



TITLE: STARK AND ANTI-KICKBACK STATUTE POLICY

DOCUMENT #: MLI.CMP.128

VERSION #: 03

PAGE #: 1 OF 4

EFFECTIVE DATE: 01-FEB-2024

DOCUMENT OWNER: COMPLIANCE

1. Purpose

1.1. This policy defines the requirements for compliance with the Federal Anti-Kickback Statute and the Physician Self-Referral law (the “Stark law”).

2. Scope

2.1. The Stark and Anti-Kickback Statute Policy applies to all Millennium Health, LLC (“Millennium” or “Company”) employees.

3. Responsibility

3.1. It is the responsibility of all Millennium Health employees to be in compliance with Stark and Anti-Kickback Statute and to follow the procedure as written.

4. Reference Documents

- 4.1. MLI.BIL.238; Revenue Cycle Billing Policy
- 4.2. MLI.CMP.130; Focus Arrangements Policy
- 4.3. MLI.CMP.141; Millennium Health Standards of Conduct
- 4.4. 42 CFR 411.350 Stark Law
- 4.5. 42 USC 1395nn Stark Law Statutes
- 4.6. 42 USC §1320a-7b(b) Anti-Kickback Statute
- 4.7. 42 CFR § 1001.952 Safe Harbors

5. Attachments

5.1. N/A

6. Definitions

6.1. The Stark Law:

6.1.1. The Stark Law 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 prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral.

6.1.2. 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.

6.2. Federal Anti-Kickback Statute:

6.2.1. The Federal Anti-Kickback Statute 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.

6.2.2. 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 comply with a safe harbor, however, does not make the conduct or activity illegal.



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6.3. Overpayment: An Overpayment is any funds that Millennium Health has received or retained, under any Federal or State Healthcare Program, in excess of the amount due and payable, to which Millennium Health, after applicable reconciliation if pertinent, is not entitled. An Overpayment may be (but is not limited to) the result of non-adherence to Federal or State Health Care Program requirements, errors by a Millennium Health Workforce Member, payment processing errors by the payer, or erroneous or incomplete information provided to Millennium Health by the patient or responsible party.

7. Policy

- 7.1. Millennium requires all employees to comply with the Anti-Kickback Statute. As such, all Millennium personnel 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.
- 7.2. In addition, Millennium requires all employees to comply with the Stark Law. As such, Millennium prohibits any physician who has (or whose immediate family member has) a financial relationship with Millennium (be it ownership, investment or structured compensation arrangements) from making a referral to Millennium for the provision of designated health services (DHS) unless a statutory exception applies to the arrangement.
- 7.3. Compliance with Stark Law and Anti-Kickback Statute
 - 7.3.1. Compliance with the Federal Anti-Kickback Statute and Stark Law is a required condition of employment or continued engagement with Millennium.
 - 7.3.2. Suspected violations of the Federal Anti-Kickback Statute, Stark Law and this policy should be reported in accordance with Millennium Health Standards of Conduct [MLI.CMP.141] (“Standards of Conduct”) and Compliance Program policies. Specifically, suspected violations are to be immediately reported to a supervisor, to the Compliance Department and/or anonymously to the Millennium Compliance Hotline or website.
 - 7.3.2.1. The anonymous Millennium Compliance Hotline is available at: 866-677-3847 or millenniumcompliance.com
 - 7.3.2.2. Suspected violations may also be reported to an email account established at compliance@millenniumhealth.com. Emails are sent to the inbox of the Chief Compliance Officer.
 - 7.3.2.3. Employees who, in good faith, report a potential violation of law, regulation, policy, procedure, or the Standards of Conduct will not be subjected to retaliation, retribution, or harassment.
 - 7.3.3. Upon receipt of a suspected violation of the Federal Anti-Kickback Statute or Stark Law, the Compliance Department:
 - 7.3.3.1. Gathers all relevant information from the disclosing individual and conducts an internal review of allegations determined to be reasonably appropriate or credible.
 - 7.3.3.2. Quantifies and repays any identified overpayments related to the disclosure in accordance with Millennium’s Revenue Cycle Billing Policy [MLI.BIL.238]; and
 - 7.3.3.3. Discloses the event to the OIG in accordance with Provider Self-Disclosure Protocol where appropriate.



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7.4. Focus Arrangements

7.4.1. Millennium maintains policies and procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Federal Anti-Kickback Statute and/or the Stark Law or the regulations, directives and guidelines related to these statutes. See Focus Arrangements Policy [MLI.CMP.130].

7.5. Millennium recognizes the complexity in the Federal Anti-Kickback and Stark Laws and the associated safe harbors (Anti-Kickback) and numerous exceptions to the Stark Law; therefore, Millennium may seek legal counsel in addressing suspected violations of these laws and this policy.



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Document Control Page

Version #	DCR #	Effective Date	Change Summary
03	17-255	13-JUL-2017	Changes made to achieve compliance required based on our corporate integrity agreement.
04	19-257	01-OCT-2019	Removal of duplicated sub-section (2.1.1). Changed title of Code of Conduct to Standards of Conduct. Addition of "Federal" when referring to the Anti-Kickback Statute. Added Scope and Responsibility sections 2 & 3; Combined related policies and references into Reference Documents, section 4, and added Attachments, section 5. Re-titled Responsibilities section to Procedure (section 8) and minor edits throughout. Updated to current standard template and format.
05	20-226	04-SEP-2020	Removal of archived policies listed as Reference Documents in Section 4.1. Addition of clarifying language in section 7.4.7.1. Minor formatting changes.
Change of ownership and document number. MLI.COR.143.05 transferred to MLI.CMP.128.01.			
01	21-182	02-AUG-2021	Initial Release.
02	22-216	16-JAN-2023	Corrected spelling error of "Statue" to "Statute" in Sections 1.1, 2.1, and 3.1. Added MLI.CMP.130 in section 4. Updated Millennium Ethics and Compliance Hotline to Millennium Compliance Hotline in Section 7.3. Removed steps 7.4.2, 7.4.3 and sections 7.5-7.6 that describe the details regarding Focus Arrangements.
03	23-190	01-FEB-2024	Revised the definition of Overpayment to be consistent across all policies in Section 6.3.