CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FLOYD HEALTHCARE MANAGEMENT, INC.

I. PREAMBLE

Floyd Healthcare Management, Inc. d/b/a Floyd Medical Center ("FMC") 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 with the reimbursement 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") as they relate to the submission of claims for professional services (such as physician services) rendered by FMC's Employees and Residents to the extent provided for below.

For the purposes of this CIA, the term "Employee" shall mean: (i) all FMC employees responsible for generating, preparing and/or submitting requests for reimbursement from the Federal Health Care Programs for professional services, and (ii) all FMC representatives for whose professional health care services (i.e., physicians, nurses, nurse practitioners, physicians' assistants, and technologists) FMC requests reimbursement from the Federal Health Care Programs. The term "Residents" shall mean medical residents and interns of FMC's Family Practice Residency Program or any other residency or physician training program subsequently established by FMC. Additionally, this CIA shall apply to any submissions by FMC to the Federal Health Care Programs for professional services rendered by persons who are not Employees of FMC.

In addition to the obligations herein, FMC shall (i) require that all third parties FMC engages as its Billing Agents comply with OIG's "Compliance Program Guidance for Third Party Medical Billing Companies" issued on November 11, 1998 or otherwise adhere to a comprehensive corporate compliance program designed to ensure compliance with Federal Health Care Program requirements; (ii) ensure that such Billing Agents possess the requisite competence and undergo training comparable to the training required under this CIA through either FMC's training program or a training program of their own; and (iii) require that such Billing Agents submit to periodic audits (through the annual review process described in Section III.E below) by FMC for the reimbursement claims such Billing Agents submit on behalf of FMC. FMC shall document its efforts to ensure the competency and training of such Billing Agents and shall make such documentation available to OIG upon reasonable request. FMC shall provide such Billing Agents with a copy of FMC's Code of Conduct (as described below), and shall ensure that such Billing Agents are made aware of the identity of FMC's Corporate Compliance Officer and of the existence of FMC's confidential disclosure mechanism.

Prior to the execution of this CIA, FMC voluntarily established a compliance program (hereinafter the "Compliance Plan" or the "Program") formally adopted by a Board of Directors' resolution in 1998. As represented by FMC in this CIA, the Compliance Plan provides for policies and procedures aimed at ensuring that its participation in the Federal Health Care Programs (which includes any requests for payments) conforms with the statutes, regulations and other directives applicable to the Federal Health Care Programs. Therefore, pursuant to this CIA, FMC hereby agrees to maintain in full operation the Compliance Plan as it relates to the submission of claims for professional services for the term of this CIA. The Compliance Plan may be modified by FMC as appropriate, but at a minimum, it shall comply with the integrity obligations set forth in this CIA.

II. TERM OF THE CIA

The period of the integrity obligations assumed by FMC under this CIA shall be five (5) years from the effective date of this CIA. The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

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

III. INTEGRITY OBLIGATIONS

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

A. COMPLIANCE COMMITTEE

FMC has represented to OIG that, pursuant to its Program, it has created a Compliance Committee to assist FMC's Corporate Compliance Officer in carrying out FMC's compliance activities. Pursuant to this CIA, FMC agrees to charge the Compliance Committee with the continued responsibility for ensuring compliance with the integrity obligations in this CIA. Accordingly, FMC hereby agrees to maintain the Compliance Committee (or in the event that such a committee ceases to exist, to create a committee) with overall responsibility for the obligations in this CIA. FMC shall ensure that the Compliance Committee is continuously composed of representatives of multiple disciplines and segments of FMC's operations. At a minimum, the Compliance Committee shall include the Corporate Compliance Officer, the directors of billing for FMC, and any other members of senior management necessary to meet the requirements of this CIA . The Corporate Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Corporate Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of FMC's risk areas and shall oversee monitoring of internal and external audits and

investigations). The Compliance Committee must be able to make reports directly to FMC's Board of Directors. Any changes in the positions that comprise the Compliance Committee must be reported to OIG within thirty (30) days of the effective date of the action. Any other matters affecting the membership or responsibilities of the Compliance Committee shall be reported to OIG in accordance with Section V below.

B. COMPLIANCE OFFICER

FMC has represented to OIG that, pursuant to the Program, it has created a compliance officer position (known as the "Corporate Compliance Officer") and it has appointed an individual to serve in that capacity. Accordingly, FMC shall formally maintain the appointment of an individual to serve as the Corporate Compliance Officer for the term of this CIA. At a minimum, the Corporate Compliance Officer must continuously be charged with the responsibility for the day-to-day activities in furtherance of the integrity obligations assumed by FMC in this CIA, as well as for any reporting obligations established under this CIA. The Corporate Compliance Officer must have the authority and ability to report directly to FMC's Board of Directors. Any changes in the appointment of the Corporate Compliance Officer (including voluntary or involuntary personnel changes) or any actions or changes that would affect substantially the Corporate Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA must be reported to OIG within thirty (30) days of the effective date of the action. Any other changes in the position, or material changes in the duties, of the Corporate Compliance Officer shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. CODE OF CONDUCT. FMC has represented to OIG that it developed and distributed to all Employees, Residents and Billing Agents a set of ethical rules known as the "Standards of Business Conduct" (hereinafter referred to as "Code of Conduct") by which all such individuals are expected to abide in conjunction with the services they render to patients of the Federal Health Care Programs. FMC shall maintain the Code of Conduct in effect for the duration of this CIA. New Employees shall receive the Code of Conduct within thirty (30) days after the commencement of their employment. New Residents shall receive a copy of the Code of Conduct within thirty (30) days of the commencement of their training programs.

   FMC shall maintain a written summary of the actions taken to distribute the Code of Conduct to all Employees and Residents. Such summaries shall be produced to OIG upon request. For the purposes of this CIA, OIG may request access to, or copies of, any underlying documents summarized by FMC.

FMC will annually review the Code of Conduct and will make any necessary revisions. Significant revisions shall be distributed to all Employees within sixty (60) days of making such a change, unless the nature of the revision is such that it warrants earlier notice. Any amendments to the Code of Conduct must be reported to OIG in accordance with Section V below.

FMC shall make adherence to the Code of Conduct an element in evaluating the performance of all Employees and Billing Agents. At all times, the Code of Conduct shall, at a minimum, set forth:

a. FMC's commitment to full compliance with all federal and state statutes and regulations applicable to the Federal Health Care Programs, including its commitment to prepare and submit accurate reimbursement claims consistent with the Federal Health Care Program statutes and regulations.

b. FMC's requirement that all of its Employees, Residents and Billing Agents comply with all federal and state statutes and regulations applicable to Federal Health Care Programs and with FMC's own policies and procedures (including the requirements arising from this CIA);

c. The requirement that FMC Employees, Residents and Billing Agents are expected to report through the Program any suspected violations of any statute or regulation applicable to the Federal Health Care Programs or of FMC's own policies and procedures;

d. The potential consequences to any Employee, Residents and Billing Agents as a result of any failure to comply with the applicable Federal Health Care Program requirements and/or with FMC's own policies and procedures or any failure to report such non-compliance; and

e. The right of all Employees, Residents and Billing Agents to use FMC's confidential disclosure mechanisms, as well as FMC's commitment to confidentiality and non-retaliation policy with respect to good faith disclosures.

2. POLICIES AND PROCEDURES. FMC has represented to OIG that it developed and distributed to all Employees and Residents written policies and procedures regarding the operation of the Program and FMC's commitment to compliance with all Federal Health Care Program statutes, regulations, and program directives issued by the agency in charge of administering the program and its agents (including the Health Care

Financing Administration and FMC's Medicare Part B carrier).

FMC agrees to maintain policies and procedures that, at a minimum, specifically address: (1) the subjects relating to the Code of Conduct identified in Section III.C.1; (2) the need for compliance in connection with all submissions for reimbursement for professional services; (3) the documentation requirements; and (4) a process for reasonable verification of compliance with these requirements. In addition, the policies and procedures shall include disciplinary guidelines and methods for Employees, Residents and Billing Agents to make disclosures or otherwise report on compliance issues to management and/or supervisors, including the Confidential Disclosure mechanisms required by Section III.F. FMC shall assess and update the policies and procedures at least annually or more frequently, as appropriate. Within thirty (30) days of the effective date of any substantive 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. At a minimum, a summary of the policies and procedures will be provided to OIG in the Implementation Report, as provided in Section V.A. The policies and procedures will be available to OIG upon reasonable request.

D. TRAINING AND EDUCATION.

1. GENERAL INITIAL TRAINING. Within one hundred twenty (120) days of the effective date of this CIA, FMC shall provide at least two (2) hours of general compliance training to its Employees and Residents. This general training shall explain FMC's:

   a. CIA requirements; and

   b. Compliance Program (including the Code of Conduct and policies and procedures established pursuant to Section III.C.2 above).

The training materials (including attendance logs) shall be maintained by FMC and made available to OIG, upon request. New Employees and Residents shall receive the general training described above within thirty (30) days of the beginning of their employment or within one hundred twenty (120) days after the effective date of this CIA, whichever is later. After receiving the general initial training described above, each Employee and Resident shall receive at least one (1) hour of general training annually for the remaining term of this Agreement.

OIG shall take into consideration for purposes of evaluating whether the general initial training obligation is met, training conducted by FMC under its Program on or after January 1, 2000 and shall credit such training for

the initial obligation to the extent such training satisfies the requirements set forth above. With respect to those individuals trained between January 1, 2000 and the effective date of this CIA, FMC will be deemed to meet the requirements of this Subsection to educate them on the CIA requirements and policies and procedures established pursuant to Section III.C.2 above, if FMC sends to such individuals written information about the CIA requirements and such policies and procedures.

2. SPECIFIC TRAINING. FMC represents that subsequent to January 1, 2000, it has provided specific training to those Employees and Residents who are responsible for generating, preparing and/or submitting requests for reimbursement from the Federal Health Care Programs for professional services through various inservice training courses. FMC shall ensure that it provides on an annual basis in addition to the general training required above, (i) with respect to Employees responsible for non-clerical aspects of generating, preparing and/or submitting requests for reimbursement from Federal Health Care Programs for professional services, at least four (4) hours of specific training, as described in this Subsection D.2; (ii) with respect to Employees responsible solely for clerical (i.e., data entry) aspects of generating, preparing and/or submitting requests for reimbursement from Federal Health Care Programs for professional services, at least two (2) hours of specific training, as described in this Subsection D.2; and (iii) with respect to Residents who provide professional services at least two (2) hours of specific training, as described in this Subsection D.2. OIG shall take into consideration for purposes of evaluating whether the specific training obligation is met, training conducted by FMC under its Program on or after January 1, 2000 and shall credit such training for the first year specific training obligation, to the extent such training satisfies the requirements set forth below. The specific training shall include a discussion of:

a. The submission of accurate requests for reimbursement for services rendered to patients of the Federal Health Care Programs;

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

c. The personal obligation of each individual to ensure that the information documented by the individual, whether relating to actual patient care, the type of services or items delivered or the coding of such services or items is accurate and meets the federal and state requirements for the Federal Health Care Programs, as well as FMC's policies;

d. Reimbursement rules and statutes applicable to FMC's Federal Health Care Program business;

e. The legal sanctions for improper reimbursement submissions (including the submission of false or inaccurate information); and

f. Relevant examples of proper and improper billing practices.

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

FMC shall provide new Employees and Residents with this training within thirty (30) days of the beginning of their employment, or within one hundred twenty (120) days of the effective date of this CIA, whichever is later. Prior to such specific training being completed for a new Employee or Resident, an FMC Employee who has completed the specific training shall conduct sporadic reviews of the untrained person's work regarding the documentation of services and/or the assignment of billing codes until such time as the new Employee or Resident receives the required general and specific training.

The substance of the training and the identity of the individuals must be documented in accordance with Subsection D.3 below.

3. CERTIFICATION. FMC shall maintain documents that reflect attendance at both general and specific training sessions by Employees and Residents, and the topics covered. FMC may choose the exact format of these documents, but it is expected that the materials will include sheets with the signatures of the persons who attended or other reliable means (including electronic means) of verifying attendance and participation. The Corporate Compliance Officer shall retain the attendance logs as well as the course materials. All of these documents shall be made available to OIG upon reasonable request.

FMC shall certify that such training has been provided in its Implementation and Annual Reports to OIG, in accordance with Section V below. Information concerning the format, dates, and copies of the materials provided will be available, upon reasonable request, for review by OIG.

E. ANNUAL AND SPECIAL REVIEWS OF BILLING POLICIES, PROCEDURES AND PRACTICES

1. GENERAL DESCRIPTION.

a. *Retention of Independent Review Organization.* Within one hundred

twenty (120) days of the effective date of this CIA, FMC shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to (1) perform agreed upon procedures to assist OIG in determining whether FMC is following the Annual Claims Review protocol, set forth in Appendix A; (2) perform a Systems Review as set forth below; and, if necessary, (3) perform a Special Review, as set forth below. Each Independent Review Organization retained by FMC 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 FMC seeks reimbursement.

b. *Annual and Special Review Reports*. FMC and/or the IRO shall prepare a report based upon each Annual Claims Review ("Claims Review Report"), Systems Review ("Systems Review Report") or Special Review ("Special Review Report") performed, respectively. The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA. The Systems Review Report shall be prepared in accordance with Subsection III.E.3, below. The Special Review Report shall be created in accordance with the procedures set forth in Appendix B to this CIA.

c. *Retention of Records*. The IRO and FMC 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 FMC) related to the annual reviews.

2. ANNUAL CLAIMS REVIEWS. FMC has developed a protocol, attached hereto as Appendix A, for reviewing, on an annual basis, a sample of claims for professional services. An objective of the Annual Claims Review is to evidence compliance with the reimbursement and billing requirements of the Federal Health Care Programs. Implementation of the agreed-upon procedures set forth in the protocol shall be an element of this Agreement.

3. ANNUAL SYSTEMS REVIEWS.

a. For each year of the CIA as part of the Annual Reviews, the IRO shall review FMC's billing and coding systems and/or operations for professional services (the "Systems Review"). The Systems Review shall consist of findings and recommendations regarding the following:

i. FMC's billing systems and/or operations relating to claims for professional services submitted to all Federal Health Care

Programs (including, but not limited to, the operation of the billing system, safeguards reasonably designed to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and

ii. FMC's coding systems and/or operations relating to claims for professional services submitted to all Federal Health Care Programs (including, but not limited to, the process by which claims are coded, safeguards reasonably designed to ensure proper coding, and procedures to correct inaccurate coding).

b. The IRO shall prepare a Systems Review Report based upon the Systems Review performed. The Systems Review Report shall include the IRO's findings and recommendations regarding:

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

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

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

3. SPECIAL REVIEWS. In the event that through the Annual Claims Reviews, Systems Reviews, or any other means, FMC identifies a Material Deficiency as defined in Section III. I.2, the Independent Review Organization shall conduct a Special Review in accordance with the procedures set forth in Appendix B.

4. VALIDATION REVIEW. In the event the OIG has reason to believe that: (a) any FMC and/or IRO Annual Claims Review, Systems Review and/or Special Review fails to conform to the requirements of this CIA or (b) the findings or results of any Annual Claims Review or Special Review performed to satisfy the requirements of Subsection III.E are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Systems Review or Special Review complies with the requirements of this CIA and/or the findings or results of any such Review are inaccurate. FMC agrees to pay for the reasonable cost of any such Review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in Section II) is received by the OIG.

F. CONFIDENTIAL DISCLOSURE

FMC has represented to OIG that it has established a confidential disclosure mechanism as a means to enable individuals to report instances of noncompliance and/or make inquiries on compliance issues. Pursuant to this CIA, FMC shall maintain its confidential disclosure mechanism and ensure that it meets the following requirements. It shall be available to all individuals for the purpose of reporting or inquiring on matters of FMC's compliance with Federal Health Care Program standards and the obligations in this CIA. FMC shall publicize the existence of the confidential disclosure mechanism (e.g., through periodic e-mails or by posting the information in prominent common areas). The confidential disclosure mechanism shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications.

FMC shall require the internal inquiry of any specific disclosure or inquiry related to matters covered by this CIA and/or Federal Health Care Program requirements, provided that such disclosure or inquiry is sufficiently specific so that it reasonably: (i) permits a determination of the appropriateness of the practice alleged to be implicated; and (ii) permits corrective action to be taken and ensure that proper follow-up is conducted. In an effort to address each disclosure and inquiry received, FMC shall, in good faith, make a preliminary inquiry for every disclosure to ensure it has obtained all of the necessary information that is reasonably required to determine whether an internal inquiry, in accordance with the language above, should be conducted. FMC shall maintain an internal tracking system to record all disclosures and inquiries received and all follow-up conducted. FMC shall ensure that it provides sufficient notice of its disclosure mechanism to all individuals.

FMC shall include in each Annual Report to OIG a summary of the communications received under its confidential disclosure mechanism (including the number of disclosures received and the dates of such disclosures) concerning FMC's practices reported as, and found to be, inappropriate. The reports shall also summarize the results of its internal inquiries and any follow-up activities on such matters. FMC hereby agrees to maintain said reports in a manner consistent with Section VII of this CIA.

FMC shall select the manner in which disclosures and inquiries are received, processed and resolved. The disclosing or inquiring individual's identity may be requested, but shall not be required. Anonymity shall not be discouraged.

G. INELIGIBLE PERSONS

1. DEFINITION. For the purposes of this CIA, an "Ineligible Person" shall be

any individual or entity who (i) is excluded, 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, but has not yet been excluded, debarred or otherwise declared ineligible.

2. SCREENING REQUIREMENTS. FMC shall not knowingly employ (either as a bona fide employee or as an independent contractor) or grant staff privileges to any Ineligible Person for any position for which the Ineligible Person's salary or the items or services furnished, directed or prescribed by the Ineligible Person will be paid in whole or part, directly or indirectly, by a Federal Health Care Program. To prevent hiring or contracting with any Ineligible Person for such a position, FMC shall screen all prospective Employees and prospective contractors and screen physicians prior to granting staff privileges prior to engaging their services for such a position, 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://epls.arnet.gov)* and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at *http://www.hhs.gov/oig*) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. REVIEW AND REMOVAL REQUIREMENT. Within one hundred twenty (120) days of the effective date of this CIA, FMC will review its list of current Employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, FMC will review the list annually. FMC shall also impose upon each Employee a continuing obligation to inform FMC immediately if the Employee becomes an Ineligible Person. If FMC has notice that an Employee or contractor or physician with staff privileges has become an Ineligible Person, FMC will remove such person from responsibility for, or involvement with, FMC's health care delivery operations that are paid in whole or in part, directly or indirectly, by a Federal Health Care Program and shall remove such person from any position for which the person's salary or the items or services furnished, directed, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Health Care Programs at least until such time as the person is no longer an Ineligible Person.

4. PENDING CHARGES AND PROPOSED EXCLUSION. FMC shall impose upon each Employee a continuing obligation to inform FMC immediately if the Employee is charged with a criminal offense related to any Federal Health Care Program, or is proposed for exclusion. If FMC 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 with FMC, FMC shall take appropriate action to ensure that the person's responsibilities do not adversely affect the quality of care rendered to any patient, or the accuracy of any reimbursement claims submitted to the Federal Health Care Programs. The term "notice" for purposes of this Subsection III.G.4 shall mean that any FMC employee occupying a supervisory, managerial or executive position or exercising supervisory, managerial or executive duties knows or has reason to know of the matters described in this Subsection III.G.4.

H. NOTIFICATION OF GOVERNMENT INVESTIGATION OR LEGAL PROCEEDINGS.

Within thirty (30) days of discovery, FMC shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a local, state or federal governmental entity or its agents involving an allegation that FMC 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. FMC shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. REPORTING.

1. OVERPAYMENTS

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

b. Reporting of Overpayments. If, at any time, FMC identifies or learns of any overpayments, FMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) as well as Department of Community Health, Division of Medical Assistance, if it relates to Medicaid, and repay any identified overpayments within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) and take remedial steps within ninety (90) 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. Notwithstanding anything to the contrary herein, notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained in the Overpayment Refund Form, provided as Appendix C 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, based upon a thorough and good faith review of the facts, 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 FMC determines that there is a Material Deficiency, FMC shall notify OIG, in writing, within sixty (60) 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 OIG shall be made at the same time as the notification to the payor required in section III.I.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 refund 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 FMC's actions taken to correct the Material Deficiency; and

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

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract or pursuant to this CIA, OIG or its duly authorized representative(s) may, upon reasonable request as defined in 42 C.F.R. § 1001.1301, examine FMC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) FMC's compliance with the terms of this CIA; and (ii) FMC's compliance with the requirements of the Federal Health Care Programs. The documentation described above shall be maintained and made available by FMC at all reasonable times for inspection, review and reproduction by OIG. By agreeing to this provision, FMC does not waive any applicable attorney-client or work product privileges; however, any such claim of privilege may not be used to avoid compliance with this CIA. FMC shall have the right to have one or more of its representatives (including legal counsel) present during such reviews. Furthermore, for the purposes of this provision, OIG or its authorized representative(s) may, upon reasonable request and notice, interview any of FMC's Employees and Residents who consent to be interviewed at their 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. Such individuals shall have the right, at their option, to have a representative of FMC present during interviews. FMC agrees to assist OIG in contacting and arranging interviews with such Employees upon OIG's reasonable request. OIG's inspection and review activities pursuant to this section may include on-site visits.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. IMPLEMENTATION REPORT

Within one hundred fifty (150) days after the effective date of this CIA, FMC 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 names and positions of the members of the Compliance Committee required by Section III.A;

2. The name, work address, and telephone number and position description of the Corporate Compliance Officer required by Section III.B;

3. A copy of FMC's Code of Conduct required by Section III.C.1;

4. A summary of the policies and procedures required by Section III.C.2 or a copy of the policies and procedures;

5. A description of the training programs required by Section III.D, including a description of the targeted audiences and a schedule of the dates on which the training sessions were held;

6. A certification by the Corporate Compliance Officer that, to the best of the Corporate Compliance Officer's knowledge and upon reasonable efforts and inquiry, the actions described in Sections III.C and III.D.1 of this CIA have taken place;

7. A description of the confidential disclosure mechanisms required by Section III.F; and

8. The certification required by Section V.C.

B. ANNUAL REPORTS

FMC shall make annual reports (each one of which is referred to throughout this CIA as the "Annual Report") to OIG describing the measures FMC has taken to ensure compliance with the terms of this CIA. In accordance with the provisions above, the Annual Report shall include the following information:

1. In the first Annual Report, copies of the document or documents that comprise FMC's Program, as adopted by FMC and implemented by the Compliance Committee and the Corporate Compliance Officer. For subsequent years, FMC shall note in the Annual Report any amendments or revisions to the Program documents made during the period covered by the Annual Report;

2. Any change in the identity or position, or any material change in the duties, of the Corporate Compliance Officer and/or the positions that comprise the Compliance Committee, as set forth in Sections III.A and III.B;

3. Copies of any revisions or amendments made to the Code of Conduct or the policies and procedures used or followed in the generation of claims submitted to the Federal Health Care Programs during the period covered by the Annual Report pursuant to Section III.C;

4. A description of the Training and Education activities engaged in pursuant to Section III.D of this CIA and a summary of the activities undertaken to implement this program with respect to Employees and Residents as well as Billing Agents to the extent FMC provides such training, including schedules, topic outlines of the training sessions, and lists of the participants organized by department or division. Additionally, FMC shall include a certification by the Corporate Compliance Officer that, to the best of the Corporate Compliance Officer's knowledge and, upon reasonable efforts and inquiry, the education and training activities required under this CIA have taken place;

5. A complete copy of all final reports prepared by FMC and/or the IRO pursuant to the Annual Claims Reviews, Systems Reviews or Special Reviews, including a copy of the methodology used, along with a copy of the IRO's engagement;

6. FMC's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. A summary of all Material Deficiencies (as defined in III. I.) identified during the period of the Annual Report and the status of any corrective and preventative action relating to all such Material Deficiencies;

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

9. A summary of communications (including the number of disclosures by Employees and the dates of disclosure) received through the mechanisms established pursuant to Section III.F concerning FMC's Federal Health Care Program business, as well as any follow up on such disclosures;

10. A summary describing any ongoing investigation, audit or legal proceeding conducted or brought by a local, state, federal governmental entity involving an allegation that FMC has committed a crime or has engaged in fraudulent activities relating to health care delivery activities. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such an inquiry, legal proceeding or requests for information;

11. A description of any personnel actions (other than hiring) taken by FMC as a result of the obligations in Section III.G. With respect to actions pursuant to Section III.G.4, provide a description of the responsibilities of the person affected by any such actions. FMC shall maintain records concerning all such personnel actions and shall make such records available to OIG upon reasonable request; and

12. The certification required by section V.C.

The period covered by the Annual Report shall be twelve (12) months. The first Annual Report shall cover the period commencing on **December 1, 2000** and ending on **November 30, 2001** and shall be due on **January 31, 2001.** Subsequent Annual Reports shall be due on **January 31** after the end of the applicable period.

C. CERTIFICATIONS

The Implementation Report and Annual Reports shall include a certification by the Corporate Compliance Officer that: (1) to the best of the Corporate Compliance Officer's belief and upon reasonable inquiry, FMC is in compliance with all of the requirements of this CIA, except as noted in the Annual Report; and (2) the Corporate Compliance Officer has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that, upon such an inquiry, the information is accurate and truthful, which belief may be based upon representations made to the Corporate Compliance Officer by others.

D. DESIGNATION OF INFORMATION

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify FMC prior to any release by OIG of information submitted by FMC pursuant to its obligations under this CIA and identified upon submission by FMC as trade secrets, information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, FMC shall have the rights set forth at 45 C.F.R. § 5.65(d). FMC shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

ATTENTION: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Phone: 202-619-2078
Fax: 202-205-0604

ATTENTION: Ms. Mary Johnson
Vice President and Corporate Compliance Officer
Floyd Medical Center
304 Turner McCall Boulevard
Rome, GA 30165
Phone: 706-802-2575
Fax: 706-291-9370

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. As stated below in Section IX of this CIA, any and all modifications to this CIA (including changes to dates on which an obligation is due to be met or a submission or response is due to be made) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

VII. DOCUMENT AND RECORD RETENTION

FMC shall maintain for inspection documents and records relating to its compliance with this CIA, as well as those relating to the reimbursement claims submitted to the Federal Health Care Programs, for a period one (1) year longer than the duration of this CIA.

VIII. BREACH AND DEFAULT

FMC 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, FMC and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of specific 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 FMC fails to have in place any of the following:

   a. a Compliance Officer as described by section III.B;

   b. a Compliance Committee as described by section and III.A;

   c. a written Code of Conduct as described by section III.C.1;

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

e. a training program as described in section III.D; and

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

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 FMC fails to retain an IRO, as required in section III.E.

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 FMC fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to the OIG;

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day FMC employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, FMC'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. Notwithstanding anything to the contrary in this CIA, this Stipulated Penalty shall not be demanded for any time period during which FMC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G) as to the status of the person.

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

6. A Stipulated Penalty of $1,000 for each day FMC fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. With respect to the Stipulated Penalty provision described in this subsection 6 only, the OIG shall not seek a Stipulated Penalty until it has provided notice to FMC stating the specific grounds for its determination that FMC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps FMC must take to comply with the CIA. This Stipulated Penalty shall begin to accrue ten (10) days after the date that OIG provides notice to FMC of failure to comply unless FMC cures such failure within the ten (10)-day period or demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the ten (10)-day period, but that (i) FMC has begun to take action to

cure the failure to comply; (ii) FMC is pursuing such action with due diligence; and (iii) FMC has provided to OIG a reasonable timetable for curing the failure to comply.

B. Timely Written Requests for Extensions. FMC 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 FMC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after FMC 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 FMC has failed to comply with any of the obligations described in section VIII.A and after determining that Stipulated Penalties are appropriate, OIG shall notify FMC of: (a) FMC'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 ten (10) days of the receipt of the Demand Letter, FMC 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 VIII.E. In the event FMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until FMC 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 VIII.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 VIII.D.1.c, these provisions for payment of Stipulated Penalties shall not

affect or otherwise set a standard for OIG's decision that FMC has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section VIII.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 FMC to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in section III.I;

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

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by FMC constitutes an independent basis for FMC's exclusion from participation in the Federal Health Care Programs. Upon a determination by OIG that FMC has materially breached this CIA and that exclusion should be imposed, OIG shall notify FMC of: (a) FMC'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.* FMC shall have thirty (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. FMC 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 (30)-day period, but that: (i) FMC has begun to take action to cure the Material Breach; (ii) FMC is pursuing such action with due diligence; and (iii) FMC has provided to OIG a reasonable timetable for curing the Material Breach.

4. *Exclusion Letter.* If at the conclusion of the thirty (30)-day period, FMC fails to satisfy the requirements of section VIII.D.3, OIG may exclude FMC from

participation in the Federal Health Care Programs. OIG will notify FMC in writing of its determination to exclude FMC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section VIII.E, below, the exclusion shall go into effect thirty (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, FMC wishes to apply for reinstatement, FMC 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 FMC 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, FMC 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 ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty-five (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 FMC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. FMC 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 FMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless FMC 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 FMC 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 thirty (30) day period, but that:

(i) FMC had begun to take action to cure the Material Breach within that period;

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

(iii) FMC provided to OIG within that period a reasonable timetable for curing the Material Breach and FMC 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 FMC, only after a DAB decision in favor of OIG. FMC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude FMC 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 twenty (20) days after the ALJ issues such a decision, notwithstanding that FMC 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 twenty (20) days after the DAB decision.

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

IX. 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 by reference, FMC and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of FMC that assume responsibility for submitting claims to the Federal Health Care Programs for professional services rendered by physicians and other health care providers who, for purposes of providing such professional services, are employed by FMC or who are independent

contractors with FMC. FMC shall also require that any entity owned or controlled by FMC that assumes responsibility for billing for professional services rendered by FMC's physician faculty members comply with this CIA;

B. This CIA shall become final and binding only upon signing by each respective party hereto;

C. Any modifications to this CIA may be made only by a writing signed by the parties to this CIA; and

D. The undersigned FMC signatories represent and warrant that they are authorized to execute this CIA on behalf of FMC. 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 the OIG.

ON BEHALF OF FLOYD HEALTHCARE MANAGEMENT, INC.

By: _____

KURT STUENKEL
Chief Executive Officer
Floyd Healthcare Management, Inc.

_____
DATE

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

_____

LEWIS MORRIS, ESQUIRE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

11/29/00
DATE

ON BEHALF OF FLOYD HEALTHCARE MANAGEMENT, INC.

By: _____ 11-28-00
KURT STUENKEL DATE
Chief Executive Officer
Floyd Healthcare Management, Inc.

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

_____ _____
LEWIS MORRIS, ESQUIRE DATE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A
ANNUAL CLAIMS REVIEW PROTOCOL

A. Introduction

The billing practices of each faculty physician for whom claims are submitted through or by FMC shall be reviewed to assure compliance with all billing requirements of Medicare and Medicaid ("the review"). The initial review will be conducted by FMC staff. The review shall consist of twenty (20) services per full-time and part-time faculty physician annually. However, FMC may chose to conduct the review on a quarterly (5 services per quarter) or semi-annual (10 services per semi-annual period) basis. Such review shall include both inpatient and outpatient physician services.

B. Audit Staff

FMC represents and warrants that the initial review shall be conducted by a Coding Specialist, who has no involvement in the initial coding of the claims to be reviewed nor does he/she supervise the Family Practice Billing Coordinator or provide billing services for the Family Practice Residency Program. Further, such Coding Specialist shall, at a minimum, report to the Compliance Officer. FMC further represents and warrants that the second-level claims review may be conducted by an Associate Medical Director, who is not a faculty physician within the Family Practice Residency Program and has no other involvement in the Residency Program. Alternatively, the second-level claims review may be conducted by an independent consultant.

The individuals conducting the review will have experience in Federal Health Care Program requirements for physician services. Each reviewer will attend relevant annual training workshops, which provide hands-on training in the review process. In addition, the Compliance Officer shall monitor the work product of each reviewer periodically, to provide reasonable assurance of the accuracy and consistency of review results.

C. Audit Process

1. Select services to be reviewed using RAT-STATS random number generator from the period under review. The population should be paid line items.

2. Review the internal charge slip and the provider's documentation in the medical record.

3. The review is based on Current Procedural Terminology (CPT) and AMA/HCFA documentation guidelines for E/M services. The elements to be considered include:

    a. Whether documentation supports the level of service and type of service paid;

b. Whether documentation reflects the attending physician's presence at the time the service was rendered;
c. Whether services paid were supported by medical record documentation;
d. Whether payment was received twice for the same service

4. If documentation matches the code selected for billing and/or supports the billing of the service and payment of the claim, then audit is complete.

5. Each piece of documentation will be reviewed and graded using the following point system:

Points	Explanation
0	Documentation meets Medicare and Medicaid requirements
2	E/M service upcoded by one level
4	E/M service upcoded by two or more levels
6	No documentation that the service paid was provided
6	No documentation of attending physician's presence
3	E/M service billed under wrong category (new vs. est., consult vs. visit); or service was paid twice (duplicate)

A cumulative total of 12 points or higher for each group of ten (10) services per physician being reviewed will result in a finding of "non-compliance."

6. If the initial review results in a finding of non-compliance, a copy of the encounter form and the medical record documentation supporting the service shall be forwarded to an Associate Medical Director and/or independent coding consultant for review.

7. If a finding of non-compliance is confirmed by the Associate Medical Director or the independent coding consultant, a refund shall be issued pursuant to the Overpayment Reporting requirements set forth in Section III. I. of the CIA.

8. If the physician is found to be in non-compliance he/she will be required to attend a training session and will be subjected to a second review of 10 services within sixty (60) days of the initial review. The scoring system set forth above will be applied to the second review group of ten (10) services.

9. If the second review results in a finding of non-compliance, the physician will be

referred to the Compliance Officer for further corrective action, pursuant to Human Resources policies.

10. In addition, if a second review results in a finding of non-compliance FMC shall (1) place one hundred percent of the services rendered by the non-compliant physician on pre-submission review, which shall continue until such time as the Compliance Officer is satisfied that such billing is found to be in compliance; (2) stop billing for that physician's services, which are not adequately supported by medical record documentation; and (3) follow the requirements for refunding overpayments as set forth in Section III. I. of the CIA.

11. At all times, all overpayments identified in the review will be duly calculated and refunded to the appropriate payor pursuant to the Overpayment Reporting obligations under III. I, regardless of whether the review indicates a "noncompliance" score.

D. Annual Claims Review Report

Pursuant to Section V.B.5 of the CIA, FMC shall submit to the OIG as part of its Annual Report a final report setting forth its findings in its Annual Claims Review. The IRO shall submit a final report setting forth its findings regarding whether FMC has followed the Annual Claims Review Protocol as required by the CIA.

APPENDIX B
SPECIAL REVIEW AUDIT PROTOCOL

A. Special Review.

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

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

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

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

d. Paid Claim: A code or line item submitted by FMC and for which FMC has received reimbursement from the Medicare and Medicaid program.

e. Population: All Items for which FMC has submitted a code or line item and for which FMC has received reimbursement from the Medicare or Medicaid program (i.e., a Paid Claim) during the 12-month period covered by the Special Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

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

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

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

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

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

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

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

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

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

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

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

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

1. ***Special Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Special Review. As noted in section A.1.b above, for purposes of this Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Special Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

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

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

2. ***Statistical Sampling Documentation***

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

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

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

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

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

3. ***Special Review Results***

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

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to FMC.

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

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

Attachment 1

Claim Review Results

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

APPENDIX C

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____ AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:

Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? _____ Yes _____ No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____