



TITLE: STARK AND ANTI-KICKBACK STATUTE POLICY

DOCUMENT #: MLI.COR.143

VERSION #: 05

PAGE #: 1 OF 5

EFFECTIVE DATE: 04-SEP-2020

DOCUMENT OWNER: COMPLIANCE

1. Purpose

1.1. Millennium is dedicated to complying with the terms of its Corporate Integrity Agreement entered into with the Office of Inspector General, Department of Health and Human Services and executed on October 16, 2015 (“CIA”). The CIA expressly requires compliance with the Federal Anti-Kickback Statute and the Physician Self-Referral law (the “Stark Law”) and sets forth procedures required of Millennium to satisfy the terms of the CIA.

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. In an effort to address Federal Anti-Kickback and Stark Law issues of particular relevance to Millennium’s business, Millennium has developed the following individual policies for reference as part of executing its compliance program and addressing Anti-Kickback and Stark Law risks:
 - 4.1.1. MLI.COR.102; Procedure for Meals, Educational Items, Gifts & Entertainment
 - 4.1.2. MLI.COR.121; Revenue Cycle Billing Policy
- 4.2. 42 CFR 411.350 Stark Law
- 4.3. 42 USC 1395nn Stark Law Statutes
- 4.4. 42 USC §1320a-7b(b) Anti-Kickback Statute
- 4.5. 42 CFR § 1001.952 Safe Harbors
- 4.6. MLI.COR.160; Millennium Health Standards of Conduct (LGL-001)
- 4.7. Millennium’s Corporate Integrity Agreement, III.D.

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.



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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.

6.3. Overpayments: the amount of money Millennium has received in excess of the amount due and payable under any Federal health care program requirements.

6.4. Reportable Event: anything that involves a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized. A reportable event may be the result of an isolated event or a series of occurrences.

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.COR.160 (“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 Ethics and Compliance Hotline or website.

7.3.2.1. The anonymous Millennium Ethics and 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 will:

7.3.3.1. gather all relevant information from the disclosing individual and conduct an internal review of allegations determined to be reasonably appropriate or credible;

7.3.3.2. quantify and repay any identified overpayments related to the disclosure in accordance with Millennium’s Revenue Cycle Billing Policy (MLI.COR.121) and the Millennium CIA; and



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7.3.3.3. disclose Reportable Events to the OIG in accordance with the Millennium CIA where appropriate.

7.4. Focus Arrangements

- 7.4.1. Millennium shall maintain 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.
- 7.4.2. The Focus Arrangement Procedures shall include the following:
- 7.4.3. Creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- 7.4.4. Tracking remuneration to and from all parties to Focus Arrangements;
- 7.4.5. Tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangements;
- 7.4.6. Monitoring the use of leased space, medical supplies, medical devices, equipment or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement;
- 7.4.7. Establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Federal Anti-Kickback Statute and Stark Law, and that includes at least:
 - 7.4.7.1. a legal review of all new Focus Arrangements, or a review of the applicable Focus Arrangement template if no changes are made, by counsel with expertise in the Federal Anti-Kickback Statute and Stark Law;
 - 7.4.7.2. a process for specifying the business need or business rationale for all Focus Arrangements; and
 - 7.4.7.3. a process for:
 - 7.4.7.3.1. determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
 - 7.4.7.3.2. requiring the Chief Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
 - 7.4.7.3.3. implementing effective responses when suspected violations of the Federal Anti-Kickback Statute and the Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments.

7.5. New or Renewed Focus Arrangement

- 7.5.1. Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Millennium shall:
- 7.5.2. Ensure that each Focus Arrangement is set forth in writing and signed by Millennium and the other parties to the Focus Arrangement;
- 7.5.3. Where applicable, include in the written agreement a requirement that each party to the Focus Arrangement who meets the definition of a Covered Person shall



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- complete at least one hour of training regarding the Federal Anti-Kickback Statute and the Stark Law and examples of arrangements that potentially implicate the Federal Anti-Kickback Statute or the Stark Law.
- 7.5.4. provide each party to the Focus Arrangement with a copy of its Standards of Conduct and this policy;
 - 7.5.5. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Federal Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.
- 7.6. Records Retention and Access
- 7.6.1. Millennium shall retain and make available to OIG upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements to the extent available and all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.
- 7.7. 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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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 polices 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.