Compliance and Organizational Business Ethics

Guidance for Meridian ACO Providers

Hackensack Meridian *Health*

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Learning Objectives

By the end of this course, you will be able to...

- Understand federal and state fraud and abuse laws.
- Identify referral restrictions in Stark and similar statutes.
- Understand compliance risks specific to an ACO.
- Understand the importance of accurate documentation and coding for CMS (Medicare/Medicaid) billing.
- Recognize potential conflict of interest situations and their relationship to Meridian policies.
- Utilize methods of raising questions and concerns.

The Meridian ACO Compliance Program *What is it?*

- It is a set of processes and programs designed to help ACO participants be aware of and follow Laws, regulations, guidelines unique to ACOs that can affect medical practitioners relationships with patients, payers, vendors, and other healthcare providers.

Physician Trust & ACO Responsibility

- Trust is at the core of the physician – patient relationship; patients rely on physicians to provide necessary, quality medical care.

<u>ACO Responsibility for Participants and Providers/Suppliers</u>

- "Notwithstanding any arrangements between or among an ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities, the ACO must have ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its agreement with CMS..."

42 CFR 425.314(c)

Law Enforcement Programs Target Healthcare Fraud & Abuse

- The Department of Justice has made healthcare fraud the second highest priority after violent crime. Why?
  - *The Federal Government has recovered over $27 billion from healthcare fraud judgments and settlements since January 2009.*
- The Office of Inspector General (OIG) is the division within the Department of Health and Human Services responsible for investigating suspected Medicare and Medicaid fraud, waste and abuse.

Major Risk Areas for Physicians

- The OIG has developed a list of potential risk areas specifically affecting physician practices. These risk areas include:
  - Coding and billing for medically necessary services;
  - Complete, accurate and timely documentation;
  - Improper inducements, kickbacks and self-referrals;
  - Potential Conflicts of Interest.
  - An ACO presents unique opportunities for patients of physicians and also different risk situations.

The 7 Basic Elements of an Effective Compliance Program

1. *Code of Conduct*, Policies & Procedures
   - *Available on the Meridian website*
2. Compliance Officer (Peter Hughes) & Professional Team
3. Effective training for all employees
4. Effective lines of communication
5. Monitoring (Internal/External Audits)
6. Investigation of alleged problems
7. Identification of deficiencies & Response

Key Fraud & Abuse Laws

The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree, or to comply with all applicable laws including, but not limited to the following:

- Federal criminal law
- The False Claims Act
- The anti-kickback statute
- The civil monetary penalties law
- The physician self-referral law" (Stark)
  - 42 CFR 425.208(b)

Fraud & Abuse Distinction

FRAUD is an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State Law.

ABUSE involves provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to a government program or in reimbursement of services that are not medically necessary or that fail to meet professionally recognized standards for health care.

Differences between Fraud and Abuse can depend on specific facts and circumstances.

Examples of Fraud & Abuse

- Examples of Medicare fraud include:
  - Knowingly billing for services not furnished, supplies not provided, or both, including falsifying records to show delivery of such items or billing Medicare for appointments that the patient failed to keep; and
  - Knowingly billing for services at a level of complexity higher than the service actually provided or documented in the file.
- Examples of Medicare abuse include:
  - Billing for services that were not medically necessary;
  - Charging excessively for services or supplies; and
  - Misusing codes on a claim, such as upcoding or unbundling codes.

Federal Law Prohibitions Relevant to Medicare ACO Compliance

False Claims Act	Knowingly submitting false or misleading claims to the federal government.
Anti-Kickback Statute	Knowingly and willfully exchanging remuneration for the referral of patients for items or services covered by a federal health care program.
"Gain Sharing CMP"	Payments by hospitals to physicians to reduce or limit medically necessary Medicare covered services.
"Patient Inducement CMP"	Offer of remuneration that persons knows or should have known is likely to influence patient's choice of provider or supplier.
Stark Law	Referrals by physician to any entity with which physician has financial relationship that does not fit within exception.

False Claims Act (FCA)

- The FCA protects the Federal Government from knowingly being overcharged for goods or services.
  - No specific intent to defraud is required.
  - "Knowing" includes actual knowledge as well as deliberate ignorance or reckless disregard (should have known).
  - Includes a "qui tam" provision that allows people who are not affiliated with the Government to file actions on behalf of the Government (called "whistleblowing").
  - Civil penalties can result in fines up to 3x the program's loss plus $11,000 per claim filed.
  - Criminal penalties can include imprisonment and criminal fines.

Anti-Kickback Statute (AKS)

- The AKS prohibits offering, paying, soliciting or receiving anything of value (cash and/or non-cash, including any kickback, bribe, or rebate) to induce or reward referrals or generate Federal healthcare business.
  - Criminal and Civil penalties and administrative sanctions can include significant fines, jail time, FCA liability and exclusion from participation in Federal healthcare programs.
  - Includes referrals from anyone, for any items or services.
- Applies to the individual offering the kickback and the recipient.

Anti-Kickback Statute (AKS)

- ***Intent based statute***, meaning the actions of the individual are intentional and knowing.
- Intent is needed in order to violate the statute; ***however***, intent will be found if even ***one purpose*** was to induce referrals (known as the One Purpose Test; used by the Courts).
- Arrangements ***must***:
  - Satisfy a safe harbor.
  - Represent Fair Market Value (FMV)* for actual / necessary services.

** The fair market value is the price at which the transaction would occur between a willing buyer and a willing seller, neither being under any compulsion to buy or to sell and both having reasonable knowledge of relevant facts.*

Checkpoint
(False Claims Act)

Which of the following is NOT an example of an illegal action under the False Claims Act?

a) A physician submits a bill to Medicare for medical services not provided.

b) A coder uses a billing code that reflects a higher payment rate for a service provided than the actual service provided for a Medicare patient.

c) The hospital charges a different rate for a private room than a semi-private room.

(C is correct – Billing for services not provided (choice (a)) and upcoding (billing for a more expensive service than actually provided – choice (b)) are both examples of knowingly overcharging the Federal Government and illegal under the False Claims Act.)

Physician Self-Referral Law (Stark Law)

If a physician (or immediate family member) has a financial relationship with an entity, then the physician may not make referrals to the entity for the furnishing of designated health services, and the entity may not submit a bill for the furnishing of any such services unless an **exception** (e.g. physician recruitment, non-monetary compensation) applies.

- Proof of specific intent is NOT required (i.e. strict liability).
- Physician compensation must always be set in advance and in writing, and not take into consideration the volume or value of referrals.
- Financial transactions with physicians should always be documented and based on fair market value.
- Be aware that gifts to physicians can implicate the Stark Law.

Designated Health Services

There are currently ten (10) categories of “designated health services:”

1. Clinical laboratory services
2. Physical therapy, occupational therapy, and speech language pathology services
3. Radiology and certain other imaging services
4. Radiation therapy services and supplies
5. Durable medical equipment (DME) and supplies
6. Parenteral and enteral nutrients, equipment and supplies
7. Prosthetics, orthotics and prosthetic devices and supplies
8. Home health services
9. Outpatient prescription drugs and
10. Inpatient and outpatient hospital services.

Gainsharing and Compliance

Gainsharing arrangements, such as an Accountable Care Organization (ACO), are designed with the goal of creating improved healthcare quality and outcomes at a lower cost through collaboration and integration among payers, health systems and physicians.

Although there are often some waivers of Federal laws in these arrangements, all parties involved should ensure the program does not implicate fraud and abuse laws by verifying that:

- Incentive compensation must not vary based on the value or volume of referrals that may be generated by physician participants;
- Total compensation earned by a participating physician must reflect fair market value;
- Metrics that drive incentive compensation must not be based on measures that reduce or limit care to patients.

ACO Waivers – Fraud & Abuse

ACO Pre-participation Waiver	Covers "start up arrangements" pre-dating Medicare Shared Savings Program (MSSP) participation agreement. Good faith intent and diligence to develop ACO. Public disclosure.
ACO Participation Waiver	ACO participates in MSSP and satisfied governance and management rules.
Shared Savings Distribution Waiver	Covers distribution of shared savings by ACO participants, providers and suppliers. Savings or incentives paid by commercial insurers may be treated differently.
Compliance With Stark Exception Waiver	Provides protection from anti-kickback statute for any arrangement that satisfies a Stark exception. Precludes need to comply with anti-kickback safe harbor.
Patient Incentives Waiver	Flexibility to offer patient inducements for healthy behavior. Covers some free or below fair market value items or services (but not cash or cost saving waivers). Reasonable connection between items or services and beneficiary's medical care. Items or services are: • For preventive care (undefined) • To advance adherence to treatment, drug regime or care plan, or chronic disease management. 42 CFR 425.304(a)

Civil Monetary Penalties Law

- The OIG may seek civil monetary penalties (CMP) and sometimes exclusion from the Medicare and Medicaid programs for a wide variety of conduct, such as the examples listed below:
  - Knowingly **presenting false claims** for items or services (or should have known);
  - Knowingly giving or causing to be given **false or misleading information** reasonably expected to influence the decision to discharge a patient;
  - Arranging for reimbursable services with an entity which is **excluded** from participation from a federal healthcare program;
  - Knowingly or willfully **soliciting or receiving remuneration for a referral** of a federal healthcare program beneficiary.
- Penalty and assessment amounts vary based on the violation type.

Checkpoint
(Patient Incentive)

Can an ACO participant offer $50 per visit to a participating patient to incentivize them to follow good health practices such following their medication schedule at home and working with the population health navigator ?

a) Yes

b) No

(B is correct - The ACO patient incentive waiver prohibits payment of cash to a patient. Items or services that will enhance preventive care can be used as incentives so long as they are reasonably connected to patient's care and treatment.)

Exclusion Statute

- The OIG is legally required to exclude from participation in all Federal healthcare programs individuals and entities convicted of the following types of criminal offenses including but not limited to:
  - Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid;
  - Patient abuse or neglect.
- **Excluded providers may not bill directly for treating Medicare and Medicaid patients**, nor may their services be billed indirectly through an employer or group practice.
- Meridian Health Compliance routinely screens all team members, Medical Staff, referring physicians and vendors for all applicable Federal and State exclusions.

Checkpoint
(Provider Exclusions)

Is it acceptable to include a physician or advanced practice nurse who is currently sanctioned by the OIG in the care of an ACO patient if he or she does not bill Medicare directly for any services rendered?

a) Yes

b) No

(B is correct – Excluded/sanctioned persons cannot participate in any healthcare services reimbursable by Medicare as part of a practice's professional services team.)

ACO Key Risk Areas

ACO compliance focuses on the quality, cost and outcomes data reported by ACO participants. Risk areas include:

- Eligibility requirements
- Quality data reporting
- Avoiding at-risk beneficiaries
- "Stinting" on care and overutilization
- Beneficiary notification of ACO participation and ability to opt-out of data-sharing
- Development of accurate Marketing activities
- Legal waivers / compliance
- Protecting privacy of patient data
- Record Retention

ACO Key Risk Areas

- ACO Eligibility
  - CMS will look for any changes that impact an ACO's ongoing satisfaction of eligibility requirements such as the ACO ***participant population meeting the 5,000 threshold*** or increases in providers/suppliers that result in ***antitrust issues***.
- Quality Data Reporting
  - ACO shared savings are based on quality measures such as clinical processes and outcomes, patient experience of care, and utilization. Quality data submitted by the ACO must be ***complete and accurate*** in order to be evaluated by CMS.

ACO Key Risk Areas

- Avoidance of "At-Risk" Beneficiaries
  - The ACO cannot avoid "at-risk" beneficiaries such as: high risk score on CMS-HCC model; high cost due to 2 or more hospitalizations/ER visits per year; high utilization pattern; has chronic conditions or recently diagnosed with increased care cost disease; or is diagnosed with mental health or substance abuse disorder.
- "Stinting" on Care and Overutilization
  - CMS will monitor ACOs to make sure they are not "creating" savings by "stinting" on care for ACO assigned beneficiaries and alternately "making up" revenue by overutilization of items and services to non-ACO assigned beneficiaries.

Checkpoint
(Provision of Care)

It is acceptable under the ACO guidelines to avoid ordering certain tests that may seem medically appropriate if that serves to reduce cost of that ACO patient's treatment regime for a particular diagnosis?

a) True

b) False

(B- False is correct – CMS has indicated it will monitor ACO's to insure any necessary medical services are not withheld from ACO assigned beneficiaries to reduce overall costs and thereby generate revenue distributions.)

ACO Key Risk Areas

Beneficiary Notification

- ACO participants must notify beneficiaries about their participation in an ACO and post signs. The beneficiaries must have the opportunity to opt-out of sharing PHI among ACO providers, and the ACO should periodically audit the list of members who opted-out of data sharing.

Marketing Guidelines

- CMS will limit and monitor ACO's marketing to ensure that it is not targeted, beneficiary specific or discriminatory. All marketing material must be approved in advance by CMS.

Legal Waivers

- Specific waivers exist to allow ACOs to operate without the risk of liability under fraud and abuse laws. ACOs audit compliance with waivers, especially when arrangements are modified over time.

Checkpoint
(Patient Information)

A new patient service is being introduced or expanded by an ACO participant. Is it acceptable for that participant or his/her representative to access ACO/Population Health databases to identify specific patients by diagnoses codes (who they have not currently or previously treated) so that they can contact those patients about the new service, believing it may be potentially beneficial to that patient?

a) Yes

b) No

(B - No is correct – Although there are several ACO waivers, CMS has not waived the HIPAA Privacy regulation which states a beneficiary must consent to being contacted for marketing purposes. Protected Health Information (PHI) cannot be accessed without patient consent.)

Documentation, Coding & Billing
A 3-Legged Stool

- Providers should maintain accurate and complete medical records and documentation of the services they provide, and ensure the claims they submit are supported by that documentation.
- Coding is reliant on documentation for accuracy. Effective coding can be measured by various outcome indicators such as 3rd party identified overpayments and underpayments or audit results indicating overall error rates.
- Billing is the process of insuring the coding and patient charging information is accurately reflected on claims.

Ongoing education and evaluation for all involved is necessary because the rules are continuously changing.

Documentation

- Clear and concise documentation helps ensure patients receive appropriate quality care from all providers.
- Each Medicare contractor has the discretion to establish which services are reasonable and necessary and therefore covered as a Medicare benefit, known as Local Coverage Determinations or LCDs.
- “If it isn’t documented, it hasn’t been done” – CMS credo.
- Specific requirements and exceptions for general documentation, coding and billing exist for teaching physicians, interns and residents:
  - Medicare Claims Processing Manual: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf
  - CMS’s Documentation Guidelines for Evaluation and Management Services: http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html

Documentation: Electronic Medical Record (EMR)

- Benefits of EMR include better coordination of patient care, improved quality and safety, and reduction in paperwork.
- Caution should be used in order to ensure accurate coding & billing:
  - Government audits will focus on improper billing and medical reviews, specifically accurate coding of patient services and medical necessity.
  - A patient's medical care information must be verified individually:
    - Cutting and pasting from previous notes or records risks medical errors and overpayments.
    - CMS credo becomes, "If it's documented, was it done this visit?"

Coding & Billing

- A claim filed for services performed for a Medicare or Medicaid beneficiary certifies that you comply with billing requirements.
- Examples of improper billing & coding include:
  - Upcoding: using billing codes that reflect a more severe illness than actually existed or a more expensive treatment than was provided.
  - Billing for services not actually provided.
  - Billing for services that were not medically necessary.
  - Billing for services performed by an improperly supervised or unqualified employee.
  - Billing for services performed by an excluded individual.
- Without proper documentation to support the coding and billing, you are at risk of violating policies and the law.

Coding & Billing
Resources within Meridian Health

- Meridian Health has the following internal resources for billing, coding and documentation:
  - For inpatients -In-House review & coding expertise in Clinical Documentation Improvement (**CDI**) program.
  - Hospital Physician Assistants in the Care Management Department.
  - Meridian Corporate Compliance coding support staff.
- These resources are available for assistance upon request.

Conflict of Interest

- Medicare Shared Savings Program (MSSP) regulations required 75% of the ACO board to consist of representatives of the ACO participants.
- Participants will all have business relationships with the ACO
- The ACO conflicts of interest protocol must:
  - Provide for disclosure of financial interests
  - Create Procedure for identifying and addressing conflicts
  - Establish remedies for violation of policy
- Examples could include:
  - If Medical Group A provided Dr. A to the ACO Board, conflicts could surface when the ACO enters into a contract with Dr. A or with Medical Group A. The COI policy provides a mechanism to disclose, identify, understand, and approve or reject conflicts. It does not prohibit the existence of disclosed conflicts.
  - When an individual has the opportunity to use his/her position for personal financial gain or to benefit a company in which he/she has a financial interest.

Managing Conflicts of Interest

Disclosure

- Although they may ultimately not be problematic, disclosure of all potential conflicts of interest are required according to Meridian Health's Medical Staff Conflict of Interest Policy which can be obtained from a Meridian hospital Office of Medical Staff services, the ACO administrative offices, or the ACO website.
- If you are unsure about an activity or relationship, err on the side of caution – apply the "newspaper test" and ask yourself how failure to disclose such a relationship would appear if published in the newspaper.

Recuse yourself from any decision making committees or at minimum from decisions specifically involving the potential conflicting entity.

Be cautious about accepting gifts from outside sources, no matter how nominal you may think they are.

Open Payments – "Sunshine Act"

- Open Payments, also known as the "**Sunshine Act**," began August 1, 2013. Since 2013 applicable manufacturers and group purchasing organizations (GPOs) have been reporting data about payments and other transfers of value made to physicians and teaching hospitals to CMS.
  - **"Applicable manufacturers" refers to companies that sell drugs, devices, biologicals, and medical supplies that are available for reimbursement** through a federal health care program, such as Medicare or Medicaid.
- Open Payments is intended to increase public awareness of financial relationships between companies and certain health care providers — ***doctors of medicine and osteopathy, dental surgeons, dentists, licensed chiropractors, optometrists, and podiatrists.***
  - Open Payments is focusing on transparency; simply having data posted under your name does not mean you have violated a law or any institutional policy. Physicians should verify that the information posted is as accurate as possible.

Open Payments:
What does this mean to you?

- ***Anyone can view this information*** once it is published, including your patients, chief or chair, institutional officials, the compliance office, government representatives, colleagues, attorneys, and the media.
- Knowledge of ***Meridian's Medical Staff Conflict of Interest Policy*** and the reporting of potential conflicts of interest becomes even more critical.
- Patients may ask you about payments or transfers of value you received. ***Reviewing your data, before and after public release***, gives you the opportunity to understand what questions you may receive.
- For more detailed information on Open Payments please refer to the following resources:
  - The Official Website for Open Payments (the Sunshine Act) http://go.cms.gov/openpayments
  - Meridian Health Physician Extranet http://www.meridianhealthdoctor.com/Portal/MHMD/

Meridian ACO ComplyLine for Questions & Concerns

- Questions and concerns on Compliance and Ethics issues can be raised through the following channels:
  - Meridian ACO Compliance Officer at 732-751-3313
  - **Meridian ACO ComplyLine**
    - 1-877-888-8030
  - A confidential, untraceable phone line that allows ACO physicians, providers/suppliers, patients and external parties to get answers to compliance related issues.
  - Used to identify potential ethical, legal, privacy violation, or diversity concerns related to ACO operations.

Meridian ACO ComplyLine

- All calls are treated confidentially; team members are protected against retaliation as required by the NJ Whistleblowers Act.
- All team members and physicians have the right to contact the Joint Commission, the NJ Dept. of Health, or a Patient Safety Organization anonymously if they have concerns about safety or quality of care. No disciplinary action will be taken for reporting.
- We recommend you contact the Vice President of Population Health & Clinical Quality or the VP of Clinical Effectiveness of the facility if you have concerns about safety or quality of care.
- The Meridian ComplyLine is an option if you want to report a concern. Reports can be made anonymously.

Physician Compliance References

- False Claims Act [31 U.S.C. §§3729-3733
- Anti-Kickback Statute [42 U.S.C. §1320a-7b(b)]
- STARK : Physician Self-Referral Law [42 U.S.C. §1395nn]
- Provider Exclusion Statute [42 U.S.C. §1320a-7]
- CMP – Civil Monetary Penalties Law [42 U.S.C. §1320a-7a]
- Medicare Claims Processing Manual
  http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf
- CMS's Documentation Guidelines for Evaluation and Management Services
  http://cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/EMDOC.html
- Medicare Claims Processing Manual – Chapter 12, Section 100
  http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf
- CMS's Guidelines for Teaching Physicians, Interns and Residents:
  http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/gdelinesteachgresfctsht.pdf
- Open Payments (Physician Payments Sunshine Act)
  http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html