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

I. PREAMBLE

The Medical Center at Princeton ("Medical Center") hereby enters into this Corporate Integrity Agreement ("Agreement") 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 Medical Center and its staff physicians, employees, and other health care professionals (hereinafter collectively referred to as "employees"). Medical Center's compliance with the terms and conditions in this Agreement shall constitute an element of Medical Center's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Medical Center is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

The period of the compliance obligations assumed by Medical Center under this Agreement shall be five (5) years from the effective date of this Agreement (unless otherwise agreed to in writing by the parties).

III. CORPORATE INTEGRITY OBLIGATIONS

Prior to the execution of this Agreement, Medical Center voluntarily adopted and is in the process of implementing a Compliance Plan ("Compliance Plan"), which provides for corporate integrity policies and procedures and which, as represented by Medical Center in this Agreement, is aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments from Federal health care programs) is in conformity with the statutes, regulations, and other directives applicable to the Federal health care programs. Therefore, pursuant to this Agreement, Medical Center hereby agrees to maintain in full operation the Compliance Plan for the term of this Agreement. The Compliance Plan may be modified by Medical Center as appropriate, but, at a minimum, shall always comply with the integrity obligations enumerated below:

A. COMPLIANCE COMMITTEE

Medical Center has represented to OIG that, pursuant to its Compliance Plan, it has created a Compliance Committee. Accordingly, Medical Center shall formally maintain a Compliance Committee, which shall be responsible for, at a minimum, compliance with the integrity obligations in this Agreement. Medical Center shall ensure that the Compliance Committee is continuously composed of representatives of the multiple disciplines and segments of Medical Center's operations. At a minimum, the Compliance Committee shall include the Compliance Officer, the Administrator, and representatives from the medical and nursing staff. The Compliance Committee shall report directly to the Board of Trustees. Any changes in the appointment of individuals or their authority, the design or other aspects relating to the Compliance Committee must be reported to OIG within fifteen (15) days of the effective date of such an action. All other matters affecting the Compliance Committee shall be reported to OIG in accordance with Section V below.

B. COMPLIANCE OFFICER

Medical Center has represented to OIG that, pursuant to its Compliance Plan, it has created a Compliance Officer position and has appointed an individual to serve in that capacity. Accordingly, Medical Center shall

formally maintain the appointment of an individual to serve as the Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with the requirements of the Federal health care programs. At a minimum, the Compliance Officer must continuously be charged with the responsibility for the day-to-day compliance activities in furtherance of the integrity obligations assumed herein, as well as for any reporting obligations established under this Agreement.

The Compliance Officer shall report directly to the Administrator of Medical Center and shall have unrestricted access to the Board of Trustees. Any changes in the appointment of the Compliance Officer (including voluntary or involuntary personnel changes) or material changes in the duties of this position must be reported to OIG within fifteen (15) days of the effective date of the action. All other matters affecting the Compliance Officer shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. *Code of Conduct.* Medical Center has represented to OIG that it has adopted its Code of Conduct and is implementing its Compliance Plan. Accordingly, Medical Center shall formally maintain the written Code of Conduct and shall maintain it in effect for the duration of this Agreement. The Code of Conduct shall be distributed to all employees, contractors and/or agents within ninety (90) days of the effective date of this Agreement.

   Medical Center shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

   a. Medical Center's commitment to full compliance with all statutes, regulations, and guidance applicable to Federal health care programs, including its commitment to prepare and submit accurate reimbursement claims 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. Medical Center's requirement that all of its employees, contractors and/or agents shall be expected to comply with all statutes, regulations, and guidance applicable to Federal health care programs and with Medical Center's own policies and procedures (including the requirements of this Agreement);

c. the requirement that all of Medical Center's employees, contractors, and/or agents shall be expected to report suspected violations of any statute, regulation, or guidelines applicable to Federal health care programs or with Medical Center's own policies and procedures;

d. the potential consequences to both Medical Center and to any employee, contractor, and/or agent as a result of any failure to comply with Federal health care program requirements and with Medical Center's own policies and procedures, or any failure to report such non-compliance; and

e. the right of all employees, contractors, and/or agents to use the confidential disclosure program, as well as Medical Center's commitment to confidentiality and non-retaliation with respect to good faith disclosures.

Within one-hundred and twenty (120) days of the effective date of the Agreement, each employee, contractor, and/or agent shall certify, in writing, that he or she has received, read, is aware of the contents of, and will abide by Medical Center's Code of Conduct. New employees, contractors, and/or agents shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment, or contract, or

within ninety (90) days of the effective date of the Agreement, whichever is later.

Medical Center 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. Employees shall certify on an annual basis that they have received, read, are aware of the contents of and will abide by the Code of Conduct.

2. *Policies and Procedures*. Within ninety (90) days of the effective date of this Agreement, Medical Center shall develop and implement written Policies and Procedures regarding the operation of Medical Center's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidance by the agency in charge of administering the program and/or its agents.

The Policies and Procedures shall incorporate the following requirements:

a. The requirement that Medical Center staff follow proper billing procedures for inpatient hospital stays and outpatient services;

b. The requirement that all inpatient claims with a bill type of 111 IP(or any successors to this code) intended for submission to Medicare shall first be subject to pre-billing review to ensure that the claim is being submitted as an inpatient claim in accordance with Medicare statutes, regulations and written HCFA directives; and

c. The requirement that the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to Medical Center management through the Confidential Disclosure Program required by section III.F.

Medical Center shall assess and update as necessary the Policies and Procedures at least annually or more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the Agreement, the relevant portions of the Policies and Procedures shall be distributed to all appropriate employees, contractors, and/or agents. Compliance staff or supervisors should be available to explain any and all policies and procedures.

D. TRAINING AND EDUCATION

1. *General Training.* Within ninety (90) days of the effective date of this Agreement, Medical Center shall provide at least two (2) hours of training to each employee, contractor, and/or agent. This general training shall explain Medical Center's:

   a. Corporate Integrity Agreement requirements;

   b. Policies and Procedures as they pertain to general compliance issues; and

   c. Code of Conduct.

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

   New employees shall receive the general training described above within thirty (30) days of the beginning of their employment or within ninety (90) days after the effective date of this Agreement, whichever is later. Every employee, contractor, and/or agent shall receive two (2) hours of general training on an annual basis.

2. *Specific Training.* Within ninety (90) days of the effective date of this Agreement, each employee, contractor, and/or agent who is

involved directly or indirectly in the preparation or submission of claims for reimbursement for the delivery of patient care (including, but not limited to, coding and billing) for any Federal health care programs shall receive at least six (6) hours of training in addition to the general training required above. This training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;

b. policies, procedures and other requirements applicable to the documentation of medical records;

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings;

f. examples of proper and improper billing practices;

g. admission, continuing stay and discharge criteria; and

h. guidance on what the Federal health care programs, including Medicare and Medicaid, consider to be appropriate criteria for determining whether a hospital stay is inpatient or outpatient in nature.

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

Affected new employees shall receive this training within thirty (30) days of the beginning of their employment or within ninety (90) days of the effective date of this Agreement, whichever is later. If a new employee has any responsibility for the delivery of patient care, the preparation or

submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Medical Center employee who has completed the substantive training shall review for accuracy all of the untrained person's work regarding the preparation or submission of claims and/or the assignment of procedure codes and the assignment of billing codes.

Every affected employee shall receive refresher sessions lasting at least three (3) hours on this specific training each year for the duration of this Agreement. The substance of the training and the identity of the individuals must be documented in accordance with section 3 below.

3. *Certification.* Upon completion of each training session, each affected employee shall certify, in writing, that he or she has attended the required general and specific 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.

E. REVIEW PROCEDURES

Within ninety (90) days of the effective date of this Agreement, Medical Center shall establish its internal review group or retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist Medical Center in assessing the adequacy of its inpatient and outpatient billings under Code 111 IP (or any successors to this code) and its compliance practices pursuant to this Agreement. This shall be an annual requirement and shall cover a twelve (12) month period. The internal review group or Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Medical Center seeks reimbursement. Prior to each review and audit, Medical Center (or its designee) shall prepare and submit for review to OIG the work plan describing the protocols it proposes to follow in conducting the review and audit. The internal review group must be established and/or the Independent Review Organization must be

retained to conduct the audit of the first year within ninety (90) days of the effective date of this Agreement.

Two separate engagements will be required pursuant to this Agreement. One will be an analysis of Medical Center's billing to the Federal health care programs to assist Medical Center and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether Medical Center is in compliance with this Agreement ("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. Medical Center shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "http://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 Federal health care program beneficiary 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 engagement conclusions will be based, including a statement that they relied upon applicable legal or other standards, 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 Medical Center'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 Medical Center is submitting accurate claims for services billed to the Federal health care programs;

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

d. findings regarding Medical Center's submitted claims with a bill type of 111 IP (or any successors to this code) in order to determine whether the claim was properly reimbursable as an inpatient claim; and

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

Upon completion of an internal audit by the internal review group, if one is used, Medical Center shall have an Independent Review Organization

verify the methodology applied in the internal audit and the findings and conclusions of the internal reviewers. If OIG is not satisfied with the objectivity and effectiveness of the internal audits performed by Medical Center's internal review group, Medical Center agrees that it will contract with an Independent Review Organization, at its own expense, to review and audit on an annual basis, the billing policies, procedures and practices of Medical Center.

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

A complete copy of the billing and compliance engagements performed by the Independent Review Organization(s) shall be included in each of Medical Center'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 Medical Center is complying with its obligations under this Agreement, Medical Center agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

F. CONFIDENTIAL DISCLOSURE PROGRAM

Medical Center has represented to OIG that, pursuant to its Compliance Plan, it has created a Confidential Disclosure Program ("CDP"). Medical Center shall formally maintain its CDP for the term of this Agreement. At a minimum, Medical Center's CDP must include measures 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 Medical Center's policies, practices or procedures with respect to the Federal health care programs, believed by the individual to be inappropriate. Medical Center 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, Medical Center 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. A copy of this confidential disclosure log shall be submitted to the OIG in accordance with section V.B.8 of this Agreement.

G. DEALING WITH EXCLUDED OR CONVICTED PERSONS OR ENTITIES

Medical Center shall implement a written internal policy stating that it shall not knowingly employ or contract with, with or without pay, any individual or entity that is listed by a federal agency as excluded, suspended, or otherwise ineligible for participation in federal programs (hereinafter "Ineligible Person Policy"). Medical Center shall formally maintain this policy. At a minimum, Medical Center's Ineligible Person Policy shall include the following requirements:

1. Definition. For purposes of this Agreement, 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. Medical Center shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Medical Center shall screen all prospective employees, prospective contractors and physicians with staff privileges prior to engaging their services 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 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 ninety (90) days of the effective date of this Agreement, Medical Center will review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, Medical Center will review the list annually. If Medical Center has notice that an employee, agent, or physician with staff privileges has become an Ineligible Person, Medical Center will remove such person from responsibility for, or involvement with, Medical Center'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 Medical Center 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, Medical Center shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and will 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.

H. NOTIFICATION OF PROCEEDINGS

Within thirty (30) days of discovery, Medical Center 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 Medical Center or its affiliated companies, corporation, divisions, parents, and subsidiaries has or have committed a crime or has or have 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. Medical Center 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.

I. REPORTING

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money Medical Center has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions. Medical Center may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Medical Center identifies or learns of any billing, coding or other policies, procedures and/or practices that result in overpayments, Medical Center shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any 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 to the contractor should be done in accordance with the contractor policies, and for Medicare

contractors, can be done pursuant to a form similar to 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:

(a) a substantial overpayment relating to any Federal health care program; and

(b) a matter that a reasonable person would consider a violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized.

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

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

(a) 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 I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(i) the payor's name, address, and contact person to whom the overpayment was sent; and

(ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

(b) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and program authorities implicated;

(c) a description of Medical Center's actions to correct the Material Deficiency; and

(d) any further steps Medical Center plans to take to address such a Material Deficiency and prevent it from recurring.

IV. NEW LOCATIONS

In the event that Medical Center, its parents, subsidiaries or divisions purchase(s) or establish(es) new business units after the effective date of this Agreement, Medical Center 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 Medical Center number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each Medical Center number. At the OIG's discretion, all employees at such locations shall be subject to the requirements in this Agreement that apply to new employees (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. IMPLEMENTATION REPORT

Within one hundred and twenty (120) days after the effective date of this Agreement, Medical Center shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This Implementation Report shall include:

1. the name, address, phone number and position description of the Compliance Officer required by section III.B;

2. the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of Medical Center's Code of Conduct required by section

III.C.1;

4. a summary of the Policies and Procedures required by section III.C.2;

5. a description of the training programs required by section III.D 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.C.2 have been developed, are being implemented, and have been distributed to all pertinent employees;

   b. all employees have completed the Code of Conduct certification required by section III.C.1; and

   c. all employees have completed the training and executed the certification required by section III.D.

7. a description of the confidential disclosure program required by section III.F;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and

9. a summary of personnel actions taken pursuant to section III.E.

B. ANNUAL REPORTS

Medical Center shall submit to OIG an Annual Report with respect to the status and findings of Medical Center'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 sections III.A and III.B;

2. a certification by the Compliance Officer that:

   a. all employees have completed the annual Code of Conduct certification required by section III.C.1; and

   b. all employees have completed the training and executed the certification required by section III.D.

3. notification of any changes or amendments to the Policies and Procedures required by section III.C.2 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. Medical Center'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 sections III.E.3 and III.I;

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 Agreement. 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 summary of communications received from the confidential disclosure program required by section III.F;

9. a description of any personnel action (other than hiring) taken by Medical Center as a result of the obligations in section III.G;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Medical Center has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.H. 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; and

11. a corrective action plan to address the probable violations of law identified in section III.I.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this Agreement. 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) Medical Center is in compliance with all of the requirements of this Agreement, 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 Agreement, all notifications and reports required under this Agreement 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

MEDICAL CENTER AT PRINCETON:
S. Gilmore Stone
Corporate Compliance Officer
The Medical Center at Princeton
253 Witherspoon Street
Princeton, New Jersey 08540
Phone: 609.497.4109
Fax: 609.497.4977
Medicare Provider Number:

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, subject to a properly asserted legal privilege, Medical Center's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Medical Center's compliance with the terms of this Agreement; and (b) Medical Center's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Medical Center 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 Medical Center's employees 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 employee and OIG. Medical Center agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. Medical Center's employees may elect to be interviewed with or without a representative of Medical Center present.

VIII. DOCUMENT AND RECORD RETENTION

Medical Center or its successor shall maintain for inspection documents and records relating to reimbursement from the Federal health care programs for a period of six (6) years following the execution of this Agreement or one (1) year longer than the duration of this Agreement.

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Medical Center prior to any release by OIG of information submitted by Medical Center pursuant to its obligations under this Agreement and identified upon submission by Medical Center as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Medical Center 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

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

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, Medical Center and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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 Agreement and concluding at the end of the term of this Agreement, Medical Center 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 Medical Center 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 Medical Center:

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 Medical Center 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

b. employs, contracts or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Medical Center'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 Medical Center 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 that Medical Center fails to grant access) for each day Medical Center fails to grant access to the information or documentation as required in section V of this Agreement.

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

B. PAYMENT OF STIPULATED PENALTIES

1. *Demand Letter.* Upon a finding that Medical Center has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify Medical Center by personal service or certified mail of (a) Medical Center'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 business (15) days of the date of the Demand Letter, Medical Center 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 Medical Center elects to request an ALJ hearing, the Stipulated Penalties

shall continue to accrue until Medical Center 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 Agreement and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* Medical Center may submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. 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 Medical Center 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 five (5) business days after Medical Center 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 Medical Center has materially breached this Agreement, 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 AGREEMENT

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Medical Center constitutes an independent basis for Medical Center'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 Medical Center has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify Medical Center by certified mail of (a) Medical Center'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.* Medical Center 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. Medical Center is in full compliance with this Agreement;

   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) Medical Center has begun to take action to cure the material breach, (ii) Medical Center is pursuing such action with due diligence, and (iii) Medical Center 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, Medical Center fails to satisfy the requirements of section X.C.2, OIG may exclude Medical Center from participation in the Federal health care programs. OIG will notify Medical Center in writing of its determination to exclude Medical Center (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 Medical Center is excluded under the provisions of this Agreement, Medical Center may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

   a. a failure by Medical Center to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E;

   b. repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section X.A of this Agreement;

   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.E.

D. DISPUTE RESOLUTION

1. *Review Rights.* Upon the OIG's delivery to Medical Center 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 Agreement, Medical Center shall be afforded certain review rights as set forth 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 Agreement. 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 receipt 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 Agreement shall be (a) whether Medical Center was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. Medical Center 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 Agreement and orders Medical Center to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Medical Center 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 Agreement shall be: (a) whether Medical Center was in material breach of this Agreement; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach could not be cured within the 35 day period, but that (i) Medical Center began to take action to cure the material breach, (ii) Medical Center pursued such action with due diligence, and (iii) Medical Center 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. Medical Center's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Medical Center 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 Medical Center may request review of the ALJ decision by the DAB.

XI. EFFECTIVE AND BINDING AGREEMENT

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

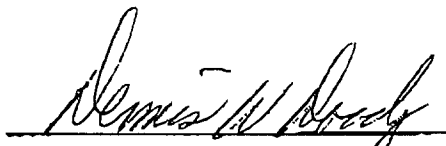
A. This Agreement shall be binding on the successors, assigns and transferees of Medical Center;

B. This Agreement shall become effective on the date the final signature is obtained on the Agreement;

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

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

ON BEHALF OF THE MEDICAL CENTER AT PRINCETON



DENNIS W. DOODY
President
The Medical Center at Princeton

1/30/00
DATE

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

1/14/00

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

DATE

EXHIBIT

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 checks is properly recorded and applied.

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

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

The Office of Inspector General ("OIG") of the Department of Health and Human Services and the Medical Center at Princeton ("Medical Center") entered into a Corporate Integrity Agreement ("CIA") on January 14, 2000.

A. Pursuant to Paragraph XI. C. of the CIA, modifications to the CIA may be made with the prior written consent of the parties to this Agreement. Therefore, the OIG and Medical Center hereby agree that Medical Center's CIA will be amended as follows:

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

The new Appendix A is hereby added to Medical Center's CIA.

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

C. Bruce Traub, Senior Vice – President/ Chief Financial Officer represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory, Lewis Morris, Chief Counsel to the Inspector General, 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 to this Amendment signs this Amendment.

ON BEHALF OF THE MEDICAL AT PRINCETON

Bruce Traub
Sr. Vice-President for Finance
Chief Financial Officer
Medical Center at Princeton

12/23/02
Date

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

Lewis Morris
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and
Human Services

2/4/03
Date

E . Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Medical Center at Princeton ("Medical Center") shall establish an internal review group or retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist the Medical Center in assessing and evaluating its billing and coding practices pursuant to this CIA and the Settlement Agreement. The internal review group or the IRO retained by Medical Center 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 Medical Center seeks reimbursement. Each internal review group or IRO shall assess, along with Medical Center, whether it can perform the review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The internal review or IRO(s) will conduct a Billing Engagement, consisting of a review of the Medical Center's billing and coding to the Federal health care programs ("Claims Review").

b. Frequency of Claims Review and Billing Engagement. The Claims Review element of the Billing Engagement shall be performed annually and shall cover each of the one-year (twelve months) periods of the CIA beginning with the effective date of this CIA. The internal review periods and/or the IRO(s) shall perform all components of each annual Claims Review.

c. Retention of Records. The IRO and Medical Center 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 Medical Center related to the engagements).

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, Medicaid or Federal health care program Paid Claims submitted by or on behalf of Medical Center. The Paid Claims shall be reviewed based on the supporting documentation available at Medical Center or under Medical Center's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

i. Results of Discovery Sample. **If the Error Rate (as defined in Appendix A) 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, Medical Center should, as appropriate, further analyze any errors identified in the Discovery Sample. Medical Center 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**, the internal review group or the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, the internal review group or 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 Medical Center or under Medical Center'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 the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the Medical Center 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 the Medical Center 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 the Medical Center's Discovery Sample identifies an Error Rate of 5% or greater**, the Medical Center's internal review group or IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the internal review group or 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 internal review group or IRO shall provide to the Medical Center, 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 **I. 1. b.** of the CIA, Medical Center 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. Medical Center 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. *Billing Engagement Report.* The IRO shall prepare a report based upon the Billing Engagement performed (the "Billing Engagement Report"). The Billing Engagement Report shall include:

a. a description of Medical Center'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).

5. *Validation Review.* In the event the OIG has reason to believe that: (a) the Medical Center's Billing Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or Billing Engagement results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complied with the requirements of the CIA and/or the findings or Billing Engagement results are inaccurate ("Validation Review"). The Medical Center 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 Medical Center's final submission is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify the Medical Center 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, the Medical Center may request a meeting with the OIG to discuss the results of any Billing Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Billing Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. The Medical Center 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 Billing Engagement and/or Claims Review issues with the Medical Center 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(s) to the Medical Center a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing Engagement and that it has concluded that it was, in fact, independent.

APPENDIX A

A. Billing Engagement's Claims Review.

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

1. a. Overpayment: The amount of money the Medical Center 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 the Medical Center and for which the Medical Center has received reimbursement from the Medicare program.

d. Population: All Items for which the Medical Center has submitted a code or line item and for which the Medical Center 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 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 Medical Center cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Medical Center 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. **Billing Engagement Report.** The following information shall be included in each Billing Engagement Report for the Claims Review(s) performed:

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. **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 description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Results**

For the Discovery Sample and Full Sample (if any), the following information shall be included in the Billing Engagement Report:

a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by the Medical Center ("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 Medical Center.

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 Billing Engagement 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 to this Appendix)

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

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 Unallowable Costs Review; and (2) performed the Claims Review and Unallowable Costs Review.