INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
COREPATH LABORATORIES, PA

I. PREAMBLE

CorePath Laboratories, PA (Provider) hereby enters into this Integrity Agreement (IA) 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 IA, Provider is entering into a Settlement Agreement with the United States.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this IA shall be the signature date of the final signatory to this IA.

B. Term. The term of this IA shall be three years from the Effective Date, except that Sections VII and X, shall continue for 120 days after OIG's receipt of: (1) Provider's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120 day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and Provider complies with the decision.

C. Definitions.

1. "Arrangements" means:

a. every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between Provider and (i) any actual or potential source of health care business or referrals to Provider or (ii) any actual or potential recipient of health care business or referrals from Provider;

i. "Source of health care business or referrals" means 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;

ii. "Recipient of health care business or referrals" means any individual or entity (a) to whom Provider refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom Provider 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; and

b. every financial relationship (as defined in 42 C.F.R. § 411.354(a)) that is between Provider 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 Provider for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. "Arrangements Covered Persons" means each Covered Person who is involved with the development, approval, management, or review of Provider's Arrangements.

3. "Covered Persons" means: (a) all owners who are natural persons and all employees of Provider; and (b) all contractors who furnish patient care items or services or who perform billing or coding functions on behalf of Provider.

4. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

5. "Focus Arrangements" means every Arrangement that:

a. is between Provider and any actual source of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value; or

b. is between Provider 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 Provider for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).

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), 42 C.F.R. § 357(u) (community-wide health information systems), shall not be considered a Focus Arrangement for purposes of this IA, provided that Provider maintains sufficient documentation to demonstrate compliance with the applicable exception to 42 U.S.C. § 1395nn (Stark Law). Such documentation shall be made available to OIG upon request.

6. "Ineligible Person" means an individual or entity who: (a) is currently excluded from participation in any Federal health care program; or (b) has been convicted of (i) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (ii) a criminal offense relating to neglect or abuse of patients; (iii) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (iv) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

7. "Overpayment" means any funds that Provider receives or retains under any Federal health care program to which Provider, after applicable reconciliation, is not entitled under such Federal health care program.

8. "Reportable Event" means (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 criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Provider.

9. "Reporting Period" means each one-year period during the term of this IA, beginning with the one-year period following the Effective Date.

III. COMPLIANCE PROGRAM REQUIREMENTS

Provider shall establish and maintain a compliance program that includes the following elements:

A. Compliance Contact. Within 90 days after the Effective Date, Provider shall designate a Compliance Contact. The Compliance Contact shall not have any job responsibilities that involve acting in any capacity as legal counsel or supervising legal functions for Provider and shall not have any non-compliance job responsibilities that involve billing, coding or claim submission (or oversight of those functions) or any other non-compliance job responsibilities

that, in OIG's discretion, may interfere or conflict with the Compliance Contact's ability to perform the duties outlined in this IA. The Compliance Contact shall be responsible for:

1. monitoring Provider's day-to-day compliance activities;

2. reviewing the policies and procedures required by Section III.B below at least annually;

3. making at least quarterly reports regarding compliance matters to the Chief Executive Officer of Provider;

4. responding to questions from OIG regarding Provider's compliance with the IA; and

5. all reporting requirements created under this IA.

Provider shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Contact within five business days after such a change.

B. Policies and Procedures. Within 90 days after the Effective Date, Provider shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of Provider's compliance program, including the compliance program requirements outlined in this CIA; and (2) Provider's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute and the Stark Law, and the regulations and other guidance documents related to these statutes, and business or financial arrangements that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law; (3) the requirements set forth in Section III.E below; and (4) the identification, quantification, and repayment of Overpayments. Provider shall enforce its Policies and Procedures and make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons.

The Compliance Contact shall review the Policies and Procedures at least annually and update the Policies and Procedures as necessary. 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. Posting of Notice. Within 60 days after the Effective Date, Provider shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the name and phone number of the Compliance Contact and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training and Education.

1. *Covered Persons Training*. All Covered Persons shall receive at least three hours of training during the first Reporting Period. Any individuals who become Covered Persons after the Effective Date and during the term of this IA shall receive at least three hours of training within 90 days of becoming a Covered Person.

Training may be completed in-person or online. These training requirements may be satisfied only by the completion of training courses that are submitted to OIG, prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics: Provider's IA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute and the Stark Law.

2. *Arrangements Covered Persons Training.* In addition to the training required in Section D.1 above, all Arrangements Covered Persons must receive at least three hours of training during the first Reporting Period regarding: (a) 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; (b) Provider's 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.E of the CIA; (c) the personal obligation of each individual involved in the development, approval, management, or review of Provider's Arrangements to know the applicable legal requirements and the Provider's policies and procedures; (d) the legal sanctions under the Anti-Kickback Statute and the Stark Law; and (e) examples of violations of the Anti-Kickback Statute and the Stark Law.

The OIG may, in its discretion, require that Covered Persons and Arrangements Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second or third years of the IA. The OIG shall provide notice to Provider of such additional required training at least 180 days prior to the required completion date for such training.

3. *Training Records.* Provider shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons and Arrangements Covered Persons required to receive training have completed such training. The documentation shall specify the type of training received, the individual who completed the training, and the date received.

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

1. *Focus Arrangements Procedures*. Within 90 days after the Effective Date, Provider shall create procedures designed to ensure that each existing, 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, new, or renewed Focus Arrangements and the information specified in Sections III.E.1.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.E.1.g, above;

i. requiring the Compliance Contact 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 Chief Executive Officer; 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 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, Provider shall comply with the following requirements (Focus Arrangements Requirements):

a. ensure that all written Focus Arrangements are signed by Provider 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.E.1.g prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement, and that Provider 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*. Provider 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.

F. Review Procedures.

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Provider shall engage a lawyer, law firm, or consulting firm (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.F.

b. *Retention of Records*. The IRO and Provider shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Provider related to the reviews described in this Section III.F.

c. *Responsibilities and Liabilities*. Nothing in this Section III.F affects Provider's 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.* Provider shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.F 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 IA, which is incorporated by reference.

3. *Certification Regarding Prohibited Relationships*. The IRO shall include in its report(s) to Provider a certification that the IRO (a) does not currently represent or is not currently employed or engaged by Provider and (b) does not have a current or prior relationship to Provider or its owners that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Section III.F. The IRO's certification shall include a summary of any current and prior relationships between Provider or its owners and the IRO.

G. Ineligible Persons.

1. *Screening Requirements*. Provider shall:

a. screen all prospective Covered Persons against the Exclusion Lists 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. screen all Covered Persons against the Exclusion Lists within 30 days after the Effective Date and on a monthly basis thereafter; and

c. Provider shall require all Covered Persons to immediately disclose immediately if they become an Ineligible Person.

Provider shall maintain documentation demonstrating that Provider: (1) has checked the Exclusion Lists (i.e., a screen print of the search results) and determined that its Covered Persons are not Ineligible Persons and (2) has required its Covered Persons to disclose if they are an Ineligible Person.

2. *Removal Requirement*. If Provider has actual notice that a Covered Person has become an Ineligible Person, Provider shall remove such Covered Person 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). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and Provider may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Provider meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Provider shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Provider has committed a crime or has engaged in fraudulent activities, within 30 days of Provider receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, Provider shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Provider shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Substantial Overpayment*. 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. the Federal health care programs affected by the Reportable Event;

c. a description of the steps taken by Provider to identify and quantify any Overpayments; and

d. a description of Provider's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, Provider 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 documentation of the repayment.

2. *Probable Violations of Law*. 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 individuals and entities 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;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the steps taken by Provider to identify and quantify any Overpayments; and

e. a description of Provider's 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, Provider shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

3. *Ineligible Persons*. 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 Lists screening that Provider completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons 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.

4. *Bankruptcy*. The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

5. *Reportable Events Involving the Stark Law*. Any Reportable Event that involves solely a probable violation of the Stark Law should be submitted by Provider to CMS through the self-referral disclosure protocol (SRDP), with a copy to OIG. However, if Provider identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then Provider is not required by this Section III.I to submit the Reportable Event to CMS through the SRDP, but shall provide OIG with a copy of the repayment documentation.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, Provider proposes to (a) sell any or all of its locations or businesses that are subject to this IA (whether through a sale of assets, sale of stock, or other type of transaction), or (b) purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by any Federal health care program, the IA shall be binding on the purchaser of any such location or business and any new location or business (and all Covered Persons at each new location or business) shall be subject to the requirements of this IA, unless otherwise determined and agreed to in writing by OIG. Provider shall notify OIG, in writing, of such sale or purchase to OIG within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new location or business.

If Provider wishes to obtain a determination by OIG that a proposed purchase or proposed acquisition will not be subject to the IA requirements, Provider must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the location or business 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 REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 90 days after the Effective Date, Provider shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Contact required by Section III.A, and a detailed description of any noncompliance job responsibilities;

2. a list of the Policies and Procedures required by Section III.B;

3. a copy of the notice required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

4. a description of (a) the Focus Arrangements Tracking System required by Section III.E.1.a, (b) the internal review and approval process required by Section III.E.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.E.1;

5. the following information regarding the IRO: (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 IA; and (d) a certification from the IRO that it does not have a prohibited relationship with Provider (as set forth in Section III.F.3) that includes a summary of any current and prior relationships between Provider or its owners and the IRO;

6. a copy of the search result screen prints demonstrating that Provider has screened all Covered Persons against the Exclusion List as required by Section III.G;

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

8. a certification by the Compliance Contact and the Chief Executive Officer that:

   a. he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference;

   b. to the best of his or her knowledge, Provider 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.E of the IA;

c. to the best of his or her knowledge, Provider has fulfilled the requirements for new or renewed Focus Arrangements under Section III.E.2 of the IA;

d. to the best of his or her knowledge, except as otherwise described in the Implementation Report, Provider is in compliance with all of the requirements of this IA;

e. he or she has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and

f. he or she understands that this certification is being provided to and relied upon by the United States.

B. Annual Reports. Provider shall submit to OIG a written report (Annual Report) for each of the three Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Contact described in Section III.A;

2. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

3. (in the first Annual Report) the following information regarding the training required by Section III.D during the first Reporting Period (and, in the second and third Annual Reports, any additional training required for the second and third Reporting Periods):

a. a copy of the training program registration for each Covered Person and Arrangements Covered Person who completed the training;

b. the title of the training course;

c. the name of the person or entity that provided the training;

d. the location, date, and length of the training; and

e. a brochure or other documentation that describes the content of the training program. (A copy of all training materials shall be made available to OIG upon request.)

4. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.E.1.a; (b) any changes to the internal review and approval process

required by Section III.E.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;

5. a complete copy of all reports prepared pursuant to Section III.F and Provider's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

6. a certification from the IRO that it does not have a prohibited relationship with Provider or its owners (as described in Section III.F.3 above) that includes a summary of any current and prior relationships between Provider or its owners and the IRO;

7. a copy of the search result screen prints demonstrating that Provider screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.G;

8. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

9. a summary of Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

10. a description of all changes to the most recently provided list of Provider's locations (including addresses) as required by Section V.A.7; and

11. a certification signed by Provider's Compliance Contact and Chief Executive Officer that:

a. he or she has reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference;

b. to the best of his or her knowledge, Provider 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.E of the IA;

c. to the best of his or her knowledge, Provider has fulfilled the requirements for new or renewed Focus Arrangements under Section III.E.2 of the IA;

d. to the best of his or her knowledge, except as otherwise described in the Annual Report, Provider is in compliance with all of the requirements of this IA;

e. he or she has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful; and

f. he or she understands that this certification is being provided to and relied upon by the United States.

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. Designation of Information. Provider 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. Provider 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

All notifications and reports required under this IA shall be submitted using the following contact information:

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, SW
Washington, DC 20201
Telephone: (202) 619-2078
Email Address: officeofcounsel@oig.hhs.gov

Provider:

Contact Name
Address
Telephone:
Email Address:

Unless otherwise requested by OIG, all notifications and reports required by this IA shall be submitted electronically. OIG shall notify Provider in writing of any changes to the OIG

contact information listed above. Provider shall notify OIG in writing within two business days of any changes to the Provider contact information listed above.

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 Provider's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Provider's locations, for the purpose of evaluating: (a) Provider's compliance with the terms of this IA and (b) Provider's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by Provider to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Provider's owners, employees, and contractors 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. Provider shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Provider's owners, employees, and contractors may elect to be interviewed with or without a representative of Provider present.

VIII. DOCUMENT AND RECORD RETENTION

Provider shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four 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 Provider prior to any release by OIG of information submitted by Provider pursuant to its requirements under this IA and identified upon submission by Provider as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Provider shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.A;

2. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.B;

3. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.C;

4. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.D;

5. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.E;

6. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.F;

7. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.G;

8. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.H;

9. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section III.I;

10. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section IV;

11. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section V;

12. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section VII;

13. A Stipulated Penalty of up to $1,000 for each day Provider fails to comply with Section VIII; or

14. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of Provider under this IA.

B. Timely Written Requests for Extensions. Provider 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 IA. 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 Provider fails to meet the revised deadline set by OIG. 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 business days after Provider 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 business 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*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Provider of: (a) Provider's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 15 business days after the date of the Demand Letter, Provider shall either: (a) 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.

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.

D. Exclusion for Material Breach.

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

a. failure to comply with any of the requirements of this IA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b. failure to comply with Section III.A;

c. failure to comply with Section III.E;

d. failure to comply with Section III.F;

e. failure to comply with Section III.I;

f. failure to comply with Section V;

g. failure to respond to a Demand Letter for Stipulated Penalties in accordance with Section X.C;

h. a false statement or false certification made to OIG by or on behalf of Provider under this IA;

i. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Provider to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or

j. failure to come into compliance with a requirement for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this IA by Provider constitutes an independent basis for Provider's 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 three years for each material breach. Upon a preliminary determination by OIG that Provider has materially breached this IA, OIG shall notify Provider of: (a) Provider's material breach and (b) OIG's intent to exclude Provider. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. Provider shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Provider in writing of its determination to exclude Provider. (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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Provider, including administrative and management services, except as stated in regulations found at 42 C.F.R. 1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Provider 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 issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this IA, Provider 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this IA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days the date of the Exclusion Letter and (b) no discovery shall be available to the parties. 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 IA shall be: (a) whether Provider was in full and timely compliance with the requirements of this IA for which OIG demands payment and (b) the period of noncompliance. Provider shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Provider has breached this IA and orders Provider to pay Stipulated Penalties, Provider must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Provider properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Provider must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 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 IA shall be whether Provider was in material breach of this IA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Provider shall waive its right to any notice of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Provider, Provider shall be reinstated effective on the date of the 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. The parties to this IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA and Provider agrees not to seek additional review of the DAB's decision (or the ALJ's decision of not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Provider and OIG agree as follows:

A. This IA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this IA.

B. All requirements and remedies set forth in this IA are in addition to and do not affect (1) Provider's 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.

C. The undersigned Provider signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

D. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this IA.

ON BEHALF OF PROVIDER

/Aamir Ehsan – President/ 12/10/23
[NAME] DATE
[TITLE]

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

/Lisa M. Re/ 2023.12.18
LISA M. RE DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Nancy Brown/ 12/18/23
NANCY W. BROWN DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Provider shall engage an IRO 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 Provider, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.5 of the IA or any additional information submitted by Provider in response to a request by OIG, whichever is later, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider may continue to engage the IRO.

2. If Provider engages a new IRO during the term of the IA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Provider shall submit the information identified in Section V.A.5 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Provider at the request of OIG, whichever is later, OIG will notify Provider if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Provider 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; and

3. have sufficient staff and resources to conduct the reviews required by the IA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the IA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the IA.

D. Provider Responsibilities

Provider shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.F of this IA and that all records furnished to the IRO are accurate and complete.

E. IRO Relationship to Provider

The IRO shall not (1) currently represent or currently be employed or engaged by Provider or (2) have a current or prior relationship to Provider or its owners that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Appendix B to this IA.

F. Assertions of Privilege

Provider 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. Provider's 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.

G. IRO Removal/Termination

1. Provider *and IRO*. If Provider terminates its IRO or if the IRO withdraws from the engagement during the term of the IA, Provider 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. Provider 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, has a prohibited relationship as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Provider in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Provider shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review

of any information provided by Provider regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Provider in writing that Provider shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Provider 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 Provider 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. If there are no material changes to Provider's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and third Reporting Periods. If Provider materially changes the Arrangements systems, processes, policies and procedures during the second Reporting Period, the IRO shall perform an Arrangements Systems Review for the second Reporting Period in addition to conducting the systems review for the first and third Reporting Periods. The Arrangements Transactions Review shall be performed annually and shall cover each of the three Reporting Periods.

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

1. Provider's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing, new, and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. Provider's 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. Provider's 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. Provider's 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) who received or were otherwise involved with the fair market value determination(s);

5. Provider's 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. Provider's 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. Provider's 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. Provider's 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 Provider, 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 Chief Executive Officer on the Focus Arrangements Tracking System, Provider's internal review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

10. Provider's 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. Provider's 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.E.2 of the IA.

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 Provider's systems, policies, processes, and procedures relating to the items identified in Section A.1-11 above;

3. findings and supporting rationale regarding weaknesses in Provider's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-11 above; and

4. recommendations to improve Provider's 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 50 randomly selected Focus Arrangements that were entered into or renewed by Provider during the Reporting Period. The IRO shall assess whether Provider has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.E.1 and III.E.2 of the IA, 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 Provider's 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 Provider's 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 Provider's 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.E.2 of the IA.

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 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 Provider 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 Provider 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 Transaction 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 required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and Provider shall furnish such documentation to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation from Provider after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall include the following in the Arrangements Transactions Review Report: (i) a

description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.

2. *Review Findings*. The IRO's findings with respect to whether Provider 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.