

MaineHealth
**Accountable Care
 Organization**

Policy # 07	Effective Date: 9/25/20	Revised Date:
Title: Stark and Anti-Kickback Statute		Owner: Compliance Official
Reviewed & Approved by: MaineHealth ACO Board		Date: 9/25/20

Policy Summary:

It is the policy of MaineHealth Accountable Care Organization (ACO) to comply with state and federal laws, including Stark law (aka Physician Self-Referral law) and the Anti-Kickback Statute.

Purpose

This policy shall apply to the activities of MaineHealth ACO, its ACO participants, ACO provider/suppliers, or other individuals or entities performing functions or services related to ACO activities, hereafter referred to as Related Individuals. This policy provides guidance for MaineHealth ACO Related Individuals in accordance with current state and federal regulations. These laws relate primarily to relationships between MaineHealth ACO Related Individuals and referral sources, including physicians, and immediate family members of physicians. MaineHealth ACO is committed to conducting its business transactions and practices in an ethical and compliant manner.

Policies:

1. MaineHealth ACO requires all Related Individuals to comply with the Anti-Kickback Statute. MaineHealth ACO Related Individuals are prohibited from offering, paying, soliciting or receiving anything of value with the intent to induce or reward referrals or generate federal health care program (including Medicare or Medicaid) business.
2. MaineHealth ACO requires all Related Individuals to comply with the Stark Law. MaineHealth ACO prohibits any physician who has a financial relationship with an entity (be it ownership, investment or structured compensation arrangements) from making a referral to the entity for the provision of designated health services (DHS), unless a statutory exception or waiver applies to the arrangement.
3. This policy supplements the MaineHealth ACO Code of Ethical Conduct. All MaineHealth ACO workforce are required to comply with Stark laws and Anti-Kickback Statutes while performing workplace functions and responsibilities.

Procedures:

1. MaineHealth ACO workforce members are encouraged to report to the MaineHealth Corporate Compliance office or MaineHealth ACO Compliance Officer any suspected violations of Stark or Anti-Kickback policies or laws.
 - a. Reports may be made to;
 - i. An individual’s immediate supervisor or
 - ii. MaineHealth ACO Compliance Committee or
 - iii. MaineHealth ACO Compliance Official
 - iv. Email: MaineHealthCorporateCompliance@MaineHealth.org or

v. MaineHealth Corporate Compliance Helpline: 1-207-662-4646.

2. Failure of any MaineHealth workforce member to comply with this policy may lead to disciplinary action, up to and including termination and legal action.
3. MaineHealth workforce members reporting suspected violations may do so without fear of retribution.
4. MaineHealth ACO recognizes the complexity in the Anti-Kickback and Stark Laws and the associated Safe Harbors (Anti-Kickback), Shared Saving Program waivers and numerous exceptions to the Stark Law; therefore, MaineHealth ACO may seek legal counsel in addressing suspected violations of institutional policy, state and federal laws.
5. MaineHealth ACO will implement effective responses of violations of the Anti-Kickback Statute and/or the Stark Law is discovered, including disclosing Reportable Events and quantifying and refunding identified overpayments.

Definitions:

ACO Activities- means activities related to promoting accountability for the quality, cost, and overall care for a population of attributed Medicare Fee-For-Service beneficiaries, including managing and coordinating care, encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery; or carrying out any other obligation or duty of the MaineHealth ACO under the MSSP.

ACO Participant - means an individual or group of Accountable Care Organization (ACO) provider(s)/supplier(s), that is identified by a Medicare-enrolled TIN, that alone or together with one or more other ACO participants comprise(s) an ACO, and that is included on the list of ACO participants.

ACO Provider/Supplier - means an individual or entity that -- (1) is a provider or a supplier; (2) is enrolled in Medicare; (3) bills for items and services it furnishes to Medicare fee-for-service beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers.

Designated Health Services (DHS) – Clinical laboratory services, physical therapy, occupational therapy, and speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; home health services; prosthetics, orthotics, and prosthetic devices and supplies; outpatient prescription drugs; and inpatient and outpatient hospital services.

The Stark Law-

- a) Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies; and
- b) Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
- c) A financial relationship can include an ownership or investment interest or a compensation arrangement. Any relationship involving the transfer of payments or benefits, including income guarantees, certain types of loans, free or discounted services, equipment or office space, constitutes a compensation arrangement

Federal Anti-Kickback Statute-

- a) Prohibits the paying, soliciting or receiving anything of value with the intent to induce or reward referrals or generate Federal health care program (including Medicare or Medicaid) business.

- b) The Office of Inspector General (OIG) has published regulations outlining certain categories of activities referred to as “safe harbors” that are deemed not to violate the Anti-Kickback Statute. The failure of a particular business arrangement to fit within a safe harbor, does not mean the arrangement violates the anti-kickback statute.

Immediate Family Member means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

Medicare Shared Savings Program- means the Medicare Shared Savings Program (MSSP), established under section 1899 of the Social Security Act.

Overpayments means any Medicare or Medicaid funds received or retained to which the recipient is not legally entitled.”

Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.

Referral Source means (a) a physician; (b) any non-physician who may be capable of making referrals to a MaineHealth Related Individual, or (c) any entity that is controlled by an individual specified in (a) or (b).

Related Individual- means ACO officers, ACO Participant, ACO Provider/Supplier, or any other individual or entity providing functions or services related to ACO activities.

Reportable Event is a violation of criminal, civil, or administrative laws applicable to any Federal health care program resulting in an overpayment. A reportable event may be the result of an isolated event or a series of occurrences.

Safe Harbor Regulations describe various payment and business practices that, although they potentially implicate the federal anti-kickback statute, are not treated as offenses under the statute. [OIG Safe Harbors](#)

References:

42 CFR § 411.350 Stark Law

42 C.F.R. § 411.351 Designated Health Services

42 CFR § 1001.952 Safe Harbors

42 CFR §1001.952 Exceptions (Safe Harbors)

42 U.S.C. § 1320a-7(a)(5) Civil Monetary Penalty

42 USC § 1395nn Stark Law Statutes

42 USC §1320a-7b Anti-Kickback Statute

MRS Title 22, Chapter 414, Health Care Practitioner Self-Referrals

MRSA § 13759 Gifts to practitioners prohibited

MaineHealth-Maine Medical Center Code of Ethical Conduct

MaineHealth-Maine Medical Center Patient Gifts, Discounts, Waivers and Inducements Policy

MaineHealth-Maine Medical Center Conflict of Interest Policy

MaineHealth-Maine Medical Center Contract and Grant Review, Approval and Signing Policy

MaineHealth Human Resources Equal Employment Opportunity & Harassment Policy