

Focused Arrangement Database Policy & Approval Process

ROWAN UNIVERSITY POLICY

Title: Focused Arrangement Database Policy & Approval Process

Subject: Office of Compliance & Corporate Integrity (OCCI)

Policy No: OCCI:2013:C03

Applies: RowanSOM

Issuing Authority: Rowan President & RowanSOM Dean

Responsible Officer: Chief Audit, Compliance & Privacy Officer

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I. PURPOSE

To set forth the general guidelines for the submission, approval and administration of all contractual agreements entered into by Rowan University School of Medicine (RowanSOM) which constitute Focus Arrangement (as defined below) under the terms of the Voluntary Compliance Plan ("VCP") effective September 26, 2014 and the expired Corporate Integrity Agreement ("CIA") dated September 25, 2009 between UMDNJ and the Office of Inspector General of the Department of Health and Human Services.

To establish procedures to activate and maintain a Focus Arrangements database through RowanSOM electronic contract management system.

II. ACCOUNTABILITY

Under the direction of the President, the Dean, General Counsel and the Chief Audit, Compliance & Privacy Officer are to ensure compliance with this policy. The Deans, Department Chairs and Chief Executive Officers shall implement this policy.

III. APPLICABILITY

This policy applies to all RowanSOM operating units, including but not limited to hospitals, physician practices, and outpatient centers.

IV. DEFINITIONS

1. *Arrangements* - every arrangement or transaction that:
 - a. Involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between RowanSOM and any actual or potential source of health care business or referrals to RowanSOM or any actual or potential recipient of health care business or referrals from RowanSOM. The term "source" shall mean any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
 - b. Is between RowanSOM and a physician (or a physician's immediate family member as defined at 42 C.F.R. §411.351)) who makes a referral (as defined at 47 U.S.C. §1395nn(h)(5)) to RowanSOM for designated health services (as defined at 42 U.S.C. §1395nn(h)(6))
2. *Focus Arrangement* - every arrangement or transaction that:
 - a. Involves directly or indirectly, the offer or payment of anything of value and is between RowanSOM and any actual source of health care business or referrals to RowanSOM; or

- b. Between RowanSOM and a physician (or a physician's immediate family member (as defined at 42 C.F.R. §411.351)) who makes a referral (as defined at 42 U.S.C. §1395nn(h)(5)) to RowanSOM for designated health services (as defined at 42 U.S.C. §1395nn(h)(6)).
 - c. The following shall not be considered Focus Arrangements: any Arrangement that satisfies the requirements of 42 C.F.R. 411.356 (ownership of investment interests), 42 C.F.R. 411.457 (g) (remuneration unrelated to the provision of designated health services), 42 C.F.R. 411.357 (i) (payments by a physician for items and services), 42 C.F.R. 411.357(m) (medical staff incidental benefits), 42 C.F.R. 411.357(o) (compliance training), 42 C.F.R. 411.357(q) (referral services), 42 C.F.R. 411.357(s) (professional courtesy), 42 C.F.R. 411.357(u) (community-wide health information systems), or any exception to the prohibition of 42 U.S.C. 1395nn enacted which does not require a written agreement
3. *Covered Persons includes:*
- a. All officers, trustees, and employees of RowanSOM (excluding housekeeping, maintenance, and food service employees); and
 - b. All contractors, subcontractors, agents and other persons who provide patient care items or services or who perform billing or coding functions on behalf of RowanSOM excluding vendors whose sole connection with RowanSOM is selling or otherwise providing medical supplies or equipment to RowanSOM and who do not bill the Federal health care programs for such medical supplies or equipment; and
 - c. RowanSOM employed medical staff. Covered Persons does not include part-time or per diem employees, contractors, subcontractors, agents or other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become Covered Persons at the point when they work more than 160 hours during the calendar year.
4. Arrangements Covered Persons includes each Covered Person involved with the development, approval, management, or review of RowanSOM Arrangements.
5. Database or Contract Management System is the electronic contract management system, authorized by the Senior Vice President and General Counsel to process, execute, and store all arrangements and focused arrangements entered into on behalf of RowanSOM.

V. REFERENCES

1. Rowan University Voluntary Compliance Plan (VCP)
2. [42 U.S.C. § 1320a-7b](#); [42 C.F.R. § 1001.952\(a\)-\(v\)](#); [42 U.S.C. § 1395nn](#); [42 C. F. R. § 411.350](#) et. seq.;
3. [60 Fed. Reg. 41914](#) (Aug. 14, 1995); [63 Fed. Reg. 1659](#) (Jan. 9, 1998);
4. [66 Fed. Reg. 856](#) (Jan. 4 2001); [69 Fed. Reg. 16054](#) (March 26, 2004); Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and the University of Medicine and Dentistry of New Jersey, September 25, 2009.
5. Contract Management

VI. POLICY

1. All Focus Arrangements shall be compliant with the requirements of the VCP. All Focus Arrangements must be reviewed and approved by the applicable Dean, Finance and RowanSOM legal counsel prior to execution, and stored in the Focus Arrangement section of RowanSOM electronic contract management system after execution, in accordance with this policy.
2. The Dean, General Counsel and the Chief Audit, Compliance & Privacy Officer will develop procedures to review all existing arrangements for compliance with the requirements of the VCP. Such procedures will include a review of existing arrangements over a period of time.
 - a. Focus Arrangements Approval and Review Procedure (New or Renewed Arrangements)
3. The department Chairs, Deans and Administrators are responsible to comply with the following requirements:
 - a. The Focus Arrangement must be set forth in a written agreement and be reviewed by the applicable Dean, Administrator, Chief Audit, Compliance & Privacy Officer and RowanSOM legal counsel.
 - b. The written agreement must contain a provision requiring that all individuals who meet the definition of an Arrangements Covered Person to comply with RowanSOM Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law.

- c. The written agreement must have a certification by each party stating that each party will not violate the Anti-Kickback Statute and/or Stark Law with respect to performance of the contract.
 - d. All parties to the Focus Arrangement must be given a copy of RowanSOM Code of Conduct and Compliance Policies and Procedures that pertain to the Anti-Kickback Statute and the Stark Law.
 - e. The Department Chairs, Deans and Administrators shall ensure that each Focus Arrangement is entered into the Focus Arrangement Database following execution.
4. Database Requirements for Focus Arrangements Agreements.
- Each executed Focus Arrangement shall be entered promptly into the Focus Arrangements section of RowanSOM electronic contract management system. For each Focus Arrangement included in the contract management system, the following information shall be recorded:
- a. Each party involved in the Focus Arrangement;
 - b. The type of Focus Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
 - c. The term of the Focus Arrangement, including the effective and expiration dates and any automatic renewal provisions;
 - d. The amount of compensation to be paid pursuant to the Focus Arrangement and the means by which compensation is paid;
 - e. The methodology for determining the compensation under the Focus Arrangement, including the methodology used to determine the fair market value of such compensation and an attestation by the Chief Audit, Compliance and Privacy Officer that he/she finds the FMV analysis methodology reasonable for the arrangement.
 - f. Whether the amount of compensation to be paid pursuant to the Focus Arrangement is determined based on the volume or value of referrals between the parties;
 - g. Whether each party has fulfilled the requirements which shall include:
 - i. ensuring that each Focus Arrangement is set forth in writing for a minimum of one year and signed by RowanSOM and the other parties to the Focus Arrangement;
 - ii. in the written agreement a requirement that all individuals who meet the definition of Arrangements Covered Persons shall comply with RowanSOM Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, it must be documented in the contract that RowanSOM has provided each party to the Focus Arrangement with a copy of its Code of Conduct and Stark Law and Anti-kickback Statute Policies and Procedures; and
 - iii. each written Focus Arrangement shall include a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Focus Arrangement.
 - h. Whether the Arrangement satisfies the requirements of an Anti-Kickback safe harbor and/or a Stark Law exception or a safe harbor, as applicable.
5. Focus Arrangements Requirements: Non-contractual transactions involving non-monetary compensation.
6. With respect to Focus Arrangements that constitute non-monetary compensation pursuant to 42 C.F.R. 411.357(k), the following information shall be noted:
- a. As the State of New Jersey does not allow for acceptance of Gifts, this requirement is not necessary.
7. On a quarterly basis, the Chief Audit, Compliance and Privacy Officer will review the Focus Arrangements section of RowanSOM electronic contract management system and the internal review and approval processes related to Focus Arrangements, and provide a quarterly certification of Compliance report containing the results of the review to the Compliance Committee.
8. In accordance with the requirements of the VCP, RowanSOM will retain this information.
9. The FAD Process
- To maintain the integrity of the database and ensure success, the following must be completed:
- a. Log into the MediTract system using your designated username and password.
 - b. Upload the contractual agreement and proceed to answer the seven compliance questions located in the compliance tab on the MediTract System cover page.
 - c. If the contractual agreement has been determined to be a Focused Arrangement, make sure the focused arrangement contains a certification by each party stating that each party will not violate

the Anti-Kickback Statue of the Stark Law with respect to performance of the focused arrangement.

- d. Review of the following key items is essential when assessing the contract:
 - i. Is this contract completed?
 - ii. Does it contain FMV documentation? Procedure to follow located at link below:
<http://www.rowan.edu/compliance/policies/documents/FocusedArrangementProtocolEstablished.pdf>
 - iii. Is it signed by both parties
 - iv. If this contract is considered a focus arrangement contract, and the contract is expired, determine whether we are still providing services.
 - v. If still providing services then this contract needs to be amended, consult legal management
 - vi. If we are not providing services, archive the contract according to NJ State Record Retention Policy. (Refer to State of New Jersey General Record Retention Schedule; State of New Jersey Four Year College Record Retention Schedule; State of New Jersey Health Care Facilities Retention Schedule).

- 10. The Office of Legal Management Attorneys will be notified by System Administrator that contracts are ready to be viewed.

Attorneys will review designated contracts located in RowanSOM Focused Arrangement Database

- a. Legal Counsel Review to include:
 - i. The names of the parties to the agreement
 - ii. The type of Focus Arrangement
 - iii. The effective and expiration dates and any automatic renewal provisions or amendments
 - iv. The amount and means by which the compensation is paid
 - v. Were applicable, that the FMV statement is attached to the agreement in the Focus Arrangement Database (FAD)
 - vi. A statement that the amount of compensation to be paid pursuant to the written terms of the Focus Arrangement has not been determined based on the volume or value of referrals between the parties
 - vii. The Focus Arrangement satisfies all requirements of the VCP
 - viii. Generate emails via MediTract to the responsible party (team member) when contract is incomplete and missing the disclosed "key items" referred to in #d above.
- b. Be requesting responsible party (team member) to locate or correct the current state of the contract.
- c. Note general emails, if contract is fully executed. The review of the contract is complete and the contract remains in the Focus Arrangement Database.

- 11. Upon receiving the email from Legal Counsel, the responsible party (team member) must work expeditiously to bring current any and all parts of the contract, which the attorney will request via email.

This entails contract clean-up and the following steps must be performed:

- a. Ensure fully executed contract with all parties signatures are located in the system as a replacement contract, not a new document.
- b. Ensure this is an FMV related to the contract.
- c. Ensure FMV is attached to MediTract as an attachment, and not within the contents of the contract.
- d. Any other requirements specified by the reviewing attorney.

- 12. Steps four through six should be performed on a continuous basis until all contracts have been updated and to secure the integrity of the database. Schools/units should develop an internal process to ensure all contractual agreements and focused arrangements contain the most current information

- a. Service and Activity Logs
 - i. Service and activity logs must be completed properly and reviewed by Department Heads or Administrators for completeness and accuracy.
 - ii. Department Administrators will check to ensure all signatures, required contractual provisions and certifications have been compiled before services are provided. Department Administrators will sign and date document to ensure services are not rendered prior to the start date of the contract.

- b. Quarterly Audits
 - i. As part of the ongoing quarterly FAD review, Compliance will audit quarterly all new contracts to ensure that no services begin prior to effective dates of contracts.
 - ii. Annual audits
- c. To ensure compliance with the Anti-Kickback Statute/Stark Statutes and the VCP, annual audits will be conducted. Tests via random selection to be done (ensure leases are included) for the three key indicators {1. Invoice; 2. Time & Effort Reporting; 3. Payments}, verifying that service and activity logs are properly completed and remuneration is properly tracked. The Chief Audit, Compliance & Privacy Officer is the responsible party for conducting the annual sample reviews for time & effort reporting and remuneration tracking.
- d. Leased Space
 - i. Usage of leased space shall be monitored quarterly and memorialized on logs, as appropriate, to ensure that usage is restricted as set forth in the contract. Under the guidance of the Administrators, front desk personnel will maintain logs monitoring and tracking usage.

VII. 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