

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES
AND
LEWIS-GALE CLINIC, LLC

I. PREAMBLE

Lewis-Gale Clinic, LLC 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”). This CIA is designed to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the “Federal health care programs.”). This CIA applies to Lewis-Gale Clinic, LLC and each of its affiliates, subsidiaries and/or any entity that it owns or operates (hereinafter collectively “LGC”), as well as each of its physicians, employees, other health care professionals, and any third parties with whom LGC may choose to engage as billing or coding agents or consultants. LGC’s compliance with the terms and conditions in this CIA shall constitute an element of LGC’s present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, LGC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by LGC under this CIA shall be five (5) years from the effective date of this CIA. The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the “effective date”).

III. CORPORATE INTEGRITY OBLIGATIONS

LGC shall establish a compliance program that includes the following elements:

A. Compliance Officer. Within ninety (90) days after the effective date of this CIA, LGC shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the

requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of LGC, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of LGC and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by LGC to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, LGC shall notify the OIG, in writing, within fifteen (15) days of such a change.

LGC shall also appoint a Compliance Committee within ninety (90) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within LGC's corporate structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

1. Code of Conduct. Within ninety (90) days of the effective date of this CIA, LGC shall establish a Code of Conduct. The Code of Conduct shall be distributed to all officers, directors, employees, and agents (hereinafter referred to collectively as the "Covered Individuals") within ninety (90) days of the effective date of this CIA. LGC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other Covered Individuals. The Code of Conduct shall, at a minimum, set forth:

a. LGC's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

b. LGC's requirement that all of its Covered Individuals shall be expected to comply with all statutes, regulations, and guidelines

applicable to Federal health care programs and with LGC's own policies and procedures (including the requirements of this CIA);

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

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

e. the right of all Covered Individuals to use the confidential disclosure program, as well as LGC's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, each Covered Individual shall certify, in writing, that he or she has received, read, understands, and will abide by LGC's Code of Conduct. New Covered Individuals shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or agency or within ninety (90) days of the effective date of the CIA, whichever is later.

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

2. Policies and Procedures. Within ninety (90) days of the effective date of this CIA, LGC shall develop and initiate implementation of written Policies and Procedures regarding the operation of its compliance program and its compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. The Policies and Procedures shall, at a minimum, also specifically address the following:

a. That any claims submitted to the Federal health care programs are accurate and correctly identify the services rendered;

- b. The proper documentation of services and billing information and the retention of such information in a readily retrievable form; and
- c. The commitment of LGC to adhere to honest and accurate billing practices.

In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to LGC's management through the Confidential Disclosure Program required by section III.E. LGC shall assess and update as necessary the Policies and Procedures at least annually, and more frequently as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report addressed below. The Policies and Procedures will be made available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all Covered Individuals. Compliance staff or supervisors should be available to explain any and all of these Policies and Procedures.

C. Training and Education.

1. General Training. Within ninety (90) days of the effective date of this CIA, LGC shall provide at least two (2) hours of training to each Covered Individual. This general training shall explain LGC's:

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

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

New Covered Individuals shall receive the general training described above within thirty (30) days of the beginning of their employment or agency or within ninety (90) days after the effective date of this CIA, whichever is later. Every Covered Individual shall receive such general training on an annual basis.

2. Specific Training. Within ninety (90) days of the effective date of this CIA, each Covered Individual who is involved directly or indirectly in the delivery of

patient care and/or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care program shall receive at least four (4) hours of training in addition to the general training required above. This training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement rules and statutes;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

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

Affected new Covered Individuals shall receive this training within thirty (30) days of the beginning of their employment or agency or within ninety (90) days of the effective date of this CIA, whichever is later. If a new Covered Individual has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, an LGC Covered Individual who has completed the substantive training shall review all of the untrained person's work regarding the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes.

Each Covered Individual shall receive such specific training on an annual basis.

3. Certification. Each Covered Individual shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG, upon request.

D. Review Procedures. LGC shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization”), to perform review procedures to assist LGC in assessing the adequacy of its billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which LGC seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within one hundred and twenty (120) days of the effective date of this CIA.

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

1. Billing Engagement. The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims submitted to the Federal health care programs for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety percent (90%) confidence level and a precision of twenty-five percent (25%). The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. LGC shall use OIG’s Office of Audit Services Statistical Sampling Software, also known as “RAT-STATS,” which is available through the Internet “www.hhs.gov/oas/ratstat.html”.

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

- a. Billing Engagement Objective: A clear statement of the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective;
- b. Billing Engagement Population: Identify the population, which is the group about which information is needed. Explain the methodology used to develop the population and provide the basis for this determination;

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

The billing engagement shall provide:

- a. findings regarding LGC's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, and the effectiveness of the system);
- b. findings regarding whether LGC is submitting accurate claims for services billed to the Federal health care programs;
- c. findings regarding LGC's procedures to correct inaccurate billings or codings to the Federal health care programs;
- d. findings regarding LGC's procedures to submit accurate billings for the services of non-physician health care personnel submitted incident to a physician's services; and
- e. findings regarding the steps LGC is taking to bring its operations into compliance or to correct problems identified by the audit.

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

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

3. Verification/Validation. In the event that OIG has reason to believe that LGC's billing engagement, internal billing review (as described below), or compliance engagement fails to conform to its obligations under this CIA or indicates improper billing not otherwise adequately addressed in any audit report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which LGC is complying with its obligations under this CIA, LGC agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

4. Internal Billing Review Option. LGC may, at its option, conduct an internal review of its billings to the Federal health care programs, which review shall comply with all of the requirements outlined in section III.D.1 above and submit such review to OIG within eight (8) months from the effective date of this CIA. The internal billing review shall also include a report from an Independent Review Organization that verifies that the requirements of section III.D.1 have been satisfied. As part of any such verification performed by an Independent Review Organization under this CIA, the Independent Review Organization shall conduct a review of at least 10% of the claims reviewed by LGC in performing its internal review. If, in its sole discretion, OIG determines that such internal review satisfactorily establishes the adequacy of LGC's billing and compliance practices pursuant to this CIA, OIG may allow LGC to perform a second internal review (with verification from the Independent Review Organization) covering the second six months of the first year in conformance with section III.D.1 in lieu of the Independent Review Organization conducting the billing engagement for the entire twelve-month period. Similarly, OIG may, in its sole discretion, allow LGC to continue to perform the internal billing review (with verification by the Independent Review Organization) in conformance with section III.D.1 for years two through five of this CIA in lieu of the Independent Review Organization conducting the billing engagement for those years. To the extent that OIG permits LGC to perform internal billing reviews, then LGC must submit all the information required in section III.D.1 as well as the results of the Independent Review Organization's verification.

E. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, LGC shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with LGC's policies, practices or procedures with respect to the Federal health care programs, believed by the individual to be inappropriate. LGC shall publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

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

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

F. Ineligible Persons.

1. Definition. For the purposes of this CIA, an “Ineligible Person” shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. Screening Requirements. LGC shall not hire as an employee or engage as a contractor any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, LGC shall screen all prospective employees and prospective contractors prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://www.arnet.gov/epls>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.dhhs.gov/oig>) (these lists and reports will hereinafter be referred to as the “Exclusion Lists”).

3. Review and Removal Requirement. Within ninety (90) days of the effective date of this CIA, LGC will review its list of current employees and contractors against the Exclusion Lists. Thereafter, LGC will review the list at least once semi-annually. If LGC has notice that an employee, agent, or physician has become an Ineligible Person, LGC will remove such person from responsibility for, or involvement

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

H. Reporting.

1. Reporting of Overpayments. If, at any time, LGC identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, LGC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within thirty (30) days of discovering the overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. If the overpayment is discovered as the result of any of the activities required by this CIA, the notice to the payor shall include:

- a. a statement that the refund is being made pursuant to this CIA;
- b. a description of the complete circumstances surrounding the overpayment;

- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- f. the provider identification number under which the repayment is being made; and
- g. any applicable Overpayment Refund Form provided and required by the payor.

2. Reporting of Material Deficiencies. If LGC determines that there is a material deficiency, LGC shall notify OIG within thirty (30) days of discovering the material deficiency. If the material deficiency results in an overpayment, the report to OIG shall be made at the same time as the report to the payor and shall include all of the information required by section III.H.1 plus: (i) the payor's name, address, and contact person where the overpayment was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the material deficiency resulted in an overpayment, the report to the OIG shall include:

- a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
- b. LGC's actions to correct the material deficiency; and
- c. any further steps LGC plans to take to address such material deficiency and prevent it from recurring.

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

4. Definition of "Material Deficiency". For the purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment relating to any Federal health care program; (ii) a probable violation of any Federal health care program statute, regulation, or directive issued by relevant regulatory agencies (e.g., HCFA) or their agents (for example, such a violation would be established by evidence of

misconduct from any source that LGC, after reasonable inquiry, has reason to believe may violate criminal, civil, or administrative law related to any Federal health care program); or (iii) the provision of items or services of a quality that fails to meet professionally recognized standards of health care. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATIONS

In the event that LGC purchases or establishes new business units after the effective date of this CIA, LGC shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All Covered Individuals employed at or contracting with such locations shall be subject to the requirements in this CIA that apply to new Covered Individuals (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

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

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

- a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all Covered Individuals;
- b. all Covered Individuals have completed the Code of Conduct certification required by section III.B.1; and
- c. all Covered Individuals have completed the training and executed the certification required by section III.C.

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

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

9. a summary of personnel actions taken pursuant to section III.F; and

10. a list of all of LGC's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. LGC shall submit to OIG an Annual Report with respect to the status and findings of its compliance activities. Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

a. all Covered Individuals have completed the annual Code of Conduct certification required by section III.B.1; and

b. all Covered Individuals have completed the training and executed the certification required by section III.C;

3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement(s), including a copy of the methodology used;
5. LGC's response/corrective action plan to any issues raised by the Independent Review Organization(s);
6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to section III.H.
7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;
8. a copy of the confidential disclosure log required by section III.E;
9. a description of any personnel action (other than hiring) taken by LGC as a result of the obligations in section III.F;
10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that LGC has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;
11. a corrective action plan to address the probable violations of law identified in section III.H; and
12. A description of all changes to the most recently provided list (as updated) of LGC's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) LGC is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

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

LGC:

Angela Short
Director of Compliance
Lewis-Gale Clinic, LLC
1802 Braeburn Drive
Salem, Virginia 24153
Phone 540.772.3673
Fax 540.989.0879

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 LGC's books, records, and other documents and supporting materials and/or conduct an onsite review of LGC's operations for the purpose of verifying and evaluating: (a) LGC's compliance with the terms of this CIA; and (b) LGC's compliance with the requirements of the Federal health

care programs in which it participates. The documentation described above shall be made available by LGC 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 LGC's Covered Individuals who consent to be interviewed at the Covered Individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the Covered Individual and OIG. LGC agrees to assist OIG in contacting and arranging interviews with such Covered Individuals upon OIG's request. LGC's Covered Individuals may elect to be interviewed with or without a representative of LGC present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

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

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

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

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

3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day LGC:

- a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which LGC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person);
- b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, LGC'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 in part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which LGC can demonstrate

that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person); or

c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, LGC's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before ten (10) days after LGC received notice of the relevant matter or after the resolution of the matter).

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

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

B. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that LGC has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify LGC by personal service or certified mail of (a) LGC's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, LGC 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.D. In the event LGC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until LGC 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.C.

2. Timely Written Requests for Extensions. LGC may submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after LGC fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after LGC receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

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

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

C. Exclusion for Material Breach of this CIA.

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

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

- a. LGC is in full compliance with this CIA;
- b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the thirty five (35) day period, but that: (i) LGC has begun to take action to cure the material breach, (ii) LGC is pursuing such action with due diligence, and (iii) LGC has provided to OIG a reasonable timetable for curing the material breach.

3. Exclusion Letter. If at the conclusion of the thirty five (35) day period, LGC fails to satisfy the requirements of section X.C.2, OIG may exclude LGC from participation in the Federal health care programs. OIG will notify LGC in writing of its determination to exclude LGC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If LGC is excluded under the provisions of this CIA, LGC may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

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

D. Dispute Resolution.

1. Review Rights. Upon OIG's delivery to LGC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligations of this CIA, LGC 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 fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

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

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be: (a) whether LGC was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the thirty-five (35) day period, but that (i) LGC has begun to take action to cure the material breach, (ii) LGC is pursuing such action with due diligence, and (iii) LGC has provided to OIG a reasonable timetable for curing the material breach.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. LGC’s election of its contractual right to appeal to the DAB shall not abrogate OIG’s authority to exclude LGC upon the issuance of the ALJ’s decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that LGC may request review of the ALJ decision by the DAB.

4. Finality of Decision. The review by an ALJ or the DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, LGC and OIG agree that the DAB’s decision (or the ALJ’s decision if not appealed) shall be considered final for all purposes under this CIA and LGC agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CIA shall be binding on the successors, assigns and transferees of LGC;
- B. This CIA shall become final and binding on the date the final signature is obtained on this CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of LGC and OIG; and
- D. The undersigned LGC 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 LGC

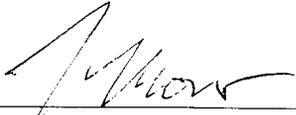
Lewis-Gale Clinic, LLC

By: *Jerry W. Patton MD President*

3/20/00
DATE

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

2/14/20
DATE

**AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LEWIS GALE CLINIC**

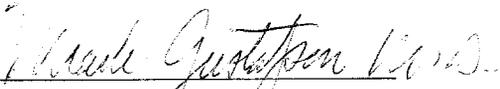
The Office of Inspector General (“OIG”) of the Department of Health and Human Services and Lewis Gale Clinic (“LGC”) entered into a Corporate Integrity Agreement (“CIA”) on April 4, 2001.

- A. Pursuant to section XI.C. of LGC’s CIA, modifications to the CIA may be made with the prior written consent of both the OIG and LGC. Therefore, the OIG and LGC agree that LGC’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 and Appendix A.

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

ON BEHALF OF LEWIS GALE CLINIC



Mark Gustafson, MD
President
Lewis-Gale Clinic

3/8/2002
DATE

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



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

3/13/02
DATE

D. Review Procedures.

1. *General Description.*

a. Internal Billing Review Option. LGC may, in the first year, conduct an internal review of its billing and coding to the Federal health care programs, which review shall comply with all of the requirements outlined in section III.D of this CIA and in Appendix A ("Claims Review"). If, in its sole discretion, OIG determines that LGC's internal Claims Review satisfactorily establishes the adequacy of LGC's billing and compliance practices pursuant to this CIA, OIG may allow LGC to continue to perform the internal Claims Review in conformance with the requirements of section III.D of this CIA and Appendix A for years two through five of this CIA. To the extent that OIG permits LGC to perform internal Claims Reviews, LGC must submit all information required by the provisions outlined in section III.D of this CIA and as in Appendix A.

b. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, LGC shall retain an entity such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") IRO, to perform review engagements to assist LGC in assessing and evaluating its billing and coding practices and systems pursuant to this CIA and the Settlement Agreement. Each IRO retained by LGC 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 LGC seeks reimbursement. Each IRO shall assess, along with LGC, whether it can perform the IRO engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

i. In the first year of this CIA, the IRO shall conduct a review of at least 10% of the claims reviewed by LGC in its internal Claims Review ("Verification Review").

ii. If LGC is permitted to perform the internal Claims Review after the first year of this CIA, the IRO shall conduct a Verification Review.

iii. If the OIG does not allow LGC to perform the Claims Review internally after the first year, then the IRO shall conduct the Claims Review.

As part of LGC's Annual Report, the IRO shall submit a report that verifies that the requirements outlined in section III.D of this CIA and in Appendix A have been satisfied and should report the claim by claim results of any Verification Review or Claims Review performed.

c. 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. LGC and/or the IRO(s) shall perform each annual Claims Review.

d. Retention of Records. LGC and the IRO 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 LGC related to the Claims Review).

2. *Claims Review*.

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

a. Discovery Sample. LGC or the IRO shall randomly select and review a sample of 50 Federal health care program Paid Claims submitted by or on behalf of LGC for each Discovery Sample. For each annual Claims Review, LGC will perform 10 separate Discovery Samples of 50 Paid Claims each, based on CPT code series (e.g., 10000 code series, 20000 code series, 30000 code series).

The Paid Claims shall be reviewed based on the supporting documentation available at LGC or under LGC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

- i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) for a 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, LGC should, as appropriate, further analyze any errors identified in the Discovery Sample. LGC 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 a Discovery Sample indicates that the Error Rate is 5% or greater, LGC and/or the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, LGC and/or the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at LGC or under LGC'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, LGC 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 LGC to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If a Discovery Sample identifies an Error Rate of 5% or greater, LGC or its IRO shall also conduct a Systems Review. Specifically, for each Item in the Discovery Sample and Full Sample that

resulted in an Overpayment, LGC or the IRO should perform a "walk through" of the system(s) and process(es), that generated the Item to identify any problems or weaknesses that may have resulted in the identified Overpayments. LGC or the IRO shall report its observations of the Systems Review and shall develop recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

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

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

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

APPENDIX A

A. Claims Review.

1. **Definitions.** For the purposes of the Claims Review, the following definitions shall be used:
 - a. Overpayment: The amount of money LGC 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 LGC and for which LGC has received reimbursement from any Federal health care program.
 - d. Population: All Items for which LGC has submitted a code or line item and for which LGC has received reimbursement from a Federal health care program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample. If LGC has elected to perform the Claims Review internally with the IRO verification the following payment errors should be included in calculating the error rate: (i) all payment errors identified by LGC and not verified by the IRO; (ii) all payment errors identified by the IRO and not identified by LGC; and (iii) all payment errors identified by LGC and verified by the IRO.
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 LGC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by LGC 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 each Claims Review Report for each Discovery Sample and Full Sample (if applicable):

1. **Claims Review Methodology**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

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

e. Source of Data: A description of the specific 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 description of LGC's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.

b. Quantitative Results.

i. Total number and percentage of instances (based on LGC's internal billing review) in which LGC determined that the Paid Claims submitted ("Claims Submitted") differed from what should

have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

ii. Total number and percentage of instances (based on LGC's internal billing review) in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to LGC.

iii. Based on LGC's internal billing review, total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. For each Discovery and Full Sample: (i) the number of Items the IRO verified; (ii) the number of instances in which the IRO disagreed with LGC's payment determinations; and (iii) the dollars associated with the difference between the IRO's and LGC's payment determinations.

v. Error Rate in the sample, as defined in section A.1.e of this Appendix.

vi. 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 LGC's internal billing review), correct procedure code (as determined by the IRO verification), correct allowed amount (as determined by LGC's internal billing review), correct allowed amount (as determined by the IRO verification), dollar difference between allowed amount reimbursed by payor and the correct allowed amount (determined by LGC's internal billing review); and dollar difference between allowed amount reimbursed by payor and the correct allowed amount (determined by the IRO verification). See Attachment 1.

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; (2) performed the Claims Review; and (3) performed the verification review, if applicable.

