Fraud and Abuse

**Compliance Program Training**

**Slide 1:**

**Healthcare Fraud and Abuse**

**General Compliance Intro:** Physicians and others working in the healthcare industry should be familiar with healthcare fraud and abuse laws. Many of these laws are extremely broad, and unless you have a general understanding of these laws, you may be unaware that your conduct is illegal.

**Slide 2:**

**Training Objectives**

* The training objectives of this fraud and abuse compliance training program include an understanding of the behavior prohibited by health care fraud and abuse laws.

**Slide 3:**

**Culture of Compliance**

* A culture of compliance is the backbone of any compliance program because it:
  + Prevents;
  + Detects; and
  + Corrects noncompliance.
* Essential to this culture of compliance is having “effective lines of communication,” which means that employees know the avenues through which to report compliance concerns without fear of retaliation for their reporting.
* Compliance is **EVERYONE’S** responsibility! Noncompliance or turning a blind eye to noncompliance should not be tolerated.
* All compliance concerns should be reported to your organization’s or practice’s designated compliance officer.

**Slide 4:**

**Compliance with Fraud and Abuse Statutes, Regulations and Policies**

* The term “fraud and abuse” laws generally describes a number of federal and state laws and regulations that regulate both the provision of healthcare services, as well as the methods and requirements for documenting and submitting claims for services to third-party payers.

**Slide 5:**

**Compliance with Fraud and Abuse Statutes, Regulations and Policies**

* The five most important federal fraud and abuse laws include: (1) the Anti-Kickback Statute; (2) the Physician Self-Referral Law (the Stark Law); (3) the Civil Monetary Penalties Law; (4) the civil and criminal False Claims Act; and (5) the Exclusion Authorities.

**Anti-Kickback Statute Intro:** Conduct that is perfectly legal in another industry may be illegal in the healthcare industry. For example, in many industries it is perfectly legal and commonplace to reward someone who refers business to you. But, in the healthcare industry, this type of conduct is prohibited by a number of laws. Rewarding individuals with kickbacks for the referral of business may lead to overutilization, increased costs to the federal healthcare programs, undue influence over healthcare decisions, patient steering and unfair competition. The Anti-Kickback Statute is designed to prevent these issues and the conduct that contributes to them.

**Slide 6:**

**Anti-Kickback Statute**

* The federal Anti-Kickback Statute is a criminal statute that prohibits anyone from ***knowingly*** and ***willfully*** offering or accepting any ***remuneration***, in cash or in kind, ***directly*** or ***indirectly***, in return for referrals or the purchasing or ordering of any service or good payable in whole or in part under a federal healthcare program.

**Slide 7:**

**Anti-Kickback Statute**

* The meaning of “remuneration” is interpreted ***very*** broadly. It includes anything of value, including but not limited to: gifts, discounts, direct payment of cash or loans, free items or services, and tangible and intangible items.
* If even ***one purpose*** for the remuneration is to induce referrals or the purchase of services, then the Anti-Kickback Statute is violated – regardless of any other legitimate purposes.
* In order to prove a violation of the Anti-Kickback Statute, the government does ***not*** have to prove that the person had ***actual knowledge*** of the Anti-Kickback Statute or the ***specific intent*** to commit a violation of it.

**Slide 8:**

**Anti-Kickback Statute Safe Harbors and Exceptions**

* While the meaning of “remuneration” is very broad, the OIG developed “safe harbors” to identify activities that do not violate the Anti-Kickback Statute.
* There are 28 safe harbors and 9 statutory exceptions to the Anti-Kickback Statute. Some common safe harbors include those for: investment interests, space and equipment rental, personal services and management contracts, discounts, and employees.
* Each safe harbor has a number of elements that must be met in order to protect the individual from liability.
* If an individual meets every requirement of a safe harbor, then the individual will not be subject to sanctions.
* Failure to meet ***any one requirement*** of a safe harbor invalidates the immunity from sanctions.

**Slide 9:**

**Anti-Kickback Statute Safe Harbors and Exceptions**

* It is always preferred for an arrangement to meet a safe harbor or exception.
* However, failure to meet a safe harbor does ***not*** mean that the Anti-Kickback Statute has been violated.

**Slide 10:**

**Anti-Kickback Statute Analysis**

* In general, there is a three-step process for analyzing arrangements under the Anti-Kickback Statute:
  1. Is the Anti-Kickback Statute implicated? In other words:
     1. Is remuneration being offered, paid, solicited, or received?
     2. Is one purpose of the remuneration to obtain, induce, or reward referrals or purchases?
     3. Are the referrals or purchases paid for, in whole or in part, with Federal health care program dollars?
  2. If yes, does the arrangement meet each and every element of a safe harbor or exception?
  3. If no, do the facts and circumstances of the arrangement pose more than a ***minimal risk of fraud and abuse***? In other words, look at the specific facts and circumstances and ask, does the arrangement have the potential to:
     1. Interfere with, or skew, clinical decision-making?
     2. Increase costs to the Federal health care programs?
     3. Increase the risk of overutilization or inappropriate utilization?
     4. Raise patient safety or quality of care concerns?

**Slide 11:**

**Examples of Arrangements Under the Anti-Kickback Statute**

* A laboratory contracts with a marketing company for business development and pays the marketing company a percentage of the business it generates for the laboratory (as opposed to a flat fee). This arrangement would implicate the Anti-Kickback Statute.
* A hospital offers free training for a physician’s office staff on CPT coding and laboratory techniques. This arrangement would implicate the Anti-Kickback Statute.

**Slide 12:**

**Anti-Kickback Statute Penalties**

* Violations of the Anti-Kickback Statute are felonies and carry criminal penalties of up to 5 years in jail and fines of not more than $25,000, or both.
* Violations may also carry civil sanctions, including exclusion from Medicare and Medicaid, Civil Monetary Penalties (CMPs) of up to $73,588 *plus* damages of up to three times the amount of the kickback.
* Additionally, violations of the Anti-Kickback Statute implicate the False Claims Act.

**Anti-Kickback Statute:**

1. Does the government prosecute physicians for Anti-Kickback violations, or does it only target larger entities, such as hospitals, where the fines will be larger? **Yes**, the government targets physicians and physician practices, as well as larger entities, for violation of the Anti-Kickback Statute. While the healthcare community may have once believed that the government only uses its resources to target larger entities on whom the government can levy larger fines, we have seen the government targets physicians and physician practices on many occasions. In June 2015, the Office of Inspector General released a Fraud Alert that put the physician community on notice that the government will closely scrutinize physicians’ financial relationships with entities to whom they refer.
2. What is an example of a physician violating the anti-kickback statute? A lab providing free point-of-care testing cups to physicians. Point-of-care testing cups contain an immunoassay testing strip that provides immediate results to the physician prior to sending the specimen to the lab. The point-of-care testing cups are not ordinary testing cups that serve to simply collect and transport a specimen to the lab. Instead, the point-of-care testing cups provides a benefit to the physicians because they do not have to pay for the cups (which would otherwise cost approximately $5) and they get the benefit of receiving the test results immediately. These benefits alone are enough to constitute remuneration and a violation of the Anti-Kickback Statute.

**Stark Law Intro:** The federal Physician Self-Referral Law is commonly referred to as the Stark Law. The Stark Law focuses, in part, on physicians’ financial relationships with entities to which they refer. One purpose of the Stark Law is to ensure that the judgment of a referring physician is not clouded by his or her own personal financial incentives.

**Slide 13:**

**Stark Law**

* The Stark Law contains two basic prohibitions:
  + ***First***, if a physician (or immediate family member) has a financial relationship with an entity, then the physician ***may not*** refer the patients to the entity for furnishing of designated health services, ***unless an exception applies***.
  + ***Second***, an entity ***may not*** bill Medicare (or any other individual or entity) for services furnished pursuant to a prohibited referral.
* Unlike the Anti-Kickback Statute, which applies to all individuals, the Stark Law only applies to physicians (and their immediate family members) and to the designated health service entities that bill for the service.
* Additionally, the Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required.

**Slide 14:**

**Designated Health Services Under Stark**

* “Designated Health Services (DHS)” include:
  + clinical laboratory services,
  + physical therapy services,
  + occupational therapy services,
  + outpatient speech-language pathology service,
  + radiology/imaging services,
  + radiation therapy services and supplies,
  + durable medical equipment 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.

**Slide 15:**

**Stark Law Exceptions**

* Unlike with the Anti-Kickback Statute, once the Stark Law is triggered, an exception ***must*** be met to avoid liability.
* There are a number of exceptions to liability under the Stark Law. In general, the exceptions can be split into three categories: (i) exceptions related to ownership and investment interests; (ii) exceptions related to compensation arrangements; and (iii) exceptions related to both ownership/investment interests and compensation arrangements.
* Examples of common Stark exceptions include the exceptions for in-office ancillary services, rental of office space, rental of equipment, personal services arrangements, and bona fide employment relationships.

**Slide 16:**

**Examples of Arrangements that Implicate Stark**

* One example of an arrangement that implicates the Stark Law is:
  + A physician leases office space from a hospital in the hospital’s medical office building for a term of one year. This creates a financial relationship between the hospital and the physician that implicated Stark, so the elements of the “rental of office space” exception must be met. In general, if the amount of space leased is reasonable and necessary for the physician’s practice, and the rent is a fixed amount per month and consistent with the fair market value of the space, then the lease will likely meet the exception.
* Another example is:
  + A physician has a written contract with a hospital to serve as the medical directory of the radiology department. This arrangement implicates the Stark Law, so an exception must be met. Under the contract, the physician is paid a fixed amount per month that is consistent with fair market value. The agreement is for one year and the physician performs all of the services contemplated under the agreement. Under these facts, the arrangement will likely meet the Stark exception for “personal services arrangements”.

**Stark Law:**

1. Can a physician enter into a lease with a hospital for the lease of space in a medical office building? **Yes.** While this would create a financial relationship between the physician and the hospital, if the lease meets Stark’s lease of space exception then it does not violate Stark. This exception requires, in part, that the lease be in writing, for a term of at least one year, that the amount of space leased by reasonable and necessary for the physician’s practice, and that the rent be fixed and consistent with fair market value for the space.
2. Can a physician enter into an agreement with a hospital to serve as a medical director? Yes, a physician and hospital can enter into a written agreement for a medical directorship under which the physician is paid a fixed amount per month if the fixed amount is consistent with fair market value, and the term of the agreement is one year.

**CMP Intro:** The Office of Inspector General may impose severe monetary penalties for certain abusive conduct, including, for example, presenting a claim for a medically unnecessary procedure or upcoding procedure codes, both of which would be considered a false claim.

**Slide 17:**

**Civil Monetary Penalties Law**

* The Civil Monetary Penalties Law (CMP) contains a general prohibition on beneficiary (patient) inducements.
* Any person or entity that offers or transfers remuneration to any individual eligible for Medicare or Medicaid that such person or entity knows, or should know, is likely to influence the individual to order or receive from a particular provider or supplier any item or service for which payment may be made under Medicare or Medicaid is liable under the CMP Law.
* Remuneration includes, for example, the routine waiver of copays and deductibles (without a good-faith determination of financial need) or the transfer of items or services for free or for below fair market value.
* On the other hand, remuneration does ***not*** include any practice permitted under the Anti-Kickback Statute safe harbors, incentives given to individuals to promote the delivery of preventive care services, or any item or service which promotes access to care and poses a low risk of harm to patients and the federal healthcare programs.
* Another example of a violation of the CMP Law is presenting a claim that the person knows or should know is for an item or service that was not provided as claimed, is false or fraudulent, or for which payment may not be made.
* Fines for violations can be up to $73,588 for each claim, *plus* damages of up to three times the amount of the claim.

**CMP:**

1. Is it okay to give a gift to a Medicare beneficiary who is a patient of the practice? The Office of Inspector General has advised that physicians are permitted to offer patients inexpensive gifts, other than cash or cash equivalents, as long as they have a retail value of no more than $15 individually and no more than $75 in the aggregate annually per patient.

**False Claims Act Intro:** The False Claims Act makes it illegal to submit false or fraudulent claims for payment to Medicare and can result in hefty fines. The False Claims Act also provides a financial incentive for individuals to report violations of the act, which can be up to 30% of the amount recovered from the wrongdoer. This sometimes results in ex-business partners, staff, competitors, or even patients reporting fraudulent conduct.

**Slide 18:**

**False Claims Act**

* It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.
* The False Claims Act prohibits knowingly and willingly making or causing to be made any false statement or representation of material fact in any claim or application of benefits under Medicare or Medicaid.
* A “false” claim may include:
  + A claim that does not conform to Medicare (or another payer) requirements for reimbursement;
  + The knowing use of false records to obtain payment on a false or fraudulent claim;
  + Retention of funds that a provider knows it is not entitled to (*e.g.*, credit balances/refunds); or
  + A claim for a service:
    - Not actually provided;
    - Covered under a different claim;
    - Miscoded; or
    - Not supported by the medical record.
* It is important to note that if a claim results from a violation of the Anti-Kickback Statute or the Stark Law, then this also may be a violation of the False Claims Act.
* Criminal penalties for violations of the False Claims Act include imprisonment and/or fines.
* Civil penalties for violations of the False Claims Act may include fines of up to three times the amount of the false claim plus up to $21,563 for each false claim filed.
* The OIG may also impose administrative civil monetary penalties for false or fraudulent claims.
* No specific intent to defraud is required for a violation to result. Instead, the term “should know” includes acts in deliberate ignorance of or in reckless disregard of the truth or falsity of the information.

**False Claims Act:**

1. What is an example of a physician being prosecuted for a **false claim**? A cardiologist submitted multiple claims for evaluation and management services he provided even though he had already been paid for those services under stress test claims he submitted. Because of these double payments, the cardiologist ended up paying the government $435,000 to settle the claims.

**Exclusion Authority Intro:** The Office of Inspector General maintains a List of Excluded Individuals/Entities, which lists the individuals and entities that have been excluded from participating in the federal healthcare programs. It is important for physicians and other healthcare providers to review this list to ensure that they do not employee or contract with anyone on the List of Excluded Individuals/Entities.

**Slide 19:**

**OIG’s Exclusion Authority**

* The Office of Inspector General (OIG) is legally required to exclude from participation in all federal healthcare programs (e.g., Medicare, Medicaid), individuals and entities convicted of certain types of criminal offenses (e.g., Medicare or Medicaid fraud; patient abuse or neglect). The OIG also has ***discretion*** to exclude individuals and entities for more ***minor*** offenses (e.g., misdemeanor convictions related to healthcare fraud (other than Medicare or Medicaid Fraud); suspension, revocation or surrender of a healthcare license for reasons bearing on professional competence, performance or financial integrity).
* The OIG’s Exclusion List should be checked for every prospective employee and for every current employee at least annually.
* Your organization or practice should not employ, contract or consult with any individuals or entities on the OIG’s Exclusion List.
* The list is available at <http://oig.hhs.gov/exclusions/index.asp>.

**Exclusion Authority:**

1. What is the effect of an exclusion on the excluded individual? The effect is that the federal healthcare programs will not make any payment for any items or services furnished, ordered or prescribed by an excluded individual or entity.
2. What is the effect of an exclusion on the entity employing or contracting with the individual? The entity will also not receive payment for any items or services furnished, ordered or prescribed by the excluded individual. The entity can also be subject to civil monetary penalty liability.

**Michigan Fraud and Abuse Intro:** Even if an arrangement or particular conduct does not violate one of the federal healthcare fraud and abuse laws, the arrangement and conduct should still be evaluated under applicable state laws.

**Slide 20:**

**Michigan Fraud and Abuse Laws**

* Michigan has a number of statutes similar to the Anti-Kickback Statute, Stark Law and False Claims Act, but there are also notable difference.
  + For example, the Michigan Medicaid False Claim Act, MCL § 400.604, applies to Medicaid funds and states that “[a] person who solicits, offers, or receives a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part [by Medicaid], who makes or receives the payment, or who receives a rebate of a fee or charge for referring an individual to another person for the furnishing of the goods and services is guilty of a felony, punishable by imprisonment for not more than 4 years, or by a fine of not more than $30,000.00, or both.”

**Slide 21:**

**Michigan Fraud and Abuse Laws**

* Another example is the Michigan Health Care False Claim Act, MCL §752.1004, which applies to all other payers and insurance companies and states that “[a] person who solicits, offers, pays, or receives a kickback or bribe in connection with the furnishing of goods or services for which payment is or may be made in whole or in part by a health care corporation or health care insurer, or who receives a rebate of a fee or charge for referring an individual to another person for the furnishing of health care benefits, is guilty of a felony, punishable by imprisonment for not more than 4 years, or by a fine of not more than $50,000.00, or both.”

**Slide 22:**

**Michigan Self-Referral Prohibition (Michigan’s Stark Law)**

* Michigan’s version of the Stark Law, MCL §333.16221(e)(iv)(B), is contained in its health professions licensing statute, which describes conduct that constitutes “unprofessional conduct” to include when a physician makes a referral in violation of the federal Stark Law.
* Note that the Michigan Department of Licensing and Regulatory Affairs has adopted the federal Stark Law regulations through “Phase III” into the Michigan Stark Law, but they have not adopted later revisions to the federal Stark Law. When analyzing an arrangement under the federal Stark Law and under Michigan law, this should be taken into account.

**Slide 23:**

**Michigan Fraud and Abuse Laws**

* Other examples of Michigan fraud and abuse laws include fee-splitting laws (e.g., MCL 333.16221(D)(II), MCL 750.428), kickback laws relating to specific services (e.g., clinical laboratory services as addressed in MCL 445.162), and insurance fraud statutes (e.g., MCL 500.4500 et seq.)

**Michigan Fraud and Abuse:**

1. If a physician does not see Medicare, Medicaid or other federal healthcare program patients, do they need to worry about the fraud and abuse laws? Yes. The physician still needs to comply with the Michigan laws we discussed in this presentation. Many of these laws apply to all sources of payments, including patients with private health insurance and cash-pay patients, not just those with Medicare or Medicaid.

**Slide 24:**

**Summary**

* It is the duty of all members of your organization’s or practice’s workforce to use good-faith efforts to comply with the law.
* If any questions arise as to whether an arrangement or activity violates one of the fraud and abuse laws, you should immediately report to your Compliance Officer, who should seek assistance from healthcare legal counsel as needed.