

EXHIBIT I

**CORPORATE COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ECEP II**

I. PREAMBLE

ECEP II, P.A. ("ECEP II") 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 with the statutes, regulations, program requirements 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") by ECEP II. This commitment to promote compliance applies to all physicians, employees, and health care providers ("Covered Persons") and all contractors of ECEP II involved in the preparation or submission of claims for purposes of claiming reimbursement for emergency physician services from the Federal health care programs on behalf of ECEP II (e.g., third parties engaged to consult, to code, to bill or submit reimbursement claims, including the preparation of claims, reports, or other requests for reimbursement, and all other third parties engaged by ECEP II for the marketing or documentation of items or services furnished by ECEP II and reimbursable by the Federal health care programs) ("Covered Contractors"). Contemporaneously with this CCA, ECEP II is entering into a Settlement Agreement with the United States on behalf of an affiliate, and this CCA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by ECEP II under this CCA shall be three years from the effective date of this CCA. The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA.

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

III. INTEGRITY OBLIGATIONS

ECEP II hereby agrees to maintain or establish, as necessary, a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days of the effective date of this CCA, ECEP II shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the CCA obligations. The name and telephone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this CCA, ECEP II shall notify the OIG, in writing, within 30 days of such a change.

B. Posting of Notice

Within the first 30 days following the effective date of this CCA, ECEP II shall post in a prominent place in its administrative offices a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business. Client shall seek approval to post such a notice in the hospital emergency department(s) in which it performs services. Client shall also furnish to each Covered Person and Covered Contractor a written copy of the notice. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct can be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 150 days after the effective date of this CCA, ECEP II agrees to develop, implement, and make available to all Covered Persons and Covered Contractors written Policies and Procedures that address the following:

1. ECEP II's commitment to operate its business in full compliance with all Federal health care program requirements;
2. The honest and accurate submission of claims in accordance with Federal health care program requirements;
3. The proper documentation of emergency physician services and billing information maintained by ECEP II in the ordinary course of business and the retention of such information in a readily retrievable form;
4. The requirement that all of ECEP II's Covered Persons and Covered Contractors shall be expected to report to ECEP II or the Compliance Contact suspected violations of any Federal health care program requirements or ECEP II's own Policies and Procedures. Any Covered Person or Covered Contractor that makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.
5. The requirement that ECEP II not hire, employ or engage as contractors any Ineligible Person. For purposes of this CCA, 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, ECEP II 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://www.epls.arnet.gov>) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.
6. The commitment of ECEP II to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements.

At least annually (and more frequently if appropriate), ECEP II 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 made available to all individuals or entities whose job functions are related to those Policies and Procedures.

Within 150 days of the effective date of the CCA and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by ECEP II's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 150 days of the effective date of the CCA, whichever is later.

Within 150 days of the effective date of the CCA and annually thereafter, ECEP II shall distribute a written copy of the Policies and Procedures to each Covered Contractor.

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 150 days following the effective date of this CCA and at least once each year thereafter, all Covered Persons 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 shall receive adequate and appropriate training conducted by individuals with expertise in the relevant subject areas, e.g., documentation necessary for the submission of claims to Federal health care programs for the types of services provided by ECEP II.

New Covered Persons 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 shall receive the training described above within 30 days after becoming a Covered Person or within 150 days after the effective date of this CCA, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity.

At a minimum, the annual and new Covered Person training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;
2. The written Policies and Procedures developed pursuant to section III.C, above;
3. The legal sanctions for improper billing or other violations of the Federal health care program requirements; and
4. Examples of proper and improper documentation practices.

Each Covered Person shall annually 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. ECEP II shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

Training provided to affected Covered Persons within six months prior to the effective date of this CCA that satisfies a requirement of section III.D shall be deemed to meet the 150 day time frame obligation imposed by this section. However, ECEP II must still maintain attendance certifications and training course materials to receive credit for any such training.

E. Third Party Billing

ECEP II presently contracts with a third party billing company to submit claims to the Federal health care programs. ECEP II represents that it does 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 ECEP II 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, ECEP II shall notify the OIG 30 days prior to any such proposed involvement.

Within 150 days of the effective date of this CCA, ECEP II 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 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 the Medicare and other Federal health care programs for those employees involved in the preparation and submission of claims to those programs. ECEP II shall include a copy of this certification in the Implementation Report. If ECEP II contracts with a new third party billing company during the term of this CCA, ECEP II shall, within 30 days of entering into such contract, obtain and send to the OIG the certification described in this section III.E.

F. Annual Review Procedures

1. *Retention of Independent Reviewer.* Within 150 days of the effective date of this CCA, ECEP II shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Reviewer" or "IR"), to perform a billing review to assess the billing and coding of claims submitted by ECEP II or on ECEP II's behalf ("Billing Engagement"). The Independent Reviewer retained by ECEP II shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CCA and in the Federal health care program requirements. ECEP II may retain the IR directly, or indirectly through a third party billing company. The IR retained by ECEP II may be a review organization retained by a third party billing company, so long as the review organization is independent of both ECEP II and the third party billing company. Regardless of the method through which ECEP II retains the IR, ECEP II maintains responsibility for ensuring that the review performed and the reports generated by the IR meet the terms of this CCA. The Independent Reviewer retained by ECEP II shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CCA and in the Federal health care program requirements.

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 CCA. The IR 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 CCA, which is incorporated by reference into this CCA.

3. *Retention of Records.* The IR and ECEP II 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 credible and specific reason to believe that: (a) ECEP II's Billing 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 limited to the determination of whether the Billing Engagement complies with the requirements of the CCA and/or the findings or Claims Review results are inaccurate. ECEP II 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 report is submitted and received by the OIG. No costs shall be assessed if there is a finding that ECEP II's Billing Engagement conforms to the requirements of this CCA and/or that the Claims Review results are accurate.

Prior to initiating a validation review, the OIG shall notify ECEP II of its intent to do so with an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, ECEP II may request a meeting with the OIG to discuss the results of any Engagement submissions or Claims Review findings present and any additional or relevant information to clarify the results of the Engagement or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed validation review.

The OIG will attempt in good faith to resolve any Claims Review issues with ECEP II 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 CCA, an "overpayment" shall mean the amount of money ECEP II has received in excess of the amount due and payable under any Federal health care program requirements. ECEP II may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this CCA.

b. Reporting of Overpayments. If, at any time, ECEP II identifies or learns of any overpayments, ECEP II shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after determining that there is credible evidence of the overpayment and take remedial steps within 60 days of such determination of credible evidence (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 after determining that there is credible evidence of the overpayment, ECEP II shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days after determining that there is credible evidence of the overpayment, ECEP II 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 policies, and for Medicare contractors, repayment must include the information contained on the Overpayment Refund Form, provided as **Appendix B** to this CCA.

Routine adjustments to claims performed as part of the normal course of business at ECEP II need not be reported as required by this section G.1.b.

2. Material Deficiencies.

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

- (i) a substantial overpayment received by ECEP II; or
- (ii) a matter that a reasonable person would consider a potential violation by ECEP II 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 ECEP II determines that there is a Material Deficiency, ECEP II shall notify the 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 (if the overpayment has not been repaid/refunded at the time of this report, ECEP II shall provide this information to the OIG at the time of repayment/refund);

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and Federal health care program authorities implicated, if known;

(iii) a description of ECEP II's actions taken to correct the Material Deficiency; and

(iv) any further steps ECEP II 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, ECEP II shall notify the OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that ECEP II 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. ECEP II shall also provide written notice to the OIG within 30 days of the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the proceedings, if any.

IV NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CCA, ECEP II changes locations or purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, ECEP II shall notify the OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), telephone number(s), facsimile number(s), Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CCA (*e.g.*, completing certifications and undergoing training).

V. REPORTS

A. Implementation Report

Within 180 days after the effective date of this CCA, ECEP II shall submit a written report to the OIG summarizing the status of its implementation of the requirements of this CCA. This report, known as the "Implementation Report," shall include:

1. The name and telephone number of ECEP II's Compliance Contact;
2. A copy of the notice posted by ECEP II as described in section III.B and a description of where and when the notice has been posted;
3. A certification from the Compliance Contact that copies of the notice have been distributed to all Covered Contractors as described in section III.B;
4. A copy of the written Policies and Procedures required by section III.C of this CCA;

5. A certification signed by the Compliance Contact attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons and distributed to all Covered Contractors;
6. A description of the training required by section III.D, including a summary of the topics covered and a schedule of when the training session(s) were held;
7. A certification signed by the Compliance Contact attesting that all Covered Persons have completed the initial training required by section III.D and have executed the required certifications;
8. A copy of the certification from the third party billing company required by section III.E of the CCA;
9. The name of the IR ECEP II has retained, pursuant to section III.F.1, to conduct the billing engagement and the proposed start and completion dates of the first annual review;
10. A list of all ECEP II's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number; and
11. A certification from the Compliance Contact stating that he or she has reviewed the Implementation Report, he or she has made a reasonable inquiry regarding its content and believes that, upon his or her inquiry, the information is accurate and truthful.

B. Annual Reports

ECEP II shall submit to the OIG Annual Reports with respect to the status of and findings regarding ECEP II's compliance activities for each of 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"). 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 the OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. If revisions were made to the written Policies and Procedures developed pursuant to section III.C of this CCA, a copy of any policies and procedures that were revised;
2. A certification by the Compliance Contact that all Covered Persons have executed the annual Policies and Procedures certification and that copies of the Policies and Procedures have been distributed to all Covered Contractors as required by section III.C;
3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with section III.D of this CCA;
4. A certification signed by ECEP II's Compliance Contact certifying that he or she is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in section III.D of this CCA;
5. A complete copy of all reports prepared pursuant to the IR's Billing Engagement, along with a copy of the IR's engagement letter;
6. ECEP II's response and corrective action plan(s) related to any issues raised by the IR;
7. A summary of any Material Deficiencies (as defined in section III.G) identified during the Reporting Period and the status of any

corrective and preventative action relating to all such Material Deficiencies;

8. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. 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;
9. A certification signed by ECEP II's Compliance Contact certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and
10. A certification signed by ECEP II's 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.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this CCA, all notifications and reports required under the terms of this CCA shall be submitted to the following:

If to the 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 ECEP II: Dale Key
ECEP II, P.A.
3710 Shipyard Boulevard
Wilmington, North Carolina 28403
Telephone: (910) 452-1400
Facsimile: (910) 791-9626

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 the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of ECEP II's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of ECEP II's locations for the purpose of verifying and evaluating: (a) ECEP II's compliance with the terms of this CCA; and (b) ECEP II's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by ECEP II to the OIG or its duly authorized representative(s) at all reasonable times and upon reasonable notice (except as already specified by Federal statute or regulation) for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of ECEP II'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 the OIG. ECEP II agrees to assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. ECEP II's employees may elect to be interviewed with or without a representative of ECEP II present, following being informed that they have the option to be interviewed with a representative of ECEP II present.

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

VIII. DOCUMENT AND RECORD RETENTION

ECEP II shall maintain for inspection, to the greatest extent possible, all documents and records relating to reimbursement from the Federal health care programs maintained by ECEP II in the ordinary course of business, or in compliance with this CCA, for four years.

IX. DISCLOSURES

Consistent with HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify ECEP II prior to any release by the OIG of information submitted by ECEP II pursuant to its obligations under this CCA and identified upon submission by ECEP II as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, ECEP II shall have the rights set forth at 45 C.F.R. § 5.65(d). ECEP II 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

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, ECEP II and the 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 \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day that ECEP II:
 - a. Fails to have in place a Compliance Contact as required in section III.A;

- b. Fails to post the notice required in section III.B;
- c. Fails to have in place the Policies and Procedures required in section III.C;
- d. Fails to ensure that each applicable Covered Person attends the training required by section III.D of this CCA within the time frames required in that section;
- e. Fails to retain an IR within the timeframe required in section III.F.1, or annually submit the IR's Claims Review Report as required in section III.F and Appendix A; or
- f. Fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to the OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day ECEP II employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, ECEP II'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 ECEP II can demonstrate that ECEP II 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 ECEP II 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 ECEP II fails to grant access.)

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

B. Timely Written Requests for Extensions

ECEP II 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 the 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 ECEP II fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this section, if the 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 ECEP II receives the 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 the 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. Notwithstanding ECEP II's right to file a timely written request for extension, the accrual of any Stipulated Penalties shall be suspended by acts of God, fires or any other casualty or occurrence, condition, event or circumstance not reasonably within ECEP II's control which could not have been avoided by reasonable measures provided that (i) the suspension of performance is of no greater scope and of no longer duration than is necessarily caused by such unavoidable acts and required by any remedial measures; and (ii) ECEP II uses its reasonable efforts to remedy the inability to perform.

C. Payment of Stipulated Penalties

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

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, ECEP II shall respond by either: (a) curing the breach to the OIG's satisfaction, notifying the OIG of its corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to the OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event ECEP II elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ECEP II cures, to the OIG's satisfaction, the alleged breach in dispute

unless the ALJ does not sustain the OIG's determination that ECEP II was in breach of this CCA. 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 the 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 the OIG's decision that ECEP II has materially breached this CCA, which decision shall be made at the 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 ECEP II 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 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.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by ECEP II that is not cured within the time frames set forth below constitutes an independent basis for ECEP II's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that ECEP II has materially breached this CCA and that exclusion should be imposed, the OIG shall notify ECEP II of: (a) ECEP II's material breach; and (b) the 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.* ECEP II shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

- a. ECEP II 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) ECEP II has begun to take action to cure the material breach; (ii) ECEP II is pursuing such action with due diligence; and (iii) ECEP II has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, ECEP II fails to satisfy the requirements of section X.D.3, the OIG may exclude ECEP II from participation in the Federal health care programs. The OIG will notify ECEP II in writing of its determination to exclude ECEP II (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, ECEP II wishes to apply for reinstatement, ECEP II 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 the OIG's delivery to ECEP II 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, ECEP II 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, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within

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 ECEP II was in full and timely compliance with the obligations of this CCA for which the OIG demands payment; and (b) the period of noncompliance. ECEP II 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 the OIG with regard to a finding of a breach of this CCA and orders ECEP II to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless ECEP II 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 the 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 ECEP II 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) ECEP II had begun to take action to cure the material breach within that period;
 - (ii) ECEP II has pursued and is pursuing such action with due diligence; and
 - (iii) ECEP II provided to the OIG within that period a reasonable timetable for curing the material breach and ECEP II has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for ECEP II, only after a DAB decision in favor of the OIG. ECEP II's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude ECEP II 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 ECEP II may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. If the DAB finds in favor of ECEP II after an ALJ decision adverse to ECEP II, the OIG shall rescind the exclusion.

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, ECEP II and the OIG agree as follows:

1. This CCA shall be binding on the successors, assigns and transferees of ECEP II;
2. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
3. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;
4. The undersigned ECEP II signatories represent and warrant that they are authorized to execute this CCA. The undersigned the OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ECEP II

Date


Theodore R. Winnieberger, M.D.
President, ECEP II

Date

Gary Eiland, Esq.
Nancy LeGros, Esq.
Vinson & Elkins
Counsel for ECEP II

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

12/12/01
Date



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

APPENDIX A

A. Billing Engagement

The Billing Engagement shall be composed a "Claims Review." The IR shall prepare Claims Review Reports to report the findings of the Claims Review.

- A. *Claims Review.* The IR shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by ECEP II to the Medicare and Medicaid programs.
- B. *Claims Review Report.* The IR shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be submitted to the OIG in the Annual Report.

B. 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: For purposes of this CCA, an Overpayment shall mean the amount of money ECEP II 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 CCA, ECEP II shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.
- d. Paid Claim: A code or line item submitted by ECEP II and for which ECEP II has received reimbursement from the Medicare or Medicaid programs.

e. Population: All Items for which ECEP II has submitted a code or line item and for which ECEP II has received reimbursement from the Medicare or 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 the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.

g. RAT-STATS: The OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/the_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. Claims Review Sample Size Options.

Option 1: Review a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (*i.e.*, semi-width of the confidence interval) of plus or minus 25% of the point estimate.

To determine how many Items must be included in the Claims Review Sample, the mean and standard deviation of overpayments in the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. 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, a text file containing the overpayment value of each Item examined shall be created. For purposes of these estimates, any underpayment identified for a Paid Claim in the Probe Sample shall

be treated as a zero overpayment. The "Difference Values Only" of the Variable Appraisals function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of overpayments in the Population.

After the estimated mean and standard deviation of the population has been calculated the number of Items that must be included in the Claims Review Sample (in order to meet the 90% confidence and 25% precision requirement) shall be determined. This determination shall be made using RAT-STATS' "Sample Size Estimators" (located under the "Utility Program" file). 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.

If no Overpayments are found in this Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample. The results of the Probe Sample shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

Option 2: Review a minimum 100 Items Claims Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report (See section B, below).

b. 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 IR 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.

c. 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 ECEP II cannot produce any documentation (i.e.,

missing medical records) to support the Paid Claim shall be reported as an error and the total reimbursement received by ECEP II for such Paid Claim shall be reported and repaid as an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

d. Use of First Samples Drawn. For the purposes of all samples (Probe Sample and Claims Review Sample) 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.

C. **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 IR 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. Documentation Required Under Option 1:

- i. The number of Items appraised in the Probe Sample and in the Claims Review Sample.
- ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for the Probe Sample and the Claims Review Sample.
- iii. 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.
- iv. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.
- v. The Sampling Frame used in the Probe Sample and the Claims Review Sample shall be available to the OIG upon request.

b. Documentation Required Under Option 2:

- i. The number of Items appraised in the Claims Review Sample.
- ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for the Claims Review Sample.
- iii. The Sampling Frame used in the Claims Review Sample shall be available to the OIG upon request.

3. *Claims Review Results*

- a. Total number and percentage of instances in which the IR determined that the Paid Claim submitted by ECEP II ("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 ECEP II.

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 by the Item Appraisal as required in section B.2.b above.) The IR may, in its report to ECEP II, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

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

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.

APPENDIX B

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

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

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

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

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp. (Including Black Lung)	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		
07 - Corrected CPT Code		