



RUTGERS POLICY

Section: 100.2.6

Section Title: Healthcare Compliance Policies

Policy Name: Responding to Suspected Violations of the Stark Law That Do Not Implicate the Anti-Kickback Statute

Formerly Book: 00-01-90-65:01

Approval Authority: RBHS Chancellor

Responsible Executive: Chief Healthcare Compliance Officer

Responsible Office: RBHS Office of Ethics, Compliance & Corporate Integrity

Originally Issued: 01/24/2013

Revisions: 7/1/2013

Errors or changes? Contact: RBHS Office of Ethics, Compliance & Corporate Integrity: 973-972-8093

1. **Policy Statement:**
Rutgers Biomedical and Health Sciences and other Rutgers University schools, units and departments that bill federal or state programs for healthcare goods or services ("Related Healthcare Entity" or "Related Healthcare Entities") shall, when appropriate, follow the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) for reporting to CMS suspected violations of the federal Stark law as set forth in this policy.
2. **Reason for Policy**
To ensure that the Related Healthcare Entities follow the Centers for Medicare and Medicaid Services' (CMS) Voluntary Self-Referral Disclosure Protocol (SRDP) when appropriate.
3. **Who Should Read This Policy**
This policy applies to and should be read by employees of schools, departments and units that are a part of Rutgers Biomedical and Health Sciences as well as employees of other University schools, units and departments that bill federal or state programs for healthcare goods or services ("Related Healthcare Entity" or "Related Healthcare Entities.") Employees of other University departments that support the Related Healthcare Entities in contracting for goods and services, including but not limited to Rutgers Finance, University Procurement and the Office of the Senior Vice President and General Counsel, should also read this policy.
4. **Related Documents**
 - A. Corporate Integrity Agreement dated September 25, 2009 between UMDNJ and the Office of Inspector General of the Department of Health and Human Services as amended by a Letter Agreement, UMDNJ-Rutgers University dated May 1, 2013 ("CIA")
 - B. CMS Voluntary Self-Referral Disclosure Protocol https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf OMB CONTROL NUMBER: 0938-1106

- C. The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b (the "Anti-kickback Statute"),
- D. Stark Exceptions, 42 CFR §§ 411.350 – 411.389
- E. Stark Law Section 1877 of the Social Security Act 42 U.S.C. 1395
- F. Patient Protection and Affordable Care Act (the Affordable Care Act) (Publ. L. 111-148) F
- G. Policy 100.2.7 - Focus Arrangement Database
- H. Policy 100.2.1 - General Statement on Agreements with Referral Sources
- I. Policy 100.2.3 - Fair Market Valuation
- J. Policy 100.2.4 - Professional Services Policy
- K. Policy 20.1.11 - Purchasing Policy
- L. Policy 20.1.16 - Policy on Notification and Approval of Certain Contracts Awarded without Competitive Bids or Proposal
- M. Policy 20.1.17 - Engagement and Payment of Professional Services Provider Policy
- N. Policy 40.2.12 - Gratuities, Guests, Gifts and Use Of University Resources

5. **Contacts**

Chief Healthcare Compliance Officer: 973-972-8093
Office of the Senior Vice President and General Counsel: 848-932-7697

6. **The Policy**

100.2.6 RESPONDING TO SUSPECTED VIOLATIONS OF THE STARK LAW THAT DO NOT IMPLICATE THE ANTI-KICKBACK STATUTE

As recommended by CMS, once it is determined by the University that an alleged violation of the Stark Law has occurred and it wishes to report this alleged violation under the SRDP, the University shall obtain and report the following information to CMS:

- A. A statement describing why the University believes a violation of the Stark Law may have occurred, including a complete legal analysis of the application of the Stark Law to the conduct related to the alleged violation, as well as any self-referral exception that may apply to the conduct;
- B. Describe the circumstances under which the disclosed matter was discovered, as well as, any immediate corrective action which has been taken to prevent the continuation of this alleged violation and/or any potential future violations;
- C. Identifying information, including the name, address, national provider identification numbers, CMS Certification Number and Tax Identification Number of the disclosing University entity;
- D. A statement identifying whether the disclosing University entity has a history of similar conduct or has any prior enforcement actions against it;
- E. An indication of whether the disclosing University entity has knowledge that the matter is under current inquiry by a government agency or contractor;
- F. A description of the nature of the matter being disclosed, including the type of financial relationship(s), the parties involved, the specific time periods of potential noncompliance, the circumstances under which the disclosed matter was discovered, the type of designated health service claims at issue, the type of transaction or other conduct at issue and the names of individuals and entities believed to be implicated, along with an explanation of their roles;

- G. A financial analysis, that states the amount that is actually or potentially due; describe the methodology for calculating the amount due; and summarize the auditing activity and documents upon which the University relied in calculating the total amount potentially due, itemized by year, including the "look back" period, (i.e. the time during which the University entity did not appear to be in Stark compliance.);
- H. The steps the University has taken to refund any applicable claims as directed by the CIA;
- I. A statement from the University certifying that the information provided is true and based on a good faith effort to resolve liability under the Stark law; and
- J. The steps the University will be taking to make disclosures under the SRDP, both electronically and by mail.