CORPORATE INTEGRITY AGREEMENT

BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SOLDIERS AND SAILORS HOSPITAL

I. PREAMBLE

Soldiers and Sailors Hospital ("Soldiers and Sailors") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, contractors and agents with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, Soldiers and Sailors is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Soldiers and Sailors established a Corporate Compliance Program (the "Compliance Program"). This Compliance Program provides for policies and procedures and, as represented by Soldiers and Sailors in this CIA, is aimed at ensuring that its participation in the Federal health care programs is in conformity with the statutes, regulations and other directives applicable to those programs. Therefore, pursuant to this CIA, Soldiers and Sailors hereby agrees to maintain in full operation the Compliance Program for the term of this CIA. The Compliance Program may be modified by Soldiers and Sailors as appropriate but, at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM OF THE CIA

A. The period of the compliance obligations assumed by Soldiers and Sailors under this CIA shall be 3 years from the Effective Date of this CIA (unless otherwise specified). The "Effective Date" of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The one-year period beginning on the Effective Date shall be referred to as the "Reporting Period."

- B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Soldiers and Sailors' final annual report; or (2) any additional materials submitted by Soldiers and Sailors pursuant to OIG's request, whichever is later.
 - C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" includes:
 - a. all employees, officers and directors of Soldiers and Sailors;
 - b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Soldiers and Sailors;
 - c. all of Soldiers and Sailors' employed medical staff.
 - 2. "Relevant Covered Persons" are defined as follows:
 - a. each Covered Person who is involved in the delivery of patient care items or services in Soldiers and Sailors' Emergency Department, or who is involved in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

Soldiers and Sailors hereby agrees to maintain its Compliance Program that, at a minimum, shall continue to include the following elements:

A. Compliance Officer and Compliance Committee.

1. Compliance Officer. Soldiers and Sailors represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Officer position and appointed an individual to serve in that capacity. 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 CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Soldiers and Sailors, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Soldiers and Sailors, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance

activities engaged in by Soldiers and Sailors as well as for any reporting obligations created under this CIA.

Soldiers and Sailors shall report to 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 CIA within 15 days of such a change.

2. Compliance Committee. Soldiers and Sailors represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Committee to monitor the implementation of the Compliance Program and to provide advice and recommendations to Soldiers and Sailors' Compliance Officer and Board of Directors on compliance issues, policies and procedures, and changes to the Compliance Program. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Soldiers and Sailors shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA within 15 days of such a change.

B. Written Standards.

- 1. Code of Conduct. Soldiers and Sailors represents to OIG that it has established a written Code of Conduct (hereafter the "Code of Conduct"). To the extent Soldiers and Sailors has not already done so, the Code of Conduct shall be distributed to all Covered Persons within 90 days of the Effective Date of this CIA. Soldiers and Sailors shall continue to 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, at a minimum, set forth:
 - a. Soldiers and Sailors' commitment to full compliance with all Federal health care program requirements;
 - b. Soldiers and Sailors' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program

requirements and with Soldiers and Sailors' own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

- c. the requirement that all of Soldiers and Sailors' Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by Soldiers and Sailors suspected violations of any Federal health care program requirements or of Soldiers and Sailors' own Policies and Procedures;
- d. the possible consequences to both Soldiers and Sailors and Covered Persons of failure to comply with Federal health care program requirements and with Soldiers and Sailors' 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 Soldiers and Sailors' commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

Within 90 days of the Effective Date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Soldiers and Sailors' 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 90 days of the Effective Date of the CIA, whichever is later.

Soldiers and Sailors 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. Within 90 days of the Effective Date of this CIA, Soldiers and Sailors shall implement (to the extent it has not already done so) written Policies and Procedures regarding the operation of Soldiers and Sailors' Compliance Program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code of Conduct identified in Section III.B.1;

- b. the proper coding and documentation requirements for emergency room physicians; and
- c. the need for compliance in connection with all submissions for professional medical services.

To the extent Soldiers and Sailors has not already done so, within 90 days of the Effective Date of the CIA, 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), Soldiers and Sailors 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 CIA, Soldiers and Sailors shall provide at least one hour of general training to each Covered Person. This training, at a minimum, shall explain Soldiers and Sailors':
 - a. CIA requirements; and
 - b. Soldiers and Sailors' 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 CIA, 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 CIA, all Relevant Covered Persons shall receive at least three (3) 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 (including the submission of false or inaccurate information);
- f. examples of proper and improper billing practices as they pertain to the rendering of physician services in the emergency department; and
- g. the personal obligation of each individual to ensure that the information documented by the individual, whether relating to actual patient care, the type of services or items delivered or the coding of such services or items is accurate and meets the Federal health care program's requirements and Soldiers and Sailors' policies.

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 CIA, whichever is later. A Soldiers and Sailors employee who has completed the specific training shall review a new Relevant Covered Person's work 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 three (3) hours of specific training annually.

3. *Certification*. Each individual who is required to attend training shall certify, in writing or in electronic form, 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.

- 4. Exception for Non-Employed Physicians. Physicians who are not employees of Soldiers and Sailors, are not required to attend training. However, Soldiers and Sailors shall make training available to non-employed physicians, shall use its best efforts to encourage their attendance and participation, and shall report to OIG in its Annual Reports the percentage of such physicians that attend training during the relevant reporting period.
- 5. Credit for Prior Training. For the purposes of this Section III.C, Soldiers and Sailors shall receive credit for any General Training or Specific Training provided to Covered Persons and/or Relevant Covered Persons since January 1, 2002.

D. Review Procedures.

- 1. General Description.
 - a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Soldiers and Sailors shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Soldiers and Sailors in assessing and evaluating its billing and coding practices and certain compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Soldiers and Sailors shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Soldiers and Sailors seeks reimbursement. Each IRO shall assess, along with Soldiers and Sailors, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Soldiers and Sailors' billing and coding to the Federal health care programs for professional services rendered in Soldiers and Sailors' emergency department ("Claims Review") and shall analyze whether Soldiers and Sailors sought payment for certain unallowable costs ("Unallowable Cost Review").

- 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 CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.
- c. <u>Frequency of Unallowable Cost Review</u>. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the effective date of the CIA.
- d. <u>Retention of Records</u>. The IRO and Soldiers and Sailors shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Soldiers and Sailors related to the reviews).
- 2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.
 - a. <u>Discovery Sample</u>. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Soldiers and Sailors for professional services rendered in its emergency department. The Paid Claims shall be reviewed based on the supporting documentation available at Soldiers and Sailors or under Soldiers and Sailors' control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.
 - i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Soldiers and Sailors should, as appropriate, further analyze any errors identified in the Discovery Sample. Soldiers and Sailors recognizes that OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid

- Claims included, or errors identified, in the Discovery Sample.)
- ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.
- b. <u>Full Sample</u>. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims based upon professional services rendered in its emergency department using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Soldiers and Sailors or under Soldiers and Sailors' control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For the purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Soldiers and Sailors 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. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Soldiers and Sailors to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.
- c. <u>Systems Review</u>. If Soldiers and Sailors' Discovery Sample identifies an Error Rate of 5% or greater, Soldiers and Sailors' IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Soldiers and Sailors

observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

- d. Repayment of Identified Overpayments. In accordance with Section III.H.1 of the CIA, Soldiers and Sailors agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Soldiers and Sailors agrees to make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.
- 3. Claims Review Report. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.
- 4. *Unallowable Cost Review*. The IRO shall conduct a review of Soldiers and Sailors' compliance with the unallowable cost provisions of the Settlement Agreement.
 - a. The IRO shall determine whether Soldiers and Sailors has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Soldiers and Sailors or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

- 5. Unallowable Cost Review Report. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include:
 - a. the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether Soldiers and Sailors has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
- 6. Validation Review. In the event OIG has reason to believe that: (a) Soldiers and Sailors' Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Soldiers and Sailors agrees to pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after Soldiers and Sailors' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Soldiers and Sailors of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Soldiers and Sailors may request a meeting with OIG to discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Unallowable Cost Review to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Soldiers and Sailors agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review with Soldiers and Sailors 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 OIG.
- 7. Independence Certification. The IRO shall include in its report(s) to Soldiers and Sailors a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it was, in fact, independent.

E. Disclosure Program.

Soldiers and Sailors represents to OIG that it has established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) 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 Soldiers and Sailors' 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. Soldiers and Sailors shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include 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, Soldiers and Sailors 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.

F. Ineligible Persons.

- 1. Definition. For the purposes of this CIA, 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. Soldiers and Sailors shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Soldiers and Sailors shall screen all prospective employees and prospective contractors prior to engaging their services 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 http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) Soldiers and Sailors 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 CIA, Soldiers and Sailors shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Soldiers and Sailors shall review its list of current employees and contractors against the Exclusion Lists annually. In addition, Soldiers and Sailors shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If Soldiers and Sailors has actual notice that an employee or contractor has become an Ineligible Person, Soldiers and Sailors shall remove such person from responsibility for, or involvement with, Soldiers and Sailors' 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 Soldiers and Sailors 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, Soldiers and Sailors 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.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. Overpayments

- a. Definition of Overpayments. For the purposes of this CIA, an "Overpayment" shall mean the amount of money Soldiers and Sailors has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, Soldiers and Sailors identifies or learns of any Overpayment, Soldiers and Sailors 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 after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Soldiers and Sailors shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Soldiers and Sailors 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 shall 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 CIA. 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 the purposes of this CIA, a "Material Deficiency" means anything that involves:
 - (i) a substantial Overpayment; or
 - (ii) a matter that a reasonable person would consider a 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 Soldiers and Sailors determines through any means that there is a Material Deficiency, Soldiers and Sailors shall notify OIG, in writing, within 30 days after making the determination that the Material Deficiency exists. The report to OIG shall include the following information:
 - (i) If the Material Deficiency results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.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 Soldiers and Sailors' actions taken to correct the Material Deficiency; and
- (iv) any further steps Soldiers and Sailors plans to take to address the Material Deficiency and prevent it from recurring.

IV. <u>New Business Units or Locations</u>

In the event that, after the Effective Date of this CIA, Soldiers and Sailors changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Soldiers and Sailors shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider 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 CIA (e.g., completing certifications and undergoing training).

V. ANNUAL REPORTS

A. <u>Annual Reports</u>. Soldiers and Sailors shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Soldiers and Sailors' compliance activities for each of the three (3) one-year Reporting Periods.

Each Annual Report shall include:

- 1. a copy of Soldiers and Sailors' Code of Conduct required by Section III.B.1;
- 2. 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;

- 3. 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. Soldiers and Sailors has completed its applicable training requirements and those Covered Persons who have received such training have executed the certification(s) required by Section III.C;
 - c. the Polices and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
 - d. Soldiers and Sailors 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.

- 4. a copy of all Policies and Procedures required by Section III.B.2;
- 5. a copy of all training materials used for the training required by Section III.C, 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;
- 6. a complete copy of all reports prepared pursuant to the IRO's engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

- 7. Soldiers and Sailors' response and corrective action plan(s) related to any issues raised by the IRO(s);
- 8. the identity of the IRO(s), a summary/description of all engagements between Soldiers and Sailors and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;
- 9. a certification from the IRO regarding its professional independence from Soldiers and Sailors;
- 10. 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;
- 11. 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;
- 12. 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;
- 13. a description of any personnel actions (other than hiring) taken by Soldiers and Sailors 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;
- 14. 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;

- 15. a list of all of Soldiers and Sailors' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number. For subsequent Reporting Periods, Soldiers and Sailors need only supply any changes to this list;
- 16. a description of Soldiers and Sailors' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
- 17. the certification required by Section V.C.

The first Annual Report shall be received by 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 Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, Soldiers and Sailors is in compliance with all of the requirements of this CIA; 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>: Soldiers and Sailors 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. Soldiers and Sailors 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 CIA, all notifications and reports required under this CIA 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

Soldiers and Sailors:

Lawrence J. Farnand - Compliance Officer Soldiers and Sailors Memorial Hospital 418 North Main Street Penn Yan, NY 14527 Phone 315-787-4030 Fax 315-787-4189

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For the 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 Soldiers and Sailors' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Soldiers and Sailors' locations for the purpose of verifying and evaluating: (a) Soldiers and Sailors' compliance with the terms of this CIA; and (b) Soldiers and Sailors' compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Soldiers and Sailors to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for the purposes of this provision, OIG or its duly authorized representative(s) may interview any of Soldiers and Sailors' 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. Soldiers and

Sailors shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Soldiers and Sailors' employees may elect to be interviewed with or without a representative of Soldiers and Sailors present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. <u>DISCLOSURES</u>

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

X. Breach and Default Provisions

Soldiers and Sailors is expected to fully and timely comply with all of its CIA obligations.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Soldiers and Sailors and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.
- 1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Soldiers and Sailors fails to have in place any of the obligations described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;

- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. 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 Soldiers and Sailors 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 Soldiers and Sailors fails to meet any of the deadlines for the submission of 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 Soldiers and Sailors employs or contracts with, or grants staff privileges to, an Ineligible Person and that person: (i) has responsibility for, or involvement with, Soldiers and Sailors' 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 Soldiers and Sailors 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 Soldiers and Sailors fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Soldiers and Sailors fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 for each day Soldiers and Sailors fails to comply fully and adequately with any obligation of this CIA. In its notice to Soldiers and Sailors, OIG shall state the specific grounds for its determination that Soldiers and Sailors has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Soldiers and Sailors must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Soldiers and Sailors receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph

shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under paragraphs 1-5 of this Section.

B. <u>Timely Written Requests for Extensions</u>. Soldiers and Sailors may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Soldiers and Sailors 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 Soldiers and Sailors receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that Soldiers and Sailors 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 Soldiers and Sailors of: (a) Soldiers and Sailors' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Soldiers and Sailors 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 Soldiers and Sailors elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Soldiers and Sailors cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section 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 Soldiers and Sailors has materially breached this CIA, 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 CIA

1. Definition of Material Breach. A material breach of this CIA

means:

a. a failure by Soldiers and Sailors 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 CIA, 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 IRO in accordance with Section III.D.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by Soldiers and Sailors constitutes an independent basis for Soldiers and Sailors' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Soldiers and Sailors has materially breached this CIA and that exclusion should be imposed, OIG shall notify Soldiers and Sailors of: (a) Soldiers and Sailors' 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. Soldiers and Sailors 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. Soldiers and Sailors is in compliance with the obligations of the CIA cited by 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) Soldiers and Sailors has begun to take action to cure the material breach; (ii) Soldiers and Sailors is pursuing such action with due diligence; and (iii) Soldiers and Sailors has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, Soldiers and Sailors fails to satisfy the requirements of Section X.D.3, OIG may exclude Soldiers and Sailors from participation in the Federal health care programs. OIG will notify Soldiers and Sailors in writing of its determination to exclude Soldiers and Sailors (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, Soldiers and Sailors wishes to apply for reinstatement, Soldiers and Sailors must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to Soldiers and Sailors of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Soldiers and Sailors shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an 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 CIA shall be: (a) whether Soldiers and Sailors was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Soldiers and Sailors shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. 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 CIA and orders Soldiers and Sailors to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Soldiers and Sailors requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:
 - a. whether Soldiers and Sailors was in material breach of this CIA;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and
 - c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Soldiers and Sailors had begun to take action to cure the material breach within that period; (ii) Soldiers and Sailors has pursued and is pursuing such action with due diligence; and (iii) Soldiers and Sailors provided to OIG within that period a reasonable timetable for curing the material breach and Soldiers and Sailors has followed the timetable.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Soldiers and Sailors, only after a DAB decision in favor of OIG. Soldiers and Sailors' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Soldiers and Sailors upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall

take effect 20 days after the ALJ issues such a decision, notwithstanding that Soldiers and Sailors 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. Soldiers and Sailors 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 Soldiers and Sailors, Soldiers and Sailors 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 CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CIA shall be binding on the successors, assigns, and transferees of Soldiers and Sailors;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Soldiers and Sailors' obligations under the CIA in the event of Soldiers and Sailors' cessation of participation in Federal health care programs. If Soldiers and Sailors withdraws from participation in Federal health care programs and is relieved from its CIA obligations by OIG, Soldiers and Sailors agrees to notify OIG 30 days in advance of Soldiers and Sailors' 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 CIA should be reactivated or modified.
- E. The undersigned Soldiers and Sailors signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents

that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF SOLDIERS AND SAILORS HOSPITAL

IAMES HISERODT

DATE

Vice President/CEO

Soldiers and Sailors Hospital

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 Soldiers and Sailors 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 Soldiers and Sailors for professional services rendered in its emergency department and for which Soldiers and Sailors has received reimbursement from the Medicare program.
 - d. <u>Population</u>: All Items for which Soldiers and Sailors has submitted a code or line item and for which Soldiers and Sailors has received reimbursement from the Medicare program (<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 identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

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

2. Other Requirements.

a. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which

Soldiers and Sailors cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Soldiers and Sailors 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 Soldiers and Sailors' 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 and supporting rationale (including reasons for 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.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Soldiers and Sailors ("Claim 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 Soldiers and Sailors.
- 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), and dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. *Systems Review*. Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).
- 5. *Credentials*. The names and credentials of the individuals who: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

Attachment 1

Claim Review Results

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

OVERPAYMENT REFUND