CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
TREND AREA MENTAL HEALTH

I. PREAMBLE

Trend Area Mental Health ("Trend") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, and individual contractors and agents who are involved in or responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons") with the statutes, regulations and written directives of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). This CIA also applies to Trend in regard to its contractual relationships with all contractors, agents, and other third parties (other than the contractors and agents who are individuals and included as Covered Persons) engaged for the provision or documentation of items or services provided to beneficiaries reimbursable by Federal health care programs or engaged to prepare claims, reports or other requests for reimbursement for such items or services ("Covered Contractors"). The parties do not intend that any of Trend's contractors or agents shall, by reason of any provision of this CIA, be deemed servants or employees of Trend. Contemporaneously with this CIA, Trend is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Trend under this CIA shall be 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 CIA.

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

III. CORPORATE INTEGRITY OBLIGATIONS

Trend hereby agrees to establish a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer*. Within 90 days after the effective date of this CIA, Trend shall appoint an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing, implementing, and maintaining policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of Trend, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Trend, 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 Trend 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*. Within 90 days of the effective date of this CIA, Trend 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 composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* Within 150 days of the effective date of this CIA, Trend shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 150 days of the effective date of this CIA. Trend 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:

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

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

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

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

Within 150 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 Trend'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 150 days of the effective date of the CIA, whichever is later.

Trend 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 such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. *Policies and Procedures*. Within 150 days of the effective date of this CIA, and to the extent such Policies and Procedures have not already been implemented, Trend shall implement written Policies and Procedures regarding the operation of Trend's compliance program and its compliance with Federal health care program requirements, especially those statutes, regulations, policies, procedures and guidelines related to the delivery of home and community care services, including the requirement that all services be accurately documented by the individual providing the service and accurately represented in any claims for payment. 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 requirement that the Compliance Officer perform on-site inspections and periodic reviews (at least quarterly) of documents, including, but not limited to, Covered Persons' time sheets, progress notes (including but not limited to progress notes for Community Inclusion ("CI") services and Client Behavior Intervention ("CBI") services), medical records, billing sheets, and census reports from each residential facility to verify compliance with Medicaid, Medicare and other Federal laws and regulations, as well as Trend's own policies and procedures;

c. requirements regarding the documentation and certification of services provided by Covered Persons, including that the number of

billed CI and CBI hours must accurately reflect the number of hours recorded in the CI and CBI progress notes and that CI and CBI progress notes and other service records must be appropriately signed and dated;

d. the requirement that the client's location must be appropriate for services provided and accurately documented;

e. the requirement that *individual* CI and CBI services be billed only for CI and CBI services that are provided to *one* client at a time

f. the requirement that all records documenting services provided be signed and certified as required *before* seeking payment for those services;

g. requirements regarding Covered Persons' time sheets, including requirements regarding the timing, accuracy, and content of time sheet signatures and certifications; and

h. the requirement that payment be returned to Medicaid or any other relevant payor for services that do not satisfy the above-listed policies or that otherwise violate the policies, regulations and laws applicable to the relevant payor.

Within 150 days of the effective date of the CIA, to the extent such Policies and Procedures have not been distributed, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training*. Within 150 days of the effective date of this CIA, Trend shall provide adequate general training to each Covered Person. This training, at a minimum, shall explain Trend'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).

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 150 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*. Trend represents to the OIG that it has voluntarily implemented a training program addressing documentation requirements ("Specific Training"), that new employees receive this Specific Training within two weeks of beginning employment, and that employees receive this Specific Training on an annual basis thereafter. Trend shall maintain its existing Specific Training program and, within 90 days of the effective date of this CIA, shall incorporate the minimum requirements set forth below, as necessary, in all future Specific Training sessions and shall ensure that each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") receives Specific Training on an annual basis according to Trend's existing training schedule. This Specific Training shall include a discussion of:

a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;

b. policies, procedures and other requirements applicable to the documentation of medical records, progress notes, daily itineraries, and other relevant documents;

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

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

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

Persons providing the training must be knowledgeable about the subject area, including, but not limited to, requirements for the proper billing of Trend's services.

A Trend employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

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

D. Review Procedures.

1. *State Reviews.* Trend represents that the North Carolina Department of Health and Human Services Division of Mental Health has conducted and will continue to conduct audits and reviews of Trend's Medicaid billing and coding practices ("Billing and Coding Review") and continuity of care activities ("Continuity of Care Review") (collectively, "State Reviews"). Trend shall submit all reports from such State Reviews to OIG within 15 days of receipt of such reports from the State. In addition, Trend shall submit to OIG:

a. any and all reports or correspondence regarding non-compliance events and/or repayments required as a result of any State Review

within 20 days of receiving any State Review report requiring such action.

b. any and all corrective action plans or other corrective measures or policies required as a result of any State Review within 30 days of receiving any State Review report requiring such action.

At any time such a corrective action plan is put in place or other corrective measures are taken by the State or Trend, Trend shall include in each annual report to the OIG an update on Trend's progress with respect to the corrective actions, improvements with respect to any areas of deficiency, and modifications to any corrective action plans to address any lack of progress with respect to the correction of any reported deficiencies. Trend shall retain and make available to the OIG, upon request, all work papers, supporting documentation, and correspondence in Trend's possession related to the State Reviews.

If at any time Trend discovers or receives notice that the State has or will suspend the Billing and Coding Review for one year or longer or that the State will terminate the Billing and Coding Reviews, Trend shall notify the OIG of such information within 15 days of such discovery or notice receipt. Within 90 days of Trend's discovery or receipt of notice regarding such suspension or termination, Trend shall retain an entity such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to perform a review engagement to assist Trend in assessing and evaluating its billing and coding practices ("Billing Engagement"). Any such Billing Engagement shall be performed annually and in accordance with Appendix A, which is incorporated by reference. Any such Billing Engagement shall cover each of the one-year periods remaining within the term this CIA after the final State audit.

2. *Compliance Engagement.* Within 120 days of the effective date of this CIA, Trend shall retain an Independent Review Organization to perform a review engagement to assist Trend in assessing and evaluating its compliance obligations pursuant to this CIA and the Settlement Agreement ("Compliance Engagement"). The IRO retained by Trend shall have expertise in the 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 Trend seeks reimbursement. The IRO shall assess, along with Trend, whether it can perform the Compliance Engagement in a professionally independent fashion taking into account any other business relationships

or other engagements that may exist. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this CIA.

a. Compliance Review. The IRO shall conduct a review of Trend's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of Trend's adherence to the obligations set forth in sections I through VIII of this CIA, and a review of Trend's compliance with certain provisions of the Settlement Agreement

i. CIA Obligations Review. The IRO shall assess and evaluate Trend's compliance with the obligations set forth in sections I through VIII of this CIA.

ii. Unallowable Costs Review. The IRO shall determine whether Trend has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or the North Carolina 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 Trend or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which of the Settlement Agreement was executed, 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 Trend's compliance with the terms of sections I through VIII of the CIA, as applicable; and

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

c. Retention of Records. The IRO and Trend shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Trend) related to the Compliance Engagement.

d. Independence Certification. Within 150 days from the effective date of this CIA, the IRO shall provide to Trend a certification or sworn affidavit that it has evaluated its professional independence with regard to the Compliance Engagement and that it has concluded that it is, in fact, independent. Such certification shall be included in Trend's Implementation Report submission.

3. *Validation Review.* In the event the OIG has reason to believe that: (a) Trend's Compliance Engagement or Trend's Billing Engagement, if any, fails to conform to the requirements of this CIA or (b) an IRO's findings or Claims Review (as this term is defined in Appendix A) results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and/or Compliance Engagement(s) comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Trend agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Trend of its intent to do so and provide an explanation for believing why such a review is necessary. In order

to resolve any concerns raised by the OIG, Trend may request a meeting with the OIG to discuss the results of any Engagement submissions or any Claims Review findings; present any additional or relevant information to clarify the results of the Engagement(s) or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Trend agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with Trend prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

E. Disclosure Program.

Within 90 days after the effective date of this CIA, Trend shall establish a Disclosure Program, that must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Trend's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law. Trend shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, 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 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, Trend shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action

taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For 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.* Trend shall not hire as employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Trend 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 90 days of the effective date of this CIA, Trend shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Trend shall review its list of current employees and contractors against the Exclusion Lists semi-annually. In addition, Trend shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Trend has notice that an employee or contractor has become an Ineligible Person, Trend shall remove such person from responsibility for, or involvement with, Trend'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 Trend 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, Trend 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. Covered Contractor Requirements.

For each of its Covered Contractors, Trend shall:

1. Provide the Covered Contractor with Trend's Code of Conduct and inform the Covered Contractor regarding:

a. Trend's Compliance Program and Trend's obligations under this CIA;

b. all Trend Policies and Procedures that are applicable to the services furnished by the Covered Contractor to Trend;

c. Trend's Disclosure Program, which shall be made available to the Covered Contractor for the reporting of compliance concerns related to the Covered Contractor's relationship(s) with Trend; and

d. Trend's obligations not to contract with any Ineligible Person.

2. For new Covered Contractor contracts, require that the Covered Contractor acknowledge Trend's Compliance Program and Code of Conduct and require that the Covered Contractor certify in writing prior to becoming a Covered Contractor that:

a. it is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to the Federal health care programs;

b. it has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to

participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and

c. it provides adequate training to its employees with regard to Federal health care program requirements as those requirements apply to the type(s) of services furnished by the Covered Contractor under its contract(s) with Trend.

Trend shall, within 30 days of entering into such contract, send to OIG the certification described in this paragraph.

3. For existing Covered Contractor contracts, seek in good faith to reform the contract(s) to require the Covered Contractor to acknowledge Trend's Compliance Program and Code of Conduct, and certify that the Covered Contractor:

a. is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs;

b. has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and

c. provides adequate training to its employees with regard to Federal health care program requirements as those requirements apply to the type(s) of services furnished by the Covered Contractor under its contract(s) with Trend.

Trend shall, within 30 days of reforming any such contract, send to OIG the certification described in this paragraph.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, Trend 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 Trend 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. Trend shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

I. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Trend has received in excess of the amount due and payable under any Federal health care program requirements. Trend may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for CIA reports.

b. Reporting of Overpayments. If, at any time, Trend identifies or learns of any overpayments, Trend shall notify the payor (e.g., the North Carolina Medicaid program) within 30 days of identification of the overpayment 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. Also, within 30 days of identification of the overpayment, Trend shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, Trend shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the 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 Trend determines through any means that there is a Material Deficiency, Trend 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 Trend's actions taken to correct the Material Deficiency; and

(iv) any further steps Trend 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, Trend 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, Trend 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 180 days after the effective date of this CIA, Trend 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, position description, and summary of other non-compliance job responsibilities 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 Trend's Code of Conduct required by section III.B.1;

4. a copy of all compliance-related Policies and Procedures required by section III.B.2 (to the extent not already furnished to OIG, or if modified) and a summary of all other Policies and Procedures required by section III.B.2;

5. a copy of all training materials used for the training required by section III.C (to the extent not already furnished to OIG, or if modified), a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

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

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

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

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

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

8. the identity of the Compliance Engagement IRO, a summary/description of all engagements between Trend and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, the proposed start and completion dates of the Compliance Review, and a certification from the IRO regarding its professional independence from Trend;

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

10. a list of all of Trend'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 Trend'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. Trend shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Trend's 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, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed any Code of Conduct certifications required by section III.B.1;

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

c. Trend has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek Medicare or Medicaid payment for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

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

4. a copy of all training materials used for the training required by section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a report with an update on any corrective action plan or corrective measures taken by the State or Trend in response to a State Review, including Trend's progress with respect to the corrective actions, improvements with respect to any areas of deficiency, and modifications to any corrective action plans to address any lack of progress with respect to the correction of any reported deficiencies;

6. a complete copy of all reports prepared pursuant to the Compliance Engagement and any Billing Engagement, including a copy of the methodology used, along with a copy of the IRO's engagement letter and, if applicable, a copy of the Billing Engagement IRO's professional independence from Trend;

7. Trend's response and corrective action plan(s) related to any issues raised by the IRO(s);

8. a revised summary/description of all engagements between Trend and any IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

9. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

10. a report of the aggregate overpayments that have been returned to the Federal health care programs, including any repayments required in connection with a State Review. Overpayment amounts should be broken down into the following categories, if applicable: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately), and other Federal health care programs;

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

12. a description of any personnel actions (other than hiring) taken by Trend as a result of the obligations in section III.F, and the name, title, and responsibilities of any person that falls within the ambit of section III.F.4, and the actions taken in response to the obligations set forth in that section;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a description of all changes to the most recently provided list (as updated) of Trend'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

15. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 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, Trend 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: Trend shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Trend 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

Trend:

Trend Area Mental Health
Attn: Executive Director
800 Fleming Street
Hendersonville, NC 28791

Phone 828.692.5741
Fax 828.693.9560

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 Trend's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Trend's locations for the purpose of verifying and evaluating: (a) Trend's compliance with the terms of this CIA; and (b) Trend's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Trend 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 Trend'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. Trend agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Trend's employees may elect to be interviewed with or without a representative of Trend present.

VIII. DOCUMENT AND RECORD RETENTION

Trend 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 Trend prior to any release by OIG of information submitted by Trend pursuant to its obligations under this CIA and identified upon submission by Trend as trade secrets, or information that is commercial or financial and

privileged or confidential, under the FOIA rules. With respect to such releases, Trend shall have the rights set forth at 45 C.F.R. § 5.65(d). Trend 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

Trend 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, Trend 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 $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Trend fails to have in place any of the obligations described in section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. a Disclosure Program.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Trend fails to retain an IRO, as required in section III.D.

3. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Trend 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 $1,500 (which shall begin to accrue on the date the failure to comply began) for each day Trend employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Trend'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 Trend 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 Trend 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 Trend fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day Trend fails to comply fully and adequately with any obligation of this CIA. In its notice to Trend, OIG shall state the specific grounds for its determination that Trend has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Trend must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Trend of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.

B. Timely Written Requests for Extensions. Trend 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 Trend fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Trend 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 Trend 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 Trend of: (a) Trend'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, Trend 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 Trend elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Trend 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 Trend 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 Trend 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 Trend constitutes an independent basis for Trend's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Trend has materially breached this CIA and that exclusion should be imposed, OIG shall notify Trend of: (a) Trend'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*. Trend 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. Trend is in compliance with the obligations of the CIA cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If at the conclusion of the 30-day period, Trend fails to satisfy the requirements of section X.D.3, OIG may exclude Trend from participation in the Federal health care programs. OIG will notify Trend in writing of its determination to exclude Trend (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, Trend wishes to apply for reinstatement, Trend 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 Trend 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, Trend 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 Trend was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Trend 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 Trend to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Trend 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 Trend 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) Trend had begun to take action to cure the material breach within that period;

(ii) Trend has pursued and is pursuing such action with due diligence; and

(iii) Trend provided to OIG within that period a reasonable timetable for curing the material breach and Trend 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 Trend, only after a DAB decision in favor of OIG. Trend's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Trend 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 Trend 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. Trend agrees to waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

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, Trend and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Trend;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of Trend's obligations under the CIA in the event of Trend's cessation of participation in Federal health care programs. If Trend withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, Trend agrees to notify OIG 30 days in advance of Trend's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

E. The undersigned Trend 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 Trend

A JEFFREY GRIMM
Executive Director, Trend

4/5/01
DATE

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

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

4/6/01
DATE

APPENDIX A

A. Billing Engagement.

If the Billing Engagement requirement of Section III.D.1.of the CIA is activated, the IRO retained by Trend for the Billing Engagement shall have expertise in the 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 Trend seeks reimbursement. Prior to conducting the Engagement, the IRO shall assess, along with Trend, whether it can perform the Billing Engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO shall provide to Trend a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing Engagement and that it has concluded that it is, in fact, independent. Such certification shall be included in the first Annual Report submitted to OIG after the retention of the Billing Engagement IRO.

The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review."

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by Trend to the Medicare and Medicaid programs. The Claims Review shall be performed in accordance with the procedures set forth in Section B of this Appendix.

b. Claims Review Report. The IRO 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 section C of this Appendix.

c. Systems Review. The IRO shall review Trend's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

i. Trend'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); and

ii. Trend'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).

d. Systems Review Report. The IRO 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 Trend's billing systems and/or operations;

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

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

e. Retention of Records. The IRO and Trend shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Trend) related to the Billing Engagement.

B. Claims Review.

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

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

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

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.H.1.a of the CIA, the amount of money Trend 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, Trend shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by Trend and for which Trend has received reimbursement from the Medicare or Medicaid programs.

e. Population: All Items for which Trend has submitted a code or line item and for which Trend has received reimbursement from the Medicare and Medicaid programs (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

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

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 Sample should contain a sufficient number of Items (according to the RAT-STATS calculation) 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) should 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 Overpayments in the Population must be estimated. Estimates for each unique Population 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 Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Trend for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" 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 Overpayments in the Population (based on the amount of Overpayments received by Trend for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Difference Values Only" function located under the "Variable Appraisals" component. 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 Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Trend for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" 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 Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review

Sample. In order to estimate the 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. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items.

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 Sample, any Paid Claim for which Trend cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Trend 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.

C. Claims Review Report.

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

1. ***Claims Review Methodology***

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

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

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

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

e. Sources of Data: A description of the documentation relied upon by the 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 Sample.

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", "Difference Values Only" function results for the Probe Sample, including a copy of the data file.

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 Claims submitted by Trend ("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 Trend.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to Trend, 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. The level of precision achieved by the Claims Review at a 90% confidence level.

e. 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.