CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CAM MEDICAL SUPPLIES, INC.

I. PREAMBLE

CAM Medical Supplies, Inc.("CAM") 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 ensure compliance by its employees and owners 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"). CAM's compliance with the terms and conditions in this CIA shall constitute an element of CAM's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, CAM is entering into a Stipulation and Order of Settlement and Dismissal ("Stipulation"), to which this CIA is attached as Exhibit A.

II. TERM OF THE CIA

The period of the compliance obligations assumed by CAM under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). 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

CAM shall establish a compliance program that includes the following elements.

A. Compliance Contact. Within ninety (90) days after the effective date of this CIA, CAM shall appoint an individual to serve as Compliance Contact, 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 Contact shall be a member of senior management of CAM, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of CAM and shall be authorized to report to the Board of Directors at any time. The Compliance Contact shall be responsible for monitoring the day-to-day activities engaged in by CAM to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Contact is appointed during the term of this CIA, CAM shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, CAM shall establish a Code of Conduct. The Code of Conduct shall be distributed to all employees within ninety (90) days of the effective date of this CIA. CAM shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. CAM'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. CAM's requirement that all of its employees shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with CAM's own policies and procedures (including the requirements of this CIA);

c. the requirement that all of CAM's employees shall be expected to report suspected violations of any statute, regulation, or guideline

applicable to Federal health care programs or of CAM's own policies and procedures;

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

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

Within ninety (90) days of the effective date of the CIA, each employee shall certify, in writing, that he or she has received, read, understands, and will abide by CAM's Code of Conduct. New employees shall receive the Code of Conduct and shall complete the required certification within three (3) weeks after the commencement of their employment or within ninety (90) days of the effective date of the CIA, whichever is later.

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

2. *Policies and Procedures.* Within ninety (90) days of the effective date of this CIA, CAM shall develop and initiate implementation of written Policies and Procedures regarding the operation of CAM's 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. At a minimum, the Policies and Procedures shall specifically address the necessity of selecting the proper procedure code when submitting claims to federal health care programs. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to CAM management through the Confidential Disclosure Program required by section III.E. CAM shall assess and update as necessary the Policies and Procedures at least annually or more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

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

C. Training and Education.

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

a. CIA requirements;

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

c. Code of Conduct.

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

New employees shall receive the general training described above within thirty (30) days of the beginning of their employment or within ninety (90) days after the effective date of this CIA, whichever is later. Each year, every employee shall receive such general training on an annual basis.

2. *Specific Training*. Within ninety (90) days of the effective date of this CIA and on an annual basis thereafter, each employee who is involved directly or indirectly 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 programs 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 employees shall receive this training within thirty (30) days of the beginning of their employment or within ninety (90) days of the effective date of this CIA, whichever is later. If a new employee has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a CAM employee who has completed the substantive training shall review all of the untrained person's work regarding the assignment of billing codes.

3. *Certification.* Each employee 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 Contact shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, CAM shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist CAM in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Stipulation. Each Independent Review Organization retained by CAM 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 CAM seeks reimbursement.

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address CAM's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall

address CAM's compliance with the obligations assumed under this CIA and the Stipulation ("Compliance Engagement").

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO and CAM shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

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

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by CAM to the Medicare program. The Claims Review

shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this CIA.

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

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

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

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

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

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

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

3. *Compliance Engagement.*

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

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

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

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

ii. if in the future CAM becomes a cost reporting entity, the IRO's findings and supporting rationale regarding whether CAM has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Stipulation) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor

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

are inaccurate. CAM 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.

E. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, CAM shall establish a Confidential Disclosure Program, which must include measures (e.g., a lock box) to enable employees, contractors, agents or other individuals to disclose, to the Compliance Contact or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with CAM's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. CAM shall publicize the existence of such measures (e.g., e-mail to employees or placement of lock box in prominent common area).

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 Contact (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct if such person is known or identified. The Compliance Contact (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, CAM shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Contact 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 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*. CAM shall not knowingly hire any Ineligible Person as an employee or engage any Ineligible Person as a contractor or consultant. To prevent hiring or contracting with any Ineligible Person, CAM 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.hhs.gov/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this CIA, CAM will review its list of current employees, consultants and contractors against the Exclusion Lists. Thereafter, CAM will review the list once semi-annually. If CAM has notice that an employee, agent, or physician has become an Ineligible Person, CAM will remove such person from responsibility for, or involvement with, CAM'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 CAM has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with CAM, within 10 days of receiving such notice, CAM will remove such individual from responsibility for, or involvement with, CAM's business operations

related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings. Within thirty (30) days of discovery, CAM 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 CAM 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. CAM 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. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, CAM identifies or learns of any overpayments, CAM shall notify the payor (e.g., Medicare fiscal intermediary or carrier) unless the notification of the overpayment came from the payor itself and repay any identified overpayments within 30 days of discovery, unless the identified overpayments have already been deducted or offset by the payor and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

i. a substantial overpayment relating to any Federal health care program; or

ii. a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws

applicable to any Federal health care program for which penalties or exclusion may be authorized; or

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

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

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

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

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

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

iii. a description of CAM's actions taken to correct the Material Deficiency; and

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

IV. NEW LOCATIONS

In the event that CAM purchases or establishes new business units after the effective date of this CIA, CAM 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 employees at such locations shall be subject to the requirements in this CIA that apply to new employees (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and twenty (120) days after the effective date of this CIA, CAM 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 Contact required by section III.A;

2. a copy of CAM's Code of Conduct required by section III.B.1;

3. the summary of the Policies and Procedures required by section III.B.2;

4. 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;

5. a certification by the Compliance Contact that:

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

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

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

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

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

8. a summary of personnel actions taken pursuant to section III.F.

B. Annual Reports. CAM shall submit to OIG an Annual Report with respect to the status and findings of CAM's compliance activities.

The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Contact described in section III.A;

2. a certification by the Compliance Contact that:

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

   b. all employees 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, including a copy of the methodology used;

5. CAM's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of material deficiencies reported throughout the course of the previous twelve (12) months pursuant to 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 CAM 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 CAM 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 or legal proceeding; and

11. a listing of all of CAM'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 payor (specific contractor) that issued each provider identification number.

The first Annual Report shall cover the period for one year beginning from the effective date of this CIA and 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 Contact under penalty of perjury, that: (1) CAM is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Contact has reviewed the Reports 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

CAM: Carlo Micceri
CAM Medical Supplies, Inc.
11 Clearbrook Road
Elmsford, New York 10523
Phone: (914) 592-2020
Fax: (914) 592-0318

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 CAM's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: CAM's compliance with the terms of this CIA. The documentation described above shall be made available by CAM 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 CAM's employees who consent to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee and OIG. CAM agrees to assist OIG in contacting and arranging interviews with such employees upon OIG's request. CAM's employees may elect to be interviewed with or without a representative of CAM present. OIG or its duly authorized representative(s) may conduct on-site visits at CAM's place of business at any time to review documents and records for the purpose of verifying CAM's compliance with the terms of this CIA.

VIII. DOCUMENT AND RECORD RETENTION

CAM 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, the OIG shall make a reasonable effort to notify CAM prior to any release by OIG of information submitted by CAM pursuant to its obligations under this CIA and identified upon submission by CAM as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. CAM 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

CAM 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, CAM 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 $1,500 (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, CAM fails to have in place any of the following:

a. a Compliance Contact;

b. a written Code of Conduct;

c. written Policies and Procedures;

d. a training program; and

e. a Confidential Disclosure Program;

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day CAM fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date the failure to comply began) for each day CAM:

a. hires or enters into a contract or consultant agreement 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 CAM 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, CAM's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which CAM 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, CAM's business operations

related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after CAM received notice of the relevant matter or after the resolution of the matter).

4. A Stipulated Penalty of $750 (which shall begin to accrue on the date the CAM fails to grant access) for each day CAM fails to grant access to the information or documentation as required in section V or VII of this CIA.

5. A Stipulated Penalty of $500 (which shall begin to accrue ten (10) days after the date that OIG provides notice to CAM of the failure to comply) for each day CAM fails to comply fully and adequately with any obligation of this CIA. In its notice to CAM, the OIG shall state the specific grounds for its determination that the CAM 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 CAM has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify CAM by personal service or certified mail of (a) CAM's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, CAM shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event CAM elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until CAM cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions*. CAM 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 CAM 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 CAM receives OIG's written denial of such request. A "timely written request" is defined

as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

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

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

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by CAM constitutes an independent basis for CAM'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 CAM has materially breached this CIA and that exclusion should be imposed, the OIG shall notify CAM by certified mail of (a) CAM'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.* CAM shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. CAM 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 35-day period, but that: (i) CAM has begun to take action to cure the material breach, (ii) CAM is pursuing such action with due diligence, and (iii) CAM 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 or such longer period if such period is agreed to by the parties, CAM fails to satisfy the requirements of section X.C.2, OIG may exclude CAM from participation in the Federal health care programs. OIG will notify CAM in writing of its determination to excluded CAM (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 CAM is excluded under the provisions of this CIA, CAM 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 CAM to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;

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 the OIG's delivery to CAM of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, CAM 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the

request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the 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 CAM was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. CAM shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders CAM to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that CAM 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 CAM 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 35 day period, but that (i) CAM has begun to take action to cure the material breach,

(ii) CAM is pursuing such action with due diligence, and (iii) CAM has provided to OIG a reasonable timetable for curing the material breach.

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

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and CAM 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 Stipulation to which this CIA is incorporated and attached as Exhibit A, CAM and OIG agree as follows:

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

B. Nothing herein is intended or shall be construed to require the waiver by CAM of any attorney-client privilege or other applicable privilege, provided, however, that the existence or assertion of any such privilege shall not affect CAM's obligation to comply with the provisions of this CIA;

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

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

E. The undersigned CAM 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 CAM MEDICAL SUPPLIES, INC.

11/13/00
DATE

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

DATE

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

ON BEHALF OF CAM MEDICAL SUPPLIES, INC.

_____ _____

DATE

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

_____ 9/26/08

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

APPENDIX A

A. Claims Review.

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims 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.H.1.a of the CIA, the amount of money CAM has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, CAM shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

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

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

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

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

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

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

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

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

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

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review

Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

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

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

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

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

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this

Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

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

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

2. ***Statistical Sampling Documentation***

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

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

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

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

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

3. ***Claims Review Results***

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

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

d. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See 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 Claims Review; and (2) performed the Claims 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 Correct Allowed Amt

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 reaso
n 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)
_____

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND CAM MEDICAL SUPPLIES, INC.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Cam Medical Supplies, Inc. ("CAM") entered into a Corporate Integrity Agreement ("CIA") on November 13, 2000.

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

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

Appendix A of CAM's CIA is hereby superceded by the attached new Appendix A.

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

C. The undersigned CAM signatory represent and warrant 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 CAM

Carlo Micceri
President/Chief Executive Officer
CAM Medical Supplies, Inc.

02/01/02
DATE

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

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

2/5/02
DATE

D. Review Procedures.

1. *General Description.*

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

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

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

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

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

2. *Claims Review.*

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

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

i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, CAM should, as appropriate, further analyze any errors identified in the Discovery Sample. CAM recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, 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 CAM or under CAM'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, CAM 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 CAM 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 CAM's Discovery Sample identifies an Error Rate of 5% or greater, CAM's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to CAM observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, CAM 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. CAM 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.* The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of CAM's compliance with the unallowable cost provisions of the Settlement Agreement.

a. the IRO shall determine whether CAM has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements,

information reports, or payment requests already submitted by CAM or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include:

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

6. *Compliance Review.* The IRO shall conduct a review of CAM's compliance activities. The Compliance Review shall consist of a review of CAM's compliance with the obligations set forth in each section of this CIA.

7. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include:

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

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

8. *Validation Review.* In the event the OIG has reason to believe that: (a) CAM's Claims Review, Unallowable Cost Review or Compliance Review

fails to conform to the requirements of this CIA; or (b) 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, Unallowable Cost Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). CAM 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 CAM's final submission is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify CAM 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, CAM may request a meeting with the OIG to discuss the results of any Claims Review, Unallowable Cost Review, or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review, Unallowable Cost Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. CAM agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review or Compliance Review issues with CAM prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

9. *Independence Certification.* The IRO shall include in its report(s) to CAM a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, Unallowable Cost Review, and Compliance 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 CAM 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 CAM and for which CAM has received reimbursement from the Medicare program.

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

e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

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

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

to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

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

1. **Claims Review Methodology.**

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

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

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

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

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

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

2. **Claims Review Findings.**

a. A description of CAM's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;

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

c. The IRO's findings and recommendations concerning the Systems Review (if any).

3. **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.

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

4. **Claims Review Results.**

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

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

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

e. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

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

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

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 Correct Allowed Amt