

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

ROWAN UNIVERSITY POLICY

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

Subject: Office of Compliance & Corporate Integrity (OCCI)

Policy No: OCCI:2013:C08

Applies: RowanSOM

Issuing Authority: Rowan President & RowanSOM Dean

Responsible Officer: Chief Audit, Compliance & Privacy Officer; Rowan General Counsel

Adopted: 07/01/2013

Last Revision: 01/26/2021

Last Reviewed: 01/26/2021

I. PURPOSE

To ensure that when considering “self-disclosure”, schools, departments, and units that are part of RowanSOM 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 the Inspector General (OIG) in the OIG’s Self-Disclosure Protocol:

1. When there are suspected violations of the Anti-Kickback Statute and Stark Law violations that potentially implicate the Anti-Kickback Statute and
2. To possibly mitigate potential exposure under section 1128J9d) 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 an 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 Penalties Law (CMPL), section 1128A of the Act, and the False Claims Act (FCA), 31 U.S.C. 3729. Penalties Law (CMPL).

II. ACCOUNTABILITY

Under the direction of the President, the Dean, General Counsel and the Chief Audit, Compliance & Privacy Officer shall ensure compliance with this policy. Schools, departments and units that are a part of Rowan University School of Osteopathic Medicine (RowanSOM) 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 OI suspected violations of the federal Anti-Kickback Statute as set forth in this policy.

III. APPLICABILITY

This policy applies to and should be read by employees of the RowanSOM that bill federal or state programs for patient goods or services (“Related Healthcare Entity” or “Related Healthcare Entities”) as well as other RowanSOM departments that support the Related Healthcare Entities in contracting for goods and services, including but not limited to Finance, University Procurement and the Office of the Senior Vice President and General Counsel.

IV. REFERENCES

1. Voluntary Compliance Plan (VCP) effective September 26, 2014
2. The Medicare and Medicaid Patient Protection Act of 1987, as amended, 42 U.S.C. §1320a-7b (the "Anti-kickback Statute")
3. Stark Law Section 1877 of the Social Security Act 42 U.S.C. 1395
4. Stark Exceptions, 42 CFR §§ 411.350 – 411.389
5. April 17, 2013 [OIG's Provider Self-Disclosure Protocol](#)
6. Focus Arrangement Database
7. General Statement on Agreements with Referral Sources
8. Fair Market Valuation
9. Professional Services Policy
10. Contracts & Purchasing Policy
11. State College Contracts Law N.J.S.A. 18A:64 and N.J.S.A. 18A-64-56
12. Engagement and Payment of Professional Services Provider Policy
13. Rowan University Code of Ethics
14. State Uniform Ethics Code
15. Rowan University Intellectual Property Policy

V. POLICY

As recommended by the OIG, when RowanSOM 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 (Self Disclosure Protocol), RowanSOM shall promptly:

1. Report to the OIG, by writing an introductory letter to notify the OIG of RowanSOM's intention to voluntarily disclose the suspected violation. The letter will identify that RowanSOM is the disclosing provider and provide a general description of the suspected violation.
2. After the initial disclosure to the OIG, RowanSOM 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 Voluntary Compliance Plan (VCP) effective 9/26/2014 and refund applicable claims per RowanSOM policy.
 - a. If at any time RowanSOM identifies or learns of any overpayment, RowanSOM shall notify the payer (Medicare/Medicaid) within 30 days after identification of the overpayment and take remedial steps within 60 days after identification to refund monies.
3. RowanSOM will also submit to the OIG a work plan describing RowanSOM's self- assessment process, and a Disclosure Report addressing the nature and scope of the non-compliance and why RowanSOM believes there is a potential violation.
4. The Chief Audit, Compliance & Privacy Officer shall be the designated responsible party to ensure suspected violations are self-disclosed and any identified overpayments refunded.

The Disclosure Report shall:

 - a. Identify the potential causes of the suspected violation;
 - b. Describe the suspected violation and/or practice in detail, including how the suspected violation and/or practice arose and continued;
 - c. Identify the School, Unit, Department(s), or related entities involved or affected;
 - d. 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 RowanSOM;
 - e. Delineate the period during which the suspected violation and/or practice occurred;
 - f. Identify RowanSOM 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;
 - g. Identify RowanSOM officials; employees or agents who should have known of, but failed to detect, the suspected violation and/or practice based on their job responsibilities;
 - h. Estimate the monetary impact of the incident or practice upon the federal health care programs, pursuant to the self-assessment guidelines;

- i. Relate the circumstances under which the suspected violation was discovered;
- j. List the measures RowanSOM has taken to address the suspected violation and prevent future violations;
- k. Include a list of all individuals interviewed in connection with the suspected violation;
- l. Include a description of files, documents and records reviewed in connection with the suspected Violation;
- m. Include a summary of auditing activities and a summary of documents relied upon in support of the estimation of losses; and
- n. Include a "Certification of Truthfulness" signed by the Chief Compliance & Privacy Officer.

VI. NON-COMPLIANCE AND SANCTIONS

Any individual who violates this policy shall be subject to discipline up to and including dismissal from the University in accordance with their union and University rules. Civil and criminal penalties may be applied accordingly. Violations of this policy may require retraining and be reviewed with employee during the annual appraisal process. The Deans of each College, Vice Presidents, and University President, with the assistance of the Department of Human Resources, will enforce the sanctions appropriately and consistently to all violators regardless of job titles or level within the University and in accordance with bargaining agreements for represented employees. Any sanction costs or fines will be borne by the Department and the Department Chair or VP will determine how these funds will be assigned.

By Direction of the President:

Signature on File

Chief Audit, Compliance and Privacy Officer