

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
EISENHOWER MEDICAL CENTER**

I. PREAMBLE

Eisenhower Medical Center (“Eisenhower”) 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”). Eisenhower is a not-for-profit corporation that operates, among other things, a general acute care hospital: Eisenhower Memorial Hospital (“EMH”). Eisenhower is entering into this CIA to promote compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the “Federal health care programs”) by: 1) all members of the Eisenhower Executive Committee; 2) all members of the Eisenhower Finance Committee; 3) all members of the EMH Board of Directors; and 4) all employees, agents, and contractors, including physicians with contracts, of EMH who are involved in: a) documentation of medical records by the staff at EMH; b) preparation or submission of claims for care provided at EMH; c) creation of policies and procedures for EMH; d) the provision of

items or services or oversight of the provision of items or services at EMH; e) providing billing services to entities or individuals who are not employees of EMH; f) the ordering of items or services for EMH or negotiating business relationships with physicians, providers, and vendors on behalf of EMH where the individual or entity is in a position to provide or receive referrals of items or services reimbursable by Federal health care programs; g) the execution of duties and responsibilities under this CIA; or h) management of any of the above mentioned individuals (hereinafter referred to as "Covered Persons"¹). Unless otherwise specified, this CIA applies to EMH's divisions, subsidiaries, operating or business units. It is understood that EMH is bound by all Eisenhower's obligations and requirements under this CIA. Compliance with the terms and conditions in this CIA shall constitute an element of EMH's and Eisenhower's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Eisenhower is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Eisenhower under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified).

¹ Excluded from the definition of "Covered Persons" are those individuals who are temporary per diem or registry personnel and are hired for a period not to exceed forty (40) hours per month.

The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the “effective date”).

Sections VII, VIII, IX, X and XI shall remain in effect until Eisenhower submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

Eisenhower shall establish a compliance program that includes the following elements.

A. Compliance Officer and Compliance Committees. Eisenhower has appointed an individual to serve as Compliance Officer. This individual shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall continue to be a member of senior management of EMH, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Eisenhower, and shall be authorized to report to the Board of Directors of Eisenhower or EMH at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by EMH to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is

appointed during the term of this CIA, Eisenhower shall notify the OIG, in writing, within fifteen (15) days of such a change.

To the extent not already accomplished, Eisenhower shall also appoint a Compliance Committee within one hundred and twenty (120) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within the provider's corporate structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. *Code of Conduct.* Eisenhower has established a Code of Conduct.

Within one hundred and twenty (120) days of the effective date of this CIA, Eisenhower shall review the Code of Conduct and make any amendments necessary to ensure that it meets the requirements set forth herein. To the extent not already accomplished, the Code of Conduct and any necessary amendments shall be distributed to all Covered Persons within one hundred and twenty (120) days of the effective date of this CIA. Eisenhower and EMH shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. Eisenhower's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its fiscal intermediaries or carriers;
- b. Eisenhower's requirement that all of its directors, staff physicians, employees, contractors, and agents shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Eisenhower's own policies and procedures (including the requirements of this CIA);
- c. the requirement that all of Eisenhower's directors, staff physicians, employees, contractors, and agents shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Eisenhower's own policies and procedures;
- d. the possible consequences to both Eisenhower and to any director, staff physician, employee, contractor, and agent for failure to comply with all statutes, regulations, and guidelines applicable to

Federal health care programs and with Eisenhower's own policies and procedures or of failure to report such non-compliance; and

e. the right of all directors, staff physicians, employees, contractors, agents to use the confidential disclosure program, as well as Eisenhower's commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred and twenty (120) days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Eisenhower's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within ten (10) days after the commencement of their employment or contract or within one hundred and twenty (120) days of the effective date of the CIA, whichever is later.

Eisenhower will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Covered Persons shall certify on an annual basis that they have received, read, understood and will abide by the Code of Conduct.

2. Policies and Procedures. Within one hundred and twenty (120) days of the effective date of this CIA, Eisenhower or EMH shall develop and initiate implementation of written Policies and Procedures regarding the operation of EMH's compliance program and its compliance with all Federal and state health care statutes,

regulations, and guidelines, including the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address the documentation required to establish medical necessity, the prohibition against billing for unnecessary items or services (including tests and consulting services), and the provisions of the anti-kickback statute (42 U.S.C. § 1320a-7b(b)) and the Stark Law (42 U.S.C. § 1395nn). In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to Eisenhower and EMH management through the Confidential Disclosure Program required by section III.E. Eisenhower and EMH shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures shall be provided to OIG in the Implementation Report. The Policies and Procedures shall be available to OIG upon request.

Within one hundred and twenty (120) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate Covered Persons. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education.

1. *General Training.* Within one hundred and twenty (120) days of the effective date of this CIA, Eisenhower shall provide at least two (2) hours of training to each Covered Person. This general training shall explain Eisenhower's:

- a. Corporate Integrity Agreement requirements;
- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
- c. Code of Conduct.

These training material shall be made available to the OIG, upon request.

New Covered Persons shall receive the general training described above within ten (10) days of the beginning of their employment or contract or within one hundred and twenty (120) days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one (1) hour of general training annually.

2. *Specific Training.* Within one hundred and twenty (120) days of the effective date of this CIA, each Covered Person who falls within the ambit of category four (4) under the definition of Covered Persons set forth in the Preamble (hereinafter referred to as "relevant Covered Persons"), shall receive the following specific training in addition to the general training required above. Individuals who fall within the ambit of

categories 4(b) through 4(h) of the definition of Covered Persons shall receive at least six (6) hours of training. This training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;
- b. the requirements that items and services billed to Federal health care programs be medically necessary;
- c. the prohibition against kickbacks (42 U.S.C. § 1320a-7b(b)) and the prohibitions contained in the Stark Law (42 U.S.C. § 1395nn);
- d. policies, procedures and other requirements applicable to the documentation of medical records;
- e. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- f. applicable reimbursement rules and statutes;
- g. the legal sanctions for improper billings; and
- h. examples of proper and improper billing practices.

Individuals who fall within the ambit of category 4(a) of the definition of Covered Persons shall receive two (2) hours of training, which shall address at a minimum: the requirements of medical documentation, its importance, and the ramifications associated with the failure to properly document a medical file, as well as any other training that is set forth above and relevant to these individuals. These training materials shall be made

available to OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within twenty (20) days of the beginning of their employment or within one hundred and twenty (120) days of the effective date of this CIA, whichever is later. If a new relevant Covered Person has any responsibility directly or indirectly relating to the documentation of medical records, the preparation or submission of claims, the assignment of procedure codes, or providing billing services, then prior to completing this specific training, an Eisenhower or EMH employee, contractor, or agent who has completed the substantive training shall review all of the untrained person's work regarding documentation of medical records, the preparation or submission of claims, and the assignment of billing codes.

After the first year, every relevant Covered Person who falls within categories 4(b) through 4(h) shall receive at least four (4) hours of specific training annually on the topics enumerated above for these categories, and every relevant Covered Person who falls within category 4(a) shall receive at least one (1) hour of specific training annually on the topics enumerated above for category 4(a).

3. *Certification.* Each Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications,

along with specific course materials. These shall be made available to OIG upon request.

D. Review Procedures.

Eisenhower shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization”), to perform review procedures to assist Eisenhower in assessing the adequacy of its contracting and billing practices at EMH and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the anti-kickback statute (42 U.S.C. § 1320a-7b(b)), the Stark Law (42 U.S.C. § 1395nn), billing, coding, reporting and other requirements of the Federal health care programs from which EMH seeks reimbursement. The Independent Review Organization must be retained to conduct the engagements as set forth below for the first year within one hundred and twenty (120) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of EMH’s billing to the Federal health care programs to assist Eisenhower and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance (“billing engagement”). The second engagement will determine whether Eisenhower is in compliance with this CIA (“compliance engagement”).

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims

for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. Eisenhower shall use OIG's Office of Audit Services Statistical Sampling Software to select the random sample, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/oas/ratstat.html".

Each annual billing engagement analysis shall include the following components in its methodology:

- a. Billing Engagement Objective: A statement stating clearly the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. Billing Engagement Population: Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination. Such population shall be stratified by department and a statistically valid sample shall be chosen from each department.

- c. Sources of Data: Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.
- e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

The billing engagement shall provide:

- a. findings regarding EMH's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
- b. findings regarding whether claims submitted to Federal health care programs by or on behalf of EMH that are not reimbursable through a DRG, are medically necessary and in accordance with the statutes, rules, and regulations of such Federal health care programs. Such findings shall be based upon claims that are stratified by department.

- c. findings regarding Eisenhower's and EMH's procedures to correct inaccurate billings or codings to the Federal health care programs by or on behalf of EMH;
- d. findings that reflect whether the contracts or agreements with individuals or entities in a position to refer business to EMH or the conduct underlying the contract or agreement violate any of the statutes, rules, and regulations of the Federal health care programs, including, but not limited to, the anti-kickback statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn;
- e. findings that reflect whether Eisenhower or EMH has any contracts or agreements to perform billing functions for individuals or entities that are in a position to refer business to the EMH, and, if so, findings that indicate whether those contracts or agreements violate any of the statutes, rules, or regulations of the Federal health care programs, including, but not limited to 42 U.S.C. § 1395u(b)(6) and the anti-kickback statute, 42 U.S.C. § 1320a-7b(b); and
- f. findings regarding the steps Eisenhower and/or EMH are taking to bring its operations into compliance or to correct problems identified by the review as set forth herein, including notification to any physician whose billing or contract may also be implicated.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether Eisenhower's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA.

A complete copy of the Independent Review Organization's billing and compliance engagement shall be included in each of Eisenhower's Annual Reports to OIG.

3. *Verification/Validation.* In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which Eisenhower is complying with its obligations under this CIA, Eisenhower agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program. Eisenhower shall continue to maintain a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with Eisenhower's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. Eisenhower shall publicize the

existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. The Compliance Officer (or designee) shall make a preliminary good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action; Eisenhower shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an “Ineligible Person” shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise

ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to conduct that would or could trigger an exclusion under 42 U.S.C. § 1320a-7, but has not yet been excluded.

2. *Screening Requirements.* EMH shall not hire, engage as agents or contractors, or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Eisenhower shall screen all prospective EMH employees, agents, and contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within one hundred and twenty (120) days of the effective date of this CIA, Eisenhower will review its list of current EMH employees, agents, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, Eisenhower will review the list once semi-annually. If Eisenhower has notice that an employee, agent, or physician has become an Ineligible Person, Eisenhower will remove such person from responsibility for, or involvement with, EMH's business operations related to the Federal health care programs and shall

remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the 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 person is reinstated into participation in the Federal health care programs. In addition, Eisenhower shall require any EMH employee, agent, or contractor to disclose immediately any debarment, exclusion or other event that makes that individual an Ineligible Person.

4. *Pending Charges and Proposed Exclusions.* If Eisenhower has notice that an EMH employee, agent, or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract, Eisenhower shall immediately take all appropriate actions to ensure that the responsibilities of that employee, agent, contractor, or staff physician do not adversely affect the quality of care rendered to any patient or resident or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings. Within thirty (30) days of discovery, Eisenhower shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that EMH 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. Eisenhower shall also provide

written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an “overpayment” shall mean the amount of money EMH has received in excess of the amount due and payable under any Federal health care program requirements. EMH may not subtract any underpayments for purposes of determining the amount of relevant “overpayments.”

b. Reporting of Overpayments. If, at any time, Eisenhower identifies or learns of any overpayments, Eisenhower shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within thirty (30) days of discovery and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information

contained on the Overpayment Refund Form, provided as Attachment A to this CIA.

2. *Material Deficiencies.*

a. *Definition of Material Deficiency.* For purposes of this CIA, a “Material Deficiency” means anything that involves:

- (i) a substantial overpayment; or
- (ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. *Reporting of Material Deficiencies.* If Eisenhower determines that there is a Material Deficiency, Eisenhower shall notify OIG, in writing, within thirty (30) days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

- (i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall

include all of the information on the Overpayment Refund Form, as well as:

- (A) the payor's name, address, and contact person to whom the overpayment was sent; and
- (B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;
- (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (iii) a description of Eisenhower's actions taken to correct the Material Deficiency; and
- (iv) any further steps Eisenhower plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW LOCATIONS

In the event that Eisenhower purchases or establishes new business units after the effective date of this CIA, Eisenhower shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has

issued each provider number. All employees at such locations shall be subject to the requirements in this CIA that apply to new employees (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and fifty (150) days after the effective date of this CIA, Eisenhower shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of Eisenhower's Code of Conduct required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;
5. a description of the training programs required by section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:

- a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - c. all Covered Persons, as applicable, have completed the training and executed the certification required by section III.C.
7. a description of the confidential disclosure program required by section III.E;
 8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first engagements;
 9. a summary of personnel actions taken pursuant to section III.F; and
 10. a list of all of Eisenhower's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. Eisenhower shall submit to OIG an Annual Report with respect to the status and findings of Eisenhower's compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;
2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;
 - b. all Covered Persons, as applicable, have completed the training and executed the certification required by section III.C;
 - c. Eisenhower has complied with its obligations under the Settlement Agreement not to charge or otherwise seek payment for Federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify and adjust any past charges of unallowable costs; and
 - d. Eisenhower has effectively implemented all plans of correction related to problems identified under this CIA, Eisenhower's Compliance Program, or internal or external audits or reviews.

3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement, including a copy of the methodology used.
5. Eisenhower's response/corrective action plan to any issues raised by the Independent Review Organization.
6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to III.H.
7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
8. a copy of the confidential disclosure log required by section III.E;
9. a description of any personnel action (other than hiring) taken by Eisenhower as a result of the obligations in section III.F;
10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that

Eisenhower has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a corrective action plan to address the potential violations of law identified in section III.H; and

12. A description of all changes to the most recently provided list (as updated) of Eisenhower's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and ninety (90) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) Eisenhower is in compliance with all of the requirements of this CIA, to the best of his or her

knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful. It shall also include a resolution (or its equivalent) for EMH's Board of Directors certifying that they have reviewed the Annual Report and agree with the statements made therein.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Eisenhower:

Chief Corporate Compliance Officer
Eisenhower Medical Center
39000 Bob Hope Drive
Rancho Mirage, California 92270
Phone 760.773.4542
Fax 760.837.8327

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 photocopy Eisenhower's books, records, and other documents and supporting materials and/or conduct an onsite review of Eisenhower's operations for the purpose of verifying and evaluating: (a) Eisenhower's compliance with the terms of this CIA; and (b) EMH's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Eisenhower to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of the Covered Persons and/or EMH's employees, contractors, or agents who consent to be interviewed at the employee'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. Eisenhower agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. EMH's employees may elect to be interviewed with or without a representative of Eisenhower present.

VIII. DOCUMENT AND RECORD RETENTION

Eisenhower shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Eisenhower prior to any release by OIG of information submitted by Eisenhower pursuant to its obligations under this CIA and identified upon submission by Eisenhower as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Eisenhower shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

Nothing in this CIA shall constitute or be construed as requiring a waiver by Eisenhower of its attorney-client privilege or other applicable privilege. Notwithstanding this fact, the existence of any such privilege does not affect Eisenhower's obligation to comply with the provisions of this CIA.

X. BREACH AND DEFAULT PROVISIONS

Eisenhower is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Eisenhower and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary

penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning one hundred and twenty (120) days after the effective date of this CIA and concluding at the end of the term of this CIA, Eisenhower fails to have in place any of the following:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. written Code of Conduct;
- d. written Policies and Procedures;
- e. a training program; and
- f. a Confidential Disclosure Program;

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 Eisenhower fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Eisenhower employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, EMH’s business operations related to the Federal health care programs; or (ii) is in a position for which the person’s salary or the items or services

rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Eisenhower can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the Eisenhower fails to grant access) for each day Eisenhower fails to grant access to the information or documentation as required in section VII of this CIA.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to Eisenhower of the failure to comply) for each day Eisenhower fails to comply fully and adequately with any obligation of this CIA. In its notice to Eisenhower, the OIG shall state the specific grounds for its determination that the Eisenhower has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Eisenhower has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Eisenhower by personal service or certified mail of: (a) Eisenhower's failure to comply; and (b) the OIG's exercise of its contractual

right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the “Demand Letter”).

Within fifteen (15) days of the date of the Demand Letter, Eisenhower shall either:

- (a) cure the breach to the OIG’s satisfaction and pay the applicable stipulated penalties;
- or (b) request a hearing before an HHS administrative law judge (“ALJ”) to dispute the OIG’s determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Eisenhower elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Eisenhower cures, to the 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.C.

2. *Timely Written Requests for Extensions.* Eisenhower may 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 Eisenhower fails to meet the revised deadline as agreed to by the OIG-approved extension. 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 two (2)

business days after Eisenhower receives OIG's written denial of such request or the due date of the obligation whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that Eisenhower has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Eisenhower constitutes an independent basis for Eisenhower's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Eisenhower has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Eisenhower by certified mail of: (a) Eisenhower's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter

referred to as the “Notice of Material Breach and Intent to Exclude”). The exclusion may be directed at Eisenhower and/or EMH, depending upon the facts of the breach.

2. *Opportunity to cure.* Eisenhower shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG’s satisfaction that:

- a. Eisenhower is in full compliance with this CIA;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the thirty five (35) day period, but that: (i) Eisenhower has begun to take action to cure the material breach; (ii) Eisenhower is pursuing such action with due diligence; and (iii) Eisenhower has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, Eisenhower fails to satisfy the requirements of section X.C.2, OIG may exclude Eisenhower from participation in the Federal health care programs. OIG will notify Eisenhower in writing of its determination to excluded Eisenhower (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also

apply to all other federal procurement and non-procurement programs. If Eisenhower is excluded under the provisions of this CIA, Eisenhower may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

- a. a failure by Eisenhower to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D and III.H;
- b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;
- c. a failure to respond to a Demand letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
- d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Eisenhower of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Eisenhower 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. § 1005 as if they applied to the Stipulated Penalties or

exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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 fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for stipulated penalties under this CIA shall be: (a) whether Eisenhower was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Eisenhower shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders Eisenhower to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Eisenhower may request review of the ALJ decision by the DAB.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 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: (a) whether Eisenhower was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the thirty five (35) day period, but that: (i) Eisenhower has begun to take action to cure the material breach; (ii) Eisenhower is pursuing such action with due diligence; and (iii) Eisenhower has 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 that is favorable to the OIG. Eisenhower's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Eisenhower upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Eisenhower may request review of the ALJ decision by the DAB.

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 and Eisenhower agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Eisenhower and OIG agree as follows:

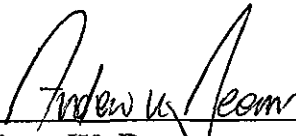
A. This CIA shall be binding on the successors, assigns and transferees of Eisenhower and EMH; if however, EMH becomes separately incorporated, that entity shall become solely responsible for all obligations under this CIA. Eisenhower shall provide notice to the OIG (in accordance with section VI), sixty (60) days prior to the incorporation of EMH;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

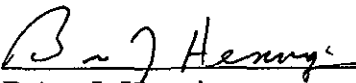
D. The undersigned Eisenhower signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF EISENHOWER AND EMH



Andrew W. Deems
President and Chief Executive Officer for
Eisenhower Medical Center and
Eisenhower Memorial Hospital


2-29-00
DATE



Brian J. Hennigan
Irell & Manell LLP
Counsel to Eisenhower and EMH

2-29-00
DATE

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



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

3/10/00
DATE

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____ Date of Deposit: _____
 Contractor Contact Name: _____ Phone # _____
 Contractor Address: _____
 Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)
(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes _____ No _____

Reason Codes:

- | | | |
|--|---|--|
| Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code | MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including
Black Lung
12 - Veterans Administration | Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify) |
|--|---|--|

**AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
EISENHOWER MEDICAL CENTER**

The Office of Inspector General (“OIG”) of the Department of Health and Human Services and Eisenhower Medical Center (“Eisenhower”) entered into a Corporate Integrity Agreement (“CIA”) on March 10, 2000.

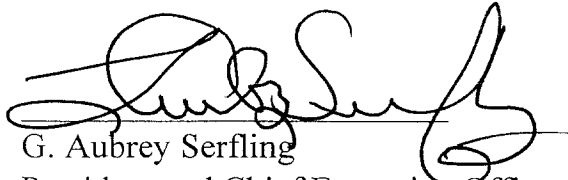
- A. Pursuant to section XI.C. of Eisenhower’s CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Eisenhower. Therefore, the OIG and Eisenhower hereby agree that Eisenhower’s CIA will be amended as follows:

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

The attached Appendix A is hereby added to Eisenhower’s CIA.

- B. The OIG and Eisenhower agree that all other sections of Eisenhower’s CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Eisenhower.
- C. The undersigned Eisenhower signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.
- D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF EISENHOWER MEDICAL CENTER



G. Aubrey Serfling
President and Chief Executive Officer for
Eisenhower Medical Center and
Eisenhower Memorial Hospital

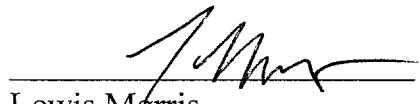
1/23/02
DATE



Brian J. Hennigen
Irell & Manell LLP
Counsel to Eisenhower and EMH

3/18/02
DATE

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



Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

5/8/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the Effective Date of this CIA, Eisenhower shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Eisenhower in assessing and evaluating its billing, coding, and contracting practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Eisenhower shall have expertise in the anti-kickback statute (42 U.S.C. § 1320a-7b(b)), the Stark Law (42 U.S.C. § 1395nn), billing, coding, reporting, and other requirements of the Federal health care program(s) from which EMH seeks reimbursement. Each IRO shall assess, along with Eisenhower, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze EMH’s contracting practices and billing and coding to the Federal health care programs (“Claims Review”), and shall analyze Eisenhower’s compliance with the obligations assumed under this CIA and Settlement Agreement (“Compliance Review”).

b. Frequency of Claims Review. The Claims Review shall be split into two six-month review periods performed semi-annually and shall cover the following time periods:

- | | |
|------------------|--|
| Annual Report #1 | August 1, 2000 - March 31, 2001 |
| Annual Report #2 | April 1, 2001 - September 30, 2001
October 1, 2001 - March 31, 2002 |
| Annual Report #3 | April 1, 2002 - September 30, 2002
October 1, 2002 - March 31, 2003 |
| Annual Report #4 | April 1, 2003 - September 30, 2003
October 1, 2003 - March 31, 2004 |
| Annual Report #5 | April 1, 2004 - September 30, 2004 |

October 1, 2004 - March 31, 2005.

The IRO(s) shall perform all components of each semi-annual Claims Review.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and Eisenhower shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Eisenhower) related to the reviews.

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of EMH. This Discovery Sample shall be split into two six-month reviews of 25 Medicare Paid Claims. The Paid Claims shall be reviewed based on the supporting documentation available at EMH or under EMH's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, EMH should, as appropriate, further analyze any errors identified in the Discovery Sample. Eisenhower and EMH recognize that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at EMH or under EMH's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, EMH may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from EMH to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If EMH's Discovery Sample identifies an Error Rate of 5% or greater, Eisenhower's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Eisenhower the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, Eisenhower agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Eisenhower agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the “Claims Review Report”). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Compliance Review.* The IRO shall conduct a review of Eisenhower’s compliance activities. The Compliance Review shall consist of a review of Eisenhower’s compliance with the obligations set forth in each section of this CIA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO’s findings, supporting rationale, and a summary of such findings and rationale regarding Eisenhower’s compliance with the terms of each section of the CIA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) Eisenhower’s Claims Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (“Validation Review”). Eisenhower agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Eisenhower’s final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Eisenhower of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Eisenhower may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Eisenhower agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with Eisenhower prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to Eisenhower a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity with regard to the Claims Review and Compliance Review and that it has concluded that it is, in fact, independent and/or objective.

APPENDIX A

A. Claims Review.

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

- a. Overpayment: The amount of money EMH has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by EMH and for which EMH has received reimbursement from the Medicare program.
- d. Population: All Items for which EMH has submitted a code or line item and for which EMH has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which EMH cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by EMH for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. Claims Review Methodology.

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the 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, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Statistical Sampling Documentation.**

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

- a. Narrative Results.
 - i. A description of EMH’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. 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 Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.
 - iii. Findings that reflect whether the contracts or agreements with individuals or entities in a position to refer business to EMH or the conduct underlying the contract or agreement violate any of the statutes, rules, and regulations of the Federal health care programs,

including, but not limited to, the anti-kickback statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn.

iv. Findings that reflect whether Eisenhower or EMH has any contracts or agreements to perform billing functions for individuals or entities that are in a position to refer business to the EMH, and, if so, findings that indicate whether those contracts or agreements violate any of the statutes, rules, or regulations of the Federal health care programs, including, but not limited to 42 U.S.C. § 1395u(b)(6) and the anti-kickback statute, 42 U.S.C. § 1320a-7b(b).

v. Findings regarding the steps Eisenhower and/or EMH are taking to bring its operations into compliance or to correct problems identified by the review as set forth herein, including notification to any physician whose billing or contract may also be implicated.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by EMH (“Claims Submitted”) differed from what should have been the correct claim (“Correct Claim”), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to EMH.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure 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. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. **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.