

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VASCULAR ACCESS CENTERS, L.P.**

I. PREAMBLE

Vascular Access Centers, L.P.; Ambulatory Care Specialists of Cranberry LLC; Vascular Access Center of Atlantic County LLC; Vascular Access Center of Bolivar County LLC; Vascular Access Center of Central New Jersey LLC; Vascular Access Center of East Memphis LLC; Vascular Access Center of Eatontown LLC; Vascular Access Center of Jacksonville LLC; Vascular Access Center of Mainline LLC; Vascular Access Center of Memphis LLC; Vascular Access Center of New Orleans LLC; Vascular Access Center of North Shore Louisiana LLC; Vascular Access Center of Pittsburgh LLC; Vascular Access Center of Prince Georges County LLC; Vascular Access Center of South Los Angeles LLC; Vascular Access Center of Southern Maryland LLC; Vascular Access Center of Trenton LLC; Vascular Access Center of West Orange LLC (Collectively “Vascular Access Centers”) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, Vascular Access Centers is entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Vascular Access Centers under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Vascular Access Centers’ final Annual Report or (2) any additional

materials submitted by Vascular Access Centers pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Arrangements" shall mean:
 - a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Vascular Access Centers and any actual or potential source of health care business or referrals to Vascular Access Centers or any actual or potential recipient of health care business or referrals from Vascular Access Centers; or
 - b. every financial relationship (as defined in 42 C.F.R. § 411.354(a)) that is between Vascular Access Centers 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 Vascular Access Centers for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).
2. The term "source of health care business or referrals" shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
3. The term "recipient of health care business or referrals" shall mean any individual or entity (1) to whom Vascular Access Centers refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Vascular Access Centers purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
4. "Focus Arrangements" means every Arrangement that:

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

Notwithstanding the foregoing provisions of Section II.C.2, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or 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(k) (non-monetary compensation); 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), or 42 C.F.R. § 357(u) (community-wide health information systems), shall not be considered a Focus Arrangement for purposes of this CIA, provided that Vascular Access Centers maintains sufficient documentation to demonstrate compliance with the applicable exceptions to 42 U.S.C. § 1395nn (Stark Law). Such documentation shall be made available to OIG upon request.

5. "Covered Persons" includes:
 - a. all owners, officers, directors, and employees of Vascular Access Centers; and
 - b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform billing or coding functions on behalf of Vascular Access Centers excluding vendors whose sole connection with Vascular Access Centers is selling or otherwise providing medical supplies or equipment to Vascular Access Centers; and

- c. all physicians and other non-physician practitioners who are members of Vascular Access Centers’s active medical staff.

6. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of Vascular Access Centers’s Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

Vascular Access Centers shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, General Partners, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Vascular Access Centers shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Vascular Access Centers, shall report directly to the Chief Executive Officer of Vascular Access Centers, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Vascular Access Centers. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the General Partners of Vascular Access Centers and shall be authorized to report on such matters to the General Partners at any time. Written documentation of the Compliance Officer’s reports to the General Partners shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Vascular Access Centers as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Vascular Access Centers shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Vascular Access Centers shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Vascular Access Centers' risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Vascular Access Centers shall report to OIG, in writing, any change in the composition of the Compliance Committee or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *General Partner Compliance Obligations.* The General Partner of Vascular Access Centers (General Partner) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

The General Partner shall, at a minimum, be responsible for the following:

- a. meeting with the Compliance Officer and the Compliance Committee at least quarterly to review and oversee Vascular Access Centers' compliance program, including but not

limited to the performance of the Compliance Officer and Compliance Committee;

- b. submitting to OIG a description of the documents and other materials it/he reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its/his oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by the General Partner summarizing its/his review and oversight of Vascular Access Centers' compliance with Federal health care program requirements and the obligations of this CIA.
- d. for each Reporting Period of the CIA, the General Partner shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of Vascular Access Centers' Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Vascular Access Centers' compliance program. The General Partner shall review the Compliance Program Review Report as part of its/his review and oversight of Vascular Access Centers' compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Vascular Access Centers. In addition, copies of any materials provided to the General by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the General Partner, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

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“The General Partner has made a reasonable inquiry into the operations of Vascular Access Centers’ Compliance Program, including the performance of the Compliance Officer and the Compliance Committee. Based on its/his inquiry and review, the General Partner has concluded that, to the best of its/his knowledge, Vascular Access Centers has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the General Partner is unable to provide such a conclusion in the resolution, the General Partner shall include in the resolution a written explanation of the reasons why it/he unable to provide the conclusion and the steps it/he is taking to implement an effective Compliance Program at Vascular Access Centers.

Vascular Access Centers shall report to OIG, in writing, any changes in the composition of the General Partner, or any actions or changes that would affect the General Partner’s ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Vascular Access Centers employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Vascular Access Centers department is in compliance with applicable Federal health care program requirements and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, Chief Medical Officer, General Partner, Controller, Director of Finance, Senior Vice President of Marketing and Business Development, Director of Clinical Operations and Compliance, Director of Human Resources, Regional Director, Manager of Reimbursement Services, Team Lead of Coding Department, Area Manager of New Jersey locations, and Area Manager of Maryland locations. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Vascular Access Centers policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name

of department] of Vascular Access Centers is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 90 days after the Effective Date, Vascular Access Centers shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

B. Written Standards

Within 90 days after the Effective Date, Vascular Access Centers shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Vascular Access Centers’ compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the Stark Law, and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; and
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute and Stark Law).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, Vascular Access Centers shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), Vascular Access Centers shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Vascular Access Centers shall develop a written plan (Training Plan) that outlines the steps Vascular Access Centers will take to ensure that all Covered Persons receive at least annual training regarding Vascular Access Centers' CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law, and that all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes; (ii) Vascular Access Centers' policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of Vascular Access Centers' Arrangements to know the applicable legal requirements and the Vascular Access Centers' policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (v) examples of violations of the Anti-Kickback Statute and the Stark Law.

The Training Plan shall include information regarding the following: training topics, identification of Covered Persons and Arrangements Covered Persons required to attend each training session, length of the training sessions(s), schedule for training, and format of the training. Vascular Access Centers shall furnish training to its Covered Persons and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *General Partner Training.* Within 90 days after the Effective Date, each General Partner shall receive at least two hours of training. This training shall address the corporate governance responsibilities of General Partners, and the responsibilities of General Partners with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities

of health care General Partners, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the General Partner and should include a discussion of the OIG's guidance on General Partner responsibilities.

New General Partners shall receive the General Partner Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Vascular Access Centers shall make available to OIG, upon request, training materials and records verifying that Covered Persons, Arrangements Covered Persons, and General Partners have timely received the training required under this section.

D. Compliance with the Anti-Kickback Statute and Stark Law

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, Vascular Access Centers shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in Sections III.D.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);
- b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;
- c. tracking all remuneration to and from all parties to Focus Arrangements, to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
- d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount

or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);

- e. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- f. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- g. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying and documenting the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
- h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;
- i. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

- j. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.J and III.K when appropriate.

2. *New or Renewed Focus Arrangements.* No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Vascular Access Centers shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that all written Focus Arrangements are signed by Vascular Access Centers and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;
- b. Ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remunerations pursuant to the Focus Arrangement, and that Vascular Access Centers maintains appropriate documentation of the review and approval of such Focus Arrangement; and
- c. Include in any written agreement 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 Arrangement.

3. *Records Retention and Access.* Vascular Access Centers shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section 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.

E. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Vascular Access Centers shall engage an entity (or entities), such as an accounting, auditing or consulting firm, to perform the claims review described in Section III.E.3 and, within 90 days after the Effective Date, Vascular Access Centers shall engage a law or consulting firm or a lawyer to perform the arrangements review described in Section III.E.2. The entity (or entities) engaged to perform the claims review and the arrangements review are referred to hereinafter as the “Independent Review Organization” or “IRO.” The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Vascular Access Centers shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Vascular Access Centers) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Vascular Access Centers’ responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.
- d. *Access to Records and Personnel.* Vascular Access Centers shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Claims Review.* The IRO shall review claims submitted by Vascular Access Centers and reimbursed by the Medicare and Medicaid programs, to determine

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whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix C to this CIA, which is incorporated by reference.

4. *Independence and Objectivity Certification.* The IRO for the Claims Review shall include in its report(s) to Vascular Access Centers a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of all current and prior engagements between Vascular Access Centers and the IRO. The IRO for the Arrangements Review shall include in its report(s) to Vascular Access Centers a certification that the IRO has (a) not previously represented or been employed or engaged by Vascular Access Centers and (b) does not have a relationship to Vascular Access Centers or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Vascular Access Centers shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above) and Vascular Access Centers' participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Vascular Access Centers shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, Vascular Access Centers shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or

questions associated with Vascular Access Centers' policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Vascular Access Centers shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Vascular Access Centers' Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by Vascular Access Centers. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Vascular Access Centers shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

H. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded from participation in any Federal health care program; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Vascular Access Centers shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Vascular Access Centers shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Vascular Access Centers shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.

c. Vascular Access Centers shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Vascular Access Centers’ responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Vascular Access Centers understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Vascular Access Centers may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Vascular Access Centers meets the requirements of Section III.G.

3. *Removal Requirement.* If Vascular Access Centers has actual notice that a Covered Person has become an Ineligible Person, Vascular Access Centers shall remove such Covered Person from responsibility for, or involvement with, Vascular Access Centers’ business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person

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from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Vascular Access Centers has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, Vascular Access Centers shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary or the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Vascular Access Centers shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Vascular Access Centers conducted or brought by a governmental entity or its agents involving an allegation that Vascular Access Centers has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Vascular Access Centers shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

J. Overpayments

1. *Definition of Overpayment.* An "Overpayment" means any funds that Vascular Access Centers receives or retains under any Federal health care program to which Vascular Access Centers, after applicable reconciliation, is not entitled to under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, Vascular Access Centers shall develop and implement written policies and procedures regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program.

K. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or
- d. the filing of a bankruptcy petition by Vascular Access Centers.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Vascular Access Centers determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Vascular Access Centers shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.K.1.a. and III.K.1.b.* For Reportable Events under Section III.K.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;

- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by Vascular Access Centers to identify and quantify any Overpayments; and
- e. a description of Vascular Access Centers' actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, Vascular Access Centers shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid (CMS) guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Vascular Access Centers completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

5. *Reportable Events under Section III.K.1.d.* For Reportable Events under Section III.K.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by Vascular Access Centers to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If Vascular Access Centers identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Vascular Access Centers is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Vascular Access Centers proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Vascular Access Centers shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Vascular Access Centers wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Vascular Access Centers must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Vascular Access Centers shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

*Vascular Access Centers
Corporate Integrity Agreement*

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the General Partner (or General Partner on behalf of the General Partner) who is responsible for satisfying the General Partner compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees;
5. a list of all the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the General Partners training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
7. a description of (a) the Focus Arrangements Tracking System required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Vascular Access Centers or that it does not have a prohibited relationship with Vascular Access Centers as set forth in Section III.E.4, as applicable;
9. a description of the risk assessment and internal review process required by Section III.F;
10. a description of the Disclosure Program required by Section III.G;
11. a description of the Ineligible Persons screening and removal process required by Section III.H;

12. a copy of Vascular Access Centers' policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.J;

13. a description of Vascular Access Centers' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business, and any individual owners;

14. a list of all of Vascular Access Centers' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number and/or supplier number(s); and

15. the certifications required by Section V.C.

B. Annual Reports

Vascular Access Centers shall submit to OIG a report on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members, the name of the General Partner (or General Partner on behalf of the General Partner) who is responsible for satisfying the General Partner compliance obligations, a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, General Partner, and Certifying Employees, and a description of any changes to the written process, including the reasons for the changes;

2. the dates of each report made by the Compliance Officer to the General Partner (written documentation of such reports shall be made available to OIG upon request);

3. the General Partner resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the General Partner, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and a copy of the Compliance Program Review Report;

4. a list of any new or revised Policies and Procedures developed during the Reporting Period;
5. a description of any changes to Vascular Access Centers' Training Plan developed pursuant to Section III.C, and a summary of any General Partners training provided during the Reporting Period;
6. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;
7. a complete copy of all reports prepared pursuant to Section III.E and Vascular Access Centers' response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
8. a certification from the IRO regarding its professional independence and objectivity with respect to Vascular Access Centers or that the IRO does not have a prohibited relationship with Vascular Access Centers, as described in Section III.E.4, as applicable;
9. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;
10. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
11. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute or Stark law (the complete disclosure log shall be made available to OIG upon request);
12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of any changes to the Overpayment policies and procedures required by Section III.J, including the reasons for such changes;

15. a summary of Reportable Events (as defined in Section III.K) identified during the Reporting Period;

16. a summary of any audits conducted during the applicable Reporting Period by any Medicare or state Medicaid program contractor or any government entity or contractor, involving a review of Federal health care program claims, and Vascular Access Centers' response/corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

17. a description of all changes to the most recently provided list of Vascular Access Centers' locations (including addresses) as required by Section V.A.14;

18. a description of any changes to Vascular Access Centers' corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business, and any individual owners; and

19. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Vascular Access Centers shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Vascular Access Centers is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, Vascular Access Centers has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of his or her knowledge, Vascular Access Centers has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;
- d. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- e. he or she understands that the certification is being provided to and relied upon by the United States

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer that, to the best of his or her knowledge, Vascular Access Centers has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); (c) to identify and adjust any past charges or claims for unallowable costs; and (d) he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Vascular Access Centers shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Vascular Access Centers shall refrain from

identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

Vascular Access Centers:

Laurie Brown, BSN, RN
Director of Clinical Operations and Compliance
Vascular Access Centers
2929 Arch Street
Suite 1705
Philadelphia, PA 19104
Telephone: 215.382.3680 ext. 312
Facsimile: 215.382.3683
Cellular: 856.404.2622
Email: lbrown@vascularcenters.com

Unless otherwise specified, all notifications and reports required by this CIA may be made by overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Vascular Access Centers may be required to provide OIG with an additional copy of each

notification or report required by this CIA, in OIG's requested format (electronic or paper).

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Vascular Access Centers' books, records, and other documents and supporting materials, and conduct on-site reviews of any of Vascular Access Centers' locations, for the purpose of verifying and evaluating: (a) Vascular Access Centers' compliance with the terms of this CIA and (b) Vascular Access Centers' compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Vascular Access Centers to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Vascular Access Centers' owners, employees, contractors, and directors who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Vascular Access Centers shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Vascular Access Centers' owners, employees, contractors, and directors may elect to be interviewed with or without a representative of Vascular Access Centers present.

VIII. DOCUMENT AND RECORD RETENTION

Vascular Access Centers shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Vascular Access Centers prior to any release by OIG of information submitted by Vascular Access Centers pursuant to its obligations under this CIA and identified upon submission by Vascular Access Centers as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Vascular Access Centers shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

Vascular Access Centers is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Vascular Access Centers and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Vascular Access Centers fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the General Partner’s compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review and the preparation of a Compliance Program Review Report, as required by Section III.A.3.;
- d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons, Arrangements Covered Persons, and General Partners;
- g. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;

- h. a risk assessment and internal review process;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments; and
- m. reporting of Reportable Events.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Vascular Access Centers fails to engage and use an IRO, as required by Section III.E, Appendix A, Appendix B, or Appendix C.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Vascular Access Centers fails to submit a complete Implementation Report, Annual Report, or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Vascular Access Centers fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Vascular Access Centers fails to submit any Claims Review Report in accordance with the requirements of Section III.E and Appendix C or fails to repay any Overpayment identified by the IRO as required by Appendix C.

6. A Stipulated Penalty of \$1,500 for each day Vascular Access Centers fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Vascular Access Centers fails to grant access.)

7. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Vascular Access Centers as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$2,500 for each day Vascular Access Centers fails to grant the IRO access to all records and personnel necessary to complete the reviews listed in Section III.E., and for each day Vascular Access Centers fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A.

9. A Stipulated Penalty of \$1,000 for each day Vascular Access Centers fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Vascular Access Centers stating the specific grounds for its determination that Vascular Access Centers has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Vascular Access Centers shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Vascular Access Centers receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-8 of this Section.

B. Timely Written Requests for Extensions

Vascular Access Centers may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Vascular Access Centers fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Vascular Access Centers receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Vascular Access Centers has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Vascular Access Centers of: (a) Vascular Access Centers' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Vascular Access Centers shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Vascular Access Centers elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Vascular Access Centers cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Vascular Access Centers has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Vascular Access Centers to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;

- b. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, Appendix B, or Appendix C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Vascular Access Centers constitutes an independent basis for Vascular Access Centers' exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Vascular Access Centers has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Vascular Access Centers of: (a) Vascular Access Centers' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure.* Vascular Access Centers shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Vascular Access Centers has begun to take action to cure the material breach; (ii) Vascular Access Centers is pursuing such action with due diligence; and (iii) Vascular Access Centers has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Vascular Access Centers fails to satisfy the requirements of Section X.D.3, OIG may exclude Vascular Access Centers from participation in the Federal health care programs. OIG shall notify Vascular Access Centers in writing of its determination to exclude Vascular Access Centers. (This letter shall be referred to as the "Exclusion Letter.") Subject to

the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Vascular Access Centers' receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Vascular Access Centers may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Vascular Access Centers of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Vascular Access Centers shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at

<http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Vascular Access Centers was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Vascular Access Centers shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Vascular Access Centers to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Vascular Access Centers requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Vascular Access Centers was in material breach of this CIA and, if so, whether:

- a. Vascular Access Centers cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Vascular Access Centers' receipt of the Notice of Material Breach: (i) Vascular Access Centers had begun to take action to cure the material breach; (ii) Vascular Access Centers pursued such action with due diligence; and (iii) Vascular Access Centers provided to OIG a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Vascular Access Centers, only after a DAB decision in favor of OIG. Vascular Access Centers' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Vascular Access Centers upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Vascular Access Centers may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Vascular Access Centers shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Vascular Access Centers, Vascular Access Centers shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Vascular Access Centers and OIG agree as follows:

- A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.
- B. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.
- C. OIG may agree to a suspension of Vascular Access Centers' obligations under this CIA based on a certification by Vascular Access Centers that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Vascular Access Centers is relieved of its CIA obligations, Vascular Access Centers shall be required to notify OIG in writing at least 30 days in advance if Vascular Access Centers plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Vascular Access Centers' responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.
- E. The undersigned Vascular Access Centers signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.
- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically-transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF VASCULAR ACCESS CENTERS

/James McGuckin/
James F. McGuckin, MD
General Partner
Vascular Access Centers, L.P.

10/9/18
DATE

/Christopher R. Hall/
Christopher R. Hall
SAUL EWING ARNSTEIN & LEHR LLP
Counsel for the VAC Defendants
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Tel: (215) 972-7180
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Email: chris.hall@saul.com

10/6/2018
DATE

/James McGuckin/
James F. McGuckin, MD
Ambulatory Care Specialists of Cranberry LLC,
by Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Centers, LLC, its
Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Bolivar County LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Central New Jersey
LLC, by Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of East Memphis LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Eatontown LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Jacksonville LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Mainline LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

*Vascular Access Centers
Corporate Integrity Agreement*

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Memphis LLC
by Vascular Access Centers, LLC, its
Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of New Orleans
LLC, by Vascular Access Centers, LLC, its
Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of North Shore
Louisiana LLC, by Vascular Access Centers,
LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Pittsburgh LLC,
by Vascular Access Centers, LLC, its
Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Prince George
County LLC by Vascular Access Centers,
LLC, its Manager

10/9/18
DATE

*Vascular Access Centers
Corporate Integrity Agreement*

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of South Los Angeles
LLC, by Vascular Access Centers, LLC, its
Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of South Maryland LLC,
by Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of Trenton LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

/James McGuckin/
James F. McGuckin, MD
Vascular Access Center of West Orange LLC, by
Vascular Access Centers, LLC, its Manager

10/9/18
DATE

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

/Lisa M. Re/
LISA M. RE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

10/09/2018
DATE

/Tamar V. Terzian/
TAMAR V. TERZIAN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

10/9/18
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. Vascular Access Centers shall engage an IRO to perform the Claims Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Vascular Access Centers shall engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to Vascular Access Centers as set forth in Paragraph F. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Vascular Access Centers in response to a request by OIG, whichever is later, OIG will notify Vascular Access Centers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Vascular Access Centers may continue to engage the IRO.

2. If Vascular Access Centers engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Vascular Access Centers shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Vascular Access Centers at the request of OIG, whichever is later, OIG will notify Vascular Access Centers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Vascular Access Centers may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review;

3. assign individuals to conduct the Claims Review who have expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed;
4. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
5. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);
6. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and
7. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review and Claims Review in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare and state Medicaid program rules and reimbursement guidelines in making assessments in the Claims Review;
3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare or state Medicaid program policy or regulation;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B and Appendix C (as applicable) to the CIA.

D. Vascular Access Centers Responsibilities

Vascular Access Centers shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Relationship to Vascular Access Centers

The IRO shall not (1) have previously represented or been employed or engaged by Vascular Access Centers or (2) have a relationship to Vascular Access Centers or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity.

G. Assertions of Privilege

Vascular Access Centers shall not assert claims of attorney-client privilege in order to avoid disclosing to OIG information related to or resulting from the IRO's engagement to perform the Arrangements Review. Vascular Access Centers' engagement letter with the IRO shall include a provision stating that the IRO agrees not to assert claims of work product privilege in order to avoid disclosing to OIG information related to or resulting from its engagement.

H. IRO Removal/Termination

1. *Vascular Access Centers and IRO.* If Vascular Access Centers terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Vascular Access Centers must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Vascular Access Centers must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E or has a prohibited relationship as set forth in paragraph F (as applicable), or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Vascular Access Centers in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Vascular Access Centers shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, relationship to Vascular Access Centers or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Vascular

Access Centers regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Vascular Access Centers in writing that Vascular Access Centers shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Vascular Access Centers must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Vascular Access Centers to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to Vascular Access Centers' systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Vascular Access Centers materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of Vascular Access Centers' systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. Vascular Access Centers' systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. Vascular Access Centers' systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;
3. Vascular Access Centers' systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
4. Vascular Access Centers' systems, policies, processes and procedures for documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the

individuals or entities that determined the fair market value amount or range, and the names and positions of the Arrangements Covered Person(s) involved with the fair market value determination(s);

5. Vascular Access Centers' systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

6. Vascular Access Centers' systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

7. Vascular Access Centers' systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

8. Vascular Access Centers' systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by Vascular Access Centers, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Vascular Access Centers' internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Vascular Access Centers' systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

11. Vascular Access Centers' systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;
2. a detailed description of Vascular Access Centers' systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;
3. findings and supporting rationale regarding weaknesses in Vascular Access Centers' systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and
4. recommendations to improve Vascular Access Centers' systems, policies, processes, or procedures relating to Arrangements described in Section A.1-11 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 14 randomly selected Focus Arrangements that were entered into or renewed by Vascular Access Centers during the Reporting Period. The IRO shall assess whether Vascular Access Centers has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

- a. verifying that the Focus Arrangement is maintained in Vascular Access Centers' centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e, items or services

actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with Vascular Access Centers' policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with Vascular Access Centers' policies and procedures;

e. verifying that the service and activity logs are properly completed and reviewed (if applicable);

f. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

2. For any Focus Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Focus Arrangements subject to the Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Arrangements Transactions Review Report, the OIG may require the IRO shall be required to select an additional

sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the IRO, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to Vascular Access Centers and OIG an Additional Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies Vascular Access Centers and its IRO that an Additional Transactions Review will be required.

D. Arrangements Transactions Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions Review Report shall include the following information:

1. *Review Methodology*.
 - a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.
 - b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions Review.
 - c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and Vascular Access Centers shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from Vascular Access Centers after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings.* The IRO's findings with respect to whether Vascular Access Centers has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO, including findings for each item listed in Sections C.1.a-g above. In addition, as applicable, the Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials.* The names and credentials of the individuals who conducted the Arrangements Systems Review and the Arrangements Transactions Review.

APPENDIX C

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review. The Claims Review shall be conducted at two Review Facilities for each Reporting Period. At least 60 days prior to the end of each Reporting Period, Vascular Access Centers shall provide the OIG with the following information for each Review Facility for the prior year: (1) The total dollar amount of the Review Facility's revenue; (2) The total dollar amount of Federal health care program reimbursement received by the Reviewing Facility; and (3) The total dollar amount of the Review Facility's Paid Claims. Within 30 days after the OIG receives this information, OIG will notify Vascular Access Centers of the two Review Facilities to be reviewed.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money Vascular Access Centers has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix C.
- b. Paid Claim: A claim submitted by Vascular Access Centers and for which Vascular Access Centers has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims at the Review Facility during the 12-month period covered by the Claims Review.

2. *Claims Review Sample*. The IRO shall randomly select and review a sample of 100 Paid Claims (Claims Review Sample) at each Review Facility selected for Review. The Paid Claims shall be reviewed based on the supporting documentation available at Vascular Access Centers' office or under Vascular Access Centers' control and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample at each Review Facility that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on

suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

3. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample at each Review Facility and Vascular Access Centers shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from Vascular Access Centers after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which Vascular Access Centers cannot produce documentation shall be considered an error and the total reimbursement received by Vascular Access Centers for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims for each Review Facility selected shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

4. *Repayment of Identified Overpayments.* Vascular Access Centers shall repay within 60 days the Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations or Centers for Medicare and Medicaid Services (CMS) guidance (the "CMS overpayment rule"). If Vascular Access Centers determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Vascular Access Centers shall repay that amount at the mean point estimate as calculated by the IRO. Vascular Access Centers shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor. OIG, in its sole discretion, may refer the

findings of the Claims Review Sample (and any related work papers) received from Vascular Access Centers to the appropriate Medicare or state Medicaid program contractor for appropriate follow up by the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*
 - a. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
 - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
 - e. Supplemental Materials. A description of any Supplemental Materials as required by A.3.a., above.
2. *Statistical Sampling Documentation.*
 - a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
 - b. A description or identification of the statistical sampling software package used by the IRO.
3. *Claims Review Findings.*
 - a. Narrative Results.

- i. A description of Vascular Access Centers' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at Vascular Access Centers to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Samples.
- b. Quantitative Results.
- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by Vascular Access Centers differed from what should have been the correct coding and in which such difference resulted in an Overpayment to Vascular Access Centers.
 - ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately documented and in which such documentation errors resulted in an Overpayment to Vascular Access Centers.
 - iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment to Vascular Access Centers.
 - iv. Total dollar amount of all Overpayments in the Claims Review Samples.
 - v. Total dollar amount of Paid Claims included in the Claims Review Samples.
 - vi. Error Rate in the Claims Review Samples. The Error Rate shall be calculated by dividing the Overpayment in the Claims Review Samples by the total dollar amount associated with the Paid Claims in the Claims Review Samples.

- vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
 - viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to Vascular Access Centers' billing and coding system or to Vascular Access Centers' controls for ensuring that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials.* The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.