CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ADVENTIST HEALTH SYSTEM SUNBELT HEALTHCARE CORPORATION AND FLORIDA HOSPITAL WATERMAN, INC.

I. PREAMBLE

Adventist Health System Sunbelt Healthcare Corporation ("Adventist") and Florida Hospital Waterman, Inc. ("Waterman Hospital") hereby enter 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 the officers, directors, and employees of Waterman Hospital as well as those Adventist employees who serve in senior management positions at Waterman Hospital ("Covered Persons") and "Covered Contractors," as defined below, 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, Adventist and Waterman Hospital are entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

For the purposes of this CIA, a "Covered Contractor" is an entity (or individual) that, although not a Covered Person, either provides patient care to Federal health care program beneficiaries in Waterman Hospital facilities or participates in billings or related submissions to Federal health care programs for Waterman Hospital on a regular basis (i.e., more often than two weeks over a 52-week period).

Prior to execution of this CIA, Adventist voluntarily established a corporate compliance program (known as the "CompassPoint Compliance Program") that applies to all Adventist's subsidiaries and facilities, including Waterman Hospital. The CompassPoint Compliance Program establishes corporate integrity policies and procedures and, as represented by Adventist, is aimed in part at ensuring that Adventist's participation in Federal health care programs is in conformity with the statutes, regulations and other directives applicable to the programs. Adventist agrees that during the term of this CIA it will continue to operate its CompassPoint Compliance Program as it pertains to Waterman Hospital in a manner that meets the requirements of this CIA. Adventist may modify the CompassPoint Compliance Program as appropriate, but at a

minimum, Adventist shall ensure that it complies with the integrity obligations for Waterman Hospital that are enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Adventist and Waterman Hospital under this CIA shall be five (5) 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 document.

Sections VII, VIII, IX, X and XI shall remain in effect until Waterman Hospital submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

Adventist and Waterman Hospital hereby agree to maintain a compliance program for Waterman Hospital that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Waterman Hospital has appointed and will continue to employ an individual to serve as its Local Compliance Officer as outlined below during the term of this CIA. The Local Compliance Officer is a member of senior management of Waterman Hospital, makes periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Waterman Hospital ("the Board of Directors"), and is authorized to report on such matters to the Board of Directors at any time. The Local Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Waterman Hospital as they pertain to this CIA including any reporting obligations created under this CIA.

Any changes in the identity of or any material changes in the position description of the Local Compliance Officer, or any actions or changes that would affect the Local Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* Waterman Hospital has appointed and will continue to maintain a Compliance Committee as outlined below during the term of this CIA. The Compliance Committee 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 Committee shall, at a minimum, include the Local Compliance Officer and any other

members of senior management of Waterman Hospital necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Local Compliance Officer or the CEO of Waterman Hospital shall chair the Compliance Committee and the Committee shall support the Local 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).

Any changes in the composition of (i.e., the positions represented on) 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, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* Adventist has established a corporate Code of Conduct that pertains to all its facilities, including Waterman Hospital. To the extent not already accomplished, the Code of Conduct will be distributed to all Covered Persons within 90 days of the effective date of this CIA. Waterman Hospital considers the promotion of, and adherence to, the Code of Conduct as an element in evaluating the performance of all employees and shall continue this practice. The Code of Conduct sets forth:

a. Adventist's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. Adventist's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Waterman Hospital's own Policies and Procedures as outlined in Section III.B.2;

c. the requirement that all Covered Persons shall be expected to report to the Local Compliance Officer or other individual designated by the Local Compliance Officer any suspected violations of any Federal health care program requirements or of Waterman Hospital's own Policies and Procedures as outlined in Section III.B.2;

d. the possible consequences to both Waterman Hospital and Covered Persons of failure to comply with all Federal health care program requirements and with Waterman Hospital's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use Adventist's Confidential Disclosure Program, as described in section III.E, and Adventist's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, to the extent not already accomplished, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by Adventist's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

Adventist shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. If Adventist makes any material changes to the Code of Conduct, a 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.

For each of its Covered Contractors, Adventist or Waterman Hospital shall: (1) require in its contract with the Covered Contractors that the Covered Contractor acknowledges Adventist's CompassPoint Compliance Program and Code of Conduct; (2) ensure that the Code of Conduct is provided (either by Adventist or the Covered Contractor) to all Covered Contractors; (3) require in the contract with the Covered Contractor that the Covered Contractor obtain and retain (subject to review by Adventist and/or the OIG) signed certification from all of its employees who provide patient care to Federal health care program beneficiaries at Waterman Hospital or participate in Waterman Hospital billings or related submissions to Federal health care programs that they have received, read, and understand the Code of Conduct and agree to abide by the requirements of the Compliance Program. Adventist or Waterman Hospital shall require future contracts with Covered Contractors to include the above-described provisions. Within 120 days of the execution of this CIA, Adventist or Waterman Hospital shall attempt in good faith to reform contracts with its then-current Covered Contractors to include a provision pursuant to which the contractors will provide assurance satisfactory to Adventist or Waterman Hospital that these requirements will be met.

2. *Policies and Procedures*. To the extent not already accomplished, within 90 days of the effective date of this CIA Waterman Hospital shall implement written Policies and Procedures regarding the operation of its 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 preparation of true and accurate claims for reimbursement (including cost reports) submitted to the Federal health care programs.

The Policies and Procedures shall be available to OIG, upon request.

To the extent not already accomplished, within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to those Covered Persons 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), Adventist shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any material revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to those Covered Persons 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, Waterman Hospital shall provide at least one and one half hours of general training to each Covered Person. This training shall explain Waterman Hospital's:

a. CIA requirements; and

b. CompassPoint Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

Those Covered Persons who have already received general training on the CompassPoint Compliance Program within one hundred and twenty (120) days prior to the effective date of this CIA need only be trained about the existence and requirements of this CIA.

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, each Covered Person who is directly involved in the preparation or submission of claims for reimbursement from any Federal health care program (including cost reports) (hereinafter referred to as "Relevant Covered Persons") shall receive at least four (4) 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 claims for reimbursement (including cost reports) for services rendered to Federal health care program patients;

b. policies, procedures and other requirements applicable to the documentation of medical records;

c. the personal obligation of each individual involved in the cost report and billing process to ensure that such claims are accurate;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the cost report and billing subject areas.

If, pursuant to the CompassPoint Compliance Program, Waterman Hospital has provided training to Relevant Covered Persons that satisfies the requirements set forth above in Section III.C.2 within the one hundred and twenty (120) days prior to the effective date, OIG shall credit that training for purposes of satisfying Waterman Hospital's specific training obligations for the first year of this CIA.

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 Waterman Hospital employee who

has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates the preparation or submission of claims for reimbursement (including cost reports) from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least four (4) hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, or in electronic form if computerized training is provided, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Local Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *General Description*

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

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. One engagement shall address Waterman Hospital's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address Waterman Hospital's compliance with the obligations assumed under this CIA and the Settlement Agreement ("Compliance Engagement").

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

each annual Billing Engagement. The Compliance Engagement shall be performed by the IRO(s) for the first one-year period beginning with the effective date of this CIA.

d. Retention of Records. The IRO(s) and Waterman Hospital shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports (exchanged between Waterman or Adventist and the IRO(s)) related to the engagements.

2. *Billing Engagement.*

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

a. Claims Review. The IRO(s) shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Waterman Hospital to the Medicare program. The Claims Review shall be performed in accordance with the specific procedures set forth in Appendix A to this CIA.

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

c. Systems Review. The IRO(s) shall review Waterman Hospital's billing and coding systems and/or operations and cost report preparation process (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

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

ii. Waterman Hospital's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to

ensure proper coding, and procedures to correct inaccurate coding); and

iii. Waterman Hospital's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps Waterman Hospital takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs).

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

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

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

iii. the strengths and weaknesses in Waterman Hospital's cost report, cost statement, information statement and payment request preparation process relating to any and all costs submitted to Federal health care programs; and

iv. any recommendations the IRO(s) may have to improve any of these systems, operations, and processes.

3. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of Waterman Hospital, and, where relevant, Adventist's, compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Waterman Hospital's and Adventist's compliance with the obligations set forth in each section of this CIA, and a review of compliance with certain provisions of the Settlement Agreement.

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

ii. Unallowable Costs Review. The IRO shall determine whether Waterman Hospital and Adventist have complied with their 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 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 Waterman Hospital or Adventist 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 of the Settlement Agreement, as well as from previous years.

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

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

ii. the IRO's findings and supporting rationale regarding whether Waterman Hospital and Adventist have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Waterman Hospital's Billing or Compliance Engagement fails to conform to

the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Waterman Hospital and/or Adventist agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in section II) is received by the OIG. Prior to proceeding with such independent review, the OIG shall notify Waterman Hospital and Adventist of its intent to do so and its reasons for believing such a review is necessary. The OIG will in good faith attempt to resolve any Billing or Compliance Engagement or Claims Review issues without proceeding with an independent review. However, the determination of whether to proceed with an independent review shall be made by the OIG at its sole discretion.

E. Confidential Disclosure Program.

Adventist has established and will continue a Confidential Disclosure Program for all its facilities including Waterman Hospital. This program included measures such as a toll-free compliance "hotline" (known as the "GuideLine") to enable individuals to disclose, to the Local Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Waterman Hospital's policies, 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. Adventist shall continue to publicize the existence of its Confidential Disclosure Program including the GuideLine.

The Confidential Disclosure Program shall continue to emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure, the Local Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Local 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, Waterman Hospital shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Local Compliance Officer (or designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For 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 related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* Waterman Hospital shall continue its policy of not hiring or engaging as contractors or granting staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Waterman Hospital shall continue to screen all prospective employees and prospective Covered Contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing 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").

3. *Review and Removal Requirement.* Within 90 days of the effective date of this CIA, Waterman Hospital shall review its list of current employees, Covered Contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, Waterman Hospital shall review the Exclusion Lists semi-annually. In addition, Waterman Hospital shall require employees and Covered Contractors to disclose immediately any debarment, exclusion or other event that makes the employee or Covered Contractor an Ineligible Person.

If Waterman Hospital has notice that an employee, Covered Contractor or physician with staff privileges has become an Ineligible Person, Waterman Hospital shall remove such person from responsibility for, or involvement with, Waterman Hospital's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Waterman Hospital has notice that an employee or Covered 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, Waterman Hospital 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, Adventist or Waterman Hospital shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Waterman Hospital 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. Adventist or Waterman Hospital 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 purposes of this CIA, an "overpayment" shall mean the amount of money Waterman Hospital has received in excess of the amount due and payable under any Federal health care program requirements. Waterman Hospital may not subtract any underpayments for purposes of determining the amount of relevant "overpayments", provided however, that nothing in this CIA shall be construed to prevent Waterman Hospital from otherwise seeking reimbursement of such underpayment in accordance with applicable law or Federal health care program regulations or instructions.

b. Reporting of Overpayments. If, at any time, Waterman Hospital identifies or learns of any overpayments, it shall notify the appropriate payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment

to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

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

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

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

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

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

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

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this CIA, Waterman Hospital changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, Waterman Hospital shall notify 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), 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. Any Covered Persons (as defined above) at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this CIA, Waterman Hospital shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Local Compliance Officer required by section III.A;

2. the names and positions of the members of the Compliance Committee required by section III.A;

3. a copy of the Code of Conduct required by section III.B.1;

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

5. a description of the training required by section III.C, 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 certification by the Local Compliance Officer that, except as otherwise noted:

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

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

c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C.;

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

7. a description of the Confidential Disclosure Program required by section III.E;

8. the identity of the IRO(s) and the proposed start and completion dates of the first annual review;

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

10. a list of all of Waterman Hospital's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number;

11. as it relates to Waterman Hospital, and to the extent not already furnished to OIG, or if modified, a description of Adventist's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business and;

12. the certification required by Section V.C.

B. Annual Reports. Waterman Hospital shall submit to OIG Annual Reports with respect to the status of, and findings regarding, its compliance activities for each of the five one-year periods beginning on the effective date of the CIA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity or position description of the Local Compliance Officer and any change in membership of the Compliance Committee described in section III.A;

2. a certification by the Local Compliance Officer that:

a. except as otherwise noted, all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1;

b. except as otherwise noted, all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

c. Adventist and Waterman Hospital have complied with their 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; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement) and to identify and adjust any past charges or claims for unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a description of the training required by section III.C conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO(s)'s billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO(s)'s engagement letter;

6. Waterman Hospital's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. 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;

8. a report of the aggregate overpayments that have been returned to the Federal health care programs by Waterman Hospital. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

9. a summary of the disclosures in the confidential disclosure log required by section III.E for Waterman Hospital that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by Waterman Hospital 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;

11. 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;

12. a description of all changes to the most recently provided list (as updated) of Waterman Hospital's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and

13. the certification required by Section V.C.

The first Annual Report shall be received by the OIG no later than one year and 60 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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Local Compliance Officer that: (1) except as otherwise described in the applicable report, Adventist and Waterman Hospital are in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Local Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: Adventist and/or Waterman Hospital shall clearly identify any portions of any submissions that they believe are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Adventist and/or Waterman Hospital 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

Adventist/Waterman Hospital:

Sandra K. Johnson
Chief Compliance Officer
Adventist Health System
111 North Orlando Avenue

Winter Park, FL 32789-3675
Phone: 407.975.1402
Fax: 407.975.1414

and to:

Local Compliance Officer
Florida Hospital Waterman, Inc.
1201 N. Eustis Street
Eustis, FL 32726
Phone: 352.589.3300
Fax: 352.589.2748

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

VII. 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 Adventist's or Waterman Hospital's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Waterman Hospital's locations for the purpose of verifying and evaluating: (a) Adventist and Waterman Hospital's compliance with the terms of this CIA; and (b) Adventist and Waterman Hospital's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Adventist or Waterman Hospital to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any Covered Persons 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. Adventist and Waterman Hospital agree to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Covered Persons may elect to be interviewed with or without a representative of Adventist or Waterman Hospital present.

VIII. DOCUMENT AND RECORD RETENTION

Adventist and Waterman Hospital 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 (6) years (or longer if otherwise required by law).

IX. DISCLOSURES

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

Adventist and Waterman Hospital are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Adventist 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 Waterman Hospital fails to have in place any of the following:

a. a Compliance Officer as described by section III.A.1;

b. a Compliance Committee as described by section III.A.2;

c. a written Code of Conduct as described by section III.B.1;

d. written Policies and Procedures as described by section III.B.2;

e. a requirement that Covered Persons be trained as described in section III.C; and

f. a Confidential Disclosure Program as described in section III.E.

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 Waterman Hospital 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 Waterman Hospital fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Waterman Hospital employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, Waterman Hospital'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 Waterman Hospital 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 Adventist and/or Waterman Hospital fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date Adventist and/or Waterman Hospital fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Adventist and/or Waterman Hospital fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs X.A.1-5. In its notice to Adventist and/or Waterman Hospital, OIG shall state the specific grounds for its determination that Adventist and/or Waterman Hospital has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Adventist and/or Waterman Hospital must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue ten (10) days after the date that OIG provides notice to Adventist and/or Waterman Hospital of the failure to comply.)

B. Timely Written Requests for Extensions. Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital of: (a) its 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, Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital 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 Waterman Hospital 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 Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this CIA by Adventist and/or Waterman Hospital constitutes an independent basis for Waterman Hospital's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Adventist and/or Waterman Hospital has materially breached this CIA and that exclusion should be imposed, OIG shall notify Adventist and/or Waterman Hospital of: (a) Adventist and/or Waterman Hospital's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure*. Adventist and/or Waterman Hospital 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. Adventist and/or Waterman Hospital is in full compliance with this CIA;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If at the conclusion of the 30-day period, Adventist and/or Waterman Hospital fails to satisfy the requirements of section X.D.3, OIG may exclude Waterman Hospital from participation in the Federal health care programs. OIG will notify Waterman Hospital in writing of its determination to exclude Waterman Hospital (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, Waterman Hospital wishes to apply for reinstatement, Waterman Hospital 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 Adventist and/or Waterman Hospital 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, Adventist and/or Waterman Hospital 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

Adventist and/or Waterman Hospital was/were in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Adventist and/or Waterman Hospital shall have the burden of proving full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Adventist and/or Waterman Hospital to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Adventist and/or Waterman Hospital 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 Adventist and/or Waterman Hospital was/were 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) Adventist and/or Waterman Hospital had begun to take action to cure the material breach within that period;

(ii) Adventist and/or Waterman Hospital pursued and is/are pursuing such action with due diligence; and

(iii) Adventist and/or Waterman Hospital provided to OIG within that period a reasonable timetable for curing the material breach and Adventist and/or Waterman Hospital followed the timetable.

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

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

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, Adventist and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Adventist and/or Waterman Hospital;

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; and

D. The undersigned Adventist and Waterman Hospital 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 ADVENTIST HEALTH SYSTEM SUNBELT HEALTHCARE CORPORATION AND FLORIDA HOSPITAL WATERMAN, INC.

Sandra K. Johnson
Chief Compliance Officer
Adventist Health System

11-27-00
DATE

Thomas L. Werner
President
Adventist Health System
Sunbelt Healthcare Corporation

11/28/00
DATE

Kenneth Mattison
Chief Executive Officer
Florida Hospital Waterman, Inc.

11-27-00
DATE

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

11/28/00

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

DATE

APPENDIX A

A. Claims Review.

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., CPT or DRG code, line item, beneficiary, patient encounter, etc.).

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Waterman Hospital has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Waterman Hospital shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

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

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

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

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

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

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

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

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Waterman Hospital for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and

standard deviation of the Population (based on the amount of Overpayments received by Waterman Hospital for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

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

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so

that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

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

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

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

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

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

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

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

2. ***Statistical Sampling Documentation***

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

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

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

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

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

3. ***Claims Review Results***

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

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

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

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

Attachment 1

Claim Review Results

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reaso
n per claim)

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

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

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

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____