

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FOUNDATIONS HEALTH SOLUTIONS, INC. AND BRIAN COLLERAN**

I. PREAMBLE

Foundations Health Solutions, Inc. (hereinafter, “FHS”) and Brian Colleran hereby enter 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, FHS and Brian Colleran entered into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by FHS and Brian Colleran 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) FHS’s final Annual Report or (2) any additional materials submitted by FHS 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 every arrangement or transaction that:

a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between FHS, Brian Colleran, or any FHS Entity (as defined in Section II.C.5 below) and any actual or potential source of health care business or referrals to any FHS Entity or any actual or potential recipient of health care business or referrals from any FHS Entity. 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 and the term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom FHS, Brian Colleran, or any FHS Entity refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom FHS, Brian Colleran, or any FHS Entity 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.

2. “Focus Arrangements” means every Arrangement that:
 - a. is between FHS, Brian Colleran, or any FHS Entity and any actual source of health care business or referrals to any FHS Entity and involves, directly or indirectly, the offer, payment, or provision of anything of value; or
 - b. is between FHS, Brian Colleran, or any FHS Entity and any recipient of health care business or referrals from any FHS Entity and involves, directly or indirectly, the offer, payment, or provision of anything of value.

3. “Covered Persons” includes:
 - a. Brian Colleran and all other owners who are natural persons (other than shareholders who have an ownership interest of less than 5%), officers, directors, and employees of FHS or any FHS Entity; 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 FHS or any FHS Entity excluding vendors whose sole connection with FHS or an FHS Entity is selling or otherwise providing medical supplies or equipment to FHS or an FHS Entity.

4. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of Arrangements entered into by or on behalf of FHS, Brian Colleran, or any FHS Entity.

5. “FHS Entity” means any skilled nursing facility owned, operated, or managed by FHS, and any skilled nursing facility in which FHS or Brian Colleran has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3.

III. CORPORATE INTEGRITY OBLIGATIONS

FHS shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Certifying Employee, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, FHS 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 FHS, shall report directly to the President of FHS, and shall not be subordinate to the General Counsel, Chief Operating Officer, or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for FHS. 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; and
- b. monitoring the day-to-day compliance activities engaged in by FHS 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.

FHS 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, FHS 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 FHS's 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.

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

3. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain employees of FHS (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Brian Colleran, all owners, the President, the Chief Operating Officer, and the Compliance Officer. 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 and entity], 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 [entity name]'s policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of [entity name] 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.

B. Written Standards

Within 90 days after the Effective Date, FHS 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 FHS's 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 regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute; and
- b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute).

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

At least annually (and more frequently, if appropriate), FHS shall assess and update, as necessary, the Policies and Procedures. Any new or revised 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, FHS shall develop a written plan (Training Plan) that outlines the steps FHS will take to ensure that all Covered Persons receive at least annual training regarding the CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute; and that all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to these statutes; (ii) FHS'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.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of Arrangements entered into by or on behalf of FHS, Brian Colleran, or any FHS Entity to know the applicable legal requirements and FHS's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) examples of violations of the Anti-Kickback Statute.

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. FHS shall furnish training to its Covered Persons and Arrangements Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Certifying Employee Training.* Within 90 days after the Effective Date, each Certifying Employee shall receive at least two hours of training on corporate governance responsibilities. Specifically, the training shall address 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 FHS and should include a discussion of the OIG's guidance on corporate responsibility and compliance oversight.

New Certifying Employees shall receive the Certifying Employee Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* FHS shall make available to OIG, upon request, training materials and records verifying that Covered Persons, Arrangements Covered Persons, and Certifying Employees have timely received the training required under this section.

D. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, FHS shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to this statute (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 (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. 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);

- d. 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);
- e. establishing and implementing a written review and approval process for all 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 that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) a process for specifying 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;
- f. 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
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute 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.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, FHS shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by FHS, Brian Colleran, or the FHS Entity (as applicable) and the other parties to the Focus Arrangement;
- b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete at least one hour of training regarding the Anti-Kickback Statute and examples of arrangements that potentially implicate the Anti-Kickback

Statute. Additionally, FHS shall provide each party to the Focus Arrangement with a copy of its Anti-Kickback Statute Policies and Procedures;

- c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* FHS 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, FHS shall engage an entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. 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 FHS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and FHS) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects FHS’s and/or Brian Colleran’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.

2. *MDS Review.* The IRO shall review claims submitted by FHS and reimbursed by Medicare Part A, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were

correctly coded, submitted and reimbursed (MDS Review) and shall prepare a MDS Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Therapy Systems Assessment.* For each Reporting Period, the IRO shall assess the effectiveness, reliability, and thoroughness of FHS's oversight of therapy services as outlined in Appendix C to this CIA, which is incorporated by reference.

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

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to FHS a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E 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 FHS or Brian Colleran and the IRO.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, FHS 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 FHS's 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 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. FHS 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, FHS 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 FHS's 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, or any identified issues or questions associated with Brian Colleran’s conduct with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. FHS 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 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 FHS. 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, FHS 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, debarred, suspended, or otherwise declared ineligible.

- 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.* FHS shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. FHS 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. FHS shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a monthly basis thereafter.
- c. FHS shall implement a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If FHS or any FHS Entity 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, FHS 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, FHS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to FHS or Brian Colleran conducted or brought by a governmental entity or its agents involving an allegation that FHS or Brian Colleran 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. FHS or Brian Colleran 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 FHS or any FHS Entity receives or retains under any Federal health care program to which FHS or the FHS Entity, 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, FHS 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 FHS or Brian Colleran.

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

2. *Reporting of Reportable Events.* If FHS determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, FHS 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 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, if any;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of the steps taken by FHS to identify and quantify any Overpayments; and
- e. a description of FHS'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, FHS shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable 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 FHS 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.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by FHS to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If any FHS Entity identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then FHS 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, FHS and/or Brian Colleran 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.

If, in advance of a proposed sale or proposed purchase, FHS and/or Brian Colleran

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, FHS and/or Brian Colleran 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, FHS 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:

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 and positions of the Certifying Employees required by Section III.A.3;
4. a list of all Policies and Procedures required by Section III.B;
5. the Training Plan required by Section III.C.1 and a description of the Certifying Employee 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);
6. 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;
7. 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 FHS and Brian Colleran;

8. a description of the risk assessment and internal review process required by Section III.F;
9. a description of the Disclosure Program required by Section III.G;
10. a description of the Ineligible Persons screening and removal process required by Section III.H;
11. a copy of FHS's policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.J;
12. a description of FHS's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
13. a list of all of FHS Entity facilities (including locations and mailing addresses), the corresponding name under which each facility is doing business, and each facility's Medicare and state Medicaid program provider number(s) and/or supplier number(s);
14. a list of all other entities in addition to FHS: (1) in which Brian Colleran has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3; and (2) that submits claims to the Federal health care programs or provides items or services that are payable, directly or indirectly, by Federal health care programs; and
15. the certifications required by Section V.C.

B. Annual Reports

FHS 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, a current list of the Certifying Employees who are responsible for satisfying the Certifying Employees compliance obligations;
2. a list of any new or revised Policies and Procedures developed during the Reporting Period;
3. a description of any changes to FHS's Training Plan developed pursuant to Section III.C, and a summary of any Certifying Employees training provided during the Reporting Period;

4. 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;

5. a complete copy of all reports prepared pursuant to Section III.E and FHS'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 regarding its professional independence and objectivity with respect to FHS and Brian Colleran;

7. a description of any changes to the risk assessment and internal review process required by Section III.F., including the reasons for such changes;

8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: work plans developed, internal audits performed, corrective action plans developed in response to internal audits, and steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective actions plans shall be made available to OIG upon request;

9. 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 (the complete disclosure log shall be made available to OIG upon request);

10. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;

11. 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;

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

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

14. a summary of any audits conducted of FHS or any FHS Entity 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 FHS's response and/or corrective action plan (including information regarding any Federal health care program refunds) relating to the audit findings;

15. a description of all changes to the most recently provided list of FHS Entity facilities (including addresses) as required by Section V.A.13;

16. a description of all changes to the most recently provided list of entities in which Brian Colleran has an ownership or control interest and that submit claims to the Federal health care programs as required by Section V.A.14; and

17. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 75 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, FHS shall include the certifications of Certifying Employees as required by Section III.A.3;

2. *Compliance Officer, President, and Brian Colleran.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer, President, and Brian Colleran that:

- a. to the best of his or her knowledge, except as otherwise described in the report, FHS is in compliance with all applicable of the requirements of this CIA;
- b. to the best of his or her knowledge, FHS has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of his or her knowledge, FHS has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA; and

- 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.

3. *Chief Financial Officer.* The first Annual Report shall include a certification by the Chief Financial Officer of FHS that, to the best of his or her knowledge, FHS 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); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

FHS 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. FHS 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

FHS and Brian Colleran:

Foundations Health Solutions, Inc.
Attn: President
25000 Country Club Blvd., Suite 255
North Olmsted, OH 44070

Unless otherwise specified, all notifications and reports required by this CIA shall be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, FHS may be required to provide OIG with an electronic copy of each notification or report required by this CIA, in addition to a paper copy.

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 any FHS books, records, and other documents and supporting materials, and conduct on-site reviews of any FHS Entity for the purpose of verifying and evaluating: (a) FHS's compliance with the terms of this CIA; and (b) FHS's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by FHS 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 Brian Colleran and any FHS owners who are natural persons (other than shareholders who have an ownership interest of less than 5%), officers, directors, contractors, and employees 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. FHS and Brian Colleran shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Any FHS owners who are natural persons (other than shareholders who have an ownership interest of less than 5%), officers, directors, contractors, and employees may elect to be interviewed with or without a representative of FHS present.

VIII. DOCUMENT AND RECORD RETENTION

FHS 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 FHS prior to any release by OIG of information submitted by FHS pursuant to its obligations under this CIA and identified upon submission by FHS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, FHS shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

FHS and Brian Colleran are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, FHS and Brian Colleran 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 FHS 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 management certification obligations;
- d. written Policies and Procedures;
- e. training and education of Covered Persons, Arrangements Covered Persons, and Certifying Employees;
- f. the Focus Arrangements Procedures and/or Focus Arrangements Requirements;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;

- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. policies and procedures regarding the repayment of Overpayments; and
- l. 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 FHS fails to engage and use an IRO, as required by Section III.E, Appendix A, Appendix B, Appendix C, or Appendix D.

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 FHS 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 FHS fails to submit any MDS Review Report or Therapy Systems Assessment Report in accordance with the requirements of Section III.E, Appendix B, and Appendix C or fails to repay any Overpayment identified by the IRO, as required by 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 FHS fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix C.

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

7. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of FHS 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 \$1,000 for each day FHS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to FHS stating the specific grounds for its determination that FHS has failed to comply fully and

adequately with the CIA obligation(s) at issue and steps FHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date FHS 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 1-6 of this Section.

B. Timely Written Requests for Extensions

FHS 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 FHS 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 FHS 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 FHS 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 FHS of: (a) FHS's 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, FHS 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 FHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until FHS 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 FHS 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. 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;
- b. a failure by FHS to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;
- 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, Appendix C, or Appendix D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by FHS or Brian Colleran constitutes an independent basis for exclusion of FHS or Brian Colleran, as applicable, 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 FHS and/or Brian Colleran has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify FHS and/or Brian Colleran, as applicable, of: (a) FHS's and/or Brian Colleran's 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.") The exclusion may be directed at FHS and/or Brian Colleran, depending upon the facts of the breach.

3. *Opportunity to Cure.* FHS 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) FHS has begun to take action to cure the material breach; (ii) FHS is pursuing such action with due diligence; and (iii) FHS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, FHS or Brian Colleran fails to satisfy the requirements of Section X.D.3, OIG may exclude FHS or Brian Colleran from participation in the Federal health care programs. OIG shall notify FHS and Brian Colleran in writing of its determination to exclude FHS and/or Brian Colleran. (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 receipt of the Exclusion Letter by FHS and Brian Colleran. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, FHS and Brian Colleran 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 FHS and/or Brian Colleran 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, FHS 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 FHS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. FHS 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 FHS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless FHS 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 FHS was in material breach of this CIA and, if so, whether:

- a. FHS 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 FHS's receipt of the Notice of Material Breach: (i) FHS had begun to take action to cure the material breach; (ii) FHS pursued such action with due diligence; and (iii) FHS 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 FHS and/or Brian Colleran, only after a DAB decision in favor of OIG. The election by FHS or Brian Colleran of the contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude FHS and/or Brian Colleran 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 FHS or Brian Colleran 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. FHS and Brian Colleran 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 FHS or Brian Colleran, FHS or Brian Colleran (as applicable) 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

FHS and Brian Colleran 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 FHS obligations under this CIA based on a certification by FHS 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 FHS is relieved of its CIA obligations, FHS shall be required to notify OIG in writing at least 30 days in advance if FHS 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. OIG may agree to a suspension of Brian Colleran's obligations under this CIA based on a certification by Brian Colleran that he 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 programs. If Brian Colleran is relieved of his CIA obligations, he shall be required to notify OIG in writing at least 30 days in advance if he plans to obtain an ownership or control interest in any entity that bills any Federal health care programs. At such time, OIG shall evaluate whether the CIA shall be reactivated or modified.

E. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) FHS's and/or Brian Colleran'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.

F. The undersigned FHS and/or Brian Colleran 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.

G. 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 Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF FHS AND BRIAN COLLERAN

/Brian Colleran/

BRIAN COLLERAN
President

6/20/17

DATE

/Aric D. Martin/

ARIC D. MARTIN
Counsel for FHS and Brian Colleran

6/20/17

DATE

/B. Scott McBride/

B. SCOTT MCBRIDE
Counsel for FHS and Brian Colleran

6/28/17

DATE

/Richard H. Blake/

RICHARD BLAKE
Counsel for FHS and Brian Colleran

6/20/17

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

7/3/17
DATE

/David W. Fuchs/

~~DAVID W. FUCHS~~ \ \
Associate Counsel
Office of Inspector General
U.S. Department of Health and Human Services

7/3/2017
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. FHS 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 conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by FHS in response to a request by OIG, whichever is later, OIG will notify FHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, FHS may continue to engage the IRO.

2. If FHS 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, FHS shall submit the information identified in Section V.A.7 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 FHS at the request of OIG, whichever is later, OIG will notify FHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, FHS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Minimum Data Set (MDS) Review who have expertise in the MDS requirements, Resource Utilization Group determination, claims submission, and other requirements of the Medicare Prospective Payment System for skilled nursing facilities and in the general requirements of the Federal health care program(s) from which FHS seeks reimbursement;

2. assign individuals to design and select the MDS Review Sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the MDS Review who have a nationally recognized MDS or Resident Assessment Instrument certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign individuals to conduct the Therapy Systems Assessment who have expertise in the Medicare requirements relating to rehabilitation therapy in skilled nursing facilities and who have expertise in the established practice guidelines and generally accepted standards of medical practice for rehabilitation therapy (including those set forth by the American Academy of Physical Medicine and Rehabilitation, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association) in the general requirements of the Federal health care program(s);

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

6. 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 MDS Review and Therapy Systems Assessment in accordance with the specific requirements of the CIA;
2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the MDS Review and Therapy Systems Assessment;
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. perform each Arrangements Review in accordance with the specific requirements of the CIA;
5. respond to all OIG inquires in a prompt, objective, and factual manner; and
6. prepare timely, clear, and well written reports that include all the information required by Appendix B, Appendix C, and Appendix D to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the MDS Review, Therapy Systems Assessment, and the Arrangements 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.

E. IRO Removal/Termination

1. *FHS and IRO.* If FHS terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, FHS 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. FHS 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 D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify FHS in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. FHS shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by FHS regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify FHS in writing that FHS shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. FHS 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 FHS to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

MINIMUM DATA SET REVIEW

A. Minimum Data Set Review. The IRO shall perform the Minimum Data Set (MDS) Review annually to cover each of the five Reporting Periods. The MDS Review shall be conducted at five FHS Entity facilities selected by OIG (each a “Subject Facility” and collectively referred to as the “Subject Facilities”) for each Reporting Period. The IRO shall perform all components of each MDS Review.

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

- a. Overpayment: The amount of money FHS has received in excess of the amount due and payable under Medicare program requirements, as determined by the IRO in connection with the MDS Reviews performed under this Appendix B.
- b. Paid Claim: A claim submitted by a Subject Facility and for which FHS has received reimbursement from the Medicare Part A program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the MDS Review. In OIG’s discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed at the Subject Facilities and shall notify FHS and the IRO of its selection of the Population to be used to create the MDS Review Sample(s) at least 30 days prior to the end of each Reporting Period. FHS, or its IRO on behalf of FHS, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 90 days prior to the end of each Reporting Period.

In connection with limiting the Population, OIG may consider (1) proposals submitted by FHS or its IRO or (2) information furnished to OIG regarding the results of FHS’s internal risk assessment or internal auditing required under Section III.A.2. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

In order to facilitate the OIG's selection of the Subject Facilities, at least 90 days prior to the end of the Reporting Period, FHS shall furnish to OIG the following information for each FHS Entity facility for the prior calendar year: (1) geographic location, (2) Federal health care program patient census, (3) Medicare revenues, (4) Medicare Part A program Resource Utilization Group (RUG) levels, (5) patient lengths of stay, or (6) other factors determined by the OIG in its discretion.

2. *MDS Review Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims from each Subject Facility (each selection of claims at a Subject Facility shall be referred to as an "MDS Review Sample") and conduct the MDS Review (as described below). The Paid Claims in each MDS Review Sample shall be reviewed based on the supporting documentation available at FHS or under FHS's control and applicable Medicare Part A program requirements to determine whether the items and services furnished were medically necessary and appropriately documented, and whether the Paid Claim in each MDS Review Sample was correctly coded, submitted, and reimbursed. For each claim in any MDS Review Sample 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. *MDS Review—Description.*

- a. The IRO shall obtain all appropriate medical records, billing records, and related supporting documentation.
- b. For each Paid Claim selected in the MDS Review Sample, the IRO shall review the MDS and the medical record documentation supporting the MDS. The review process shall consist of an evaluation of the MDS and verification that each MDS entry that affects the RUG code outcome for the MDS is supported by the medical record for the corresponding period of time consistent with the assessment reference date specified on the MDS.
- c. The IRO shall perform an evaluation of the data on the Paid Claim and determine whether the variables that affect the RUG assignment outcome for the MDS are supported by the medical record for the corresponding time period consistent with the assessment reference date specified in the MDS. This shall include the following issues:

- i. The accuracy of the MDS coding based on the documentation within the medical record.
- ii. Verification of medical necessity in the medical record by verifying the presence of physician orders for the services reflected as necessary in the MDS.
- iii. The accuracy of the associated Paid Claims. At a minimum, these shall be reviewed for the following:
 - A. Coverage period;
 - B. Revenue codes;
 - C. HIPPS codes (RUG categories and the modifiers for assessment type); and
 - D. Units of service.
- d. In those cases where an incorrect MDS data point(s) has been identified, the IRO shall re-enter data from that MDS into the IRO's grouper software to verify that the correct RUG code assignment was properly assigned on the Paid Claim. If an incorrect RUG code was assigned, this shall be considered an error.
- e. If there is insufficient support for an MDS data point(s) that results in a downward change in RUG assignment, the IRO shall consider the dollar difference to be an overpayment.
- f. If an incorrect RUG was used, but it did not result in an overpayment, it shall be noted in the MDS Review Report.

4. *Repayment of Overpayments.* FHS, or the applicable FHS Entity, shall repay within 60 days the Overpayment(s) identified by the IRO in the MDS Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 42 C.F.R. § 401.301-305 (and any applicable CMS guidance) (the "CMS overpayment rule"). If FHS determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, FHS, or the applicable FHS entity shall repay that amount at the mean point estimate as calculated by the IRO. FHS 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 MDS Review Sample (and any related work papers) received from FHS to the appropriate Medicare contractor for appropriate follow up by the payor.

5. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in each MDS Review Sample and FHS shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the MDS Review Sample. If the IRO accepts any supplemental documentation or materials from FHS after the IRO has completed its initial MDS review of the MDS Review Sample (Supplemental Materials), the IRO shall identify in the MDS 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 MDS 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 FHS cannot produce documentation shall be considered an error and the total reimbursement received by FHS 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 each MDS Review Sample discussed in this Appendix, the first set of Paid Claims selected for each Subject Facility 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 a MDS Review Sample).

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

1. *MDS Review Methodology.*
 - a. Population. A description of the Population subject to the MDS Review.
 - b. Review Objective. A clear statement of the objective intended to be achieved by the MDS 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 MDS 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 MDS Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.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 to select the MDS Review Sample.

3. *MDS Review Findings.*

- a. Narrative Results.
 - i. A description of FHS’s billing and coding system(s), for submission of claims to Medicare Part A, including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at FHS to ensure that all items and services billed to Medicare Part A 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 MDS Review, including the results of the MDS Review Sample.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims submitted by FHS differed from what should have been the correct coding and in which such difference resulted in an Overpayment to FHS.
- 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 FHS.
- 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 FHS.
- iv. Total dollar amount of all Overpayments in the MDS Review Sample.
- v. Total dollar amount of Paid Claims included in the MDS Review Sample.
- vi. Error Rate in the MDS Review Sample. The Error Rate shall be calculated dividing the Overpayments identified in the Sample by the total dollar amount associated with the Paid Claims in the MDS Review Sample.
- vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
- viii. A spreadsheet of the MDS 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 FHS's billing and coding system or to FHS's controls for ensuring that all items and services billed to Medicare are medically necessary and appropriately documented, based on the findings of the MDS Review.

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

APPENDIX C

THERAPY SYSTEMS ASSESSMENT

A. Therapy Systems Assessment.

1. For each Reporting Period, the IRO shall assess the effectiveness, reliability, and thoroughness of FHS's rehabilitative therapy systems and FHS's oversight of rehabilitative therapy staff at the Subject Facilities. The systems assessment shall include, but is not limited to, ensuring that FHS:

- a. provides only skilled rehabilitation therapy that is:
 - i. delivered pursuant to an individualized plan of care;
 - ii. consistent with the nature and severity of the resident's and/or patient's individual illness or injury;
 - iii. in compliance with accepted standards of medical practice;
 - iv. reasonable and necessary given the resident's and/or patient's condition and plan of care to improve his or her condition, prevent or slow deterioration of his or her condition, or restore his or her prior levels of function; and
 - v. limited to services that are inherently complex and require the skills of physical, speech, or occupational therapists, among other types of professionals;
- b. complies with Medicare program requirements relating to the tracking of therapy minutes (e.g., only includes services that are inherently complex and require the skills of physical, speech, or occupational therapists, among other types of professionals; appropriately accounts for group and concurrent therapy);
- c. complies with all Medicare and FHS requirements relating to the documentation of medical records;
- d. obtains an assessment, by a physician, of the resident's and/or patient's need for skilled therapy and that the skilled services will improve his or her condition, prevent or slow deterioration of his or her condition, or restore his or her prior levels of function;

- e. receives appropriate and effective training that, at a minimum, includes the subject matters set forth in Section III.C.1 of the CIA; and
- f. communicates and interacts effectively among the corporate, regional, and facility level employees who provide, manage, or oversee the delivery of skilled rehabilitative therapy services to FHS's residents and/or patients.

2. If, at any time during the term of the CIA, FHS contracts for the provision of therapy services to its residents and/or patients or provides therapy services through an arrangement other than employment, the IRO shall assess the effectiveness, reliability, and thoroughness of FHS's oversight of those therapy services, including, but not limited to, the areas described in Section A.1 of this Appendix C.

3. In conducting the Therapy Systems Assessments, the IRO shall, at minimum, review policies and procedures, medical records, and other therapy-related documentation, observe the provision of therapy services, observe therapy-related care planning meetings, and interview key employees and contractors at the Subject Facilities. FHS shall take all necessary steps to ensure the IRO has access to FHS's facilities, documents, employees, and contractors to perform the activities set forth in this Section A.3 in a legally and clinically appropriate manner.

B. Therapy Systems Assessment Report.

1. The IRO shall submit a written report to FHS and OIG (hereinafter the "Therapy Systems Assessment Report") that sets forth, at a minimum:

- a. A summary of the IRO's activities in conducting the Therapy Systems Assessment;
- b. The IRO's findings regarding the effectiveness, reliability, and thoroughness of the oversight described in Section A.1 of this Appendix C;
- c. The IRO's recommendations to FHS as to how to improve the effectiveness, reliability, and thoroughness of the oversight described in Section A.1 of this Appendix C;
- d. The IRO's assessment of FHS's response to the IRO's recommendations in the prior Therapy Systems Assessment Reports

(this does not need to be included in the Therapy Systems Assessment Report for the first Reporting Period); and

- e. The names and credentials of the individuals who performed the Therapy Systems Assessment.

2. The IRO shall submit each Therapy Systems Assessment Report to FHS and OIG no later than 30 days after the end of each Reporting Period.

C. FHS's Response to the IRO's Therapy System Assessment Report.

Within 30 days after receipt of each IRO Therapy Systems Assessment Report, FHS shall submit to OIG and the IRO a written response to each recommendation contained in the Therapy Systems Assessment Report stating what action FHS took in response to each recommendation or why FHS has not elected to take action based on the recommendation.

APPENDIX D

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 FHS's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If FHS 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 FHS's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. FHS's 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. FHS's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. FHS'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);
4. FHS'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);
5. FHS's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by FHS, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

6. the Compliance Officer’s annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, FHS’s internal review and approval process, and other Arrangements systems, process, policies, and procedures;

7. FHS’s systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

8. FHS’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.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 FHS’s systems, policies, processes, and procedures relating to the items identified in Section A.1-8 above;

3. findings and supporting rationale regarding weaknesses in FHS’s systems, processes, policies, and procedures relating to Arrangements described in Section A.1-8 above; and

4. recommendations to improve FHS’s systems, policies, processes, or procedures relating to Arrangements described in Section A.1-8 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 or 10%, whichever is less, randomly selected Focus Arrangements that were entered into or renewed by FHS or an FHS Entity during the Reporting Period. The IRO shall assess whether FHS 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.

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

1. verifying that the Focus Arrangement is maintained in FHS’s centralized tracking system in a manner that permits the IRO to identify the parties to the Focus

Arrangement and the relevant terms of the Focus Arrangement (i.e., the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.);

2. 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;

3. verifying that the remuneration related to the Focus Arrangement is properly tracked;

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

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

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

D. Arrangements Transaction 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 detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for the sample reviewed.

b. Sources of Data. A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction 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 Transaction Review and FHS 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 FHS after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction 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 Transaction 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 Arrangements Transactions Review Report shall include the IRO's findings with respect to whether FHS 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. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to FHS's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.