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 e-mailing HHSTIPS@oig.hhs.gov.

VI. 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 Affordable Care Act, physicians who treat Medicare beneficiaries will be required to establish a compliance program.

More Information on:
Compliance Programs for Physicians

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

VII. 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' local contractor medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices. For contact information, visit http://www.cms.gov/MLNProducts/Downloads/CallCenterTollNumDirectory.zip on the CMS website.
- For more information on the Medicare Program and information on Medicare reimbursement and payment policies, refer to CMS' "Medicare Physician Guide" at http://www.cms.gov/MLNProducts/downloads/MedicarePhysicianGuide_ICN005933.pdf on the CMS website.
- For more information on substantial fraud and abuse guidance, visit http://oig.hhs.gov on the OIG website.
- For more information on OIG compliance recommendations and discussions of fraud and abuse risk areas, refer to OIG's Compliance Program Guidance documents available at http://oig.hhs.gov/compliance/compliance-guidance on the OIG website. For compliance education, visit http://oig.hhs.gov/compliance/101 on the OIG website.
- OIG issues advisory opinions to parties who seek advice on the application of the Anti-Kickback Statute, CMP Law, and Exclusion Authorities. For more information on how to request an OIG advisory opinion and links to previously published OIG advisory opinions, visit http://oig.hhs.gov/compliance/advisory-opinions on the OIG website.
- CMS issues advisory opinions to parties who seek advice on the Physician Self-Referral Law (Stark Law). For more information on how to request a CMS advisory opinion and links to previously published CMS advisory opinions, visit http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp on the CMS website.

VIII. 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.
- Undo the problematic investment by taking all necessary steps to free yourself from your involvement in the investment.
- Disentangle yourself from the suspicious relationship.
- Consider using OIG's or CMS' 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 gives providers the opportunity to avoid the costs and disruptions associated with a Federal Government-directed investigation and civil or administrative litigation. For more information on the OIG Provider Self-Disclosure Protocol, visit http://oig.hhs.gov/compliance/self-disclosure-info on the OIG website.

CMS Self-Referral Disclosure Protocol (SRDP)

The Self-Referral Disclosure Protocol (SRDP) enables health care providers and suppliers to self-disclose actual or potential violations of the Physician Self-Referral Law (Stark Law). For more information, visit http://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp on the CMS website.

IX. 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. You may also contact your local Medicare Contractor.

Phone: 1-800-HHS-TIPS (1-800-447-8477)

Fax: 1-800-223-8164

E-mail: 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

You can also visit http://www.stopmedicarefraud.gov on the Internet.

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