Please see https://oig.hhs.gov/newsroom/video/2011/heat_modules.asp for referenced videos.

Video 3: GUIDANCE FOR HEALTH CARE BOARDS –Federal Anti-kickback statute [1]

Four things every health care provider should know about the Anti-kickback statute:

1. Know what the Anti-kickback statute prohibits;

    a. You may not knowingly or willingly offer or receive anything of value to induce or reward referrals of Federal health care program business;
    b. The law applies to those who pay or receive the kickback.

2. Know the penalties under the law;

    a. Criminal:
        i. Fines – up to $25,000 per violation and/or;
        ii. Felony – up to a 5-year prison term.
    b. Civil:
        Up to three times the government program's loss, plus $11,000 per claim
    c. Exclusion from Federal health care programs;
    d. Up to a $50,000 civil penalty per violation and an assessment of up to three times the total kickback payment, even if some of the payment went to a legitimate purpose.

3. Know the types of programs the law covers – the Law does not apply to all referrals The law only applies to Federal health care programs, e.g., Medicare & Medicaid; and

4. Most of you know the law has numerous "safe harbors" – some of these exceptions are:

    a. Employment arrangements;
    b. Space and equipment leases.

As of December 2, 2020 there are New and Modified Anti-Kickback Statute Safe Harbors

Value-Based Arrangement Exceptions: OIG finalized three new safe harbors for remuneration exchanged between eligible participants in a value-based arrangement that fosters better coordinated and managed patient care. The three value-based safe harbors are similar in some respects but not identical to the Stark exceptions and include:

[1] Given by: Meredith Williams, Attorney at the Office of the Inspector General

- Care coordination arrangements to improve quality, health outcomes, and efficiency that does not require the participants to take on risk but protects only in-kind remuneration
- Value-based arrangements with substantial downside financial risk (at least 5%)
- Value-based arrangements with full financial risk for the cost of all items or services covered by a payor for each patient in the target population for a term of one year

Patient Engagement and Support Safe Harbor: OIG finalized a new safe harbor for certain tools and supports furnished to patients to improve quality, health, outcomes, and efficiency.

CMS Sponsored Models: OIG finalized new safe harbor for certain remuneration provided in connection with a CMS-sponsored model, which reduces the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models.

Cybersecurity Technology and Services: OIG finalized a new safe harbor for donations of cybersecurity technology and services essentially the same as the Stark Cybersecurity Exception described above.

Electronic Health Records Items and Services: OIG modified the safe harbor for electronic health records items and services to allow donations of certain related cybersecurity technology to update provisions regarding interoperability, and to remove the December 31, 2021, sunset date.

Outcomes-Based Payments and Part-Time Arrangements: The final rule modifies the AKS safe harbor for personal services and management contracts to add flexibility for certain clinical outcomes-based payments and to eliminate the requirement that part-time arrangements have a schedule of services specifically set out in the agreement.

Warranties: OIG modified the safe harbor for warranties to revise the definition of warranty and provide protection for bundled warranties for one or more items and related services provided they are paid for under the same payment.

Local Transportation: OIG modified the AKS safe harbor for local transportation to expand and modify mileage limits for rural areas (to 75 miles) and for transportation for patients discharged from an inpatient facility or released from a hospital after being placed in observation status for at least 24 hours. Ridesharing arrangements are also permissible under this safe harbor.

Accountable Care Organization (ACO) Beneficiary Incentive Programs: The final rule codifies the statutory exception to the definition of remuneration under the AKS related to ACO Beneficiary Incentive Programs for the Medicare Shared Savings Program to allow incentive payments made by an ACO to a beneficiary.

Telehealth for In-Home Dialysis: OIG amended the definition of remuneration in the Beneficiary Inducements Civil Money Penalties statute to incorporate a new statutory exception to the prohibition on beneficiary inducements for "telehealth technologies" furnished to certain in-home dialysis patiways Norris McLaughlin IP Attorneys Volunteer to Judge Higher Education Moot Courts.

Note: An important message here is that what's often a common practice in other industries can be a CRIME when you are talking about Medicare and Medicaid.

Video 4: GUIDANCE FOR HEALTH CARE BOARDS –False Claims Act[i]

[2]The False Claims Act ("FCA") prohibits the submission of false or fraudulent claims to the Government including the Medicare & Medicaid programs.

Claims that may be false include claims where the service:

- Is not rendered;
- Is already covered under another claim;
- Is miscoded;
- Is not supported by the patient's medical record;
- If a claim violates the anti-kickback statutes or the Stark Law.

When the government targets FCA claims, it does not target innocent billing mistakes. False claims are those that the provider knew, or should have known, were false or fraudulent. It is the providers responsibility that claims submitted to Medicare and Medicaid must be true and accurate. However, innocent billing mistakes should be addressed and repaid to the government within 60 days or be subject to penalties.

If a provider fails to comply with the FCA, penalties are up to three times the Government's loss, plus an additional $11,000 per claim (with each occurrence being a separate claim for liability);

The FCA provides incentives to whistleblowers to report fraud by receiving up to 30% of an FCA recovery. Common whistleblowers are:

a. ex-business partners;
b. current or former employees;
c. competitors; or
d. patients.

It is important to keep in mind that any person can be a "whistleblower." A whistleblower could be a disgruntled employee, a contractor, a patient, or a vendor.

Video 5: GUIDANCE FOR HEALTH CARE BOARDS –Physician Self-Referral Law[3]

The Physician's Self-Referral Law a/k/a The Stark Law

The Stark Law is intended to prohibit improper referral relationships that can harm the Federal health care programs and program beneficiaries. Improper referral relationships can lead to over-utilization, increased costs and corruption of the medical decision-making process. The Stark Law

[2] Given by Katy Fink, Attorney at the Office of the Inspector General
[3] Given by: James Cannoti, Attorney at the Office of the Inspector General

limits physician referrals of Medicare patients to entities with a financial relationship with the entity. The Law also prohibits those entities from submitting a claim.

How do you know if you violated the Stark Law? There are three basic questions:

1. Is there is a referral from a physician for a designated health service ("DHS"*)? If yes, then

2. Does the physician (or an immediate family member) have a financial relationship with the entity providing the DHS? If yes, then

3. Does the financial relationship fit within an exemption? If no, then you have a Stark Law problem.

Parties that knowingly submit a claim to Medicare in violation of the Stark Law are subject to the following significant penalties:

1. Owing back the entire amount of the claim even if services were rendered and medically necessary;

2. False Claims Act Liability;

3. Civil Monetary Penalties;

4. Program Exclusions

New and Modified Stark Exceptions promulgated as of December 2, 2020

Value-Based Arrangement Exceptions: CMS finalized three new exceptions for value-based arrangements between a physician and an entity that pays physicians based on the quality of patient care delivered rather than the volume of services provided. The value-based exceptions include:

- Full financial risk exception in which the value-based enterprise assumes the full financial risk for the cost of all patient care for each covered patient for a specified time period
- Meaningful downside financial risk exception where the physician is at meaningful downside financial risk (at least 10% of remuneration) for failure to achieve the value-based goals
- Value-based arrangements exception regardless of the level of risk undertaken that permits both monetary and non-monetary remuneration between the parties

Cybersecurity Exception: CMS finalized a new exception that permits the donation to physicians of cybersecurity hardware, software, and services that are necessary and used to implement, maintain, or reestablish cybersecurity. Unlike the existing Stark exception for electronic health records, there is no requirement for the physicians to share in the cost of such hardware or software.

Limited Remuneration Exception: CMS finalized a new exception that permits limited remuneration (not more than $5,000 per calendar year) to a physician including instances where the amount or formula for calculating the remuneration is not set in advance.

Clarification of Commercial Reasonableness, Volume, or Value Standard and Fair Market Value Requirements: CMS's final rule clarifies these three requirements that are found in most of the Stark exceptions. Commercial reasonableness is defined to mean that the arrangement furthers a legitimate business purpose of the parties and is sensible, considering the size, type, scope, and specialty of the parties. It is not based on whether the arrangement is profitable or not. Under the new rule, the amount of compensation will be considered to take into account the volume or value of referrals only when the formula used to calculate compensation includes the volume or value of referrals as a variable that caused compensation to increase or decrease directly with referrals. The new rule further defines fair market value as the value in an arm's length transaction (between a well-informed buyer and seller that are not in a position to refer to each other) consistent with the general market value of the subject transaction.

Indirect Compensation Arrangement Exception: The modifications to this Stark exception provide that the value-based arrangements exceptions will protect a physician's referrals to the entity when an indirect compensation arrangement includes a value-based arrangement to which the physician is a party.

Direct Referrals: CMS added the specific conditions required under the existing special rule for directed referrals (that require patient preference, insurer determinations, and the patient's best medical interest to override any requirement to refer to a specific provider) to the following Stark exceptions: academic medical centers, bona fide employment arrangements, personal services arrangements, physician incentive plans, group practice arrangements with a hospital, fair market value compensation, and indirect compensation arrangements.

Clarification of Set in Advance Requirement: CMS modified the definition of set in advance used in many Stark exceptions to allow modification of compensation during the term of an arrangement (including in the first year) if the modified compensation is not based on the volume or value of referrals. The modification (or formula) must be set forth in writing prior to the furnishing of services but need not remain in place for a year. There is no limit on the number of times that compensation may be modified.

Group Practice Special Rule for Profit Shares and Productivity Bonuses: CMS modified the special rule for profit shares and productivity bonuses to provide that distribution of profits from designated health services directly attributable to a physician's participation in a value-based arrangement are deemed not to take into account the volume or value of the physician's referrals, thereby enabling physicians in a group practice to be rewarded for their participation in a value-based arrangement.

Electronic Health Records: CMS modified the Stark EHR exception to allow donations of cybersecurity software and services, to remove the December 31, 2021, sunset provision, to remove the requirement that donors ensure they are not replacing equivalent EHR technology

already owned by physicians, and to allow the physicians to pay their portion of the EHR at reasonable intervals (as opposed to upfront).

*A list of DHSs may be found in the Stark Law Regulations

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2020 ANNUAL TRAINING
EMPLOYEE ACKNOWLEDGEMENT

1. Employee Occupational Incident Reporting
2. What You Should Know About Human Trafficking/Sexual Coercion/Domestic Violence
3. Child and Elder Abuse Reporting
4. Infection Control and Universal Precautions
5. Medical Equipment Management
6. Safety-Fire-Security
7. HIPAA and Corporate Compliance
8. Risk Management for Health Centers
9. Patient Bill of Rights
10. Cultural Competency-Sensitivity
11. Gender Identity
12. Hazardous Material and Waste Management

I understand that it is my responsibility to ensure full knowledge and retention of this information for annual review and testing.

Employee Name: _____ Site/Department_____
(Print)

Signature: _____ Date: _____