CORPORATE COMPLIANCE AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MEDICAL CENTER EMERGENCY SERVICES

I. PREAMBLE

Medical Center Emergency Services ("MCES") hereby enters into this Corporate Compliance Agreement ("CCA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors and agents, physicians, third parties engaged to bill/submit reimbursement claims, and all other individuals responsible for the provision or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") 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 CCA, MCES is entering into a Settlement Agreement with the United States, and this CCA is incorporated by reference into the Settlement Agreement.

MCES currently has compliance measures in place, which include a Code of Conduct, a Policies and Procedures Statement, a Fraud and Ethics hotline, and a Compliance Officer.

II. TERM OF THE CCA

The period of the compliance obligations assumed by MCES under this CCA shall be three (3) years from the Effective Date of this CCA (unless otherwise specified). The "Effective Date" of this CCA shall be the date on which the final signatory of this CCA executes this CCA. MCES shall be notified upon the execution of this CCA by the Office of Inspector General of the Department of Health and Human Services.

Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from the OIG's receipt of: (1) MCES' final annual report; or (2) any additional materials submitted by the MCES pursuant to the OIG's request, whichever is later.

III. CORPORATE INTEGRITY OBLIGATIONS

MCES hereby agrees to maintain and revise as necessary its Compliance Program to include the following elements:

A. Compliance Officer and Committee.

1. Compliance Officer. MCES has appointed an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CCA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of MCES, and shall be responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance matters. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by MCES as well as for any reporting obligations created under this CCA.

MCES shall report to the OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CCA within 15 days of such a change.

B. Written Standards.

- 1. Code of Conduct. MCES has established a written Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 120 days of the Effective Date of this CCA. MCES shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall be revised as necessary to set forth, at a minimum:
 - a. MCES' commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

- b. MCES' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with MCES' own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CCA);
- c. the requirement that all of MCES' Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by MCES suspected violations of any Federal health care program requirements or of MCES' own Policies and Procedures;
- d. the possible consequences to both MCES and Covered Persons of failure to comply with Federal health care program requirements and with MCES' own Policies and Procedures and the failure to report such non-compliance; and
- e. the right of all individuals to use the Disclosure Program described in section III.E, and MCES' commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

Within 120 days of the Effective Date of the CCA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by MCES' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within one month after becoming a Covered Person or within 120 days of the Effective Date of the CCA, whichever is later.

MCES shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. Policies and Procedures. MCES has implemented written Policies and Procedures regarding the operation of MCES' compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall be revised as necessary to address:

- a. the subjects relating to the Code of Conduct identified in section III.B.1;
- b. proper and improper billing and coding practices.

Within 90 days of the Effective Date of the CCA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), MCES shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

- 1. General Training. Within 90 days of the Effective Date of this CCA, MCES shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain MCES':
 - a. CCA requirements; and
 - b. MCES' Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the Effective Date of this CCA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. Specific Training. Within 90 days of the Effective Date of this CCA, each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive

at least two hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

Persons providing the training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the Effective Date of this CCA, whichever is later. An MCES employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his/her applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least one hour of specific training annually. All training may fulfill the purposes of both this CCA and MCES' compliance plan, to the extent that the topics overlap. MCES shall not receive credit for their compliance plan training that occurred prior to the effective date of this CCA.

3. Certification. Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall

specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Third Party Billing

MCES presently contracts with a third party billing company (Emergency Physicians Billing Services) to submit claims to the Federal health care programs. MCES represents that it down not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If MCES intends to obtain an ownership or control interest (as defined in 42 U.S.C. §1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this CCA, MCES shall notify the OIG 30 days prior to any such proposed involvement.

Within 120 days of the effective date of this CCA, MCES shall obtain a certification from the third party billing company that (i) to the best of its knowledge, it is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to the Federal health care programs; (ii) it maintains policies that address the proper procedures for honest and accurate submission of claims in accordance with Federal health care program requirements; (iii) it has a policy of not knowingly employing any person who has been excluded, debarred or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iv) it provides at least five hours of training per year in billing and coding related to Medicare and other Federal health care programs for those employees involved in the preparation and submission of claims to those programs. MCES shall include a copy of this certification in the Implementation Report. If MCES contracts with a new third party billing company during the term of the CCA, MCES shall, within 30 days of entering into such a contract, obtain and send to the OIG the certification described in this section III.C.

E. Review Procedures.

1. General Description.

a. <u>Retention of Independent Review Organization</u>. Within 90 days of the effective date of this CCA, MCES shall retain an entity (or entities), such as an accounting, auditing or consulting firm

(hereinafter "Independent Review Organization" or "IRO"), to perform a review engagement to assist MCES in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CCA and the Settlement Agreement. Each IRO retained by MCES shall have expertise in the billing, coding, reporting and other requirements of physician groups and in the general requirements of the Federal health care program(s) from which MCES seeks reimbursement. The IRO(s) engagement shall address and analyze MCES' billing and coding to the Federal health care programs ("Claims Review"). Each IRO shall assess, along with MCES, whether it can perform the IRO engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

- b. <u>Frequency of Claims Review</u>. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CCA beginning with the effective date of this CCA. The IRO(s) shall perform all components of each annual Claims Review.
- c. <u>Retention of Records</u>. The IRO and MCES 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 MCES related to the 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 CCA, which is incorporated by reference.
 - a. <u>Discovery Sample</u>. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of MCES. The Paid Claims shall be reviewed based on the supporting documentation available at MCES or its third party billing company or under MCES's or the third party billing company'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. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, MCES should, as appropriate, further analyze any errors identified in the Discovery Sample. MCES 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.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 estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. The Paid Claims shall be reviewed based on supporting documentation available at MCES or its third party billing company or under MCES's or the third party billing company'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 the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, MCES 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 MCES 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.

3. Validation Review. In the event the OIG has reason to believe that: (a) MCES' Billing or Compliance Engagement fails to conform to the requirements of this CCA; 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 Engagements comply with the requirements of the CCA and/or the findings or Claims Review results are inaccurate. MCES 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.

Prior to initiating a Validation Review, the OIG shall notify MCES 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, MCES 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. MCES 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 MCES prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

5. Independence Certification. Within 120 days from the Effective Date of this CCA, the IRO shall provide to MCES a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it is, in fact, independent. Such certification shall be included in MCES' Implementation Report submission. Annual independence certifications shall be included in each Annual Report.

F. <u>Disclosure Program.</u>

MCES has established a Non Retribution Policy ("Disclosure Program") which includes a hotline number of 1-800-484-9200 to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with MCES' policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. MCES shall

appropriately publicize the existence of the disclosure mechanism (e.g., via periodic emails to employees or by posting the information in prominent common areas).

The Disclosure Program emphasizes a non-retribution, non-retaliation policy, and includes a reporting mechanism for anonymous communications for which appropriate confidentiality will be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, MCES shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

G. Ineligible Persons.

- 1. Definition. For purposes of this CCA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred or otherwise declared ineligible.
- 2. Screening Requirements. MCES shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, MCES screens all employees annually by searching the National Practitioners Data Bank. Further, MCES shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the

HHS/OIG List of Excluded Individuals/Entities (available through the Internet at www.oig.hhs.gov) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) MCES to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Review and Removal Requirement. Within 90 days of the Effective Date of this CCA, MCES shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, MCES shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists annually. In addition, MCES shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If MCES has actual notice that an employee or contractor or physician with staff privileges has become an Ineligible Person, MCES shall remove such person from responsibility for, or involvement with, MCES' 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 MCES has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, MCES shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, MCES shall notify OIG, in writing, of any ongoing investigation known to MCES or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that MCES 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. MCES 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.

I. Reporting.

1. Overpayments

- a. Definition of Overpayments. For purposes of this CCA, an "overpayment" shall mean the amount of money MCES has received in excess of the amount due and payable under any Federal health care program requirements. MCES may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for CCA reports.
- b. Reporting of Overpayments. If, at any time, MCES identifies or learns of any overpayments, MCES shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, MCES shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, MCES shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Material Deficiencies.

- a. Definition of Material Deficiency. For purposes of this CCA, a "Material Deficiency" means anything that involves:
 - (i) a substantial overpayment; or
 - (ii) a matter that a reasonable person would consider a probable 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 MCES determines through any means that there is a Material Deficiency, MCES 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) by 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 MCES' actions taken to correct the Material Deficiency; and

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

V. IMPLEMENTATION AND ANNUAL REPORTS

- A. <u>Implementation Report</u>. Within 120 days after the Effective Date of this CCA, MCES shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CCA. This Implementation Report shall include:
 - 1. the name, address, phone number, and position description of the Compliance Officer required by section III.A, and a summary of other non-compliance job responsibilities the Compliance Officer may have;
 - 2. a copy of MCES' Code of Conduct required by section III.B.1;
 - 3. a copy of all compliance-related Policies and Procedures required by section III.B.2 and a summary of all other Policies and Procedures required by section III.B.2;
 - 4. a copy of all training materials used for the training required by section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
 - 5. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by section III.B.1; and
 - c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.

The documentation supporting this certification shall be available to OIG, upon request.

- 6. a description of the Disclosure Program required by section III.E;
- 7. the identity of the IRO(s), a summary/description of all engagements between MCES and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
- 8. a certification from the IRO regarding its professional independence from MCES;
- 9. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;
- 10. a list of all of MCES' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the name and address of the Medicare contractor to which MCES currently submits claims;
- 11. a description of MCES' corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and
- 12. the certification required by section V.C.
- B. <u>Annual Reports</u>. MCES shall submit to OIG Annual Reports with respect to the status of, and findings regarding, MCES' compliance activities for each of the three one-year periods beginning on the Effective Date of the CCA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

- 1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;
- 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;
 - c. MCES has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

The documentation supporting this certification shall be available to OIG, upon request.

- 3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
- 4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

- 5. a complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
- 6. MCES' response and corrective action plan(s) related to any issues raised by the IRO(s);
- 7. a revised summary/description of all engagements between MCES and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
- 8. a certification from the IRO regarding its professional independence from MCES;
- 9. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 10. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable) and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate overpayment report;
- 11. a summary of the disclosures in the disclosure log required by section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 12. a description of any personnel actions (other than hiring) taken by MCES as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

- 13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 14. a description of all changes to the most recently provided list (as updated) of MCES' locations (including locations and mailing addresses) as required by section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and
- 15. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, MCES is in compliance with all of the requirements of this CCA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.
- D. <u>Designation of Information</u>: MCES shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. MCES shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date of this CCA, all notifications and reports required under this CCA shall be submitted to the following entities:

OIG:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

Cohen Building, Room 5527 330 Independence Avenue, SW

Washington, DC 20201 Phone: 202.619.2078 Fax: 202.205.0604

MCES:

Mark Harrison, Compliance Officer Medical Center Emergency Services

4201 St. Antoine Detroit, MI 48201 Phone: 313.745.3330 Fax: 313.745.3653

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

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of MCES' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of MCES' locations for the purpose of verifying and evaluating: (a) MCES' compliance with the terms of this CCA; and (b) MCES' compliance with the requirements of the Federal health care programs in which it participates. The

documentation described above shall be made available by MCES 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 MCES' 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. MCES agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. MCES' employees may elect to be interviewed with or without a representative of MCES present.

VIII. DOCUMENT AND RECORD RETENTION

MCES shall maintain for inspection all documents and records in its possession relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law), and shall engage in good faith efforts to assist OIG in obtaining any documents in the possession of other entities that may be required by the OIG in the course of its efforts to assess MCES' compliance with Federal health care program requirements or the terms of this CCA.

IX. DISCLOSURES

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

X. Breach and Default Provisions

MCES is expected to fully and timely comply with all of its CCA obligations.

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, MCES and OIG hereby agree that failure to comply with certain obligations set forth in this CCA may lead to the imposition of the following monetary

penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MCES fails to have in place any of the obligations described in section III:
 - a. a Compliance Officer;
 - b. a written Code of Conduct;
 - c. written Policies and Procedures;
 - d. a requirement that Covered Persons be trained; and
 - e. a Disclosure Program.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MCES fails to retain an IRO, as required in section III.D.
- 3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MCES fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.
- 4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day MCES employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, MCES' 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 MCES can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

- 5. A Stipulated Penalty of \$1,500 for each day MCES fails to grant access to the information or documentation as required in section VII of this CCA. (This Stipulated Penalty shall begin to accrue on the date MCES fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 for each day MCES fails to comply fully and adequately with any obligation of this CCA. In its notice to MCES, OIG shall state the specific grounds for its determination that MCES has failed to comply fully and adequately with the CCA obligation(s) at issue and steps MCES must take to comply with the CCA. (This Stipulated Penalty shall begin to accrue 10 days after MCES receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.
- B. <u>Timely Written Requests for Extensions</u>. MCES 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 CCA. 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 MCES fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after MCES 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. <u>Payment of Stipulated Penalties</u>.

- 1. Demand Letter. Upon a finding that MCES has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify MCES of: (a) MCES' failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, MCES shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law

judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event MCES elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until MCES 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 CCA and shall be grounds for exclusion under section X.D.

- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.
- 4. Independence from Material Breach Determination. Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that MCES has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CCA

- 1. Definition of Material Breach. A material breach of this CCA means:
 - a. a failure by MCES to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in section III.H;
 - b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in section X.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or
 - d. a failure to retain and use an Independent Review Organization in accordance with section III.D.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CCA by MCES constitutes an independent basis for MCES' exclusion from participation in the Federal health care programs. Upon a determination by OIG that MCES has materially breached this CCA and that exclusion should be

imposed, OIG shall notify MCES of: (a) MCES' 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. MCES 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. MCES is in compliance with the obligations of the CCA cited by the OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) MCES has begun to take action to cure the material breach; (ii) MCES is pursuing such action with due diligence; and (iii) MCES has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, MCES fails to satisfy the requirements of section X.D.3, OIG may exclude MCES from participation in the Federal health care programs. OIG will notify MCES in writing of its determination to exclude MCES (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, MCES wishes to apply for reinstatement, MCES must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

1. Review Rights. Upon OIG's delivery to MCES of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, MCES 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

- CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether MCES was in full and timely compliance with the obligations of this CCA for which the OIG demands payment; and (b) the period of noncompliance. MCES shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to stipulated penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders MCES to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless MCES 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 CCA shall be:
 - a. whether MCES was in material breach of this CCA;
 - 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) MCES had begun to take action to cure the material breach within that period;

- (ii) MCES has pursued and is pursuing such action with due diligence; and
- (iii) MCES provided to OIG within that period a reasonable timetable for curing the material breach and MCES 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 MCES, only after a DAB decision in favor of OIG. MCES' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude MCES upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that MCES 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. MCES agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of MCES, MCES will be reinstated effective on the date of the original exclusion.

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 CCA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CCA.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CCA shall be binding on the successors, assigns, and transferces of MCES;
- B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
- C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;
- D. OIG may agree to a suspension of MCES' obligations under the CCA in the event of MCES' cessation of participation in Federal health care programs. If MCES withdraws from participation in Federal health care programs and is relieved from its CCA obligations by the OIG, MCES agrees to notify OIG 30 days in advance of MCES' intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CCA should be reactivated or modified.
- E. The undersigned MCES signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

ON BEHALF OF MCES

Brooks F. Bock

President

DATE:

DATE

Robert H. Schwartz, Esq. Raymond & Prokop, P.C.

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

APPENDIX A

A. Claims Review.

- 1. **Definitions**. For the purposes of the Claims Review the following definitions shall be used:
 - a. <u>Overpayment:</u> The amount of money MCES has received in excess of the amount due and payable under any Federal health care program requirements.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
 - c. <u>Paid Claim</u>: A code or line item submitted by MCES and for which MCES has received reimbursement from the Medicare or Medicaid programs.
 - d. <u>Population</u>: All Items for which MCES has submitted a code or line item and for which MCES has received reimbursement from the Medicare or Medicaid programs (<u>i.e.</u>, 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. <u>Error Rate</u>: 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 identifies 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. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which MCES cannot produce documentation sufficient to support the Paid Claim

shall be considered an error and the total reimbursement received by MCES for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

- b. <u>Use of First Samples Drawn</u>. 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. <u>Claims Review Report.</u> 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. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review.
- b. <u>Claims Review Population</u>. A description of the Population subject to the Claims Review.
- c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.
- d. <u>Sampling Frame</u>: 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. <u>Source of Data</u>: 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. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated.

2. Statistical Sampling Documentation

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. Claims Review Findings.

a. Narrative Results.

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

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by MCES ("Claims

Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to MCES.
- iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- iv. Error Rate in the sample.
- v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. Systems Review. Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.
- 5. Credentials. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

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 Reimbursed (IRO determined)
							Dollar Difference between Amt Reimbursed and Correct Allowed Amt

MCES CCA Attachment 1.wpd