CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE CARRIER CLINIC AND CARRIER CLINICAL MEDICAL ASSOCIATION

I. PREAMBLE

The Carrier Clinic and Carrier Clinical Medical Association ("Carrier") hereby enter into this Corporate Integrity Agreement ("CIA" or "Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, physicians, contractors, agents, third parties engaged to bill/submit reimbursement claims, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, Carrier is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this Agreement, Carrier represents that it has implemented a Corporate Compliance Program ("Compliance Program") designed, in part, to educate its employees about the Federal health care program requirements and to assist its employees in identifying and correcting any actual or perceived violations of Carriers' Code of Ethics, policies and procedures and any applicable rules and regulations. Pursuant to this CIA, Carrier agrees to maintain the full operation of its Compliance Program as it relates to the submission of claims for professional services for the term of this CIA. The Compliance Program may be modified by Carrier as appropriate, but at a minimum, shall comply with the integrity obligations described in this Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Carrier under this CIA shall be 5 years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Carrier pursuant to OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

Pursuant to this CIA, and for its duration, Carrier will make the following integrity obligations features of its Compliance Program, which shall be established in accordance with the provisions below:

A. Compliance Officer and Committees.

1. *Compliance Officer*. Within 90 days after the effective date of this CIA, Carrier shall appoint an individual to serve as its 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 CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Carrier, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Trustees of Carrier, and shall be authorized to report on such matters to the Board of Trustees at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Carrier as well as for any reporting obligations created under this CIA.

Any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Board of Trustees Compliance Committee.* Prior to the execution of this CIA, Carrier has represented to OIG that its Board of Trustees ("BOT") has established a Compliance Committee whose function is to oversee Carrier's compliance activities on behalf of the BOT. Accordingly, Carrier hereby agrees to maintain the BOT Compliance Committee which will maintain and continue its compliance oversight duties on behalf of the BOT.

3. *Compliance Committee.* Within 90 days of the effective date of this CIA, Carrier shall appoint a Compliance Committee composed of its senior management ("Compliance Committee"). The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Code of Ethics.* Carrier has represented to the OIG that it has developed and distributed to all Covered Persons a Code of Ethics by which all Covered Persons are to abide. Carrier shall maintain its Code of Ethics and incorporate the minimum requirements set forth below (if necessary) for the duration of this Agreement and shall make the promotion of, and adherence to, the Code of Ethics an element in evaluating the performance of all Covered Persons.

New Covered Persons shall receive the Code of Ethics within 30 days of the commencement of their employment or relationship with Carrier. Within 120 days of the effective date of the CIA, Carrier shall obtain and maintain certification, in writing, that all Covered Persons have received, read, understood, and will abide by Carrier's Code of

Ethics. New Covered Persons shall complete the required certification within 30 days after receipt of the Code of Ethics or within 120 days of the effective date of the CIA, whichever is later. Carrier shall maintain a written summary of the actions taken to distribute the Code of Ethics to all Covered Persons and such summaries shall be produced to OIG upon request. For purposes of this CIA, OIG may request access to, or copies of any underlying documents summarized by Carrier. Carrier shall annually review the Code of Ethics to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Ethics shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Ethics within 30 days of the finalization of such revisions.

At all times, the Code of Ethics shall, at a minimum, set forth:

a. Carrier's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Carrier's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Carrier's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of Carrier's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by Carrier suspected violations of any Federal health care program requirements or of Carrier's own Policies and Procedures;

d. the possible consequences to both Carrier and Covered Persons of failure to comply with all Federal health care program requirements and with Carrier's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in section III.E, and Carrier's commitment to

maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 120 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Carrier's Code of Ethics. New Covered Persons shall receive the Code of Ethics and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days of the effective date of the CIA, whichever is later.

Carrier shall annually review the Code of Ethics to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Ethics shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Ethics within 30 days of the finalization of such revisions.

2. *Policies and Procedures*. Within 90 days of the effective date of this CIA, Carrier shall implement written Policies and Procedures regarding the operation of Carrier's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Ethics identified in section III.B.1; and

b. the Federal health care program documentation requirements for billing and submitting claims for payment, including, but not limited to, the requirement that all submissions be supported by accurate medical records, identifying bona fide reimbursable services that have actually been provided.

The Policies and Procedures shall be available to OIG, upon request.

Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), Carrier shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training*. Within 120 days of the effective date of this CIA, Carrier shall provide at least two hours of general training to each Covered Person. This training shall explain Carrier's:

a. CIA requirements; and

b. Compliance Program (including the Code of Ethics and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training*. Within 120 days of the effective date of this CIA, each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least 3 hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;

b. policies, procedures and other requirements applicable to the documentation of medical records, including, but not limited to, the

requirement that all claims submitted to the Federal health care programs be supported by accurate medical records;

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

d. applicable reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

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

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of this CIA, whichever is later. A Carrier employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least 3 hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form if Carrier utilizes computerized training, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Carrier shall 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 Carrier in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by Carrier shall have expertise in the billing, coding, reporting and other physician and mental health care provider requirements and in the general requirements of the Federal health care program(s) from which Carrier seeks reimbursement.

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address Carrier's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Carrier's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement").

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement except, subject to approval from OIG and subject to the conditions set forth in section III.D.5, after 2 annual Billing Engagement periods, Carrier may elect to conduct an internal billing review for Billing Engagement periods 3 through 5. The Compliance Engagement shall be performed by the IRO only for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and Carrier shall retain and make available to the OIG upon request all work papers, supporting

documentation, correspondence, and draft reports related to the engagements.

2. *Billing Engagement.* The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this CIA, which is incorporated by reference.

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Carrier to the Medicare program. The Claims review shall be limited to an analysis of the 10 most frequently billed Current Procedural Terminology ("CPT") codes that are submitted by Carrier to Medicare on an annual basis. To determine these codes, the IRO shall perform a utilization analysis whereby it evaluates the frequency and percentile levels of each CPT code in relation to Carrier's overall billing. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA and shall include all utilization analysis documentation used by the IRO to determine the 10 most frequently billed CPT codes.

c. Systems Review. The IRO shall review Carrier's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

i. Carrier's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and

ii. Carrier's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

i. the strengths and weaknesses in Carrier's billing systems and/or operations;

ii. the strengths and weaknesses in Carrier's coding systems and/or operations; and

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

3. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of Carrier's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Carrier's compliance with the obligations set forth in each section of this CIA, and a review of Carrier's compliance with certain provisions of the Settlement Agreement.

i. CIA Obligations Review. The IRO shall evaluate Carrier's compliance with the obligations set forth in each section of this CIA; and

ii. Unallowable Costs Review. The IRO shall determine whether Carrier has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement

Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Carrier or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year of the Settlement Agreement, as well as from previous years.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

i. the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Carrier's compliance with the terms of each section of the CIA, as applicable; and

ii. the IRO's findings and supporting rationale regarding whether Carrier has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

4. *Validation Review.* In the event OIG has reason to believe that: (a) Carrier's Billing or Compliance Engagement fails to conform to the requirements of this CIA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Carrier agrees to pay for the reasonable cost of any such

review performed by OIG or any of its designated agents so long as it is initiated before one year after the final report is submitted.

5. *Internal Billing Review Option.* Subject to approval from OIG and subject to the conditions set forth below, after the second complete Billing Engagement period in which the IRO has performed the Billing Engagement as required in section III.D.2, Carrier may, at its option, conduct an internal review of its billings to the Federal health care programs for Billing Engagement periods 3 through 5 in lieu of having the IRO conduct the Billing Engagement. This internal review shall be validated by an IRO and shall comply with all of the requirements outlined herein and in section III.D.2 above.

Prior to conducting its internal billing review, Carrier agrees: i) to develop and adopt a written formal internal audit workplan consistent with the terms of this CIA and in conjunction with the IRO; ii) to devote sufficient resources and staff to enable it to accomplish an internal billing review based on its internal workplan; and iii) that its internal billing review staff shall at all times include persons qualified and experienced in accepted auditing and control processes, who possess expertise in billing, coding and Medicare program requirements. In addition, Carrier agrees that its internal billing review staff shall not include persons who were involved in the submission of bills or claims to the Medicare programs during the period to be audited and shall not include persons who are presently involved in such submissions.

Consistent with the requirements of section III.D.2, the internal billing review shall include a Claims Review and Systems Review and the required respective reports of Carrier's findings. The internal billing review shall also include a report from an IRO that verifies that the requirements of section III.D.2 have been satisfied. As part of any such verification performed by an IRO under this CIA, the IRO shall conduct a review of at least 20% of the claims reviewed by Carrier in performing its internal review during Carrier's first internal review year and shall conduct a review of at least 10% of the claims reviewed by Carrier in each remaining year. If, in its sole discretion, OIG determines that such internal review satisfactorily establishes the adequacy of Carrier's billing and compliance practices pursuant to this CIA, OIG will allow Carrier to perform an internal review (with verification from the IRO) in lieu of the IRO conducting the Billing Engagement for the year following receipt of each satisfactory IRO verification report.

In the event Carrier is unable to satisfactorily implement an audit workplan, devote sufficient resources and appropriate qualified staff, or conduct a satisfactory internal review, Carrier agrees, at OIG's discretion, to engage the IRO to complete all remaining Billing Engagement requirements under this CIA. To the extent that OIG permits Carrier to perform internal billing reviews, Carrier must submit all the information required in section III.D.2 as well as the results of the IRO's verification. If Carrier decides not to exercise its internal review option, the requirements of the IRO Billing and Compliance Engagements shall remain in effect for the term of the CIA.

E. Confidential Disclosure Program.

Within 90 days after the effective date of this CIA, Carrier shall establish a Confidential Disclosure Program, which must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Carrier's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. Carrier shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information 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 communications. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. 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, Carrier 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 (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the

status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

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

3. *Review and Removal Requirement*. Within 90 days of the effective date of this CIA, Carrier shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Carrier shall review the list semi-annually. In addition, Carrier shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Carrier has notice that an employee or contractor has become an Ineligible Person, Carrier shall remove such person from responsibility for, or involvement with, Carrier'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 Carrier 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, the Carrier shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, Carrier 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 Carrier has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Carrier shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, Carrier identifies or learns of any overpayments, Carrier shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery 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.

Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

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

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

(iii) a description of Carrier's actions taken to correct the Material Deficiency; and

(iv) any further steps Carrier plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, Carrier changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Carrier shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare Carrier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare Carrier number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CIA, Carrier shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

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

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

3. a copy of Carrier's Code of Ethics required by section III.B.1;

4. the summary of the compliance Policies and Procedures required by section III.B.2 and those implemented after the execution of this CIA or those implemented in response to this CIA;

5. a description of the training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

   b. all Covered Persons have completed the Code of Ethics certification required by section III.B.1; and

   c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

The documentation supporting this certification shall be available to OIG, upon request.

7. a description of the Confidential Disclosure Program required by section III.E;

8. the identity of the IRO(s) and the proposed start and completion dates of the first annual review;

9. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

10. a list of all of Carrier's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Carrier identification number(s) and the contractor's name and address that issued each Carrier identification number;

11. to the extent not already furnished to OIG, or if modified, a description of Carrier's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

12. the certification required by section V.C.

B. Annual Reports. Carrier shall submit to OIG Annual Reports with respect to the status of and findings regarding Carrier's compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committees described in section III.A;

2. a certification by the Compliance Officer that:

a. All Covered Persons have completed any Code of Ethics certifications required by section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

c. Carrier has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the

Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

The documentation supporting this certification shall be available to OIG, upon request.

3. a summary of any significant 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 description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter and complete copies of all equivalent reports prepared in response to Carrier's internal audits and internal billing engagements;

6. Carrier's response and corrective action plan(s) related to any issues raised by the IRO(s) or any internal audits, as applicable;

7. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

9. a summary of the disclosures in the confidential disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by Carrier as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

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

12. a description of all changes to the most recently provided list (as updated) of Carrier's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program Carrier identification number(s), and the contractor name and address that issued each Carrier identification number; and

13. the certification required by section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, Carrier 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 the information is accurate and truthful.

D. Designation of Information: Carrier shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Carrier shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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

Carrier:

Trish Toole
Compliance Officer
Route 601
Belle Mead, NJ 08502
Phone 908.281.1563
Fax 908.281.1680

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

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 or request copies of Carrier's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Carrier's locations for the purpose of verifying and evaluating: (a) Carrier's compliance with the terms of this CIA; and (b) Carrier's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Carrier 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 Carrier's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Carrier agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Carrier's employees may elect to be interviewed with or without a representative of Carrier present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Carrier prior to any release by OIG of information submitted by Carrier pursuant to its obligations under this CIA and identified upon submission by Carrier as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Carrier shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Carrier and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Carrier fails to have in place any of the following:

a. a Compliance Officer as described by section III.A.1;

b. Compliance Committees as described by section III.A.2 and III.A.3;

c. a written Code of Ethics as described by section III.B.1;

d. written Policies and Procedures as described by section III.B.2;

e. a requirement that Covered Persons be trained as described in section III.C; and

f. a Confidential Disclosure Program as described in section III.E.

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 Carrier fails to retain an IRO, as required in section III.D.

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Carrier fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Carrier employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Carrier's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are

paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Carrier 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).

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

6. A Stipulated Penalty of $1,000 for each day Carrier fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. In its notice to Carrier, OIG shall state the specific grounds for its determination that Carrier has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Carrier must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Carrier of the failure to comply.)

B. Timely Written Requests for Extensions. Carrier may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Carrier fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Carrier receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five 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.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that Carrier has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Carrier of: (a) Carrier'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").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Carrier shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Carrier elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Carrier cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by 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 set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Carrier has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

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

a. a failure by Carrier to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.H;

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Carrier constitutes an independent basis for Carrier's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Carrier has materially breached this CIA and that exclusion should be imposed, OIG shall notify Carrier of: (a) Carrier'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").

3. *Opportunity to Cure*. Carrier shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Carrier 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 30-day period, but that: (i) Carrier has begun to take action to cure the material breach; (ii) Carrier is pursuing such action with due diligence; and (iii) Carrier has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, Carrier fails to satisfy the requirements of section X.D.3, OIG may exclude Carrier from participation in the Federal health care programs. OIG will notify Carrier in writing of its determination to exclude Carrier (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Carrier wishes to apply for reinstatement, Carrier must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Carrier of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Carrier shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an 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 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt 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 Carrier was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Carrier shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Carrier to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Carrier requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or 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 Carrier was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) Carrier had begun to take action to cure the material breach within that period;

(ii) Carrier has pursued and is pursuing such action with due diligence; and

(iii) Carrier provided to OIG within that period a reasonable timetable for curing the material breach and Carrier has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the Carrier, only after a DAB decision in favor of OIG. Carrier's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Carrier upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Carrier may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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 Carrier 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 CARRIER

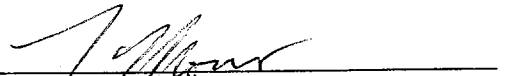
C. RICHARD SARLE
President and CEO
Carrier Clinic and Carrier Clinical
Medical Association

11/28/00
DATE

PETER HARVEY, Esq.
Riker, Danzig, Scherer, Hyland & Perretti, LLP
Counsel for Carrier Clinic and Carrier Clinical
Medical Association

11/29/00
DATE

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



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

11/21/00
DATE

APPENDIX A

A. Claims Review.

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

a. Claims Review Sample: A statistically valid, randomly selected, sample items selected for appraisal in the Claims Review.

b. Item: Any CPT code reimbursed by the Medicare program.

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Carrier has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Carrier shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A CPT code submitted by Carrier and for which Carrier has received reimbursement from the Medicare program.

e. Population: All of the 10 most frequently billed Items for which Carrier has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. The Population may vary from year to year because the 10 most frequently billed Items may change. To be included in the Population, an Item must have resulted in at least one Paid Claim.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Confidence and Precision Requirements. The Claims Review Sample must contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Carrier for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall

be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Carrier for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items*. The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Carrier for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

d. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

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

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

B. Claims Review Report. The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any CPT code reimbursed by the Medicare program.

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have 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. Sources 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, HCFA 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.

g. Utilization Analysis: A description of the materials relied upon to determine the 10 most frequently billed CPT codes, including identification of the frequency and percentage of all codes reimbursed by the Medicare program.

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

d. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.

e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by Carrier ("Claim 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 Carrier.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to Carrier, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. 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 Appendix B attached hereto)

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

APPENDIX B

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt