

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



WASHINGTON, DC 20201

The Office of Inspector General (OIG) for the U.S. Department of Health & Human Services has created the educational materials listed below to assist in teaching physicians about the Federal laws designed to protect the Medicare and Medicaid programs and program beneficiaries from fraud, waste, and abuse.

- 1. A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse, which is a booklet for physicians' self-study. The Roadmap is available on OIG's Web site at http://oig.hhs.gov/compliance/physician-education/roadmap web version.pdf.
- 2. A companion PowerPoint presentation that we encourage you to use to teach the material contained in the *Roadmap*. The PowerPoint presentation is available on OIG's Web site at http://oig.hhs.gov/compliance/physician-education/roadmap_powerpoint.ppt.
- 3. The speaker note set, which will assist you in giving the PowerPoint presentation. The speaker note set is available below and on OIG's Web site at http://oig.hhs.gov/compliance/physician-education/roadmap_speaker_notes.pdf.
- 4. For physicians who may be unable to attend a live, didactic presentation of the material contained in the *Roadmap*, we also have provided a narration of the speaker notes to accompany the PowerPoint slides. This narration is available to watch on OIG's Web site at http://oig.hhs.gov/compliance/physician-education/index.asp or to download at http://oig.hhs.gov/compliance/physician-education/roadmap_audio_narration.wmv.

These materials summarize the five main Federal fraud and abuse laws (the False Claims Act, the Anti-Kickback Statute, the Stark Law, the Exclusion Statute, and the Civil Monetary Penalties Law) and provide tips on how physicians should comply with these laws in their relationships with payers (e.g., the Medicare and Medicaid programs), vendors (e.g., drug, biologic, and medical device companies), and fellow providers (e.g., hospitals, nursing homes, and physician colleagues).

OIG hopes you find these free educational materials helpful and appreciates your willingness to educate physicians about fraud, waste, and abuse.

DISCLAIMER

These educational materials were current at the time they were published and uploaded onto OIG's Web site. They were prepared as tools to assist in teaching physicians; they are not intended to create any rights, privileges, or benefits. Although every reasonable effort has been made to assure the accuracy of the information within these materials, the ultimate responsibility for complying with the Federal fraud and abuse laws lies with the provider of services.

OIG employees, agents, and staff make no representation, warranty, or guarantee that these compilations of information are error free and will bear no responsibility or liability for the results or consequences of the use of these materials. These educational materials are summaries that explain certain aspects of the Federal fraud and abuse laws, but are not legal documents. The official information is contained in the relevant laws and regulations.

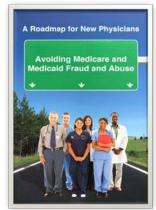


As a new physician, you must be knowledgeable about the Medicare and Medicaid fraud and abuse laws.

I expect that everyone in this room will be an upstanding and honest physician who will comply with these laws because it is the right thing to do. That said, these laws are very broad and can affect you.

Almost all physicians practicing clinical medicine in the United States will treat some Federal health care program beneficiaries at some point in their careers.

Violating the fraud and abuse laws can result in criminal penalties; civil fines; exclusion from the Federal health care programs, which include Medicare and Medicaid; and even loss of your medical license by your State medical board.





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

To help you learn about these laws, the Office of Inspector General (OIG) has prepared a booklet entitled "A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse," which you received today.

OIG is the independent oversight agency for the United States Department of Health & Human Services. OIG's mission is to protect the integrity of the Federal health care programs and to promote the health and welfare of program beneficiaries.

This booklet provides an overview of the pertinent fraud and abuse laws and is a must-read for your self-education.

I encourage each of you to explore this booklet and make special note of the resources listed to obtain additional information.

I will spend the next 45 minutes providing you with an overview of the booklet.

Health care fraud is a serious problem

The Government spends almost a trillion dollars each year on the Medicare and Medicaid programs.

Although there is no precise measure of health care fraud, experts estimate that fraudulent billings to the programs are in the range of 3–10 percent.

That means that fraud, waste, and abuse cost taxpayers \$30 billion to \$100 billion dollars each year.

Not only does fraud drain the taxpayers' money, but also it puts beneficiaries' health and welfare at risk by exposing them to unnecessary services and taking money away from needed patient care.

When the Federal Government recovers money from fraud cases, it returns the money to the Medicare Trust Fund to pay for legitimate patient care.

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<u>Fraud</u> includes obtaining a benefit through intentional misrepresentation or concealment of material facts

<u>Waste</u> includes incurring unnecessary costs as a result of deficient management, practices, or controls

<u>Abuse</u> includes excessively or improperly using government resources

<u>Fraud</u> includes the obtaining of something of value through intentional misrepresentation or concealment of material facts.

<u>Waste</u> includes the incurring of unnecessary costs as a result of deficient management, practices, systems, or controls.

Abuse includes any practice that is not consistent with the goals of providing patients with services that (1) are medically necessary, (2) meet professionally recognized standards, and (3) are fairly priced.



Physicians are an important part of the Medicare and Medicaid programs, in terms of both the care you personally provide and the items and services you prescribe, order, and recommend for your patients.

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Fraud and Abuse Laws

- False Claims Act
- Anti-Kickback St
- Physician Self-Referral Statute
- Exclusion Statut
- Civil Monetary
 Penalties Law



You also are an important part of protecting the integrity of the Medicare and Medicaid programs.

The Government needs physicians to understand the fraud and abuse laws so that you can be partners in preventing fraud, waste, and abuse.

We cannot cover all of the laws in the time we have today, so we will focus on the five Federal fraud and abuse laws that are most relevant to you:

- The False Claims Act
- The Anti-Kickback Statute
- The Physician Self-Referral Statute
- The Exclusion Authorities
- The Civil Monetary Penalties Law

Because you likely will treat Federal health care program beneficiaries, you need to understand these laws.



1. False Claims Act

The False Claims Act makes it illegal to submit false or fraudulent claims for payment to Medicare or Medicaid.

Claims may be false if the service is not actually rendered to the patient, is provided but already covered under another claim, is miscoded, or is not supported by the medical record.

 For example, a cardiologist was prosecuted under the False Claims Act for submitting claims for evaluation and management (E&M) services even though he had already received payment for the same services under previously billed stress test claims.

He paid the Government \$435,000 and entered into a 5-year Integrity Agreement.

For False Claims Act violations, you can be fined up to three times the program's loss, plus \$11,000 per claim.

And fines add up quickly because each claim can be a separate ground for liability.

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You do not have to intend to defraud the Government to violate the False Claims Act.

You can be punished if you act with **deliberate ignorance or reckless disregard** of the truth.

This means you cannot hide your head in the sand and avoid liability.

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Incentives to report fraud



The False Claims Act also provides a strong financial incentive to whistleblowers to report fraud.

Whistleblowers can receive up to 30 percent of any False Claims Act recovery.

Often whistleblowers turn out to be exbusiness partners, hospital or office staff, competitors, or even patients.

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Anti-Kickback Statute



Prohibits asking for or receiving anything of value in exchange for referrals of Federal health care program business

2. Anti-Kickback Statute

In some industries, it is acceptable to reward those who refer business to you.

However, asking for or receiving any remuneration in exchange for your referrals of Federal health care program business is a crime under the Anti-Kickback Statute.

The Anti-Kickback Statute applies to both payers and recipients of kickbacks. Just asking for or offering a kickback could violate the law.

Anti-Kickback Statute

Prohibited kickbacks include:

- Cash for referrals
- · Free rent for medical offices
- Excessive compensation for medical directorships



"Remuneration" is basically anything of value.

The law prohibits obvious kickbacks, like cash for referrals, as well as more subtle kickbacks, like free rent, below fair market value rent, free clerical staff, or excessive compensation for medical directorships.

Numerous physicians have been sanctioned for selling their product loyalty to drug or device companies or other vendors.

• For example, an orthopedic surgeon accused of accepting kickbacks from device manufacturers in exchange for preferentially using their artificial hip and knee joints recently paid \$650,000 to settle the case against him.

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Kickbacks

- · Increased costs
- Corruption of medical decisionmaking Patient steering
- **Unfair competition**



Kickbacks are illegal because they harm the Federal health care programs and program beneficiaries. They can lead to:

- overutilization of items or services,
- increased program costs,
- corruption of medical decisionmaking,
- patient steering, and
- unfair competition.

As physicians, you owe your patients the benefit of your best clinical judgment.

can lead to:









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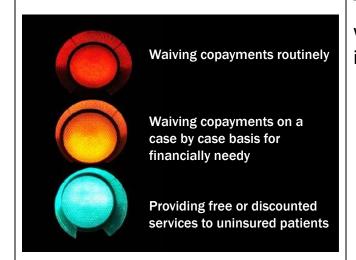
Violating the Anti-Kickback Statute carries stiff penalties. Violators can be found liable under the False Claims Act as well.

Violations can result in prison sentences and fines and penalties of up to \$50,000 per kickback plus three times the amount of the remuneration.

Additionally, physicians can be excluded from participation in the Federal health care programs for violating the Anti-Kickback Statute.

Some refer to exclusions as a "financial death sentence" because excluded physicians may not receive payment for treating any Medicare and Medicaid beneficiaries.

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The Anti-Kickback Statute also is implicated when physicians give patients financial incentives to use their services.

• [Red Light] Federal law does not prohibit you from offering free care to Medicare and Medicaid patients.

However, if you choose to waive copayments from patients but bill Medicare or Medicaid, you are not providing free care. In some circumstances, you could be in violation of the Anti-Kickback Statute.

 [Yellow Light] You are free to waive a copayment if you determine that the individual patient cannot afford to pay or if reasonable collection efforts fail.

However, you may never advertise that your practice has a policy of forgiving copayments.

• [Green Light] This rule prohibiting routine waivers of copayments does **not** apply to uninsured patients.

You may treat uninsured patients for free or offer them discounted fees.

Physician Self-Referral Statute

Limits physician referrals when you have a financial relationship with the entity

3. Physician Self-Referral Statute

The Physician Self-Referral Statute, or Stark law as it is sometimes called, prohibits you from referring Medicare or Medicaid patients for designated health services to entities with which you have a financial relationship, unless an exception applies.

 <u>Financial relationships</u> covered by this law include ownership/investment interests, as well as compensation relationships.

This law applies to your financial relationships and those of your immediate family members.

 <u>Designated health services</u> include clinical laboratory services, physical therapy, and home health services, among others.

A complete list is found in the booklet.

For example, unless an exception applies, you may not refer patients to an imaging center for designated health services if you have a financial investment in that center.

A physician was charged with violating the Stark law for routinely referring Medicare beneficiaries to an oxygen supply company he owned. He paid \$203,000 to settle the case.

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Consequences of violating the Physician Self-Referral Statute:

- Payment denial
- Monetary penalties
- Exclusion

The Physician Self-Referral Statute is a strict liability law, which means proof of specific intent to violate the law is not required.

The <u>entity</u> submitting improper claims is subject to repayment of all amounts received from Medicare and Medicaid that are connected with the improper relationship and may be subject to additional penalties.

<u>Physicians</u> who violate the law may be subject to monetary penalties as well as exclusion from participation in the Federal health care programs.



Avoid violating the Anti-Kickback Statute and Physician Self-Referral Statute by fitting into a "safe harbor" or exception

Many arrangements can be structured to avoid the risk of fraud.

Additionally, the law provides for "safe harbors" and exceptions to the Anti-Kickback and Stark laws.

To fit into an Anti-Kickback safe harbor or Stark law exception, you must fit squarely within the requirements. If the safe harbor or exception contains multiple elements or conditions, you must satisfy each element or condition.

For example, a full-time lease agreement between a physician and a provider to whom the physician refers patients can meet the space rental safe harbor if the agreement:

- is set out in writing and signed by the parties;
- covers all of the premises rented by the parties;
- is for a term not less than 1 year;
- has an aggregate rental charge set in advance, is consistent with fair market value in arm's length transactions, and does not take into account the volume or value of Federal health care program referrals; and
- the aggregate space rented may not exceed the space that is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

You may want to consult with a health care attorney for assistance in structuring your arrangements properly.



4. Exclusion Authorities

Under the Exclusion Authorities, OIG may exclude providers from participation in the Federal health care programs.

There are two categories of exclusions:

- mandatory exclusions—imposed on the basis of certain criminal convictions and
- permissive exclusions—based on sanctions by other agencies, such as a state medical board suspending or revoking a medical license, or other misconduct including defaulting on health education loans or providing unnecessary or substandard care.

Examples of both are included in your booklet.

The effect of exclusion is very serious. Excluded physicians may not bill for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice.

Because of this prohibition, some refer to exclusion as a "financial death sentence" for any health care provider.

Currently, more than 5,200 physicians are excluded from participating in these programs.



Civil Monetary Penalties Law

Penalties range from \$10,000 to \$50,000 per violation

5. Civil Monetary Penalties Law

You should also be aware that OIG may seek civil monetary penalties for a wide variety of abusive conduct, including presenting a claim that is false or fraudulent because it is for a medically unnecessary procedure.

OIG also may impose civil monetary penalties for violating the Medicare assignment agreement by overcharging or double billing Medicare beneficiaries.

 For example, a physician paid \$107,000 to settle charges that he violated the Medicare assignment agreement by charging Medicare beneficiaries an annual fee when some of the services he promised in exchange for that annual fee were already covered by Medicare.

Your booklet contains additional examples of Civil Monetary Penalties Law violations.

Penalties range from \$10,000 to \$50,000 per violation.

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No matter your specialty or practice setting, as a physician you may develop relationships with three important groups.

And your relationships with these groups will be subject to the provisions of the five key fraud and abuse laws.

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You may have relationships with --

- 1. **Payers**, like Medicare, Medicaid, patients, and private insurance companies;
- 2. **Other providers**, including physicians and hospitals; and
- 3. **Vendors**, including drug, biologic, and medical device companies.

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First we will discuss physician relationships with the payers of health care.

Many health care costs are borne by third party payers, including health insurance companies and the Federal and State governments.

When the Federal Government pays for items or services provided to Medicare or Medicaid beneficiaries, the Federal fraud and abuse laws apply.

Fraudulent billings result in stiff penalties



The Government trusts that you will accurately document the services you provide.

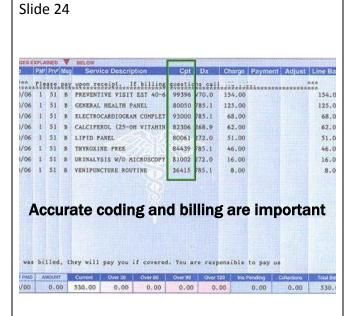
If a physician abuses that trust and fraud is proven, the Government may impose stiff penalties.

 For example, an endocrinologist billed routine blood draws as critical care blood draws to capture higher reimbursement.

He paid \$447,000 to settle allegations of upcoding and other billing violations.

 In another case, a dermatologist was sentenced to 2 years of probation and 6 months' home arrest and paid \$2.9 million for impeding a criminal investigation of fraudulent billings.

He admitted to falsifying lab tests and backdating letters to referring physicians to substantiate false diagnoses and make the documentation appear that his patients had Medicare-covered conditions when they did not.



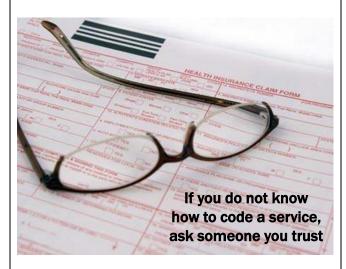
It is important to submit accurate and truthful bills.

Some examples of dishonest coding and billing practices include:

- billing for services of such low quality that they are virtually worthless;
- billing separately for services already included in a global fee (like billing for an E&M service the day after surgery when the followup already is included in the global surgical fee); and
- upcoding, which occurs when a provider bills for higher item or service codes than were actually performed and may result in a higher payment by Medicare.

An example of upcoding is an instance when you provide a followup inpatient consultation but bill using a higher level E&M code as if you had provided an initial inpatient consultation.

Other examples of improper coding and billing practices are in your booklet.



If you do not know how to properly code a service or claim reimbursement, then ask someone you trust, like the Centers for Medicare & Medicaid Services (CMS), State Medicaid agencies, or billing experts.

Your booklet lists a number of resources that provide guidance on appropriate billing practices.

Do not just select the code that offers you the most favorable reimbursement.

Remember, when you bill a Federal health care program, you certify that the payment requested complies with the Federal billing requirements.

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Maintenance of accurate and complete medical records to support payment of claims is critical.

The Medicare and Medicaid programs may review the patient's medical records to verify the claim, as well as the quality of care.

If the medical record does not support the claimed service, the claim may be denied.

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Good documentation is also a quality of care issue.

It helps ensure that your patients get the best possible clinical care from you and other providers who may rely on your records.

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Participating Physicians...



- May not overcharge Medicare
 beneficiaries
- May not sell the same service twice

Each year, Medicare issues a reimbursement fee schedule for each physician service.

Once patients satisfy their annual deductible, Medicare pays 80 percent of the fee schedule amount and the patient pays 20 percent.

To receive payment from Medicare, physicians bill as either participating physicians or non-participating physicians.

Most physicians bill Medicare as <u>participating</u> <u>physicians</u> and receive Medicare's 80 percent directly from Medicare and bill patients for the remaining 20 percent.

This means that you accept the Medicare payment, plus any copayment or deductible Medicare requires the patient to pay, as the full payment. You may not require any extra payment from your patient.

In other words, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid.

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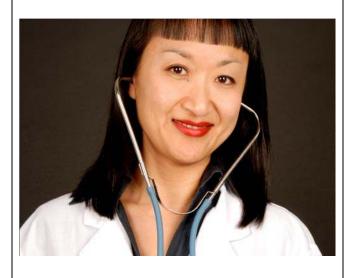
The second, less common, way to obtain Medicare reimbursement is to bill as a non-participating physician.

If you are a non-participating physician, you do not receive direct payment from Medicare.

Rather, you bill your patients and they seek reimbursement from Medicare.

It is illegal for a non-participating physician to charge patients more than 15 percent above the Medicare fee schedule.

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Some physicians also require patients to pay additional fees to receive care from the practice. These fees go by many names, including "annual fees" and "concierge fees."

Whether you are a participating or nonparticipating physician, if you decide to seek extra payment from your Medicare patients, make sure that you are providing additional service beyond what is already covered by Medicare.

OIG has pursued enforcement actions against physicians for charging improper and excessive fees.

For example, a physician paid \$107,000 to resolve potential liability for charging patients an annual fee for services that were already covered by Medicare.

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Future Business Relationships

Colleagues

Hospitals

Nursing Homes



Next I want to discuss your future business relationships with other health care providers, including:

- your physician colleagues,
- hospitals, and
- nursing homes.

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Physicians are frequently approached with investment opportunities in enterprises related to the delivery of health care.

Sometimes, you are a legitimate source of capital. Other times, you merely are a source of patient referrals to keep the enterprise busy and profitable.

Because the return on an investment sometimes is used to pay kickbacks in exchange for referrals, you should be vigilant when considering health care business opportunities.

Knowledgeable legal counsel may be helpful in understanding the purpose of the business venture and its fraud and abuse risks.

In any case, you should send your patients to the provider that, in your medical judgment, can best meet their medical needs.



Stay alert if you are invited to invest in a health care business whose products you might order or to which you might refer your patients. Questions you should ask yourself are included in the booklet.

For example:

- Is the venture promising you high rates of return for little or no financial risk?
- Are you being asked to guarantee that you will refer patients or order services from the venture?

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The recruitment of physicians by hospitals and clinics can fill an important community need.

However, recruitment packages can cross the line into illegal arrangements for which both you and the hospital can be liable.

You should seek knowledgeable legal counsel when considering recruitment offers, particularly if you would be required to admit patients to a specific hospital or practice group.

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Medical directors should exercise substantive responsibility Physicians can play an important role in ensuring quality of care by serving as medical directors.

However, hospitals, nursing homes, and other facilities should not offer you a position as a medical director to funnel you extra money in return for your referring your patients to the facility.

To be paid to serve as a medical director, you should spend an appropriate amount of time performing necessary services, including:

- actively overseeing clinical care in the facility;
- leading the medical staff to meet the standard of care;
- ensuring proper training, education, and oversight for physicians, nurses and other staff members; and
- identifying and addressing quality problems.

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Finally, I want to discuss your relationships with vendors, including drug, biologic, and medical device companies.

Some physicians are more closely involved with industry than others.

But all physicians will encounter representatives of drug, device, and biologic manufacturers or other suppliers at some point in their careers.



It is illegal to sell free samples

Some physicians accept free drug samples; some physicians do not.

If you do choose to accept free drug samples, you must establish procedures to ensure that you do not allow the free samples to be commingled with your commercial stock.

While you are free to give these samples to your patients at no charge, it is illegal to sell these samples or to bill the Medicare or Medicaid programs for free samples.

For example, several urologists paid tens of thousands of dollars and were sanctioned for billing Medicare for drugs they had received for free from pharmaceutical companies.

The drug companies paid \$1.4 billion for their part in the scheme.

Additionally, various ethics rules govern the extent to which you may use the samples yourself or give them to your friends and family.

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Scrutinize
promotional
speaking or
consulting
opportunities

As a physician, you may have opportunities to consult with or be a promotional speaker for the drug or medical device industry.



To avoid violation of the fraud and abuse laws, test the propriety of any proposed engagement 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 and appropriate 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 you want to pursue an industry relationship but are not sure it is legitimate, take affirmative steps to learn whether the arrangement is proper.

Give yourself the newspaper test: "How would I feel if this arrangement were featured on the front page of my hometown newspaper?"

Gift Reporting Requirements



Although some physicians believe that free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows that these types of perquisites and humans' natural desire to reciprocate can influence prescribing practices and generally affect how physicians act.

Some States have already implemented Sunshine laws requiring public disclosure of gifts and limiting the types of gifts physicians may accept.

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. This information will be posted on the Internet.

So the public will soon know what gifts and payments a physician receives from industry. The "newspaper test" will become the "Internet test" and be even more important to apply to your relationships with the health care industry.

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Before you join any medical practice, learn whether it has an effective compliance program.

The Affordable Care Act will make compliance programs a requirement for medical practices.

Establishing and embracing a compliance program will help you avoid fraudulent activities and ensure that you are submitting true and accurate claims.

The booklet includes guidance on how to establish an effective compliance program.

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No one expects that after a few hours study, you will be an expert on all these issues.

But, you hopefully will be able to recognize when you need help and what questions to ask.



You can learn more from sources like OIG's Web site or CMS' educational materials.

You also can consult with private counsel or ask CMS's contractor medical director for your region.

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Finally, you can help combat fraud, waste, and abuse in the Federal health care programs by reporting incidents of abuse to the OIG Fraud Hotline.

You can identify yourself or report anonymously.