

**FIRST AMENDMENT TO THE  
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. (FHS) and Brian Colleran, and the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) hereby enter into this First Amendment to the Corporate Integrity Agreement (CIA) that was executed by and between FHS and Brian Colleran and OIG that became effective on July 3, 2017.

Pursuant to Section XI.B of the CIA, the CIA may not be amended except by written consent of the parties to the CIA. FHS and Brian Colleran hereby agree that the CIA between FHS and Brian Colleran and OIG shall be amended as described below in this Amendment.

**II. AMENDMENT**

A. Appendix A is replaced in its entirety by the attached Appendix A, incorporated by reference.

B. Appendix B is replaced in its entirety by the attached Appendix B, incorporated by reference.

C. Appendix C is struck in its entirety.

D. Section III.E.2 of the CIA is replaced in its entirety as follows:

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

E. Section III.E.3 of the CIA is struck in its entirety.

F. Section X.A.4 of the CIA is replaced in its entirety as follows:

“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 Claims Review Report in accordance with the requirements of Section III.E, Appendix B, or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

G. All references in the CIA made to “Appendix C” are struck.

### **III. EFFECTIVE AND BINDING AGREEMENT**

A. All terms and conditions of the CIA not modified in this Amendment shall remain in effect for the remainder of the five-year period of compliance obligations that began on the CIA’s Effective Date of July 3, 2017. The Effective Date of this Amendment shall be the date the final signatory signs this Amendment (Amendment Effective Date).

B. The undersigned FHS and Brian Colleran signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatories represent that they are signing this Amendment in their official capacities and that they are authorized to execute this Amendment.

C. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Amendment.





## 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 to perform the Claims Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the Claims Review in a professionally independent and objective fashion, as set forth in Paragraph E.

2. FHS shall engage an IRO to perform the Arrangements Review that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to FHS as set forth in Paragraph F.

3. 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.

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

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

C. IRO Responsibilities

The IRO shall:

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

D. FHS Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Relationship to FHS

The IRO engaged to perform the Arrangements Review shall not (1) currently represent or currently be employed or engaged by FHS or (2) have a current or prior relationship to FHS or its owners, officers, or directors that would cause a reasonable person to question the IRO's objectivity in performing the Arrangements Review.

G. Assertions of Privilege

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

H. 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 E or has a prohibited relationship as set forth in paragraph F (as applicable), or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify 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, relationship to FHS 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

### SKILLED NURSING FACILITY CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Skilled Nursing Facility Claims Review (Claims Review) annually to cover each of the Reporting Periods. The Claims Review shall be conducted at at three FHS Entity facilities (each a “Subject Facility” and collectively referred to as the “Subject Facilities”), for each Reporting Period. The IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims 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 Claims Review performed under this Appendix B.
- b. Patient Stay: A covered Medicare Part A stay in a Subject Facility during the Reporting Period under review.
- c. Paid Claim: A claim submitted by FHS and for which FHS has received reimbursement from the Medicare Part A program.
- d. Population: The Population shall be defined as all Patient Stays for which at least one Paid Claim was submitted during the 12-month period covered by the Claims Review.

2. *Selection of Subject Facilities*. OIG shall select the Subject Facilities and provide the identities of those facilities to the IRO at least 30 days before the end of each Reporting Period. 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 most recent Program for Evaluating Payment Patterns Electronic Report (“PEPPER”) and the following data for each FHS facility for the prior calendar year: (1) geographic location, (2) Federal health care program patient census, (3) Medicare revenues, (4) average patient lengths of stay, and (5) other data determined by the OIG in its discretion.

3. *Claims Review Sample*. The IRO shall randomly select and review a sample of 50 Patient Stays in the Population at each Subject Facility (each selection of Patient Stays at a Subject Facility shall be referred to as a “Claims Review Sample”). The IRO shall review the Patient Stay and all Paid Claims associated with each selected Patient Stay. The Patient Stay and associated Paid Claims shall be reviewed based on the

supporting documentation available at FHS's office or under FHS's control, and applicable Medicare program requirements and practice guidelines endorsed by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association to determine whether the items and services furnished were (a) medically necessary and reasonable, (b) appropriate and sufficient to meet the needs of a patient in the assigned Case-Mix Groups, (c) appropriately documented, and (d) whether the associated Paid Claims were correctly coded, submitted, and reimbursed. The IRO's review shall include a review of the following:

- a. eligibility for skilled nursing, rehabilitation therapy services, and non-therapy ancillary services
- b. required physician orders;
- c. comprehensive assessments to determine the individual needs of the patient;
- d. comprehensive care planning;
- e. provision of nursing, therapy, and non-therapy ancillary services according to the individualized care plans;
- f. provision of rehabilitation therapy services that are medically necessary and reasonable given the patient's condition to improve, maintain, or slow deterioration of the patient's condition, or restore his or her prior levels of function;
- g. discharge planning; and
- h. whether the information in the Minimum Data Set (MDS) associated with a Patient Stay that affects reimbursement is supported by the medical record.

For each Paid Claim associated with a Patient Stay in the Claims 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 process(es) that generated the Paid Claim.

4. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of each Paid Claim associated with each Patient Stay selected as part of the Claims Review Sample and FHS shall furnish such documentation and materials for each Paid Claim associated with each Patient Stay selected as part of the Claims Review Sample to the IRO prior to the IRO initiating its review of a specific Patient Stay in the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from FHS after the IRO has completed its initial review of a Patient Stay selected as part of the Claims Review Samples (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which 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 the Claims Review Sample discussed in this Appendix, the first set of Patient Stays selected for the 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 Claims Review Sample).

5. *Repayment of Identified Overpayments.* FHS, or the applicable FHS Entity, shall repay within 60 days any Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and 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 for any of the Subject Facilities, 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 Claims Review (and any related work papers) received from FHS to the appropriate Medicare contractor for appropriate follow up by the payor.

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

1. *Claims Review Methodology.*
  - a. Review Population. A description of the Population subject to the Claims Review.
  - b. Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
  - c. Source of Data. A description of (1) the process used to identify the Patient Stays in the Population and (2) the specific documentation and other information sources relied upon by the IRO when performing the Claims Review (e.g., patient medical records, FHS policies and procedures; Medicare carrier or intermediary manual or bulletins (including issue and date); practice guidelines endorsed by the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association; and other policies, regulations, or directives).
  - d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
  - e. Supplemental Materials. A description of any Supplemental Materials as required by A.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.
3. *Claims Review Findings.*
  - a. Narrative Results.

- i. A description of FHS’s billing and coding system(s), including the identification, by position description, of the personnel involved in the coding and billing.
  - ii. A description of the controls in place at FHS to ensure that all items and services billed to Medicare Part A are medically necessary and reasonable, appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups, and appropriately documented.
  - iii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample and the IRO’s findings regarding items A.3.a-h above.
- 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 number and percentage of instances in which the IRO determined that a Paid Claim was for items and services that were not appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups and resulted in an Overpayment to FHS.
  - v. Total dollar amount of all Overpayments in the Claim Review Sample.

- vi. Total dollar amount of Paid Claims in the Claims Review Sample.
  - vii. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
  - viii. An estimate of the Overpayment in the Population at the mean point estimate.
  - ix. A spreadsheet of the Claims Review results for each Subject Facility that includes the following information for each selected Patient Stay and the associated Paid Claims: the Federal health care program billed; beneficiary health insurance claim number, dates of service, code submitted (e.g., PDPM or RUG code), code reimbursed, allowed amount 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 Part A are medically necessary and reasonable, appropriate and sufficient to meet the needs of a patient in the assigned Case Mix Groups, and appropriately documented, based on the findings of the Claims Review.

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