CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TENDER LOVING CARE, INC.

I. PREAMBLE

Staff Builders, Inc. (a New York corporation), Staff Builders Services, Inc., Staff Builders International, Inc., Staff Builders Home Health Care Services, Inc., St. Lucie Home Health Agency, Inc. and Tender Loving Care Health Care Services, Inc. (as successor-in-interest to Staff Builders Inc.) (all of these are referred to collectively as "Tender Loving Care") 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"). The intent of this CIA is to promote compliance by Tender Loving Care's officers, directors, employees, contractors and agents who provide home health services and/or are engaged in the preparation and/or submission of claims, cost reports or other requests for reimbursement for such services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). The term Covered Persons does not include part-time or per diem employees who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become Covered Persons at the point when they work more than 160 hours during any 12 month period. Contemporaneously with this CIA, Tender Loving Care 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, Tender Loving Care established a compliance program that includes corporate integrity policies and procedures and, as represented by Tender Loving Care, is aimed in part, at ensuring that Tender Loving Care's participation in Federal health care programs is in conformity with the Federal health care program requirements. Pursuant to this CIA, Tender Loving Care agrees to continue the operation of its compliance program during the term of this CIA in a manner that meets the

requirements of this agreement. Tender Loving Care may modify its compliance program as appropriate, but at a minimum, Tender Loving Care shall ensure that it complies with the integrity obligations that are enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Tender Loving Care under this CIA shall be five years from the effective date of the Medicare Prospective Payment System ("PPS") reimbursement for home health services (unless otherwise specified). For purposes of this CIA, the effective date of PPS will be deemed to be the earlier of the actual implementation date of PPS by the Health Care Financing Administration ("HCFA") or December 1, 2000. The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

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

III. CORPORATE INTEGRITY OBLIGATIONS

Tender Loving Care hereby agrees to establish or maintain, as appropriate, a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Tender Loving Care has appointed an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer is and shall continue to be a member of senior management of Tender Loving Care, shall make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or President and/or to the Board of Directors of Tender Loving Care, 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 Tender Loving Care as well as for any reporting obligations created under this CIA.

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, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* To the extent not already accomplished, within 90 days of the effective date of this CIA, Tender Loving Care shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management 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 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).

Any changes in the membership 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, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* Prior to the execution of this CIA, Tender Loving Care established a Code of Conduct that, as represented to the OIG, meets the requirements of this Section III.B.1. To the extent not already accomplished, the Code of Conduct shall be distributed to all Covered Persons within 120 days of the effective date of this CIA. Tender Loving Care shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth the following:

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

b. Tender Loving Care's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Tender Loving Care's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

c. the requirement that all of Tender Loving Care's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by Tender Loving Care any suspected violations of any Federal health care program requirements or of Tender Loving Care's own Policies and Procedures;

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

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

To the extent not already accomplished, within 120 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 Tender Loving Care's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 120 days of the effective date of the CIA, whichever is later.

Tender Loving Care shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any significant changes in the 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*. To the extent not already accomplished, within 120 days of the effective date of this CIA, Tender Loving Care shall implement written Policies and Procedures regarding the operation of Tender Loving Care's 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 or equivalent reporting mechanisms) submitted to the Federal health care programs; and

c. compliance with Federal health care program requirements prohibiting kickback arrangements and the establishment of certain self-referral arrangements; including, but not limited to, the anti-kickback statute found at 42 U.S.C. § 1320a - 7b(b)(1) & (2), 42 U.S.C. § 1320a-7a(a)(7) and 42 U.S.C. 1320a-7(b)(7) and the Ethics in Patient Referrals Act (commonly known as the "Stark law") found at 42 U.S.C. § 1395nn.

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

Within 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available 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), Tender Loving Care shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

C. <u>Training and Education</u>.

1. *General Training*. Within 90 days of the effective date of this CIA, Tender Loving Care shall notify all Covered Persons of the key terms of this CIA and Tender Loving Care's Compliance Program. Within 90 days of the effective date of PPS, Tender Loving Care shall provide at least one hour of general training to the first group of Covered Persons as specified below. This training shall explain Tender Loving Care's:

a. CIA requirements; and

b. 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 at least one hour of general training on the Compliance Program within one hundred and twenty (120) days prior to the Effective Date of this CIA need only to be trained about the existence and requirements of this CIA.

Tender Loving Care will provide this general training to thirty-five percent of all Covered Persons, including the Covered Persons at the Port St. Lucie facility and the Tender Loving Care headquarters, within 90 days of the effective date of PPS. Tender Loving Care will provide general training to all the remaining Covered Persons no later than one year after the effective date 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 PPS, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of refresher training sessions annually.

2. *Specific Training*. Within 120 days of the effective date of this CIA, each Covered Person who works primarily in the Corporate Quality Assurance and Billing Departments and is involved in the preparation or submission of claims for reimbursement (including cost reports or equivalent reporting mechanisms) from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least 6 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 patients;

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

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

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

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the proper coding and billing for services rendered to Federal health care program beneficiaries.

If Tender Loving Care has provided specific training that satisfies the requirements set forth above in Section III.C.2 to Relevant Covered Persons within one hundred and twenty (120) days prior to the Effective Date of this CIA, OIG shall credit that training for purposes of satisfying Tender Loving Care's specific training obligations for the first year of this CIA.

New Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of PPS, whichever is later. A Tender Loving Care employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes the applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive refresher training sessions annually during the period of this CIA. These refresher training sessions shall provide thorough and meaningful training on the items specified above in Section III.C.2.

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

D. <u>Review Procedures</u>.

1. *Retention of Independent Review Organization.* Within 120 days of the effective date of this CIA, Tender Loving Care shall retain an independent review organization ("IRO"), such as an accounting, auditing, or consulting firm, to perform review engagements to assist Tender Loving Care in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. The IRO must have expertise in the billing, coding, reporting (including

preparation of cost reports), and other requirements of Federal health care programs from which Tender Loving Care seeks reimbursement.

2. *Types of Reviews to Be Conducted.*

a) Tender Loving Care shall conduct a Billing Review in accordance with the provisions outlined below in Section III.D.4 using its internal audit personnel. The internal audit personnel conducting the Billing Review must have expertise in the billing, coding, reporting, and other requirements of the Federal health care programs from which Tender Loving Care seeks reimbursement.

b) The IRO(s) shall conduct two separate engagements. First, the IRO shall conduct a review to determine whether Tender Loving Care has performed the internal Billing Reviews in conformance with agreed-upon procedures described below in Section III.D.4 (Verification Review). Second, the IRO shall conduct a review to determine whether Tender Loving Care has complied with the obligations assumed under this CIA and the Settlement Agreement (Compliance Review).

3. *Frequency of Billing, Verification and Compliance Reviews.* The Billing and Verification Reviews shall be performed annually and shall cover each of the one-year periods beginning with the effective date of PPS. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of PPS.

4. *Design of Billing Reviews.*

a) Selection of Facilities Subject to Review: The annual Billing Review shall consist of a review of a sample of Medicare claims from each of one-tenth of the total number of distinct Tender Loving Care Medicare certified home health locations[1] ("TLC Medicare Locations"). In addition, every year the Billing Review shall include a review of a sample of Medicare claims for the Port St. Lucie location. Tender Loving Care shall

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[1] For purposes of the audit provisions of this CIA, the term "locations" means physical locations, staffed by administrators and other personnel where clinical records are maintained and from which Tender Loving Care provides Medicare services. The term location is not synonymous with a Medicare provider number and the Parties recognize that one Medicare provider number may apply to more than one location. The term "locations" does not include Tender Loving Care "drop sites" - that is, sites utilized solely for purposes of dropping off patient records and payroll documentation which is then transported to other Tender Loving Care locations. Tender Loving Care has represented to the OIG that the drop sites are maintained for the convenience of the caregivers, no clinical records are maintained at the drop sites and no administrators are located at such sites.

select the other TLC Medicare Locations to be reviewed (other than the Port St. Lucie location) at random with all TLC Medicare Locations in the universe of potential selections. If, during the term of this CIA, either the OIG or Tender Loving Care determines that a method other than a random selection method would identify a sample of more pertinent locations for review, the Parties agree to consider adopting that alternative method of selection, subject to final approval by the OIG. If, during the term of this CIA, the number of TLC Medicare Locations increases substantially, either TLC or the OIG may propose an alternate percentage or population of such locations to be reviewed in accordance with this Section III.D.4, subject to final review by the OIG.

b) Selection of Units for Review and Protocol for Review: Except for the Port St. Lucie location, for each Medicare location selected, Tender Loving Care shall review a randomly selected sample of 30 units (each unit shall consist of the file of a Medicare beneficiary as it represents all claims submitted for thirty days of service). For the Port St. Lucie location, the sample size of units subject to review shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units from a representative universe of units and cannot be used as part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of units for the Port St. Lucie location, the projection provides a minimum 90% confidence level and precision of at least twenty-five percent (25%).

Each of the unit samples referenced above must be selected through random number sampling. In addition, unless otherwise agreed by the OIG and Tender Loving Care, the sample of TLC Medicare Locations subject to annual audit shall be selected through random number sampling. To generate the random samples, Tender Loving Care shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html."

Tender Loving Care shall review the sample units in accordance with section I of the Tender Loving Care audit tool, Client Case and Documentation (attached hereto as Exhibit A).

c) Components for Inclusion in Billing Review Reports: Each annual Billing Review and its corresponding report shall include the following components:

1. Billing Review Objective: a clear statement of the objective intended to be achieved by the Billing Review and the procedures or combination of procedures that will be applied to achieve the objective.

2. Billing Review Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

3. Sources of Data: a full description of the source of the information upon which the Billing Review conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

4. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest. For the Billing Review, a sampling unit shall be the file of a Medicare beneficiary representing all claims submitted for that beneficiary for up to thirty days of service.

5. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

d) Findings of Billing Review: Tender Loving Care's annual Billing Reviews shall provide:

1. Findings regarding Tender Loving Care's billing operations (including, but not limited to, operations of the billing systems, internal control, and the strengths, weaknesses and effectiveness of the systems);

2. Findings regarding whether Tender Loving Care is submitting accurate claims for services billed to Federal health care programs. The analysis will focus on the risk areas identified in this CIA and any applicable risk areas identified in the OIG's Compliance Program Guidance for Home Health Agencies, 63 Federal Register 42409 (August 7, 1998). For example, the analysis will examine whether Federal health care patients met coverage criteria (e.g., homebound) when they received services from Tender Loving Care;

3. Findings regarding Tender Loving Care's compliance with the requirements of the Federal health care programs for home health services. Specifically, the reviews shall provide findings regarding whether Tender Loving Care is submitting accurate information to Federal health care programs regarding home health patients and whether Tender Loving Care is meeting all requirements of the Federal health care programs;

4. Findings regarding Tender Loving Care's procedures to correct inaccurate billings or codings for claims submitted to Federal health care programs; and

5. Findings regarding the steps Tender Loving Care is taking or has taken to bring its operation into compliance or to correct programs identified by any audits or by any Regional Home Health Intermediary and whether the problems have been corrected.

5. *CIA Compliance Review*: For the first year of the term of the CIA, the IRO shall conduct a Compliance Review to provide an assessment of whether Tender Loving Care has complied with the terms of the Settlement Agreement and this CIA. The report produced by the IRO shall include section-by-section findings regarding Tender Loving Care's fulfillment of the its obligations under this CIA. The report shall also contain a determination whether Tender Loving Care 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 any such applicable payors any unallowable costs included in payments previously sought from the United States or any State Medicaid program in accordance with the side letter agreement on this issue entered between the OIG and Tender Loving Care.

6. *Billing and Compliance Review Reports*: The IRO(s) and Tender Loving Care's audit staff will produce written reports for each Billing, Verification and Compliance Review. The reports shall include all of the information required to be provided by this CIA in each respective Review. A complete copy of these reports will be included in each of the annual Reports submitted to the OIG. The Billing Review reports shall include the methodology used to make each determination, the review results, and the identification of overpayments.

7. *OIG Review.* In the event the OIG has reason to believe that: (a) Tender Loving Care's Billing, Verification or Compliance Reviews fail to conform to the requirements of this CIA or (b) the findings of the reports of such Reviews are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing, Verification or Compliance Reviews comply with the requirements of the CIA and/or the findings of the reports of such Reviews are inaccurate. Tender Loving Care agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final report is submitted. Prior to proceeding with such an independent review, the OIG shall notify Tender Loving Care of its intent to do so and its reasons for believing such a review is

necessary, and shall in good faith attempt to resolve any Billing, Verification or Compliance Review issues without proceeding with an independent review.

E. Confidential Disclosure Program.

Tender Loving Care has established and will maintain for the term of this CIA a Confidential Disclosure Program, which includes 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 Tender Loving Care'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. Tender Loving Care shall continue to publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

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 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 sufficient information 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, Tender Loving Care 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 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.* Tender Loving Care shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Tender Loving Care 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) 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 120 days of the effective date of this CIA, Tender Loving Care shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Tender Loving Care shall review the list semi-annually. In addition, Tender Loving Care shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Tender Loving Care has notice that an employee or contractor has become an Ineligible Person, Tender Loving Care shall remove such person from responsibility for, or involvement with, Tender Loving Care'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 Tender Loving Care has 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, Tender Loving Care 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. <u>Notification of Government Investigation or Legal Proceedings</u>.

Within 30 days of discovery, Tender Loving Care 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 Tender Loving Care 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. Tender Loving Care 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 Tender Loving Care has received in excess of the amount due and payable under any Federal health care program requirements. Tender Loving Care may not subtract any underpayments for purposes of determining the amount of relevant "overpayments", but may report both the overpayment and underpayment numbers to the OIG.

b. Reporting of Overpayments. If, at any time, Tender Loving Care identifies or learns of any overpayments, Tender Loving Care shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery (or such additional time as may be agreed to by the payor) 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 Attachment 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 Tender Loving Care determines that there is a Material Deficiency, Tender Loving Care 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 Tender Loving Care's actions taken to correct the Material Deficiency; and

(iv) any further steps Tender Loving Care 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, Tender Loving Care 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, Tender Loving Care 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. All Covered Persons 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 150 days after the effective date of this CIA, Tender Loving Care 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 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 Tender Loving Care's 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) that has been conducted to date, 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 Compliance Officer:

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

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

c. as to the percentage of the Covered Persons, including those at the Port St. Lucie and headquarters locations, who 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 Verification Review and the Compliance Review;

9. a summary of personnel actions (other than hiring) taken pursuant to section III.F.;

10. a list of all of Tender Loving Care'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. to the extent not already furnished to OIG, or if modified, a description of Tender Loving Care'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. Tender Loving Care shall submit to OIG Annual Reports with respect to the status of and findings regarding of Tender Loving Care's compliance

activities for each of the five one-year periods beginning on the effective date of PPS. (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 Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

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

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

c. Tender Loving Care 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; 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 in accordance with the side letter agreement entered between Tender Loving Care and the OIG;

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 Billing, Validation and Compliance Reviews, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. Tender Loving Care'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. Overpayment amounts should be broken down into the following categories: 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 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 Tender Loving Care 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; and

12. a description of all changes to the most recently provided list (as updated) of Tender Loving Care'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 Compliance Officer that: (1) except as otherwise described in the applicable report, Tender Loving Care is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: Tender Loving Care 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 exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Tender Loving Care 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

Tender Loving Care:

Renee J. Silver, Esq.
Vice President and General Counsel
Tender Loving Care/Staff Builders
1983 Marcus Ave
Lake Success, NY 11042
Phone 516.327.3372
Fax 516.327.8636

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 Tender Loving Care's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Tender Loving Care's locations for the purpose of verifying and evaluating: (a) Tender Loving Care's compliance with the terms of this CIA; and (b) Tender Loving Care's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Tender Loving Care to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Tender Loving Care's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Tender Loving Care agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Tender Loving Care's employees may elect to be interviewed with or without a representative of Tender Loving Care present.

VIII. DOCUMENT AND RECORD RETENTION

Tender Loving Care 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. 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 Tender Loving Care prior to any release by OIG of information submitted by Tender Loving Care pursuant to its obligations under this CIA and identified upon submission by Tender Loving Care as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Tender Loving Care shall have the rights set forth at 45 C.F.R. § 5.65(d). Tender Loving Care shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA. Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as any waiver by Tender Loving Care of Tender Loving Care's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privileges does not affect Tender Loving Care's obligation to comply with the provisions of this CIA.

X. BREACH AND DEFAULT PROVISIONS

Tender Loving Care is expected to fully and timely comply with all of its CIA obligations.

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

a. a Compliance Officer (or Acting 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 Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Tender Loving Care'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 Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Tender Loving Care fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. In its notice to Tender Loving Care, OIG shall state the specific grounds for its determination that Tender Loving Care has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Tender Loving Care must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Tender Loving Care of the failure to comply.) With respect to the Stipulated Penalty provision described in this section X.A.6 only, the OIG shall not seek a Stipulated Penalty if Tender Loving Care demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) Tender Loving Care has begun to take action to cure the failure to comply, (ii)Tender Loving Care is pursuing such action with due diligence, and (iii) Tender Loving Care has provided to OIG a reasonable timetable for curing the failure to comply.

B. Timely Written Requests for Extensions. Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care of: (a) Tender Loving Care's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Tender Loving Care 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 Tender Loving Care elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care 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 Tender Loving Care constitutes an independent basis for

Tender Loving Care's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Tender Loving Care has materially breached this CIA and that exclusion should be imposed, OIG shall notify Tender Loving Care of: (a) Tender Loving Care'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.* Tender Loving Care 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. Tender Loving Care 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) Tender Loving Care has begun to take action to cure the material breach; (ii) Tender Loving Care is pursuing such action with due diligence; and (iii) Tender Loving Care has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Tender Loving Care fails to satisfy the requirements of section X.D.3, OIG may exclude Tender Loving Care from participation in the Federal health care programs. OIG will notify Tender Loving Care in writing of its determination to exclude Tender Loving Care (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, Tender Loving Care wishes to apply for reinstatement, Tender Loving Care 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 Tender Loving Care 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, Tender Loving Care shall be afforded

certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal by TLC or the OIG, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Tender Loving Care was in full and timely compliance with the obligations of this CIA for which the OIG demands payment, (b) the period of noncompliance, and (c) with respect to a Stipulated Penalty authorized under section X.A.6 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) Tender Loving Care had begun to take action to cure the failure to comply, (ii)Tender Loving Care was and is pursuing such action with due diligence, and (iii) Tender Loving Care had provided to OIG a reasonable timetable for curing the material breach which is being followed. Tender Loving Care shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Tender Loving Care to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Tender Loving Care 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 Tender Loving Care 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) Tender Loving Care had begun to take action to cure the material breach within that period;

(ii) Tender Loving Care has pursued and is pursuing such action with due diligence; and

(iii) Tender Loving Care provided to OIG within that period a reasonable timetable for curing the material breach and Tender Loving Care has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the Tender Loving Care, only after a DAB decision in favor of OIG. Tender Loving Care's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Tender Loving Care 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 Tender Loving Care 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, Tender Loving Care and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Tender Loving Care. However, OIG shall waive this successor liability provision upon receipt of verified proof to the OIG's satisfaction that the Tender Loving Care has wholly divested itself of any interest or involvement, direct or indirect, in the transferred or assigned

entity, that the successor is an independent entity unrelated in any manner to Tender Loving Care, that the successor has acquired its interest at fair market value in an arms' length transaction, and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs;

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 Tender Loving Care 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 TENDER LOVING CARE

Dale R. Clift
President & Chief Operating Officer
Tender Loving Care

8/18/00
DATE

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

Lewis Morris

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

8/24/00
DATE