CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TRUMAN MEDICAL CENTER, INC.

I. PREAMBLE

Truman Medical Center, Inc. ("TMC"), a hospital located in Kansas City, MO, 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 ensure 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 its full and part time non-occasional physicians, employees, contractors, and third parties who are involved in the provision of health care services or are involved directly or indirectly in billing or coding (those person hereinafter collectively referred to as "covered persons").[1] TMC's compliance with the terms and conditions in this CIA shall constitute an element of TMC's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, TMC in conjunction with Hospital Hill

[1] "Non-occasional" employee includes any individual serving temporary assignments of at least two weeks cumulative over a twelve-month period. "Covered Persons" shall not include those allied health care professionals participating in practicums at TMC.

Health Services Corporation (HHHSC) is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. Previously, on March 11, 1999 TMC and the OIG executed a CIA. The parties to this CIA acknowledge that TMC has on an ongoing basis been implementing the requirements of the March 11, 1999 CIA. For instance, it has already submitted its Implementation Report pursuant to the March 11, 1999 CIA. Therefore, the obligations set forth in this CIA will reflect and incorporate the ongoing implementation efforts. Notwithstanding, this CIA upon its execution shall supersede the March 11, 1999 CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by TMC under this CIA shall be five (5) years from the March 11, 1999 CIA effective date of the prior CIA (unless otherwise specified). However, the effective date of this CIA, shall be the date on which the final signatory of this CIA executes this CIA.

III. CORPORATE INTEGRITY OBLIGATIONS

TMC represents that on September 24, 1997 TMC formally commenced a Corporate Compliance Plan (hereinafter referred to as the "Compliance Program") to promote "its continuing commitment to full compliance with all legal duties applicable to this organization and the health care industry, and to ethical conduct within TMC." Therefore, pursuant to this CIA and for the duration of this CIA, TMC hereby agrees to

maintain in full operation its current Compliance Program (the documents, which the parties recognize may be updated or revised during the terms of this CIA, describing this Program shall be attached to this CIA as Schedule A).

TMC hereby agrees to amend, to the extent necessary, its current Compliance Program to include the following additional elements or requirements:

A. Compliance Officer In the event a new Compliance Officer is appointed during the term of this CIA, TMC shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. *Code of Conduct.* TMC shall ensure that its Code of Conduct meets the following elements or requirements.

a. TMC'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 agents;

b. TMC's requirement that all of its covered persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with TMC's own policies and procedures (including the requirements of this CIA);

c. the requirement that all of TMC's covered persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or with TMC's own policies and procedures;

d. the possible consequences to both TMC and to any covered persons of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with TMC's own policies and procedures or of failure to report such non-compliance; and

e. the right of all employees to use the confidential disclosure program (Employee Reporting program), as well as TMC's commitment to confidentiality and non-retaliation with respect to disclosures.

TMC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and covered persons.

New covered persons shall receive the Code of Conduct and shall complete the required certification within thirty (30) days after the commencement of their employment or contractual relationship or within one hundred twenty (120) days of the effective date of this CIA, whichever is later.

TMC 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, understand and will abide by the Code of Conduct.

2. *Policies and Procedures*. TMC shall ensure that its existing Compliance Program written Policies and Procedures meet the following requirements:

a. The Policies and Procedures shall demonstrate TMC's commitment to compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs.

b. The Policies should articulate specific procedures personnel should follow when submitting initial or follow-up claims to Federal health care programs, with a particular focus on appropriate diagnosis codes, DRG coding, individual Medicare Part B claims (including documentation guidelines for evaluation and management services) and the use of patient discharge codes. At a minimum, the Policies and Procedures shall

specifically address the proper coding and billing of pre-operative diagnostic tests and the regulations, rules and guidelines governing the use of "screening" tests.

c. The Policies and Procedures shall also address the proper provision, documentation, coding and billing of prenatal and other OB/GYN services, including deliveries of newborn children. For prenatal and other OB/GYN services, to the extent that TMC Covered Persons participate in preparing the documentation used to support the submission of claims to the Federal health care programs or participate in the preparation of claims for submission to Federal health care programs, TMC shall ensure that it prepares such documentation or claims in accordance with the relevant Medicaid rules and regulations governing prenatal visits and OB/GYN services.

TMC shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures will be available to OIG upon request.

Within one hundred twenty (120) days of the effective date of this CIA, any new 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[2].

[2] OIG recognizes that HHHSC is simultaneously executing a CIA which requires training be administered to physicians employed by HHHSC. It is not the intention of the OIG to impose

1. *General Training.* TMC shall supplement its current employee training program by providing general training program for every covered person. This general training shall explain TMC'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 thirty (30) days of the beginning of their employment or within one hundred twenty (120) days after the effective date of this CIA, whichever is later. Every covered person shall receive such general training on an annual basis. This training requirement described above shall be in addition to TMC's current training and education activities, which it shall continue to maintain for the duration of this CIA.

2. *Specific Training.* TMC warrants and represents that its current training and education program includes annual training for each covered person who is involved directly or indirectly in the preparation or submission of claims for reimbursement

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duplicate training requirements upon physicians serving TMC; therefore, physicians providing services at TMC and meeting the training requirements in the HHHSC CIA are expressly exempted from the training provisions contained herein.

(including but not limited to coding and billing) to Federal health care programs on all applicable reimbursement laws, regulations and rules as well as appropriate billing policies, procedures and practices. TMC will continue for the duration of this CIA to provide such annual training, as that described in the Agreement made and entered into on December 1, 1998 by and between Transcend Services, Inc. and TMC ("Transcend agreement"), or such other training that is substantially similar to that provided for in the Transcend agreement

2. *Certification.* Every 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. TMC shall perform review procedures to assess the adequacy of its billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. TMC shall retain an Independent Review Organization ("IRO") such as an accounting, auditing or consulting firm, which shall verify TMC's annual audit findings. The IRO must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which TMC seeks reimbursement.

TMC will conduct two separate annual audits. One audit will analyze TMC's billing to the Federal health care programs to determine compliance with all applicable statutes, regulations, and directives from HCFA and/or its contractors ("billing audit"). The other audit will determine whether TMC is in compliance with this CIA ("compliance audit").

1. *Billing Audit.* The billing audit shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs 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 (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). 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. TMC shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual billing audit analysis shall include the following components in its methodology to be performed by TMC and verified by the IRO:

a. Billing Audit Objective: A clear statement of the objective intended to be achieved by the billing audit and the procedure or combination of procedures that will be applied to achieve the objective.

b. Billing Audit 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.

c. Sources of Data: Provide a full description of the source of the information upon which the billing audit 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 audit shall provide:

a. findings regarding TMC'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 TMC is submitting accurate claims for services billed to the Federal health care programs;

c. findings regarding TMC's procedures to correct inaccurate billings or codings to the Federal health care programs;

d. findings regarding whether TMC's programs, policies, operations, and procedures comply with the applicable statutes, regulations and other requirements the Federal health care programs from which TMC seeks reimbursement; and

e. findings regarding the steps TMC is taking to bring its operations into compliance or to correct problems identified by the audit.

2. *Compliance Audit.* TMC shall also conduct a compliance audit that shall provide an analysis of whether TMC's programs, policies, procedures and operations comply with the terms of this CIA. This audit shall include a section by section analysis of the requirements of this CIA.

3. *Verification/Validation.* In the event that the OIG believes that TMC's internal audit fails to conform to its obligations under the CIA or indicates improper billings not otherwise adequately addressed in the audit report and thus determines that it

is necessary to conduct an independent review to determine whether or the extent to which TMC is complying with its obligations under this CIA, TMC 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. TMC shall continue to maintain its Employee Reporting program, including the hotline for the duration of this CIA. The TMC Employee Reporting program shall include the following elements or requirements:

For any disclosure made through one of TMC's Employee Reporting program 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, TMC 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 the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

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

3. *Review and Removal Requirement*. TMC will review on a semi-annual basis its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. If TMC has notice that an employee, agent, or physician has become an Ineligible Person, TMC will remove such person from responsibility for, or involvement with, TMC'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.

4. *Pending Charges and Proposed Exclusions*. If TMC has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, TMC shall take all appropriate actions to ensure that the responsibilities of that employee or contractor 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, TMC 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 TMC has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. TMC 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. *Reporting of Overpayments.* If, at any time, TMC determines that it has received an overpayment from a Federal health care program, TMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the overpayment and take remedial steps within 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.

2. *Reporting of Material Deficiencies.* If, at any time, TMC determines that there is a material deficiency, TMC shall notify the OIG within 30 days of such determination. TMC's notification to the OIG shall include the following information; however, if the material deficiency does not involve an overpayment, the requirements of a and b below do not apply:

a. all of the information provided to the payor in returning the overpayment;

b. the name and the address of the payor to whom the overpayment was returned;

c. a complete description of the material deficiency; including the relevant facts, persons involved, and legal and program authorities;

d. TMC's actions to correct the problem; and

e. any further steps TMC plans to take to address the problem and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" means the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations, and program directives including carrier and intemediary instructions.

4. *Definition of "Material Deficiency."* For purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statute or regulations issued by HCFA and/or its agents and relating to billing and coding; or (iii) a violation of the obligation to provide items or services of a quality that meet professionally recognized standards of health care where such violation has occurred in one or more instances that presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary to places the beneficiary unnecessarily in a high-risk situation. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATIONS

In the event that TMC purchases or establishes new business units after the effective date of this CIA, TMC 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. ANNUAL REPORTS

TMC shall submit to OIG Annual Reports with respect to the status and findings of TMC'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; and

   b. all covered persons have completed the training and executed the certification required by section III.C.

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 audit report prepared by TMC and the verification prepared by the IRO pursuant to the billing and compliance audit procedure, including a copy of the methodology used;

5. TMC's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of material deficiencies identified and reported throughout the course of the previous twelve (12) months pursuant to section 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 taken by TMC 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 TMC 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 probable violations of law identified in section III.H; and

12. a listing of all of the TMC 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 payor (specific contractor) that issued each provider identification number.

Given that upon execution of this CIA, TMC will have been more than 9 months into the implementation of the March 11, 1999 CIA, no implementation report is required; however, the first Annual Report for this CIA shall be received by the OIG no later than April 11, 2000. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Annual Reports shall include a certification by the Compliance Officer under penalty of law, that: (1) TMC 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.

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

TMC:

Donna Douthit
Truman Medical Center
2310 Holmes
Kansas City, MO 64108
Phone 816.556.3157
Fax 816.556.4050

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 TMC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) TMC's compliance with the terms of this CIA; and (b) TMC's compliance with the

requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by TMC 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 TMC's contract physicians, employees, other health care professionals and third party 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 contract physician, employee, other health care professional or third party agent and OIG. TMC agrees to assist OIG in contacting and arranging interviews with such contract physician, employee, other health care professional or third party agent upon OIG's request. TMC's employees may elect to be interviewed with or without a representative of TMC present.

VIII. DOCUMENT AND RECORD RETENTION

TMC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, six (6) years (or longer if otherwise required by law).

IX. PRIVILEGES AND DISCLOSURES

Nothing in this CIA shall constitute or be construed as a waiver by TMC of its attorney-client privilege or any other applicable privilege. Notwithstanding that fact, the

existence of any such privilege does not affect TMC's obligations to comply with the provisions of this CIA.

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 TMC prior to any release by OIG of information submitted by TMC pursuant to its obligations under this CIA and identified upon submission by TMC as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. TMC 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.

X. BREACH AND DEFAULT PROVISIONS

TMC 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, TMC 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 $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day after the effective date of this CIA and concluding at the end of the term of this CIA, TMC 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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day TMC fails meet any of the deadlines to submit the Annual Reports to the OIG.

3. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date the failure to comply began) for each day TMC:

a. hires or enters into a contract with or grants staff privileges to an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this

Stipulated Penalty shall not be demanded for any time period during which TMC 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);

b. employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, TMC'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 (this Stipulated Penalty shall not be demanded for any time period during which TMC 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); or

4. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date the TMC fails to grant access) for each day TMC 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 TMC of the failure to comply) for each day TMC fails to comply fully and adequately with any obligation of this CIA. In its

notice to TMC, the OIG shall state the specific grounds for its determination that TMC 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 TMC has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify TMC by personal service or certified mail of (a) TMC'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, TMC 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 TMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until TMC 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*. TMC 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 TMC 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 TMC receives OIG's written denial of such request. 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 TMC 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 TMC constitutes an independent basis for TMC'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 TMC has materially breached this CIA and that exclusion should be imposed, the OIG shall notify TMC by certified mail of (a) TMC'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").

2. *Opportunity to cure.* TMC 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. TMC 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 35-day period, but that: (i) TMC has begun to take action to cure the material breach, (ii) TMC is pursuing such action with due

diligence, and (iii) TMC 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, TMC fails to satisfy the requirements of section X.C.2, OIG may exclude TMC from participation in the Federal health care programs. OIG will notify TMC in writing of its determination to excluded TMC (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 TMC is excluded under the provisions of this CIA, TMC 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 TMC to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;

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 verification purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights*. Upon the OIG's delivery to TMC 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, TMC 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, 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 TMC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. TMC 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 TMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that TMC 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 TMC 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 35 day period, but that (i) TMC has begun to take action to cure the material breach, (ii) TMC is pursuing such action with due diligence, and (iii) TMC 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. TMC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude TMC 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 TMC 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 TMC 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, TMC and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of TMC;

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 TMC 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 TMC

JOHN W. BLUFORD
Executive Director
CEO/Executive Director
Truman Medical Center, Inc.

1/20/00
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

1/24/00
DATE

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND TRUMAN MEDICAL CENTER, INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Truman Medical Center, Inc. (TMC) entered into a Corporate Integrity Agreement ("CIA") on January 24, 2000.

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

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

The attached Appendix A is hereby added to TMC's CIA.

B. The OIG and TMC agree that all other sections of TMC's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and TMC.

C. The undersigned TMC signatory represents and warrants that he is 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. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF TMC

John W. Bluford
Executive Director
CEO/Executive Director
Truman Medical Center, Inc.

2/11/02
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

2/13/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, TMC shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to verify TMC's annual Claims Reviews. The IRO retained by TMC shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which TMC seeks reimbursement. The IRO shall assess, along with TMC, 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.

b. Frequency and Types of Claims Reviews. The Claims Reviews shall be performed annually and shall cover the previous calendar year. TMC shall perform all components of each annual Claims Review. The following claims reviews will be conducted each year: (i) inpatient DRGs claims; and (ii) radiology, cardiology, pulmonary and ambulatory surgery Outpatient Prospective Payment System (OPPS) claims.

c. Retention of Records. The IRO and TMC 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 TMC related to the reviews).

2. *Claims Reviews.* The Claims Reviews 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. TMC shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of TMC. The Paid Claims shall be reviewed based on the supporting documentation available at TMC or under TMC'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, TMC should, as appropriate, further analyze any errors identified in the Discovery Sample. TMC recognizes 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, TMC 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, TMC 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 TMC or under TMC'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, TMC 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 TMC 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 TMC's Discovery Sample identifies an Error Rate of 5% or greater, TMC's IRO shall 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 TMC 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, TMC 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. TMC agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

3. *Claims Review Report.* TMC 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. *IRO Report.* The IRO shall prepare a report based on its verification review. The IRO Report shall include findings and recommendations concerning TMC's Claims Reviews, specifically with respect to the sampling procedures used by TMC and the coding assignment made by TMC.

5. *Validation Review.* In the event the OIG has reason to believe that: (a) TMC's Claims Reviews fail to conform to the requirements of this CIA; or (b) the TMC's or the IRO's findings or Claims Reviews results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Reviews complied with the requirements of the CIA and/or the findings or Claims Reviews results are inaccurate ("Validation Review"). TMC 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 [the Provider's] final submission (either TMC's final annual report, or any additional materials submitted by TMC pursuant to OIG's request, whichever is later) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify TMC 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, TMC may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any

additional or relevant information to clarify the results of the Claims Reviews, or to correct the inaccuracy of the Claims Reviews; and/or propose alternatives to the proposed Validation Review. TMC 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 Reviews with TMC 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.

6. *Independence Certification.* The IRO shall include in its report to TMC a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Reviews and that it has concluded that it was, in fact, independent.

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 TMC 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 TMC and for which TMC has received reimbursement from the Medicare program.

d. Population: All Items for which TMC has submitted a code or line item and for which TMC 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. 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 TMC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by TMC 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. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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. **Claims Review Findings.**

a. a description of TMC's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;

b. the IRO's findings, supporting rationale, and a summary of such findings and rationale 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. 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; and

c. the IRO's findings and recommendations concerning the Systems Review (if any).

3. **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.

4. **Claims Review Results.**

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

b. 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 TMC.

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

d. Error Rate in the sample.

e. 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.)

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

6. **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.