

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

I. PREAMBLE

Northeast Georgia Medical Center, Inc. (“NGMC”) hereby enters into this Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance by its officers, directors, employees, physicians and subsidiaries; contractors agents or other 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”)¹ 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, NGMC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. For purposes of establishing compliance with this CIA, NGMC is deemed to include the recently-acquired Lanier Park Hospital facility.

NGMC represents and warrants that as of September 30, 2000 it has divested itself of any and all business operations and/or entities providing home health care services.² During the term of this CIA, NGMC shall notify the OIG in advance of any decision by NGMC to provide home health care services under the Federal health care programs through any entity owned and/or operated by NGMC, and prior to engaging in such

¹ Notwithstanding the above, this term does not include part-time or per diem employees who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point that they work more than 160 hours during any 12-month period.

² For purposes of this CIA, NGMC’s Hospice Program is not considered a provider of home health care services.

services agree to modify its CIA under terms and conditions agreeable to the OIG to specifically address compliance regarding the provision of home health care services.

II. TERM OF THE CIA

The period of the compliance obligations assumed by NGMC 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 NGMC pursuant to OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

NGMC warrants and represents that it currently operates and maintains a compliance program ("Program"). Pursuant to and for the duration of this CIA, NGMC shall maintain its current Program, and, as required below, amend the Program to adhere to or include the following obligations or elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* For the duration of this CIA, NGMC shall continue to maintain an individual to serve as its Compliance Officer, consistent with the following requirements. 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 NGMC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of NGMC, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by NGMC 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. *Compliance Committee.* For the duration of this CIA, NGMC shall continue to maintain its Compliance Committee, and to the extent necessary, shall amend the Program within 90 days of the effective date of this CIA to ensure that the Compliance Committee meets the following requirements. 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 Conduct.* NGMC shall continue to maintain its Code of Conduct and amend it to meet the following requirements. After it has been amended, the Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. NGMC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. NGMC'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. NGMC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with NGMC's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);
- c. the requirement that all of NGMC's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by the NGMC suspected violations of any Federal health

care program requirements or of NGMC's own Policies and Procedures;

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

e. the right of all individuals to use the Disclosure Program described in section III.E, and NGMC'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 NGMC's Code of Conduct. New Covered Persons shall receive the Code of Conduct 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.

NGMC shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct 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 Conduct within 45 days of the distribution of such revisions.

2. Policies and Procedures. For the duration of this CIA, NGMC shall continue to maintain written Policies and Procedures regarding the operation of NGMC's compliance program and its compliance with Federal health care program requirements. To the extent necessary, NGMC shall amend its Policies and Procedures within 90 days of the effective date of this CIA, to ensure that the Policies and Procedures address the subjects relating to the Code of Conduct identified in section III.B.1;

Within 90 days of the effective date of the CIA, the relevant amended 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), NGMC 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, NGMC shall provide at least two hours of general training to each Covered Person. This training, at a minimum, shall explain NGMC's:

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

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. Notwithstanding this provision, any Covered Person who has received training on the Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues) within 6 months of the effective date of this CIA, shall be deemed to have met the initial training described above as it pertains to the Compliance Program. Such Covered Persons will, however, be required to receive training on the CIA requirements. 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 for which NGMC claims reimbursement from any Federal health care program 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 4 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;
- 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.

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 NGMC 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, 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.

4. *Non-employed Staff Physician Training.* Notwithstanding that "physicians" is included in the definition of Covered Person for all other provisions in this CIA, non-employed staff physicians shall not be considered Covered Persons for purposes of this Training and Education paragraph. With respect to non-employed staff physicians, NGMC shall make each of the types of training described above (i.e., general and specific) available to such non-employed staff physicians but attendance shall not be mandatory for such physicians. NGMC shall notify such physicians of the training and

encourage them to attend. NGMC shall keep records reflecting which physicians attend compliance training and shall include in its annual report the percentage of physicians who attended compliance training during the reporting period.

D. Review Procedures.

1. *General Description.*

a. **Retention of Independent Review Organization.** Within 90 days of the effective date of this CIA, NGMC 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 NGMC in assessing and evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by NGMC 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 NGMC seeks reimbursement. Each IRO shall assess, along with NGMC, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

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

c. **Frequency of Billing and Compliance Engagements.** Except as set forth in section III.D.2.e below, the Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA (“review period”). The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by

the IRO for the first one-year period beginning with the effective date of this CIA.

d. **Retention of Records.** The IRO and NGMC 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 NGMC) 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 NGMC to the Medicare program. Each annual Claims Review shall focus on 5 DRG codes that will be selected by the OIG. Prior to performing the Claims Review, and no later than 90 days prior to the end of the review period, the IRO shall submit to the OIG a list of NGMC’s 30 most frequently billed DRG codes, the number of times each individual DRG code was billed to the Federal health care programs, and the dollar amount associated with each DRG code to date for that review period. The OIG will select from this list 5 DRG codes to be reviewed by the IRO. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA. The process described above for the selection of 5 DRG codes for review shall be repeated for each annual Claims Review.

b. **Claims Review Report.** The IRO shall prepare a report based upon each Claims Review or Verification Review (as further described below) performed (“Claims Review or Verification Review Report”). The Claims Review or Verification Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

c. **Systems Review.** The IRO shall review NGMC’s billing and coding systems and/or operations and cost report preparation process

(the “Systems Review”). The Systems Review shall consist of a thorough review of the following:

i. NGMC’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);

ii. NGMC’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); and

iii. NGMC’s cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps NGMC takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

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 NGMC’s billing systems and/or operations;

ii. the strengths and weaknesses in NGMC’s coding systems and/or operations;

iii. the strengths and weaknesses in NGMC’s cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs; and

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

e. Implementation of Internal Auditing Procedures.

Notwithstanding the provisions of the Billing Engagement paragraph, the OIG may at its sole discretion, upon written request from NGMC, waive the above described IRO Billing Engagement requirements for years two, three and four of this CIA and allow NGMC to internally perform the annual Claims and Systems Reviews for those years, provided that NGMC:

i. establishes an internal auditing mechanism capable of undertaking the above-described Claims and Systems Reviews;

ii. initiates said written request within 18 months from the effective date of this CIA;

iii. provides the OIG such information as is necessary to establish the internal auditing mechanism's independence and expertise in the billing, coding, reporting, auditing procedures 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 NGMC seeks reimbursement; and

iv. performs such internal audits in accordance with the requirements set forth in this Section III.D. (e.g., Claims Review in accordance with Appendix A).

f. Verification Review. In the event that the OIG allows NGMC to perform internal audits for purposes of satisfying the Annual Review requirement, the IRO shall perform a Verification Review of NGMC's internal audit, which shall include a 10% review of the claims subject to the NGMC internal audit. Based upon, but not limited to, the results of the first Verification Review, the OIG may, at its sole discretion, reduce or dismiss NGMC's obligation to retain

an IRO to perform a Verification Review for years three and/or four of this CIA.

3. Compliance Engagement.

a. **Compliance Review.** The IRO shall conduct a review of NGMC's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of NGMC's adherence to the obligations set forth in sections I through VIII of this CIA, and a review of NGMC's compliance with certain provisions of the Settlement Agreement

i. **CIA Obligations Review.** The IRO shall assess and evaluate NGMC's compliance with the obligations set forth in sections I through VIII of this CIA.

ii. **Unallowable Costs Review.** The IRO shall determine whether NGMC 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 (limited to unallowable costs as defined in the Settlement Agreement) shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by NGMC 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 in which of the Settlement Agreement was executed, 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 NGMC’s compliance with the terms of sections I through VIII of the CIA, as applicable; and

ii. the IRO’s findings and supporting rationale regarding whether NGMC 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 the OIG has reason to believe that:

(a) NGMC's Billing or Compliance Engagement or Internal Audit fails to conform to the requirements of this CIA; or (b) the findings or Claims Review or Internal Audit results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagements or Internal Audit comply with the requirements of the CIA and/or the findings or Claims Review or Internal Audit results are inaccurate. NGMC 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 NGMC’s final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify NGMC of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, NGMC may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review or Internal Audit findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review or Internal Audit; and/or propose alternatives to the proposed Validation Review. NGMC 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 or Compliance Engagement and/or Claims Review or Internal Audit issues with NGMC 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.

5. *Independence Certification.* Within 150 days from the effective date of this CIA, the IRO shall provide to NGMC a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in NGMC's Implementation Report submission.

E. Disclosure Program.

NGMC shall continue to maintain its Disclosure Program, and to the extent necessary, shall amend the Disclosure Program within 90 days after the effective date of this CIA to ensure that the Disclosure Program meets the following requirements. The Disclosure Program 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 NGMC's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. NGMC shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a 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, NGMC 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 disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action

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

3. *Review and Removal Requirement.* Within 120 days of the effective date of this CIA, NGMC shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, NGMC shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists annually. In addition, NGMC shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If NGMC has notice that an employee or contractor, or physician with staff privileges has become an Ineligible Person, NGMC shall remove such person from responsibility for, or involvement with, NGMC’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 NGMC 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 NGMC 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, NGMC 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 NGMC 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. NGMC 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 NGMC has received in excess of the amount due and payable under any Federal health care program requirements. NGMC may not subtract any underpayments for purposes of determining the amount of relevant “overpayments” for CIA reports.

b. Reporting of Overpayments. If, at any time, NGMC identifies or learns of any overpayments, NGMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, NGMC shall repay the overpayment to the appropriate payor to the extent such

overpayment has been quantified. If not yet quantified, within 30 days of identification, NGMC shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. 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 NGMC determines through any means that there is a Material Deficiency, NGMC 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 NGMC's actions taken to correct the Material Deficiency; and

(iv) any further steps NGMC 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, NGMC 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, NGMC 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 provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider 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 150 days after the effective date of this CIA, NGMC 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, position description, and summary of other non-compliance job responsibilities of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of NGMC's Code of Conduct required by section III.B.1;
4. a copy of all compliance-related Policies and Procedures required by section III.B.2;
5. a copy of all training materials used for the training required by section III.C, a description of such training, 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 Conduct 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 Disclosure Program required by section III.E;
8. the identity of the IRO(s), a summary/description of all engagements between NGMC and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
9. a certification from the IRO regarding its professional independence from the NGMC;
10. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

11. a list of all of NGMC'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 provider identification number(s) and the contractor's name and address that issued each provider identification number;

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

13. the certification required by section V.C.

B. Annual Reports. NGMC shall submit to OIG Annual Reports with respect to the status of, and findings regarding, NGMC'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, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct 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. NGMC 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) and copies of any compliance-related Policies and Procedures;
4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training 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;
6. NGMC's response and corrective action plan(s) related to any issues raised by the IRO(s);
7. a revised summary/description of all engagements between NGMC and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
8. 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;
9. 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;

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

11. a description of any personnel actions (other than hiring) taken by NGMC 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;

12. 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;

13. a description of all changes to the most recently provided list (as updated) of NGMC'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 provider identification number(s), and the contractor name and address that issued each provider identification number; and

14. the certification required by section V.C.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, NGMC 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: NGMC shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure

under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552. NGMC 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

NGMC:

Anthony M. Herdner
Northeast Georgia Medical Center
743 Spring St.

Gainesville, GA 30501
Phone 770.538.7246
Fax 770.535.3566

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

VIII. DOCUMENT AND RECORD RETENTION

NGMC 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 NGMC prior to any release by OIG of information submitted by NGMC pursuant to its obligations under this CIA and identified

upon submission by NGMC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, NGMC shall have the rights set forth at 45 C.F.R. § 5.65(d). NGMC shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

NGMC 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, NGMC 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 NGMC fails to have in place any of the obligations described in section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a 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 NGMC 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 NGMC 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 NGMC employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, NGMC'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 NGMC 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 NGMC 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 NGMC fails to grant access.)

6. A Stipulated Penalty of \$1,000 for each day NGMC fails to comply fully and adequately with any obligation of this CIA. In its notice to NGMC, OIG shall state the specific grounds for its determination that NGMC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the NGMC must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to NGMC of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

B. Timely Written Requests for Extensions. NGMC 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 NGMC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after NGMC 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 NGMC 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 NGMC of: (a) NGMC'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, NGMC 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 NGMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until NGMC 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 NGMC 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 NGMC 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 NGMC constitutes an independent basis for NGMC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that NGMC has materially breached this CIA and that exclusion should be imposed, OIG shall notify NGMC of: (a) NGMC'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.* NGMC 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. NGMC is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, NGMC fails to satisfy the requirements of section X.D.3, OIG may exclude NGMC from participation in the Federal health care programs. OIG will notify NGMC in writing of its determination to exclude NGMC (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, NGMC wishes to apply for reinstatement, NGMC

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 NGMC 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, NGMC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days 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 NGMC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. NGMC 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 NGMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless NGMC 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 NGMC 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) NGMC had begun to take action to cure the material breach within that period;

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

(iii) NGMC provided to OIG within that period a reasonable timetable for curing the material breach and NGMC 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 NGMC, only after a DAB decision in favor of OIG. NGMC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude NGMC 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 NGMC 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. NGMC agrees to waive its/his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

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

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, NGMC and OIG agree as follows:

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

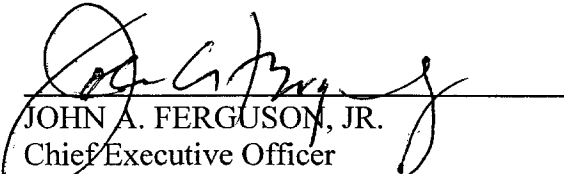
B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

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

D. OIG may agree to a suspension of NGMC's obligations under the CIA in the event of NGMC's cessation of participation in Federal health care programs. If NGMC withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, NGMC agrees to notify OIG 30 days in advance of NGMC's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

E. The undersigned NGMC 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 NORTHEAST GEORGIA MEDICAL CENTER, INC.



JOHN A. FERGUSON, JR.
Chief Executive Officer
Northeast Georgia Medical Center, Inc.

5/3/01

DATE

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



LEWIS MORRIS

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

5/2/09
DATE

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

The Office of Inspector General (“OIG”) of the Department of Health and Human Services and Northeast Georgia Medical Center (“NGMC”) entered into a Corporate Integrity Agreement (“CIA”) on May 4, 2001.


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

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

Appendix A of NGMC’s CIA is hereby superceded by the attached new Appendix A.

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

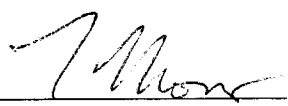
ON BEHALF OF NORTHEAST GEORGIA MEDICAL CENTER, INC.



JOHN A. FERGUSON, JR.
Chief Executive Officer
Northeast Georgia Medical Center, Inc.

2/25/02
DATE

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



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

2/12/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, NGMC shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist NGMC in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by NGMC 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 NGMC seeks reimbursement. Each IRO shall assess, along with NGMC, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze NGMC's billing and coding to the Federal health care programs ("Claims Review"), shall analyze whether NGMC sought payment for certain unallowable costs ("Unallowable Cost Review"), and shall analyze NGMC's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

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

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

e. Retention of Records. The IRO and NGMC 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 NGMC) related to the reviews.

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The Claims Review shall be performed in accordance with the procedures set forth below (hereinafter referred to as the "agreed-upon procedures"). The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Claim Selection. Each annual Claims Review shall focus on 5 DRG codes that will be selected by the OIG. Prior to performing the Claims Review, and no later than 90 days prior to the end of the review period, the IRO shall submit to the OIG a list of NGMC's 30 most frequently billed DRG codes, the number of times each individual DRG code was billed to the Federal health care programs, and the dollar amount associated with each DRG code to date for that review period. The OIG will select from this list 5 DRG codes to be reviewed by the IRO ("Identified DRGs").

b. Discovery Sample. From the universe of all Paid Claims grouped to an Identified DRG, the IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of NGMC. The Paid Claims shall be reviewed based on the supporting documentation available at NGMC or under NGMC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, NGMC should, as appropriate, further analyze any errors identified in the Discovery Sample. NGMC 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 IRO shall perform a Full Sample and a Systems Review, as described below.

c. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.b, the IRO shall perform an additional sample of Paid Claims assigned an Identified DRG with one of the 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 NGMC or under NGMC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, NGMC 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 NGMC 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.

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

e. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, NGMC 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. NGMC agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

f. Internal Audit Procedures. Notwithstanding the provisions of Section III.D.2, the OIG may at its sole discretion, upon written request from NGMC, waive the above described IRO Claims Review requirements for years two, three, and four of this CIA and allow NGMC to internally perform the annual Claims and Systems Reviews for those years, provided that NGMC:

i. establishes an internal auditing mechanism capable of undertaking the above-described Claims and Systems Reviews;

ii. initiates said written request within 18 months from the effective date of this CIA;

iii. provides the OIG such information as is necessary to establish the internal auditing mechanism' independence and expertise in the billing, coding, reporting, auditing procedures and other requirements of the particular section of the healthcare industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which NGMC seeks reimbursement; and

iv. performs such internal audits in accordance with the agreed-upon procedures set forth in Section III.D.2 and Appendix A of this CIA.

f. Verification Review. In the event that the OIG allows NGMC to perform internal audits for purposes of satisfying the Annual Review requirement, the IRO shall perform a Verification Review of NGMC's internal audit, which shall include a 10% review of the claims subject to the NGMC internal audit. Based upon, but not limited to, the results of the first Verification Review, the OIG may, at its sole discretion, reduce or dismiss NGMC's obligation to retain an IRO to perform a Verification Review for years three and/or four of this CIA.

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

4. *Unallowable Cost Review.* The IRO shall conduct a review of NGMC's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether NGMC has complied with its obligations 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 (limited to unallowable costs as defined in the Settlement Agreement) shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by NGMC or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO will determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether NGMC 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.

6. *Compliance Review.* The IRO shall conduct a review of NGMC's compliance activities. The Compliance Review shall consist of a review of NGMC's compliance with the terms of Sections I through VIII of the CIA, as applicable.

7. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding NGMC's compliance with the terms of Sections I through VIII of the CIA, as applicable.

8. *Validation Review.* In the event the OIG has reason to believe that: (a) NGMC's Claims Review (whether conducted by an IRO or NGMC's internal audit staff), Systems Review, Internal Audit, Unallowable Cost Review, or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's (or NGMC's internal audit, if applicable) findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). NGMC 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 NGMC's final submission (as described in section II) and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify NGMC 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, NGMC may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review, or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. NGMC agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review or Compliance Review issues with NGMC 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.

9. *Independence Certification.* Within 150 days from the effective date of this CIA, the IRO shall provide to NGMC a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, Unallowable Cost Review, or Compliance Review and that it has concluded that it is, in fact, independent. Such certification shall be included in NGMC's Implementation Report submission.

APPENDIX A

A. Claims Review.

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

- a. **Overpayment:** The amount of money NGMC 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 NGMC and for which NGMC has received reimbursement from the Medicare program. Each Paid Claim that will be reviewed as part of the Claims Review described in Section III.D.2 of this CIA must have been billed under one of the 5 Identified DRG codes as defined in Section III.D.2.a of this CIA.
- d. **Population:** All Items for which NGMC has submitted a code or line item and for which NGMC has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. **Error Rate:** The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

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

2. Other Requirements.

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

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

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

1. Claims Review Methodology.

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. Statistical Sampling Documentation.

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

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

3. Claims Review Findings.

a. Narrative Results.

i. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by NGMC ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to NGMC.
- iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- iv. Error Rate in the sample.
- v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

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