

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE UNIVERSITY OF MISSOURI HEALTH SYSTEM**

I. PREAMBLE

The Curators of the University of Missouri, on behalf of the University of Missouri Health System (UMHS), hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, The Curators of the University of Missouri is entering into a Settlement Agreement with the United States.

“UMHS” means “Designated Operating Units,” “Designated Facilities,” and “Controlled Entities” as defined in this paragraph. “Designated Operating Units” means the following operating units of the Columbia campus of The Curators of the University of Missouri: University of Missouri Health Care, the University of Missouri School of Medicine, and University Physicians. “Designated Operating Units” does not include the University of Missouri’s School of Health Professions, Sinclair School of Nursing, and the Thompson Center for Autism and Neurodevelopmental Disorders. “Designated Facilities” means health care facilities, clinics, or clinical care locations owned and operated by a Designated Operating Unit. “Controlled Entities” means other health care entities (a) that are owned and controlled by The Curators of the University of Missouri, (b) that are operated for the benefit of a Designated Operating Unit, and (c) that furnish items or services payable by the Federal health care programs at any point during the term of this CIA. Capital Region Medical Center, Inc., Fulton Medical Center, LLC, Rusk Rehabilitation Center, LLC, Health Network of Missouri, LLC, and mPact Health, LLC shall not be considered Controlled Entities.

The Curators of the University of Missouri represents that, prior to this CIA, UMHS voluntarily established a Compliance Program that includes a Chief Compliance Officer and Office of Corporate Compliance. UMHS’s Compliance Program also includes compliance training and education; a confidential disclosure reporting hotline; exclusion screening; auditing and monitoring activities; and various policies, procedures, and guidance that seek to ensure compliance with Federal health care program

requirements. UMHS shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. UMHS may modify its Compliance Program, as appropriate, but at a minimum, UMHS shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by UMHS 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) UMHS’s final Annual Report; or (2) any additional materials submitted by UMHS pursuant to OIG’s request, whichever is later.

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

1. “Covered Persons” includes:

- a. all owners, officers, directors, and employees of UMHS, and employees of the Curators of the University of Missouri whose services are billed through University Physicians;
- 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 UMHS, excluding vendors whose sole connection with UMHS is selling or otherwise providing medical supplies or equipment to UMHS; and
- c. all physicians and other non-physician practitioners who are members of any UMHS Covered Facility’s active medical staff.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

2. “Covered Facility” means any UMHS hospital, UMHS outpatient clinic, or other UMHS location at which Covered Persons render items or services payable by the Federal health care programs.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee, Board of Curators, and Management Compliance Obligations

1. *Chief Compliance Officer.* UMHS has appointed a Chief Compliance Officer and shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be an employee and a member of senior management of UMHS, shall report directly to the University of Missouri’s Executive Vice Chancellor for Health Affairs, and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for UMHS. The Chief Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Curators of the University of Missouri (or a committee of the Board) (Board), and shall be authorized to report on such matters to the Board of Curators at any time. Written documentation of the Chief Compliance Officer’s reports to the Board of Curators shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by UMHS, as well as any reporting obligations created under this CIA.

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

UMHS shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief 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, UMHS shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Chief 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 Chief Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of UMHS'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.

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

3. *Board of Curators Compliance Obligations.* The Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (*i.e.*, non-executive) members.

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

- a. meeting at least quarterly to review and oversee UMHS's Compliance Program, including, but not limited to, the performance of the Chief Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the Compliance Program and in support of making the resolution below during each Reporting Period; and

- c. for each Reporting Period of the CIA, adopting a resolution signed by each member of the Board summarizing its review and oversight of UMHS's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Curators [or the designated Board committee] has made a reasonable inquiry into the operations of UMHS's Compliance Program including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board [or the designated Board committee] has concluded that, to the best of its knowledge, UMHS has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at UMHS.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain UMHS employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable UMHS department or Covered Facility is in compliance with applicable Federal health care program requirements and with the obligations of this CIA.

For all Designated Operating Units, these Certifying Employees shall include any Covered Person with the following title or comparable job functions:

- a. Executive Vice Chancellor for Health Affairs
- b. Chief Financial Officer
- c. Chief Planning Officer
- d. Chief Quality Officer
- e. Chief Medical Officer

For the University School of Medicine and University Physicians, these Certifying Employees shall include any Covered Person with the following title or comparable job functions:

- a. Dean of the School of Medicine
- b. Chair of University Physicians
- c. Executive Director of University Physicians
- d. Clinical department chairs of the School of Medicine
- e. Associate Vice Chancellor of Human Resources (campus position)

For University of Missouri Health Care, these Certifying Employees shall include any Covered Person with the following title or comparable job functions:

- a. Chief Executive Officer
- b. Chief Operating Officer
- c. Chief of Staff
- d. Chief Nurse Executive
- e. Chief Human Resources Officer
- f. Chief Medical Information Officer
- g. Executive Directors of Ambulatory Care, Professional Services, Support Services, Surgical Services, University Hospital, Women's and Children's Hospital, Missouri Orthopaedic Institute, MU Psychiatric Center, and Ellis Fischel Cancer Center

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 UMHS department or Covered Facility], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of UMHS department or Covered Facility] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and UMHS policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of UMHS department or Covered Facility] is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity

Agreement. I understand that this certification is being provided to and relied upon by the United States.”

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

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

B. Written Standards

1. *Code of Conduct.* UMHS has developed, implemented, and distributed a written Code of Conduct to all Covered Persons and shall maintain this Code of Conduct for the duration of the CIA. Within 90 days after the Effective Date, UMHS shall review and revise its Code of Conduct as necessary to comply with the requirements of this Section III.B.1. UMHS shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. UMHS’s commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
- b. UMHS’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with UMHS’s Policies and Procedures;
- c. the requirement that all of UMHS’s Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by UMHS, suspected violations of any Federal health care program requirements or of UMHS’s own Policies and Procedures;
- d. the possible consequences to both UMHS and Covered Persons of failure to comply with Federal health care program

requirements and with UMHS's own Policies and Procedures, and the failure to report such noncompliance; and

- e. the right of all individuals to use the Disclosure Program described in Section III.F, and UMHS's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

UMHS shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be distributed at least annually to all Covered Persons.

2. *Policies and Procedures.* Within 90 days after the Effective Date, UMHS 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 UMHS's compliance with Federal health care program requirements (Policies and Procedures). Throughout the term of this CIA, UMHS shall enforce and comply with its Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

The Policies and Procedures shall address, at a minimum:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the Compliance Program requirements outlined in this CIA;
- c. UMHS's compliance with Federal health care program requirements regarding the accurate coding, preparation, and submission of claims;
- d. UMHS's compliance with Federal health care program requirements regarding teaching physician supervision of services rendered by residents and the submission of claims for such services;
- e. UMHS's compliance with Federal health care program requirements regarding complete and accurate documentation of medical records;

- f. the expectation that all Covered Persons are aware of relevant Federal health care program requirements and: (i) the personal obligation of each individual involved in the medical record documentation process to ensure that such records are complete and accurate, and (ii) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- g. the expectation that all Covered Persons shall comply with UMHS's Code of Conduct, the Policies and Procedures under this Section III.B.2, and the terms of this CIA, as well as the legal sanctions for non-compliance; and
- h. UMHS's risk assessment and internal review process, including conduction of audits and appropriate remediation.

Within 90 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), UMHS shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, a description of the revisions shall be communicated to all affected Covered Persons and any revised or new Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

1. *Training Plan.* Within 90 days after the Effective Date, UMHS shall develop a written plan (Training Plan) that outlines the steps UMHS will take to ensure that: (a) all Covered Persons receive adequate training regarding UMHS's CIA requirements and Compliance Program, including the Code of Conduct; and (b) all appropriate Covered Persons receive adequate training regarding: (i) the Federal health care program requirements regarding the accurate coding and submission of claims; (ii) policies, procedures, and other requirements applicable to the documentation of medical records; (iii) the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate; (iv) the personal obligation of each individual involved in the medical records documentation process to ensure that such records are accurate; (v) applicable reimbursement statutes, regulations, and program requirements and directives; (vi) the legal sanctions for violations of the Federal health care program requirements; (vii) examples of proper and improper claims submission

practices; (viii) examples of proper and improper medical record documentation practices; and (ix) the Federal health care program requirements for teaching physician supervision of services rendered by residents.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of UMHS's Training Plan, OIG will notify UMHS of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, UMHS may implement its Training Plan. UMHS shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 90 days after the Effective Date, UMHS shall provide at least two hours of training to each member of the Board of Curators. This training shall address UMHS's CIA requirements and Compliance Program (including the Code of Conduct), the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of the OIG's guidance on Board member responsibilities.

New members of the Board of Curators shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief Compliance Officer (or designee) shall retain the certifications, along with all course materials.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training Plan.* UMHS shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Claims Review, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the revised

Training Plan. Within 30 days of OIG's receipt of any updates or revisions to UMHS's Training Plan, OIG will notify UMHS of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, UMHS may implement the revised Training Plan.

6. *Computer-based Training.* UMHS may provide the training required under this CIA through appropriate computer-based training approaches. If UMHS chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, UMHS shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.D. 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 UMHS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and UMHS) related to the reviews.

2. *Claims Review.* The IRO shall review UMHS's Covered Facilities' coding, billing, and claims submission to the Medicare and Medicaid programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). UMHS shall pay for the reasonable cost of any such review performed by OIG

or any of its designated agents. Any Validation Review of a Claims Review submitted as part of UMHS's final Annual Report shall be initiated no later than one year after UMHS's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify UMHS in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. UMHS shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review and/or propose alternatives to the proposed Validation Review. The final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to UMHS a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Risk Assessment and Internal Review Process

UMHS has established a centralized annual risk assessment and internal review process to identify and address risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. Within 90 days after the Effective Date, UMHS shall develop a written policy describing its centralized annual risk assessment and internal review process. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. UMHS shall maintain the risk assessment and internal review process for the term of the CIA. Copies of any internal audit reports developed pursuant to the risk assessment and internal review process shall be made available to OIG upon request.

F. Disclosure Program

UMHS has established a Disclosure Program that includes a mechanism (*e.g.*, a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with UMHS'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. UMHS shall continue to maintain this Disclosure Program for the duration of the CIA. UMHS shall continue to 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. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief 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, UMHS shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief 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.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
 - a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or nonprocurement programs; 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, or suspended.

- b. “Exclusion Lists” include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

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

- a. UMHS shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. UMHS shall screen all current Covered Persons against the Exclusion Lists within 90 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.
- c. UMHS shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, or suspension.

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

3. *Removal Requirement.* If UMHS has actual notice that a Covered Person has become an Ineligible Person, UMHS shall remove such Covered Person from responsibility for, or involvement with, UMHS’s business operations related to the Federal health care programs 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 Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If UMHS 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, UMHS 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.

H. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, UMHS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to UMHS conducted or brought by a governmental entity or its agents involving an allegation that UMHS 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. UMHS 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.

I. Overpayments

1. *Definition of Overpayments.* For purposes of this CIA, an "Overpayment" shall mean the amount of money UMHS has received in excess of the amount due and payable under any Federal health care program requirements.

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

J. 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.G.1.a; or
- d. the filing of a bankruptcy petition by UMHS.

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall be made within 30 days after making a determination that a substantial Overpayment exists and shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by UMHS to identify and quantify the Overpayment; and
- d. a description of UMHS'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, UMHS shall provide OIG with a copy of the notification and repayment (if quantified) to the appropriate payor.

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

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions, or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event;
- c. the Federal health care programs affected by the Reportable Event;
- d. a description of UMHS's actions taken to correct the Reportable Event and prevent it from recurring; and
- e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by UMHS to identify and quantify the Overpayment.

5. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.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 Lists screening that UMHS 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 Reportable Event was discovered; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

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

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, UMHS 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 a proposed purchase, UMHS 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, UMHS 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, UMHS 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board of Curators compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of UMHS's Code of Conduct required by Section III.B.1;
6. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);
7. the Training Plan required by Section III.C.1 and a description of the Board of Curators 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);
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between UMHS and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to UMHS;
9. a description of the risk assessment and internal review process required by Section III.E;
10. a description of the Disclosure Program required by Section III.F;

11. a certification that UMHS has implemented the screening requirements described in Section III.G regarding Ineligible Persons, or a description of why UMHS cannot provide such a certification;

12. a copy of UMHS's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.I;

13. a list of all of UMHS's locations (including physical locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which UMHS currently submits claims;

14. a description of UMHS's institutional structure, including identification of any subsidiaries, affiliates, and joint ventures; and

15. the certifications required by Section V.C.

B. Annual Reports

UMHS shall submit to OIG annually a report with respect to the status of, and findings regarding, UMHS's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer; any change in the membership of the Compliance Committee described in Section III.A.2; any change in the Board members who are responsible for satisfying the Board of Curators compliance obligations described in Section III.A.3; and any change in the group of Certifying Employees described in Section III.A.4;

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

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

4. a copy of the written process that UMHS developed for Certifying Employees to follow for the purpose of completing the certifications required by Section III.A.4;
5. a summary of any significant changes or amendments to UMHS's Code of Conduct or the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy);
6. a copy of UMHS's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered, the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which UMHS ensures that all designated Covered Persons receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request;
7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter, and UMHS's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
8. a summary and description of any and all current and prior engagements and agreements between UMHS and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to UMHS;
9. a description of the risk assessment and internal review process required by Section III.E, a summary of any changes to the process, and a description of the reasons for such changes;
10. a summary of all internal audits performed pursuant to Section III.E during the Reporting Period and any corrective action plans developed in response to those internal audits. Copies of the internal audit reports and corrective action plans shall be made available to OIG upon request;
11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

12. a certification that UMHS has completed the screening required by Section III.G regarding Ineligible Persons;

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

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

15. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

16. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

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

18. a description of all changes to the most recently provided list of UMHS's locations (including addresses) as required by Section V.A.13; and

19. the certifications required by Section V.C.

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

C. Certifications

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

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

- a. to the best of his or her knowledge, except as otherwise described in the report, UMHS is in compliance with all of the requirements of this CIA; and
- b. 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 of UMHS.* The first Annual Report shall include a certification by the UMHS Chief Financial Officer that, to the best of his or her knowledge, The Curators of the University of Missouri 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

UMHS 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. UMHS 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:

Corporate Integrity Agreement
University of Missouri Health System

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

University of Missouri Health System:

Peggy Ford
Chief Compliance Officer
One Hospital Drive
Columbia, MO 65212
Telephone: 573.884.0632
Facsimile: 573.882.3234

With a Copy to:

The Curators of the University of Missouri
Attn: General Counsel
227 University Hall
Columbia, MO 65211
Telephone: 573.882.3211
Facsimile: 573.882.0050

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, UMHS may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), 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 examine and/or request copies of UMHS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UMHS's locations for the purpose of verifying and evaluating: (a) UMHS's compliance with the terms of this CIA and (b) UMHS's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by UMHS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UMHS's Covered Persons 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. UMHS shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UMHS's Covered Persons may elect to be interviewed with or without a representative of UMHS present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

UMHS is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, UMHS 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

Corporate Integrity Agreement
University of Missouri Health System

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 UMHS fails to establish and implement any of the following obligations as described in Sections III and IV:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Curators compliance obligations;
- d. the management certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the development and/or implementation of a Training Plan for the training of Covered Persons and Board members;
- h. a risk assessment and internal review process as required by Section III.E;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of government investigations or legal proceedings;
- l. policies and procedures regarding the repayment of Overpayments;
- m. the repayment of Overpayments as required by Section III.I and Appendix B;
- n. reporting of Reportable Events; and
- o. disclosure of changes to business units or locations.

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 UMHS fails to engage and use an IRO, as required by Section III.D, Appendix A, or Appendix B.

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 UMHS fails to submit the Implementation Report or any Annual Reports 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 UMHS fails to submit any Claims Review Report in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of UMHS 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.

7. A Stipulated Penalty of \$1,000 for each day UMHS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to UMHS stating the specific grounds for its determination that UMHS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps UMHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date UMHS 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

UMHS 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 UMHS 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 UMHS 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 UMHS 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 UMHS of: (a) UMHS'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, UMHS 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 UMHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UMHS 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 UMHS 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 UMHS to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- 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.D, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by UMHS constitutes an independent basis for UMHS's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that UMHS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify UMHS of: (a) UMHS'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.")

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

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

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

UMHS 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 UMHS's obligations under this CIA based on a certification by UMHS 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 UMHS is relieved of its CIA obligations, UMHS shall be required to notify OIG in writing at least 30 days in advance if UMHS plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) UMHS'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.

E. The undersigned UMHS signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF THE UNIVERSITY OF MISSOURI HEALTH SYSTEM

\Brian Burnett/
BRIAN BURNETT
Vice President for Finance and Chief Financial Officer
University of Missouri System
The Curators of the University of Missouri,
acting on behalf of the University of
Missouri Health System

6/24/16
DATE

/Carol A. Poindexter/
CAROL POINDEXTER, ESQ.
Norton Rose Fulbright US LLP
Counsel for The Curators of the University of Missouri

6/24/2016
DATE

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

/Robert K. DeConti/
ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

6/30/16
DATE

/Kenneth Kraft/
KENNETH D. KRAFT
Senior Counsel
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

6-27-2016
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. UMHS 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.8 of the CIA or any additional information submitted by UMHS in response to a request by OIG, whichever is later, OIG will notify UMHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, UMHS may continue to engage the IRO.

2. If UMHS 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, UMHS shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by UMHS at the request of OIG, whichever is later, OIG will notify UMHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, UMHS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare and state Medicaid program requirements applicable to the claims being reviewed;

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

3. 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); and

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

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

1. *UMHS and IRO.* If UMHS terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, UMHS 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. UMHS 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 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 UMHS in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. UMHS 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

UMHS regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify UMHS in writing that UMHS shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. UMHS 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 UMHS to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review. The Claims Review shall be conducted at 5 Covered Facilities or 10% of UMHS's Covered Facilities, whichever is greater, for each Reporting Period.

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

- a. Overpayment: The amount of money UMHS has received in excess of the amount due and payable under Medicare or any state Medicaid program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, determined in accordance with Section A.2 of this Appendix B.
- b. Paid Claim: A claim for inpatient physician services and outpatient physician services submitted by UMHS and for which UMHS has received reimbursement from the Medicare program or a state Medicaid program.
- c. Population: The Population shall be defined as all Paid Claims at the selected Covered Facilities during the 12-month period covered by the Claims Review. In OIG's discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify UMHS and the IRO of its selection of the Paid Claims to be reviewed at least 60 days prior to the end of each Reporting Period.

In connection with limiting the Population, OIG also may select the UMHS Covered Facilities that will be subject to the Claims Review in each Reporting Period. In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, UMHS shall furnish to OIG the following information for each UMHS Covered Facility for the prior calendar or fiscal year: (1) Federal health care program patient census; and (2) Federal health care program payor mix.

UMHS, or its IRO on behalf of UMHS, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed and the UMHS Covered Facilities selected for review at least 90 days prior to the end of each Reporting Period. In choosing

the subset(s) of Paid Claims to be reviewed, OIG may consider (1) proposals submitted by UMHS or its IRO or (2) information furnished to OIG regarding the results of UMHS's internal risk assessment and internal auditing. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

2. *Claims Review Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims at each UMHS Covered Facility selected for review (Claims Review Sample). The Paid Claims shall be reviewed based on the supporting documentation available at UMHS's office or under UMHS's control and applicable Medicare and state Medicaid program requirements to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the 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. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from UMHS to the appropriate Federal health care program payor (e.g., Medicare contractor) for appropriate follow-up by that payor.

3. *Repayment of Identified Overpayments.* UMHS shall repay within 60 days any Overpayment(s) identified in the Claims Review Sample, as determined by the IRO in accordance with Section A.2 above, 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 UMHS determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, UMHS shall repay that amount at the mean point estimate as calculated by the IRO. UMHS shall make available to OIG all documentation that reflects the refund of any Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from UMHS to the appropriate Medicare or state Medicaid program for appropriate follow up by that payor.

4. *Other Requirements.*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Claims Review Sample and UMHS shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from UMHS after the IRO

has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

- b. Paid Claims without Supporting Documentation. Any Paid Claim for which UMHS cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by UMHS for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

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. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify claims in the Population, and (2) the specific documentation relied upon by the IRO when performing the Claims Review (*e.g.*, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or

bulletins (including issue and date), other policies, regulations, or directives).

- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.4.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 UMHS’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place at UMHS to ensure that all items and services billed to Medicare or a state Medicaid program are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review 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 UMHS differed from what should have been the correct coding and in which such difference resulted in an Overpayment to UMHS.

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

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