



Gifts to Referral Sources



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(11-17)

Overview

- Some relevant laws
- Applying those laws to common situations
 - Gifts to or from referral sources
 - Gifts to physicians
 - Gifts to or from patients
 - Gifts from vendors
- Focusing on gifts, not all potential issues re items or services below fair market value.
- Please send questions to kcstanger@hollandhart.com or use the “chat” feature.

Written Materials

- Copy of .ppt slides
- Stanger, *Gifts to Referral Sources and Patients*
- OIG Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (8/02)
- OIG *Supplemental Compliance Program Guidance for Hospitals*, 70 FR 4858 (1/05)
- CMS, *Avoiding Fraud and Abuse: A Roadmap for Physicians* (6/14)
- Sample Compliance Plan Standards of Conduct

- If you did not receive the link to written materials, please e-mail me at kcstanger@hollandhart.com

Disclaimer

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What's the big deal?

Govt concerned that gifts or other kickbacks may cause:

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

(OIG, *Roadmap for New Physicians: Fraud and Abuse Laws*)

Govt response:

- Anti-Kickback Statute (“AKS”)
- Ethics in Patient Self-Referrals Act (“Stark”)
- Civil Monetary Penalties Law (“CMPL”)
- State laws
- Grant requirements

Anti-Kickback Statute

- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by government program unless arrangement structured to fit within regulatory safe harbor.

(42 USC 1320a-7b(b); 42 CFR 1001.952)

- “One purpose test”
 - AKS applies if one purpose of the remuneration is to induce referrals even if there are other legitimate purposes.

(*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985)).

- Ignorance of the law is no excuse.



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Anti-Kickback Statute

AKS Penalties

- 5 years in prison
- \$25,000 criminal fine
- \$50,000 administrative penalty
- 3x damages
- Exclusion from Medicare/Medicaid
(42 USC 1320a-7b(b); 42 CFR 1003.102)
- OIG Self-Disclosure Protocol: minimum \$50,000 settlement.

AKS = False Claims Act Violation

- Lower standard of proof
- False Claims Act penalties
 - \$5,500 to \$11,000 per claim
- Subject to *qui tam* whistleblower suit.
- Affirmative obligation to report and repay.

(42 USC 1320a-7a(a)(7))

Stark

- If a physician (or their family member) has a financial relationship with an entity:
 - The physician may not refer patients to that entity for designated health services, and
 - The entity may not bill Medicare for such designated health services

unless arrangement structured to fit within a regulatory exception or safe harbor.

(42 USC 1395nn; 42 CFR 411.351 et seq.)



Stark

- Penalties
 - No payment for services provided per improper referral.
 - Repayment of payments improperly received within 60 days.
 - Civil penalties.
 - \$15,000 per claim submitted if fail to repay within 60 days
 - \$100,000 per scheme

(42 CFR 411.353, 1001.102(a)(5), and 1001.103(b))

- May also constitute AKS violation
- May trigger False Claims Act.

Stark

Applies to referrals by a physician to entities with which physician (or their family member) has a financial relationship.

- Physician =
 - MDs
 - DOs
 - Oral surgeons
 - Dentists
 - Podiatrists
 - Optometrists
 - Chiropractors
- Family member =
 - Spouse
 - Parent, child
 - Sibling
 - Stepparent, stepchild, stepsibling
 - Grandparent, grandchild
 - In-law

(42 CFR 411.351)

Stark

- Applies to referrals for designated health services (“DHS”) payable in whole or part by Medicare.
 - Inpatient and outpatient hospital services
 - Outpatient prescription drugs
 - Clinical laboratory services
 - Physical, occupational, or speech therapy
 - Home health services
 - Radiology and certain imaging services
 - Radiation therapy and supplies
 - Durable medical equipment and supplies
 - Parenteral and enteral nutrients, equipment, and supplies
 - Prosthetics and orthotics
- CMS website lists some of the affected CPT codes.

(42 CFR 411.351)

Civil Monetary Penalties Law

- Prohibits certain specified conduct, including:
 - Offering, soliciting, giving or receiving remuneration to induce referrals (i.e., kickbacks).
 - Offering inducements to program beneficiaries if know or should know that remuneration is likely to influence beneficiary to order or receive items or services payable by federal or state programs from a particular provider.
 - Failing to report and repay an overpayment.

(42 USC 1320a-7a; 42 CFR 1003.102)



Civil Monetary Penalties Law

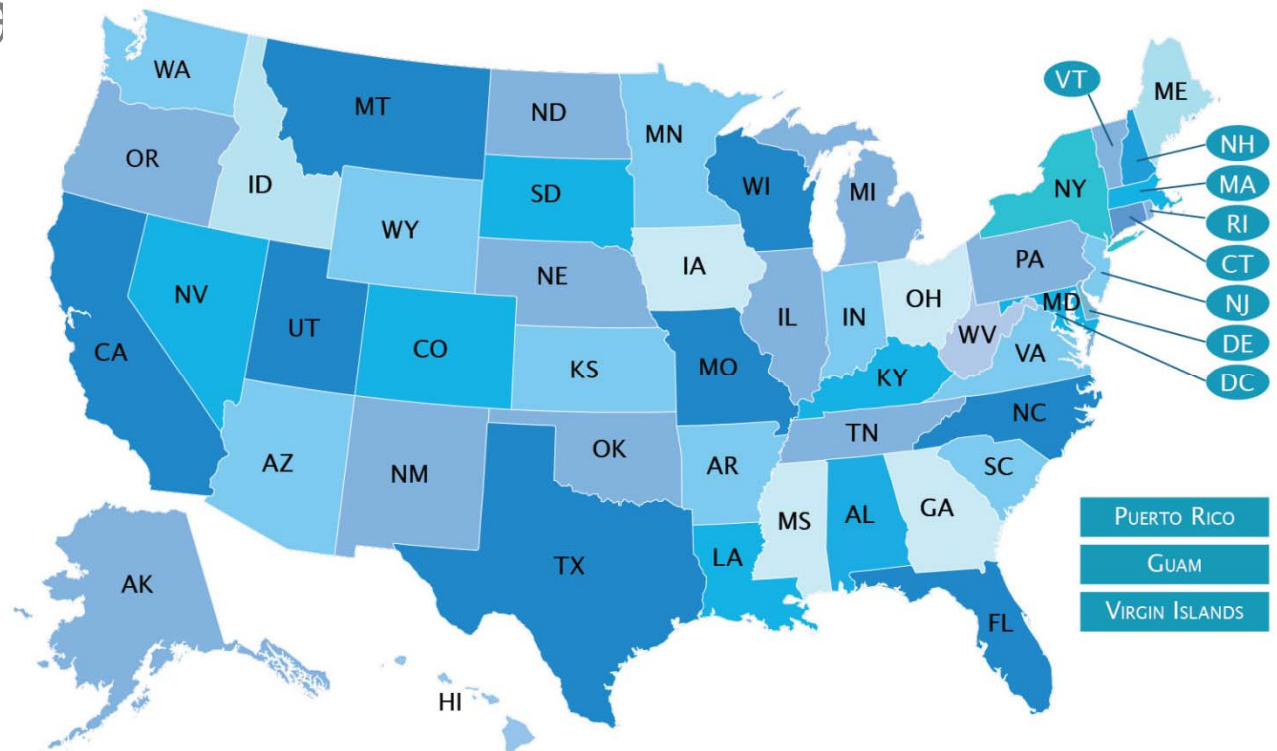
- Penalties vary depending on conduct, but generally range from:
 - \$2,000 to \$50,000 fines
 - 3x amount claimed
 - Denial of payment
 - Repayment of amounts improperly paid
 - Exclusion from govt programs
- CMPL violations may also violate:
 - False Claims Act
 - Anti-Kickback Statute
 - Stark

False Claims Act

- Cannot knowingly submit a false claim for payment to the federal government.
- Must report and repay a false claim within 60 days.
(18 USC 1347)
- Penalties
 - Repayment plus interest
 - Civil monetary penalties of \$5,500 to \$11,000 per claim
 - 3x damages
 - Exclusion from Medicare/Medicaid
 - *Qui tam* or whistleblower lawsuits by private parties

Common State Laws

- Anti-Kickback Laws
- Mini-Stark Laws
- Disclosure La
- Fee Splitting
- Rebates
- Others?



Gifts to Referral Sources



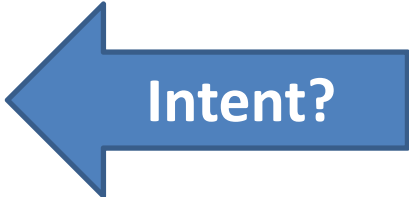
Gifts to Referral Sources

- “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.” (OIG, *A Roadmap for New Physicians: Fraud & Abuse Laws*)



Gifts to Referral Sources

May include:

- Other providers
 - Physicians
 - Other providers
 - Staff of providers offices
 - Hospitals
 - Groups
 - Other staff
 - Payers
 - Vendors
 - Patients
 - Others?
- 
- Cash
 - Gift cards
 - Gift baskets
 - Food
 - Wine or alcohol
 - Meals
 - Parties
 - Tickets
 - Events
 - Services
 - Any other form of remuneration or item of value

Gifts to Referral Sources

- Anti-Kickback Statute applies if:
 - Offer, give, solicit or receive remuneration
 - Applies to giver and receiver.
 - One purpose is to induce referrals
 - May be difficult to disprove.
 - For items or services covered by govt program
 - Probably does not apply to referrals for private pay business.
 - But OIG has warned that inducing referrals for private pay business may also induce govt program business. (*See, e.g., Adv. Op. 12-06*).

Gifts to Referral Sources

- AKS does not have a *de minimus* exception.
- Per OIG, AKS may apply to “[s]oliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice’s referral of Federal health care program business.” (*OIG Compliance Program for Individual and Small Group Physician Practices*, 65 FR 59441 (10/5/00), emphasis added)
- What is “nominal value”?

Gifts to Referral Sources

- Govt program referral sources:
 - Beware AKS, especially if more than “nominal” value.
- Private pay referral sources:
 - Less risky, but no guarantees.
- Beware state laws.

Gifts to Referring Physicians



Gifts to Referring Physicians

- AKS applies if one purpose of gift is to induce referrals for items or services payable by govt programs.
- Stark applies if:
 - Gift to physician or physician's family member, and
 - Physician refers DHS payable by Medicare.

unless the transaction is structured to fit within a regulatory safe harbor.

 - No improper intent is required.
 - Does not apply to referrals for private pay **business**.

Gifts to Referring Physicians

Stark Bona Fide Employment Safe Harbor applies if:

- Physician is a bona fide employee.
- The employment is for identifiable services.
- The amount of the remuneration under the employment is
 - Consistent with the fair market value of the services; and
 - Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
- The remuneration is provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

(42 CFR 411.357(c))

Gifts to Referring Physicians

Stark Non-Monetary Compensation Safe Harbor applies if:

- Items or services are not cash or cash equivalents.
- Aggregate value is less than \$392 (as adjusted per CPI) per calendar year.
- Not determined in manner that takes into account volume or value of referrals or other business generated by referring physician.
- Not solicited by physician or physician's practice.
- Does not violate the AKS or other state or federal law.

(42 CFR 411.357(k))

Gifts to Referring Physicians

Stark Non-Monetary Compensation Safe Harbor:

- In addition to non-monetary gifts valued at no more than \$392 aggregate, an entity that has a formal medical staff (e.g., a hospital) may provide one local staff appreciation event per year for the entire medical staff.
- Any gifts or gratuities provided in connection with the medical staff appreciation event are subject to the \$392 limit.

(42 CFR 411.357(k))

Gifts to Referring Physicians

Stark Non-Monetary Compensation Safe Harbor

- Where entity has inadvertently provided nonmonetary compensation in excess of the limit, such compensation is deemed to be within limit if:
 - Value of excess is no more than 50% of the limit, and
 - Physician returns the excess by the earlier of:
 - End of the calendar year in which compensation received, or
 - Within 180 days after compensation received.
- May use this only once every 3 years for same physician.

(42 CFR 411.357(k))

Gifts to Referring Physicians

Stark Medical Staff Incidental Benefits Safe Harbor applies to hospitals and other entities with bona fide medical staffs if:

- Give items or services that are not cash or cash equivalents.
- Used on the hospital's campus.
- Offered to all members of medical staff practicing in same specialty without regard to referrals or business generated between the parties.
- Provided only during periods when medical staff members are making rounds or engaged in other services that benefit hospital or patients.
- Reasonably related to the provision of services at hospital.
- Value is less than \$33 (adjusted annually per CPI).
- Does not violate AKS.

(42 CFR 411.357(m))

Gifts to Referring Physicians

Stark Charitable Donations Safe Harbor applies to:

- Bona fide charitable donations made by a physician (or immediate family member) to a tax-exempt organization.
- Donation is neither solicited, nor offered, in any manner that takes into account the volume or value of referrals or other business generated between the physician and the entity.
- The donation arrangement does not violate the AKS or fed or state law governing billing or claims submission.

(42 CFR 411.357(j))

Gifts to Patients



Gifts to Patients

- AKS applies if one purpose of gift is to induce referrals for items or services payable by govt programs.
- Stark applies if patient is a physician who refers designated health services or a referring physician's family member.
- Civil Monetary Penalties Law ("CMPL") applies if know or should know that remuneration is likely to influence beneficiary to order or receive items or services payable by federal or state programs from a particular provider.

Gifts to Patients

- “The OIG has interpreted the [CMPL] prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of
 - no more than \$10 individually, and
 - no more than \$50 in the aggregate annually per patient.”

(OIG Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (8/02); 66 FR 24410-11 (4/26/00))

Gifts from Patients

“Some gifts signal psychological needs that require the physician’s attention. Some patients may attempt to influence care or to secure preferential treatment through the offering of gifts or cash. Acceptance of such gifts is likely to damage the integrity of the patient-physician relationship. Physicians should make clear that gifts given to secure preferential treatment compromise their obligation to provide services in a fair manner.

“There are no definitive rules to determine when a physician should or should not accept a gift. No fixed value determines the appropriateness or inappropriateness of a gift from a patient; however, the gift’s value relative to the patient’s or the physician’s means should not be disproportionately or inappropriately large. One criterion is whether the physician would be comfortable if acceptance of the gift were known to colleagues or the public....”

(AMA Ethics Op. 10.017, *Gift from Patients*, emphasis added)

Gifts from Vendors



Gifts from Vendors

- For example,
 - Trips
 - Equipment
 - Supplies
 - Meals
 - CME
 - Sham services arrangements
 - Other?

Gifts from Vendors

- AKS applies if one purpose of gift is to induce referrals for items or services payable by govt programs.
 - **OIG has suggested that “nominal” gifts likely would not be challenged. (*OIG Compliance Guidance for Physicians*, 65 FR 59441)**
- Stark applies if the physician refers patients to, or orders designated health services from, the giver.
 - **Prohibits physician from making such referrals.**
 - **Prohibits the vendor from billing Medicare for items improperly referred.**

Gifts from Vendors

- Free drug 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.” (OIG, *A Roadmap for New Physicians: Fraud and Abuse*)

Gifts from Vendors

- AMA: “To preserve the trust that is fundamental to the patient-physician relationship and public confidence in the profession, physicians should:
 - (a) Decline cash gifts in any amount from an entity that has a direct interest in physicians’ treatment recommendations.
 - (b) Decline any gifts for which reciprocity is expected or implied.
 - (c) Accept an in-kind gift for the physician’s practice only when the gift: (i) will directly benefit patients, including patient education; and (ii) is of minimal value.”

(AMA Ethical Opinion 8.061, *Gifts to Physicians from Industry*)

- PhRMA Code on Interactions with Healthcare Professionals
- AvaMed Code of Ethics on Interactions with Health Care Professionals

Gifts from Vendors

- Physician Payment Sunshine Act
 - Medical device and pharmaceutical companies must submit annual report to CMS identifying “payments or other transfers of value” made to physicians or teaching hospitals.
 - Excludes payments of less than \$10/\$100 aggregate annual, certain educational materials, and in-kind items for charity care.
 - Report includes:
 - the name and address of the physician
 - the amount and date of the payment
 - the form of the payment, such as cash or stocks
 - the nature of the payment, such as consulting fees, gifts, or entertainment expenses
- Increases likelihood of govt investigation.

cms.gov/openpayments/

The screenshot shows the CMS.gov Open Payments website. At the top, the CMS.gov logo is displayed with the tagline "Centers for Medicare & Medicaid Services". A navigation bar includes links for Home, About CMS, Newsroom, FAQs, Archive, Share, Help, and Print. A search bar is located on the right side of the header. Below the header, a horizontal menu lists various CMS services: Medicare, Medicaid/CHIP, Medicare-Medicaid Coordination, Private Insurance, Innovation Center, Regulations & Guidance, Research, Statistics, Data & Systems, and Outreach & Education. The main content area features a breadcrumb trail "Home > Open Payments" and a primary navigation bar with buttons for Open Payments, About, Explore the Data, Program Participants, FAQs, and Contact Us. On the left, there are sections for "Announcements" and "View the Data" with links to view summary data, search data, create charts, and download datasets. The main content area is titled "Open Payments" and includes an introductory paragraph explaining the program's purpose. Below this, three columns provide further information: "Search & Explore Open Payments Data", "Open Payments Data in Context", and "Program Participants: Access the System". A yellow "Open Payments" button is located at the bottom right of the main content area. The Windows taskbar at the bottom shows the time as 7:10 AM on 11/12/2015.

Open Payments - Ce x
https://www.cms.gov/openpayments/

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Home > Open Payments

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Announcements

View the Data

View Summary Data
Search the Data
Create Charts and Graphs with the Data Explorer
Download Open Payments Datasets

Open Payments

Sometimes, doctors and hospitals have financial relationships with health care manufacturing companies. These relationships can include money for research activities, gifts, speaking fees, meals, or travel. The Affordable Care Act requires CMS to collect information from applicable manufacturers and group purchasing organizations (GPOs) in order to report information about their financial relationships with physicians and hospitals. Open Payments is the federally run program that collects the information about these financial relationships and makes it available to you. [View the summary data dashboard](#) for an overview of the published data.

Search & Explore Open Payments Data

Use the search tool to look up a doctor or hospital, or a company that's made payments. Download all Open Payments data in detail. Interact with all the data sets. States can create and download custom reports.

Open Payments Data in Context

What is a conflict of interest? What is nature of payment? Learn about Open Payments and what it may mean for physicians, industry, and you.

Program Participants: Access the System

Learn more about system registration requirements:

- Physician registration information
- Industry registration information

Already registered? [Login here.](#)

Open Payments

7:10 AM 11/12/2015

Summary

Summary

- When you accept govt money or participate in govt programs, there are always strings attached...



Summary

- Gifts to or from entities that are not involved in govt programs are less risky.
 - But no guarantees.
- Gifts to/from entities involved in govt programs may implicate:
 - AKS, if one purpose is to induce or reward referrals.
 - “Nominal” gifts are probably okay.
 - Stark, if physician refers designated health services payable by Medicare.
 - Unless fit within safe harbor.
 - CMPL, if gift would influence govt beneficiary to obtain services.
 - \$10 gift/\$50 aggregate okay.

Summary

Before giving (or receiving) more than a nominal gift, ask yourself:

- Is the recipient a referral source for items or services covered by govt programs?
 - Referring providers?
 - Patients who are govt beneficiaries?
- Why are you giving the gift?
 - To thank them for past referrals or business?
 - To encourage future referrals or business?
- Why are you giving the gift to this person and not others? Is it because—
 - The recipient is a good source of business?
 - You hope to receive future business as a result of the gift?

Summary

- Beware state laws!
 - May be broader than federal laws.
 - May apply to any gifts or giver.
 - Common state laws include:
 - Anti-kickback statutes
 - Mini-stark statutes
 - Fee splitting statutes
 - Rebate statutes
 - Disclosure of relationships
 - Others?
- Beware conflicts of interest created by gifts
 - Grant requirements
 - Ethical concerns

Red Flag Situations

- Gifts to or from sources who refer govt program business.
- Gifts to govt program beneficiaries.
- Gifts to physicians who refer designated health services payable by Medicare.
- Gifts based on referral patterns.
 - **Gifts are only given to those who refer business.**
 - **Bigger gifts are given to those who refer more business.**
- Gifts to patients who receive significant services.
- Gifts that are given shortly after significant services were provided.

An Ounce of Prevention is
Worth a Pound of Cure
- Benjamin Franklin -

Action Items

- Develop a gift policy as part of your compliance program.
 - Limits on gift giving.
 - Require Compliance Officer review before giving or accepting gift of more than “nominal” value (e.g., \$10).
 - Gifts received belong to entity, not individuals.
 - Questions should be directed to Compliance Officer.
 - Must report suspected violations to the Compliance Officer.
 - Violations may be subject to appropriate discipline.

Action Items

- Implement method to track gifts to patients or referral sources.
 - \$10 individual / \$50 aggregate per CMPL
 - \$392/year for physicians
- Train staff on policy and document training.
- See *OLG Compliance Program Guidance*, available at oig.hhs.gov/compliance/compliance-guidance.

Action Items

- If you identify significant non-compliant gifts:
 - It may prohibit you from referring to the giver, or providing items or services in response to a prohibited referral from the giver.
 - If you have received payment for govt programs for items or services provided per an improper referral, you may have an affirmative obligation to report and repay amounts received per improper referrals.
 - Gifts in violation of Stark or Anti-Kickback Statute.
 - False Claims Act requires entities to report and repay overpayments within 60 days, or you may be subject to False Claims Act Penalties.
 - Consult with your attorney.

Additional Resources



oig.hhs.gov/compliance

The screenshot shows a web browser window displaying the "Compliance 101" page on the oig.hhs.gov website. The browser's address bar shows the URL "https://oig.hhs.gov/compliance/101/index.asp". The page features a dark blue header with the "REPORT FRAUD" logo and navigation links for Home, FAQs, FOIA, Careers, Contact, HEAT, and Download Reader. The main content area is titled "Compliance Education Materials" and includes a "Compliance 101" banner. Below the banner, there is a welcome message and sections for "General Compliance Education Materials", "Compliance Program Guidance", and "Provider Compliance Training". A sidebar on the right contains a search bar, a "I'm looking for" dropdown menu, and a list of topics such as "Accountable Care Organizations", "Advisory Opinions", and "Compliance 101 and Provider Education". The footer of the page includes a "HHS-OIG Compliance Training" logo and a "REPORT" button. The Windows taskbar at the bottom shows the system time as 7:05 AM on 11/21/2014.

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https://oig.hhs.gov/compliance/101/index.asp

REPORT FRAUD

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Home > Compliance > Compliance 101

Compliance Education Materials

Tweet 14



Welcome to OIG's Compliance 101 Web page. OIG developed the free educational resources listed on this Web page to help health care providers, practitioners, and suppliers understand the health care fraud and abuse laws and the consequences of violating them. These compliance education materials can also provide ideas for ways to cultivate a culture of compliance within your own health care organization.

General Compliance Education Materials

Compliance Program Guidance

OIG has developed a series of voluntary compliance program guidance documents directed at various segments of the health care industry, such as hospitals, nursing homes, third-party billers, and durable medical equipment suppliers, to encourage the development and use of internal controls to monitor adherence to statutes, regulations, and program requirements. The documents provide principles to follow when developing a compliance program that best suits your organization's needs. The documents also identify fraud and abuse risks to watch out for when creating a program.

- Compliance Guidance

Provider Compliance Training

Below are links to free training for health care providers, compliance professionals, and attorneys. OIG's Provider Compliance Training was an outreach initiative developed as part of HHS's and the U.S. Department of Justice's Health Care Fraud Prevention and Enforcement Action Team.

- Videos and Audio Podcasts

HHS-OIG
Compliance
Training
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EXCLUSIONS DATABASE

REPORT

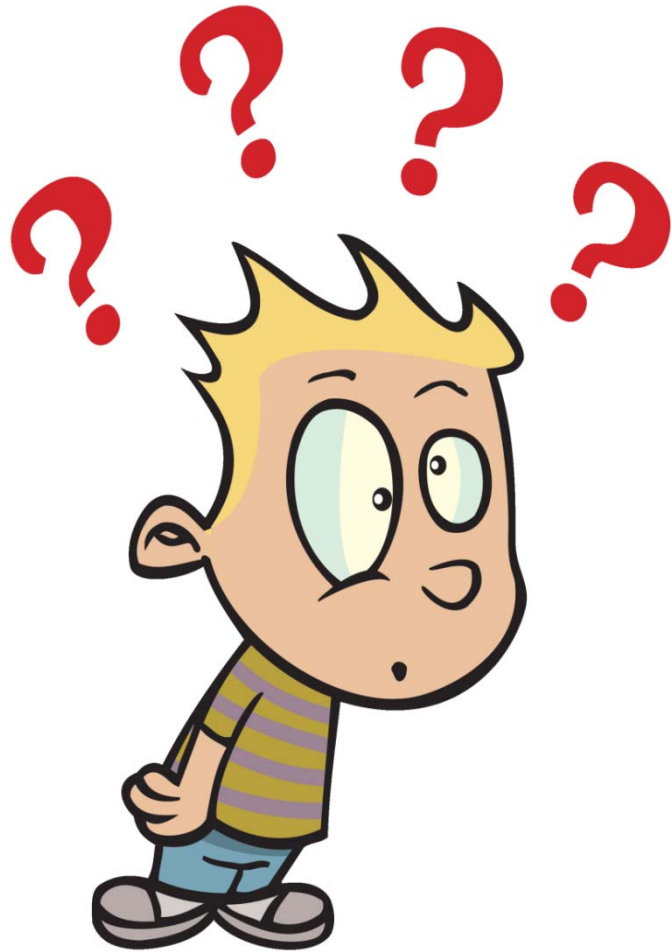
https://oig.hhs.gov/compliance/101/index.asp

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OIG Website

- Compliance 101 series
- **OIG Compliance Program Guidance**
 - **OIG Supplemental Compliance Program Guidance for Hospitals**
 - **OIG Compliance Program Guidance for Physicians**
 - **OIG Compliance Program Guidance for Pharmaceutical Industry**
- Advisory Opinions
- Special Fraud Alerts
- Fraud Bulletins
- Letters
- Other materials

Questions



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