



RUTGERS POLICY

Section: 100.2.7

Section Title: Healthcare Compliance Policies

Policy Name: Focus Arrangements Database Policy and Approval Procedure

Formerly Book: 00-01-15-60:00

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? RBHS Office of Ethics Compliance & Corporate Integrity: 973-972-8093

1. **Policy Statement**

Rutgers University has committed to ongoing compliance with the terms of the Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and the University of Medicine and Dentistry of New Jersey dated 9/25/09 as amended by a Letter Agreement, UMDNJ-Rutgers dated 5/1/13 ("CIA"). This policy provides guidance to each Rutgers Biomedical and Health Sciences entity (school, unit or department) which transitioned from UMDNJ to Rutgers University on July 1, 2013 (referred to herein as "RBHS Legacy entity" or collectively as, "RBHS Legacy entities") on the maintenance and operation of the CIA-required Focus Arrangements Database and the approval of focus arrangements.

2. **Reason for Policy**

- A. To set forth the general guidelines for the submission, approval and administration of all contractual agreements entered into by all RBHS Legacy entities which constitute Focus Arrangements (as defined below) under the terms of the 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. To establish procedures to activate and maintain a Focus Arrangements database through the Rutgers MediTract electronic contract management system.

3. **Who Should Read This Policy**

This policy applies to and should be read by all employees in RBHS Legacy entities, including but not limited to schools, operating units, hospitals, physician practices, and outpatient centers. It should also be read by other Rutgers departments that support the RBHS Legacy 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. Policy 100.2.3 Fair Market Valuation
- C. Policy 100.2.1 General Statement on Agreements with Referral Sources
- D. Policy 100.2.4 Professional Services Agreements
- E. Policy 10.1.9 Research Grant and Contract Administration, Support, and Management
- F. Policy 20.1.11 Purchasing Policy
- G. Policy 20.1.16 Policy on Notification and Approval of Certain Contracts Awarded without Competitive Bids or Proposal
- H. Policy 20.1.17 Engagement and Payment of Professional Services Provider Policy
- I. Policy 40.2.12 Gratuities, Guests, Gifts and Use Of University Resources
- J. Policy 40.2.5 Consulting or Other Personal Services, Intellectual Property, Honoraria and Other Miscellaneous Activities Policies and Procedures for Payment
- K. Policy 50.3.13 Signatory Authority

5. Contacts

RBHS Office of Ethics, Compliance and Corporate Integrity: 973-972-8093
Office of the Senior Vice President and General Counsel: 848-932-7697

6. The Policy

100.2.7 FOCUS ARRANGEMENTS DATABASE POLICY AND APPROVAL PROCEDURE

- A. All Focus Arrangements shall be compliant with the requirements of the CIA. All Focus Arrangements must be reviewed and approved by the applicable RBHS Legacy Entity department chair, dean, chief executive officer and Office of Senior Vice President and General Counsel before execution, and stored in the Focus Arrangement section of Rutgers MediTract electronic contract management system after execution, in accordance with this policy.

The Senior Vice President and General Counsel and the Chief Healthcare Compliance Officer will develop procedures to review all existing arrangements for compliance with the requirements of the CIA. Such procedures will include a review of existing arrangements over a period of time, not to exceed 120 days from the CIA Effective Date, in order to determine whether existing arrangements are Focus Arrangements.

- B. The definition of “Focus Arrangement” is found in Section II C 2 the 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”):

“Focus Arrangement” shall mean every arrangement that:

- a. involves, directly or indirectly, the offer or payment of anything of value and is between UMDNJ and any actual source of health care business or referrals to UMDNJ; or b. is between UMDNJ 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 UMDNJ for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

Provided, however, that any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership of investment interests), 42 C.F.R. § 411.357(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(0) (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 prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date of this CIA does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.”

C. Focus Arrangements Approval and Review Procedure (New or Renewed Arrangements)

The applicable RBHS Legacy Entity department chairs, deans, chief executive officers and RBHS Chancellor are responsible to comply with the following requirements:

1. The Focus Arrangement must be set forth in a written agreement and be reviewed by the applicable department chair, dean, chief executive officer, unit compliance officer and Office of the Senior Vice President and General Counsel.
2. The written agreement must contain a provision requiring that all individuals who meet the definition of an Arrangements Covered Person to comply with Rutgers Biomedical and Health Sciences (RBHS) Ethics, Compliance and Corporate Integrity Program, including the training related to the Anti-Kickback Statute and the Stark Law.
3. 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.
4. All parties to the Focus Arrangement must be given a copy of Rutgers Biomedical and Health Sciences' Code of Conduct and Compliance Policies and Procedures that pertain to the Anti-Kickback Statute and the Stark Law.
5. The applicable RBHS Legacy Entity department chairs, deans and chief executive officers shall ensure that each Focus Arrangement is entered into the Focus Arrangement Database following execution.

D. Database Requirements for Focus Arrangements Agreements.

Each executed Focus Arrangement shall be entered promptly into the Focus Arrangements section of the Rutgers MediTract electronic contract management system; for each Focus Arrangement included in the contract management system, the following information shall be recorded:

1. Each party involved in the Focus Arrangement;
2. The type of Focus Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Focus Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Focus Arrangement and the means by which compensation is paid;
5. 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 Healthcare Compliance Officer's designated unit/school compliance officer that he/she finds the fair market valuation (FMV) analysis methodology reasonable for the arrangement.
6. 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;

7. Whether each party has fulfilled the requirements of Section III.D.2 of the CIA which shall include:
 - a. ensuring that each Focus Arrangement is set forth in writing for a minimum of one year and signed by the University and the other parties to the Focus Arrangement;
 - b. in the written agreement a requirement that all individuals who meet the definition of Arrangements Covered Persons shall comply with the RBHS Ethics, Compliance and Corporate Integrity Program, including the training related to the Anti-Kickback Statute and the Stark Law; additionally it must be documented in the contract that the University has provided each party to the Focus Arrangement with a copy of the RBHS Code of Conduct and Stark Law and Anti-kickback Statute Policies and Procedures; and
 - c. in each written Focus Arrangement 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.
 8. Whether the Arrangement satisfies the requirements of an Anti-Kickback safe harbor and/or a Stark Law exception or a safe harbor, as applicable.
- E. Focus Arrangements Requirements: Non-contractual transactions involving non-monetary compensation.
- With respect to Focus Arrangements that constitute non-monetary compensation pursuant to 42 C.F.R. 411.357(k), the following information shall be recorded:
1. Each party involved in the Focus Arrangement;
 2. The type of Focus Arrangement (e.g., the type of non-contractual transaction);
 3. The aggregate value of all non-contractual transactions with each entity or individual during the Reporting Period;
 4. Whether the amount of compensation to be paid pursuant to the Focus Arrangement is determined based on the volume or value or referrals between the parties; and
 5. Whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.
- F. On a quarterly basis during the term of the CIA, the Chief Healthcare Compliance Officer's designee will review the Focus Arrangements section of the Rutgers' MediTract electronic contract management system and the internal review and approval processes related to Focus Arrangements, and provide a quarterly certification to RBHS Senior Vice President, Chief Ethics and Compliance containing the results of the review to the Compliance Committee.
- G. In accordance with the requirements of the CIA, the University will retain and make available to the OIG, upon request, the Focus Arrangements section of the Database and all supporting documentation of the Arrangements subject to this policy and the Focus Arrangements Approval Procedure, and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.