

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ARLINGTON EMERGENCY MEDICINE ASSOCIATES**

I. PREAMBLE

Arlington Emergency Medicine Associates (“AEMA”) hereby enters into this Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance by AEMA and AEMA’s physicians (both employees and contractors), employees, and agents, including all third parties whom AEMA engages to prepare or submit claims for reimbursement, (hereinafter collectively “Covered Persons”) with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”). Contemporaneously with this CIA, AEMA is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into that Settlement Agreement.

II. TERM OF THE CORPORATE INTEGRITY AGREEMENT

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

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

III. INTEGRITY OBLIGATIONS

AEMA hereby agrees to establish an Integrity Program that includes the following elements:

A. Compliance Contact

Within 30 days after the effective date of this CIA, AEMA shall appoint or designate an individual to serve as its Compliance Contact for the purposes of the obligations in this CIA. At all times during the term of this CIA, there shall be a Compliance Contact who shall have operational responsibility for ensuring AEMA's compliance with the obligations of this CIA. The Compliance Contact shall also be responsible for any reporting obligations created under this CIA. Any changes in the identity or position description of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 20 days of such a change.

B. Notice of Compliance

Within 15 days of the effective date of this CIA, AEMA shall post in the emergency waiting room area, which is a prominent place accessible to all physicians, other health care professionals, patients and employees a notice detailing AEMA's commitment to comply with applicable statutes, regulations and directives applicable to the Federal health care programs ("Federal health care program requirements") in the conduct of AEMA's medical practice and in seeking reimbursement from the Federal health care programs for services and items furnished to patients of the Federal health care programs (the "Notice of Compliance"). The Notice of Compliance shall identify a means (*i.e.*, telephone number, address, etc.) through which matters of concern can be reported anonymously. Within 30 days of the effective date of this CIA, AEMA shall distribute a copy of the Notice of Compliance to each Covered Person.

C. Written Policies and Procedures

AEMA agrees to compile, develop as necessary, and implement written Policies and Procedures within 60 days of the effective date of this CIA. The written Policies and Procedures shall address the following:

1. AEMA's commitment to adhere to honest and accurate billing practices;
2. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;
3. The proper documentation of services provided and other billing information as required for the submission of complete and accurate claims to the Federal health care programs, and the retention of such information in a readily retrievable form;
4. A mechanism for physicians, employees and agents to make inquiries regarding compliance with medical practice standards and Federal health care program requirements without risk of retaliation or other adverse effect;
5. The requirement that AEMA not hire, employ or engage as contractors any Ineligible Person. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement 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. To prevent hiring or contracting with any Ineligible Person, AEMA shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

D. Training and Certification

Within 60 days of the effective date of this CIA, AEMA, AEMA's physicians (both employees and contractors), employees and agents shall be trained in the proper reimbursement standards, program policies, and verification procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal health care program beneficiaries. The training shall be designed to ensure that AEMA and each of AEMA's physicians, employees and agents are aware of all applicable Federal health care program requirements, and the consequences (*i.e.*, overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal health care programs, etc.) both to the individual and to AEMA that may ensue from any violation of such requirements.

AEMA agrees to arrange for each new physician, employee and agent to participate in such training no later than 20 days after the person begins to work for AEMA. Such training may be provided in whole or in part by an outside vendor, including a Health Care Financing Administration ("HCFA") contractor. Until a person has received all required training, such person shall work under the direct supervision of another individual who has completed the required training.

AEMA shall ensure that each person required to receive this training shall receive no less than four (4) hours of training annually.

At a minimum, the training sessions shall cover the following topics:

1. AEMA's obligations under this CIA;
2. All applicable Federal health care program requirements related to reimbursement, and the legal sanctions for improper billing or other violations of these standards.
3. The written Policies and Procedures developed pursuant to Section III.C, above;

Each physician, employee and agent shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the Policies and Procedures developed pursuant to Section III.C and all

applicable Federal health care program requirements addressed in training. These certifications will be maintained by AEMA and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be maintained with the certifications.

E. Third Party Billing Services

If AEMA contracts or otherwise retains an independent third party to perform any billing and/or coding services for AEMA ("Third Party Biller"), AEMA shall, as a term of its contract or other agreement with the Third Party Biller, require that such Third Party Biller certify that all individuals who, by virtue of AEMA's relationship with the Third Party Biller, are involved with the preparation or submission of claims for reimbursement to any Federal health care program for services provided by AEMA receive, at a minimum, annual training regarding applicable Federal health care program requirements related to reimbursement. Such certifications shall be in writing and AEMA shall require such certifications on an annual basis.

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days of the effective date of this CIA, AEMA shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a billing review to assess AEMA's billing and coding practices ("Billing Engagement"). The Independent Review Organization retained by AEMA shall have expertise in the billing, coding, reporting and other requirements relevant to AEMA's business.

2. *Frequency of the Billing Engagement.* 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 shall perform all components of each annual Billing Engagement and prepare the required reports in accordance with the procedures detailed in **Appendix A** to this CIA, which is incorporated by reference into this CIA.

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

4. *Validation Review.* In the event the OIG has reason to believe that: (a) AEMA's Billing 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 Engagement complies with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. AEMA 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 is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify AEMA of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, AEMA may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. AEMA agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with AEMA 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.

G. Reporting of Overpayments and Material Deficiencies

1. Overpayments

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

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

overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

b. Reporting of Material Deficiencies. If AEMA determines that there is a Material Deficiency, AEMA 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.G.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 AEMA's actions taken to correct the Material Deficiency; and

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

H. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, AEMA 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 AEMA 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. AEMA shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of AEMA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of AEMA's locations for the purpose of verifying and evaluating: (a) AEMA's compliance with the terms of this CIA; and (b) AEMA's compliance with the requirements of the Federal health care programs in which AEMA participates. The documentation described above shall be made available by AEMA 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 AEMA's employees, contractors, or agents who consent to be

interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. AEMA agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AEMA's employees may elect to be interviewed with or without a representative of AEMA present.

Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by AEMA or AEMA's attorney-client, attorney-work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect AEMA's obligation to comply with the provisions of this CIA, *e.g.*, by providing all documents necessary to determine whether AEMA is in compliance with the terms of this CIA.

V. REPORTS

A. IMPLEMENTATION REPORT

Within 90 days of the effective date of this CIA, AEMA shall provide the OIG with a written report demonstrating that AEMA has complied with the requirements of this CIA. This report, known as the "Implementation Report," shall include:

1. The name, address, and telephone and facsimile numbers of the Compliance Contact, as described in Section III.A;
2. A copy of the posted Notice of Compliance described in Section III.B, and a description of where such Notice of Compliance is posted;
3. A description, schedule and topic outline of the training programs implemented or relied upon pursuant to Section III.D. of this CIA, and a certification signed by the Compliance Contact attesting that all physicians, other health care professionals, employees and agents have completed the initial training required by Section III.D (the individual training certifications required by Section III.D. and the training materials will be made available to OIG upon request);

4. The identity of the IRO and the proposed start and completion dates of the first Billing Engagement;
5. A listing of all hospitals or other entities with which AEMA contracts for the provision of emergency room medical services; and
6. A certification from the Compliance Contact stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information provided in the Implementation Report is accurate and truthful and that AEMA has met each of its obligations under this CIA.

B. ANNUAL REPORTS

AEMA agrees to make annual written reports (each one of which is referred to throughout this CIA as the "Annual Report") to OIG describing the measures taken to implement and maintain the Program and ensure compliance with the terms of this CIA. Each Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented or relied upon pursuant to Section III.D. of this CIA, and a certification signed by the Compliance Contact attesting that all physicians, employees and agents have completed the annual training required by Section III.D. The individual training certifications required by Section III.D and the training materials will be made available to OIG upon request;
2. A copy of the Claims Review Report prepared pursuant to Section III.F of this CIA and relating to the year covered by the Annual Report; and a description of any corrective actions taken in response to the findings of the Billing Engagement;
3. A listing, including locations, of all hospitals or other entities with which AEMA contracts for the provision of emergency room medical services;

4. A report of the aggregate overpayments that have been identified through AEMA's Compliance Program and returned to the Federal health care programs during the one-year period covered by the Annual Report, pursuant to Section III.G. Overpayment amounts should be broken into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs; and
5. A certification signed by the Compliance Contact certifying that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful and that AEMA has met each of its obligations under this CIA..

The Annual Reports shall be due within 45 days of the end of the one-year period covered by the Annual Report. The first one-year period shall commence on the effective date of this CIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with Section IX.D. below, all correspondence, notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to 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
 330 Independence Avenue, SW
 Cohen Building, Room 5527
 Washington, DC 20201
 Telephone : (202) 619-2078
 Facsimile: (202) 205-0604

If to AEMA: Dr. Howell Davis
 Arlington Emergency Medicine Associates, P.A.
 800 West Randal Mill Road
 Arlington, TX 76012
 Telephone: (817) 548-6205

Facsimile: (817) 561-1924

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

VII. DOCUMENT AND RECORD RETENTION

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

VIII. DISCLOSURES

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

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by AEMA shall be expected throughout the duration of this CIA with respect to all of the obligations herein agreed to by AEMA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, AEMA 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day AEMA:

- a. Or each applicable Covered Person fails to attend the training required by section III.D. of the CIA within the time frames required in that section;
- b. Fails to annually submit the IRO's Claims Review Report and Process Review Report as required in section III.F and Appendix A; or
- c. Fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day AEMA employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, AEMA's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which AEMA can demonstrate that AEMA did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.C.5.) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day AEMA fails to grant access to the information or documentation as required in section IV of this CIA. (This Stipulated Penalty shall begin to accrue on the date AEMA fails to grant access.)

4. A Stipulated Penalty of \$750 for each day AEMA fails to comply fully and adequately with any obligation of this CIA not already covered in sections IX.A.1-3, above. In its notice to AEMA, OIG shall state the specific grounds for its determination that AEMA has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the AEMA must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to AEMA of the failure to comply.)

B. Timely Written Requests for Extensions

AEMA 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 AEMA 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 AEMA 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 AEMA has failed to comply with any of the obligations described in section IX.A and after determining that Stipulated Penalties are appropriate, OIG shall notify AEMA of: (a) AEMA's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, AEMA shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his or her corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for 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 IX.E. In the event AEMA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AEMA 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 IX.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 IX.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AEMA has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section IX.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 AEMA to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.G;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section IX.A(1);

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by AEMA constitutes an independent basis for AEMA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that AEMA has materially breached this CIA and that exclusion should be imposed, OIG shall notify AEMA of: (a) AEMA'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.* AEMA shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. AEMA is in full compliance with this CIA;

- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) AEMA has begun to take action to cure the material breach; (ii) AEMA is pursuing such action with due diligence; and (iii) AEMA has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, AEMA fails to satisfy the requirements of section IX.D.3, OIG may exclude AEMA from participation in the Federal health care programs. OIG will notify AEMA in writing of its determination to exclude AEMA (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, AEMA wishes to apply for reinstatement, AEMA 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 AEMA 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, AEMA shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only

issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether AEMA was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. AEMA 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 AEMA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AEMA 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 AEMA was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that:
 - (i) AEMA had begun to take action to cure the material breach within that period;
 - (ii) AEMA has pursued and is pursuing such action with due diligence; and
 - (iii) AEMA provided to OIG within that period a reasonable timetable for curing the material breach and AEMA 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 AEMA, only after a DAB decision in favor of OIG. AEMA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude AEMA upon the issuance of an ALJ's decision in

favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that AEMA may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

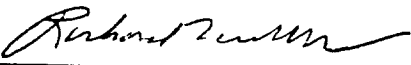
4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for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

X. 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, AEMA and the OIG agree as follows:

1. This CIA shall be binding on the successors, assigns and transferees of AEMA;
2. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
3. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
4. The undersigned AEMA 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.

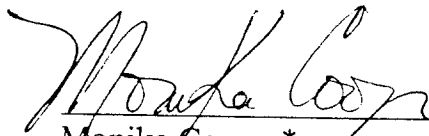
FOR: ARLINGTON EMERGENCY MEDICINE ASSOCIATES



Dr. Richard Neville
President
Arlington Emergency Medicine Associates, P.A.

3-14-01

Date



Monika Cooper*
Shannon, Gracey, Ratliff & Miller, L.L.P.

3-72-01

Date

* Signing in the capacity of Counsel for Arlington Emergency Medicine Associates only

**FOR: 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

Date

FOR: ARLINGTON EMERGENCY MEDICINE ASSOCIATES

Dr. Richard Neville
President
Arlington Emergency Medicine Associates, P.A.

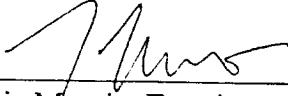
Date

Monika Cooper*
Shannon, Gracey, Ratliff & Miller, L.L.P.

Date

* Signing in the capacity of Counsel for Arlington Emergency Medicine Associates only

**FOR: OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Lewis Morris, Esquire
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Date

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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 AEMA 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, AEMA shall not subtract or “net out” underpayments when determining the amount of relevant Overpayments.
- d. Paid Claim: A code or line item submitted by AEMA and for which AEMA has received reimbursement from the Medicare and Medicaid programs.
- e. Population: All Items for which AEMA has submitted a code or line item and for which AEMA has received reimbursement from the Medicare and Medicaid programs (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 Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population are to be used to calculate the minimum number of Items that shall be included in the Claims Review Sample in order to achieve the required confidence and precision levels.
- 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 should contain a sufficient number of Items (according to the RAT-STATS calculation) 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) should 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 Overpayments in the Population must be estimated. Estimates for each unique Population 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 Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by AEMA for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes

of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the “Variable Appraisals”, “Difference Values Only” 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 Overpayments in the Population (based on the amount of Overpayments received by AEMA for each sample Item) shall be determined from this Probe Sample, using RAT-STATS’ “Difference Values Only” function located under the “Variable Appraisals” component. 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 Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by AEMA for each Item in the sample. The “Difference Values Only” function located under the “Variable Appraisals” component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the “Variable Appraisals”, “Difference Values Only” 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 Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review Sample. In order to estimate the 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. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items.

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 AEMA cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by AEMA 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”, “Difference Values Only” function results for the Probe Sample, including a copy of the data file.
- 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 Claims submitted by AEMA (“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 AEMA.
- 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 AEMA, 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. The level of precision achieved by the Claims Review at a 90% confidence level.

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.)

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.

**AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ARLINGTON EMERGENCY MEDICAL ASSOCIATES, L.L.P.**

The Office of Inspector General (“OIG”) of the Department of Health and Human Services and Arlington Emergency Medicine Associates, P.A. (“AEMA”) entered into a Corporate Integrity Agreement (“CIA”) on March 22, 2001.

- A. Pursuant to section X.3. of AEMA’s CIA, modifications to the CIA may be made with the prior written consent of both the OIG and AEMA. Therefore, the OIG and AEMA hereby agree that AEMA’s CIA will be amended as follows:

Section III.F., Annual Review Procedures of the CIA is hereby superseded by the attached new section III.F., Annual Review Procedures.

Section III.G.1.a. is superseded by the following:

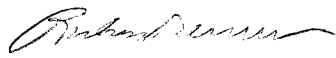
Definition of Overpayment. For purposes of this CIA, an “overpayment” shall mean the amount of money AEMA has received in excess of the amount due and payable under any Federal health care program requirements.

Appendix A of AEMA’s CIA is hereby superseded by the attached new Appendix A.

- B. The OIG and AEMA agree that all other sections of AEMA’s CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and AEMA.
- C. The undersigned AEMA signatory[ies] represent[s] and warrant[s] that he or she is [they are] 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 AEMA



Dr. Richard Neville
President
Arlington Emergency Medical Associates, P.A.

4-5-02

DATE




Monika Cooper*
Shannon, Gracey, Ratliff & Miller, L.L.P.

4-10-02

DATE

*Signing in the capacity of Counsel for Arlington Emergency Medical Associates only

**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

4/17/02

DATE

* The 2002 audit of the 2001 calendar year, shall be completed, pursuant to an agreement with the OIG, under the terms of the "Amendment to the Corporate Integrity Agreement."

F. Annual Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, AEMA shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a billing review to assess AEMA's billing and coding practices ("Billing Engagement"). The IRO retained by AEMA 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 AEMA seeks reimbursement.

b. Frequency of Billing Engagement. The Billing Engagement shall consist of a Claims Review as described in section III.F.2 below. The Billing Engagement 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 shall perform all components of each annual Billing Engagement and prepare the required reports in accordance with the procedures detailed below.

c. Retention of Records. The IRO and AEMA shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports related to the Billing Engagements.

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 Paid Claims submitted by or on behalf of AEMA. The Paid Claims

shall be reviewed based on the supporting documentation available at AEMA or under AEMA'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, AEMA should, as appropriate, further analyze any errors identified in the Discovery Sample. AEMA 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 as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.F.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 AEMA or under AEMA'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, AEMA 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 AEMA to the appropriate Federal health care program payor, including the

Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

d. Repayment of Identified Overpayments. In accordance with section III.G.1 of the CIA, AEMA 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. AEMA 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 between AEMA and the payor.

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. *Validation Review.*

In the event the OIG has reason to believe that: (a) AEMA's Billing Engagement 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 Billing Engagement complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). AEMA 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 AEMA's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify AEMA 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, AEMA may request a meeting with the OIG to discuss the results of any Billing Engagement submissions or any Claims Review findings; present

any additional or relevant information to clarify the results of the Billing Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. AEMA agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Billing Engagement and/or Claims Review issues with AEMA prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

5. *Independence Certification.* The IRO shall include in its report(s) to AEMA a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and that it has concluded that it was, in fact, independent.

APPENDIX A

A. Claims Review.

1. *Definitions.*

For the purposes of the Claims Review, the following definitions shall be used:

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

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

2. *Other Requirements.*

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which AEMA cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by AEMA 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 AEMA'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 AEMA ("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 AEMA.

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.

