



RUTGERS POLICY

Section: 100.2.5

Section Title: Healthcare Compliance Policies

Policy Name: Responding to Suspected Violations of the Anti-Kickback Statute or for Stark Law Violations that Potentially Implicate the Anti-Kickback Statute

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

Approval Authority: RBHS Chancellor

Responsible Executive: Chief Healthcare Compliance Officer

Responsible Office: RBHS Office of Ethics Compliance & Corporate Integrity

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

1. **Policy Statement**

Schools, departments and units that are a part of Rutgers Biomedical and Health Sciences as well as 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, consider use of the HHS Office of the Inspector General Self-Disclosure Protocol for reporting to the OIG suspected violations of the federal Anti-kickback statute as set forth in this policy.

2. **Reason for Policy**

To ensure that when considering "self-disclosure", schools, departments and units that are a part of Rutgers Biomedical and Health Sciences and other University schools, units and departments that bill federal or state programs for patient goods or services ("Related Healthcare Entity" or "Related Healthcare Entities") follow the recommendations of the Office of Inspector General in the OIG's Self Disclosure Protocol:

- When there are suspected violations of the Anti-kickback statute and Stark law violations that potentially implicate the Anti-kickback statute and
- To possibly mitigate potential exposure under section 1128J(d) of the Act, 42 U.S.C. 1320a-7k(d). Section 1128J(d)(2) of the Act requires that a Medicare or Medicaid overpayment be reported and returned by the later of (1) the date that is 60 days after the date on which the overpayment was identified or (2) the date any corresponding cost report is due, if applicable. Any overpayment retained by a "person," as defined in section 1128J(d)(4)(C) of the Act after this deadline may create liability under the Civil Monetary

3. **Who Should Read This Policy**

This policy applies to and should be read by employees of the Rutgers Biomedical and Health Sciences and other Rutgers schools, units and departments that bill federal or state programs for patient goods or services ("Related Healthcare Entity" or "Related Healthcare Entities") as well as other Rutgers 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.

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. The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b (the "Anti-kickback Statute")
- C. Stark Law Section 1877 of the Social Security Act 42 U.S.C. 1395
- D. Stark Exceptions, 42 CFR §§ 411.350 – 411.389
- E. April 17, 2013 OIG's Provider Self-Disclosure Protocol <http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf>
- F. Policy 100.2.7 Focus Arrangement Database
- G. Policy 100.2.1 General Statement on Agreements with Referral Sources
- H. Policy 100.2.3 Fair Market Valuation
- I. Policy 100.2.4 Professional Services Policy
- J. Policy 20.1.11 Purchasing Policy
- K. Policy 20.1.16 Policy on Notification and Approval of Certain Contracts Awarded without Competitive Bids or Proposal
- L. Policy 20.1.17 Engagement and Payment of Professional Services Provider Policy
- M. Policy 40.2.12 Gratuities, Gifts, and Use Of University Resources
- N. Policy 40.2.5 Consulting or Other Personal Services, Intellectual Property, Honoraria and Other Miscellaneous Activities Policies and Procedures for Payment
- O. Policy 50.3.13 Signatory Authority

5. **Contacts**

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

6. **The Policy**

100.2.5 RESPONDING TO SUSPECTED VIOLATIONS OF THE ANTI-KICKBACK STATUTE OR FOR STARK LAW VIOLATIONS THAT POTENTIALLY IMPLICATE THE ANTI-KICKBACK STATUTE

As recommended by the OIG, when Rutgers has reasonable grounds to believe that a suspected violation of the Anti-Kickback Act of 1986 may have occurred and a disclosure should be made under the SDP, the University shall promptly:

- A. Report to the OIG, by writing an introductory letter to notify the OIG of the University's intention to voluntarily disclose the suspected violation. The letter will identify that the University is the disclosing provider and provide a general description of the suspected violation.

¹ In its Notice of Proposed Rulemaking, 77 Fed. Reg. 9179-9187 (February 16, 2012), the Centers for Medicare & Medicaid Services (CMS) proposes to suspend the obligation to report overpayments under section 1128J(d) of the Act when OIG acknowledges receipt of a submission to the SDP so long as the submission is timely made. CMS also proposes to suspend the obligation to return overpayments until a settlement agreement is entered into, or the provider or supplier withdraws or is removed from the SDP. As necessary, we will provide additional guidance on OIG's web site concerning section 1128J of the Act and the SDP after CMS issues its final rule.

- B. After the initial disclosure to the OIG, the University will conduct an internal investigation and a self-assessment of the financial impact of the suspected violation(s) and report the findings to the OIG as directed by the University's Corporate Integrity Agreement (CIA) and refund applicable claims per University policy.
- C. The University will also submit to the OIG a work plan describing the University's self-assessment process, and a Disclosure Report addressing the nature and scope of the non-compliance and why the University believes there is a potential violation.

The Disclosure Report shall:

- Identify the potential causes of the suspected violation;
- Describe the suspected violation and/or practice in detail, including how the suspected violation and/or practice arose and continued;
- Identify the School, Unit, Department(s), or related entities involved or affected;
- Identify the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed with sufficient information to allow the OIG to assess the immediacy of the impact and risks, the steps that should be taken to address them, as well as the measures taken by the University;
- Delineate the period during which the suspected violation and/or practice occurred;
- Identify the University officials, employees or agents who knew of, encouraged, or participated in, the suspected violation and/or practice and any individuals who may have been involved in detecting the matter;
- Identify the University officials; employees or agents who should have known of, but failed to detect, the suspected violation and/or practice based on their job responsibilities;
- Estimate the monetary impact of the incident or practice upon the federal health care programs, pursuant to the self-assessment guidelines;
- Relate the circumstances under which the suspected violation was discovered;
- List the measures the University has taken to address the suspected violation and prevent future violations;
- Include a list of all individuals interviewed in connection with the suspected violation;
- Include a description of files, documents and records reviewed in connection with the suspected violation;
- Include a summary of auditing activities and a summary of documents relied upon in support of the estimation of losses; and
- Include a "Certification of Truthfulness" signed by the person who is responsible for reporting the suspected violation to the OIG.