CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
INSTITUTE FOR THERAPY AND PSYCHOLOGICAL SOLUTIONS, L.L.C.
AND
CHRISTINE SECRIST, PH.D.

I. PREAMBLE

Institute for Therapy and Psychological Solutions, L.L.C. ("ITPS"), and Christine Secrist, Ph.D. ("Dr. Secrist"); (collectively "Providers" or either in the alternative, "Provider") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). This CIA includes, but is not limited to, the Federal health care program requirements identified in agreements that relate to the Providers' provision of Medicaid services. This CIA applies to (1) the Providers; (2) any entity in which either Provider has an ownership or control interest at any time during the term of the CIA (as defined in 42 U.S.C. § 1320a-3(a)(3)) and that provides behavioral health services to Federal health care program beneficiaries; and (3) any other Covered Persons as defined in Section II.C. Contemporaneously with this CIA, the Providers are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

A. This CIA shall have a term of five years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) the Providers' final Annual Report; or (2) any additional materials submitted by the Providers pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. all owners and employees of the Providers;

2. all employees of any entity that provides behavioral health services to Federal health care program beneficiaries and in which any Provider has an ownership or control interest at any time during the term of this CIA (as defined in 42 U.S.C. §1320a-3(a)(3)) and any contractors, agents, or other persons who provide patient care items or services or who perform billing or coding functions on behalf of such entity; and

3. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Providers (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of the Providers shall not be considered Covered Persons, provided that the Providers and the third party billing company provide the certifications required by Section III.J).

III. CORPORATE INTEGRITY OBLIGATIONS

The Providers shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer

Within 90 days after the Effective Date, the Providers shall appoint a Covered Person to serve as their Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall report directly to the senior management of the Providers, shall make periodic (at least quarterly) reports regarding compliance matters directly to the senior management of the Providers, shall be authorized to report on such matters to the senior management at any time, and shall not be legal counsel to the Providers. Written documentation of the Compliance Officer's reports to the senior management shall be made available to OIG upon request. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by the Providers as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must

not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

The Providers shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

B. Policies and Procedures

Within 90 days after the Effective Date, the Providers shall develop and implement written Policies and Procedures regarding appropriate billing and medical documentation requirements for compliance with Federal health care programs. Throughout the term of this CIA, the Providers shall enforce and comply with their Policies and Procedures and shall make such compliance an element of evaluating the performance of all employees.

Within 90 days after the Effective Date, the Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), the Providers shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Posting of Notice

Within 30 days after the Effective Date, the Providers shall post in a prominent place accessible to all patients/customers and Covered Persons a notice that provides the name and phone number of the Compliance Officer, and the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

D. Training

All Covered Persons shall receive at least three hours of training during the first Reporting Period, including at least one hour of training to be completed within 60 days after the Effective Date. Training may be completed in-person or online. These training

requirements may be satisfied only by training courses that are submitted to OIG, prior to registration for the training course, for review and approval, and may include courses provided by the Centers for Medicare & Medicaid Services (CMS) Medicare Learning Network (MLN), or the Providers' Medicare or Medicaid contractor (including, but not limited to, any Medicare managed care organization to which the Providers submit claims), if they fulfill the requirements below.

At a minimum, the required training sessions must include the following topics:

a. the Federal health care program billing, coding and claim submission statutes, regulations, and program requirements and directives (as may be described or contained in the Providers' agreements with or guidance from Medicaid managed care organizations or their subcontractors) relating to the services furnished by the Providers;

b. the Federal health care program medical record documentation requirements relating to services furnished by the Providers; and

c. the personal obligation of each individual involved in the medical record documentation and claims submission processes to ensure that medical records and claims are accurate.

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

E. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, the Providers shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this

Section III.E. The IRO must have the qualifications and must be able to meet the other requirements relating to the IRO outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Retention of Records*. The IRO and the Providers shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and the Providers) related to the reviews.

2. *Claims Review.* The IRO shall conduct a review of the Providers' coding, billing, and claims submission to the Federal health care program(s) and the reimbursement received and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Validation Review*. In the event OIG has reason to believe that: (a) any Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (Validation Review). The Providers shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after the Providers' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify the Providers in writing of its intent to conduct a Validation Review and the reasons OIG has determined a Validation Review is necessary. The Providers shall have up to 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review and/or to propose alternatives to the proposed Validation Review. OIG will attempt in good faith to resolve any Claims Review issues with the Providers prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* Prior to performing the first Claims Review, and annually thereafter, the IRO shall provide to the Providers a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded that it is,

in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

F. Ineligible Persons

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (SAM) (available through the Internet at http://www.sam.gov)

2. *Screening Requirements*. The Providers shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. the Providers shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.

b. the Providers shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and thereafter shall screen against the LEIE on a monthly basis and screen against SAM on an annual basis.

c. the Providers shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

The Providers shall maintain documentation demonstrating that the Providers: (1) have checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) have required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the Providers' responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. The Providers understand that items or services furnished by excluded persons are not payable by Federal health care programs and that the Providers may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether the Providers meet the requirements of Section III.D.

3. *Removal Requirement*. If the Providers have actual notice that a Covered Person has become an Ineligible Person, the Providers shall remove such Covered Person from responsibility for, or involvement with, the Providers' business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services rendered, ordered, or prescribed by the Covered 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 Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If the Providers have actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, the Providers shall take all appropriate actions to ensure that the responsibilities of that Covered Person 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 under any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

Within 30 days after discovery, the Providers shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to the Providers conducted or brought by a governmental entity or its agents involving an allegation that the Providers have committed a crime or have 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. The Providers shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this CIA, an "Overpayment" shall mean the amount of money the Providers have received in excess of the amount due and payable under any Federal health care program requirements.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, the Providers shall develop and implement written policies and procedures regarding the identification, quantification and repayment of Overpayments received from any Federal health care program.

3. *Reporting of Overpayments*. If, at any time, the Providers identifies or learns of any Overpayment, the Providers shall repay the Overpayment to the appropriate payor (e.g., Medicaid managed care organization) within 60 days after identification of the Overpayment and take steps to correct the problem and prevent the Overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor). If not yet quantified within 60 days after

identification, the Providers shall notify the payor at that time of their efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. The Providers should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

1. *Definition of Reportable Event*. For purposes of this CIA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

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

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by the Providers.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If the Providers determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Providers shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists, and shall include:

a. a complete description of all details relevant to the Reportable Event, including, at minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated,

including an explanation of their roles in the Reportable Event;

b. the Federal health care programs affected by the Reportable Event;

c. a description of the steps taken by the Providers to identify and quantify the Overpayment; and

d. a description of the Providers' actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, the Providers shall send to OIG a copy of the notification and repayment (if quantified) to the payor required by Section III.H.3.

4. *Reportable Events under Section III.I.1.b.* For Reportable Events under Section III.I.1.b, the report to the OIG shall include

a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event; the period during which the conduct occurred; and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event;

c. the Federal health care programs affected by the Reportable Event;

d. a description of the Providers' actions taken to correct the Reportable Event and prevent it from recurring; and

e. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by the Providers to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, the report to OIG shall include:

a. the identity of the Ineligible Person and the job duties performed by that individual;

b. the dates of the Ineligible Person's employment or contractual relationship;

c. a description of the Exclusion Lists screening that the Providers completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;

d. a description of how the Reportable Event was discovered; and

e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

6. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by the Providers to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP. If the Providers identify a probable violation of the Stark Law and repay the applicable Overpayment directly to the CMS contractor, then the Providers are not required by this Section III.H to submit the Reportable Event to CMS through the SRDP.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this CIA the Providers contract with a third party billing company to submit claims to the Federal health care programs on behalf of the Providers, the Providers must certify to OIG that they do not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and are not employed by, and do not act as a consultant to, the third party billing company.

The Providers also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens their prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's System for Award Management; and (iii) provides training in the applicable requirements of the Federal health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in the Providers' Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS

A. Change or Closure of Location. In the event that, after the Effective Date, the Providers change locations or close a location related to the furnishing of items or services that may be reimbursed by Federal health care programs, the Providers shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location(s).

B. Purchase or Establishment of New Location or Business. In the event that, after the Effective Date, either or both Providers purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, the Provider(s) shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider identification number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor (including, but not limited to, any Medicaid managed care organization) to which the Provider(s) currently submits claims. Each new location or business and all Covered Persons at each

new location or business shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business. In the event that, after the Effective Date, either or both Providers propose to sell any or all of their locations or businesses that are subject to this CIA, the Provider(s) shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such location or business, unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. At least 30 days prior to Dr. Secrist becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Secrist shall notify OIG of her plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of her responsibilities with respect to such potential employer or contractor. In addition, prior to Dr. Secrist becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Secrist shall notify that party of this CIA. This notification shall include a copy of the CIA and a statement indicating the remaining term of the CIA. The CIA shall continue to apply to Dr. Secrist following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 90 days after the Effective Date, the Providers shall submit a written report to OIG summarizing the status of their implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. a copy of the policies and procedures required by Section III.B.;

3. a copy of the notice the Providers posted in their office(s) as required by Section III.C, a description of where the notice is posted, and the date the notice was posted;

4. the following information regarding the training required by Section III.D: a copy of the training certifications for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program.

A copy of all training materials shall be made available to OIG upon request.

5. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between the Providers and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to the Providers;

6. a copy of the documentation demonstrating that the Providers have screened all Covered Persons against the Exclusion Lists, as required by Section III.F within 30 days of the Effective Date;

7. a copy of the Providers' policies and procedures regarding the identification, quantification and repayment of Overpayments required by Section III.H;

8. a copy of any certifications from the Providers and the third party billing company required by Section III.J (if applicable);

9. a list of all of the Providers' 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 and state Medicaid program provider identification number(s), and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor (including, but not limited to, any Medicaid managed care organization) to which the Providers currently submit claims; and

10. certifications by the Compliance Officer and Dr. Secrist that: (a) they each have reviewed the CIA in its entirety, understand the requirements described within, and maintain a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Implementation Report, they are in compliance with all of the requirements of this CIA; and (c) they each have reviewed the Implementation Report,

have made a reasonable inquiry regarding its content, and believe that the information is accurate and truthful.

B. Annual Reports. The Providers shall submit to OIG Annual Reports with respect to the status of, and findings regarding, the Providers' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;

2. a description of any changes to the policies and procedures required by Section III.B.;

3. a description of any changes to the notice required by Section III.C, and the reason for such changes, along with a copy of the revised notice4. (in the first Annual Report) the following information regarding the training required by Section III.D: a copy of the training program registration for each Covered Person who completed the training, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program;

A copy of all training materials shall be made available to OIG upon request.

5. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter;

6. the Providers' response to the reports prepared pursuant to Section III.E, along with corrective action plan(s) related to any issues raised by the reports;

7. a summary and description of any and all current and prior engagements and agreements between the Providers and the IRO (if different from what was submitted as part of the Implementation Report);

8. a certification from the IRO regarding its professional independence and objectivity with respect to the Providers;

9. a copy of the documentation demonstrating that the Providers screened all prospective and current Covered Persons against the Exclusion Lists, as required by Section III.F;

10. 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;

11. a description of any changes to the Overpayment policies and procedures required by Section III.H, including the reasons for such changes;

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs;

13. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

14. a copy of any certifications from the Providers and the third party billing company required by Section III.J (if applicable);

15. a description of all changes to the most recently provided list of the Providers' locations (including addresses) as required by Section V.A.9; and

16. a certification signed by the Providers' Compliance Officer and Dr. Secrist that: (a) they have reviewed the CIA in its entirety, understand the requirements described within, and maintain a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Annual Report, the Providers are in compliance with all of the requirements of this CIA; and (c) they have reviewed the Annual Report, and made a reasonable inquiry regarding its content, and believe that the information is accurate and truthful.

The first Annual Report shall be received by 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. Designation of Information. The Providers shall clearly identify any portions of their submissions that they believe 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. The Providers 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, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
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
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

ITPS:
P.O. Box 516
Perry, IA 50220
Telephone: (515) 465-5739
Facsimile: (515) 465-5744
Email: Chris.Secrist@miftc.com

Dr. Secrist:
Christine Secrist, Ph.D.
P.O. Box 516
Perry, IA 50220
Telephone: (515) 465-5739
Facsimile: (515) 465-5744
Email: Chris.Secrist@miftc.com

Unless otherwise specified, all notifications and reports required by this CIA shall 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. Upon request by OIG, the Providers may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

The Providers are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Providers and OIG hereby agree that failure to comply with certain obligations set forth in this CIA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day the Providers fail to:

a. appoint a Compliance Officer as required by Section III.A;

b. implement the policies and procedures required by Section III.B;

c. establish and/or post a notice in accordance with the requirements of Section III.C;

d. complete the training required for Covered Persons and maintain training certifications, in accordance with the requirements of Section III.D;

e. engage and use an IRO in accordance with the requirements of Section III.E, Appendix A, and Appendix B;

f. screen Covered Persons in accordance with the requirements of Section III.F or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

g. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

h. establish policies and procedures regarding the repayment of Overpayments;

i. repay any Overpayments in accordance with Section III.H;

j. report a Reportable Event in accordance with Section III.I.;

k. provide to OIG the certifications required by Section III.J relating to any third party biller engaged by the Providers during the term of the CIA; or

l. disclose any changes to location or business under Section IV.

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 the Providers fail to submit the Implementation Report, IRO Report, or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $1,000 for each day the Providers fail to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date the Providers fail to grant access.)

4. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of the Providers as part of their Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this CIA.

5. A Stipulated Penalty of $1,000 for each day the Provider(s) fail to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to the Providers stating the specific grounds for its determination that the Providers have failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Providers shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date the Providers receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions. The Providers 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 the Provider(s) 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 days after the Providers receive 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 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 the Provider(s) have failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify the Provider(s) of: (a) the Providers' failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days of the receipt of the Demand Letter, the Providers shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for 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 the Providers elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Providers 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

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 the Providers have 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 the Providers to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.I;

b. repeated violations or a flagrant violation of any 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 engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B.

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

3. *Opportunity to Cure*. The Provider(s) shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate that:

a. the alleged material breach has been cured; or

b. the alleged material breach cannot be cured within the 30-day period, but that: (i) the Provider(s) have begun to take action

to cure the material breach; (ii) the Provider(s) are pursuing such action with due diligence; and (iii) the Provider(s) have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, the Provider(s) fail to satisfy the requirements of Section X.D.3, OIG may exclude the Provider(s) from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. OIG shall notify the Provider(s) in writing of its determination to exclude the Providers. (This letter shall be referred to 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 Providers' receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, the Provider(s) may apply for reinstatement, by submitting 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 the Providers 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, the Providers 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 after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

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 the Providers were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. The Providers shall have

the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders the Providers to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Providers 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 whether the Providers were in material breach of this CIA and, if so, whether:

a. the Providers cured such breach within 30 days of their receipt of the Notice of Material Breach; or

b. the alleged material breach could not have been cured within the 30-day period, but that, during the 30-day period following the Providers' receipt of the Notice of Material Breach: (i) the Providers had begun to take action to cure the material breach; (ii) the Providers pursued such action with due diligence; and (iii) the Providers provided to OIG a reasonable timetable for curing the material breach.

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 Providers, only after a DAB decision in favor of OIG. The Providers' election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the Providers upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that the Providers 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. the Providers shall waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of the Providers, the Providers shall be reinstated effective the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

The Providers and OIG agree as follows:

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

B. This CIA constitutes the complete agreement between the parties and may not be amended except by prior written consent of the parties to this CIA.

C. OIG may agree to a suspension of the Providers' obligations under this CIA based on a certification by the Providers that they are no longer providing health care items or services that will be billed to any Federal health care programs and they do not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If the Providers are relieved of their CIA obligations, the Providers shall be required to notify OIG in writing at least 30 days in advance if the Providers plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, the OIG shall evaluate whether the CIA will be reactivated or modified.

D. All requirements and remedies set forth in this CIA are in addition to, and do not affect (1) the Providers' responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable program requirements.

E. The undersigned Provider signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF INSTITUTE FOR THERAPY AND PSYCHOLOGICAL SOLUTIONS, L.L.C.

/Christine Secrist/ 8-29-14

CHRISTINE SECRIST DATE
President, Chief Executive Officer, and Owner,
Institute for Therapy and
Psychological Solutions, L.L.C.

/F. Montgomery Brown/ 8/29/14

F. MONTGOMERY BROWN DATE
Brown & Scott, P.L.C.
Counsel for Institute for
Therapy and Psychological Solutions, L.L.C.

CHRISTINE SECRIST, PHD

/Christine Secrist/ 8-29-14

CHRISTINE SECRIST DATE

/F. Montgomery Brown/ 8/29/14

F. MONTGOMERY BROWN DATE
Brown & Scott, P.L.C.
Counsel for Christine Secrist

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

_____/Robert K. DeConti/_____ ___9/9/14_____
ROBERT K. DECONTI DATE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

_____/Sarah K. Kessler_____ ____9/3/2014_____
SARAH K. KESSLER DATE
Senior Counsel
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

A. IRO Engagement

1. The Providers shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.5 of the CIA or any additional information submitted by the Providers in response to a request by OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

2. If the Providers engage a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, the Providers shall submit the information identified in Section V.A.5 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by the Providers at the request of OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of behavioral health care services and in the general requirements of the Federal health care program(s) from which the Providers seek reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have

maintained this certification (e.g., completed applicable continuing education requirements); and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicaid or other Federal health care programs' rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicaid or other Federal health care programs' policy or regulation, request clarification from the appropriate authority (e.g., Medicaid managed care organization);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO*. If the Providers terminate their IRO or if the IRO withdraws from the engagement during the term of the CIA, the Providers must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. The Providers must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require the Providers to engage a new IRO in accordance with Paragraph A of this Appendix. The Providers must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring the Providers to engage a new IRO, OIG shall notify the Providers of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, the Providers may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with the Providers prior to requiring the Providers to terminate the IRO. However, the final determination as to whether or not to require the Providers to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

a. Overpayment: The amount of money the Providers have received in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by the Providers and for which the Providers have received reimbursement from the Medicaid program, including from Medicaid managed care organizations or their subcontractors.

c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

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

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 100 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at the Providers' office or under the Providers' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, the Providers should, as appropriate, further analyze any errors identified in the Discovery Sample. The Providers recognize that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample*. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at the Providers or under the Providers' control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. The findings of the Full Sample shall be used by the IRO to estimate the actual Overpayment in the Population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from the Providers to the appropriate Federal health care program payor, including the Medicaid contractor (e.g., Medicaid managed care organization), for appropriate follow-up by that payor.

4. *Systems Review*. If the Providers' Discovery Sample identifies an Error Rate of 5% or greater, the Providers' IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

a. a review of the Providers' billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded,

safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and the Providers shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from the Providers after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Paid Claims without Supporting Documentation. Any Paid Claim for which the Providers cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the Providers for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* The Providers shall repay within 30 days any Overpayment(s) identified in the Discovery Sample, regardless of the Error Rate, and (if applicable) the Full Sample, including the IRO's estimate of the actual Overpayment in the Population as determined in accordance with Section A.3 above, in accordance with payor refund policies. The Providers shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*

a. Claims Review Population. A description of the Population subject to the Claims Review.

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

c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, treatment plans, care plans, behavioral intervention plans, individualized education programs, physician orders, psychotherapy notes or narratives, psychological examination report or notes, Medicaid managed care organization contract terms, manual or bulletins (including issue, version, and date), other policies, regulations, or directives).

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

e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

   a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

   b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

   c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings*

   a. Narrative Results

      i. A description of the Providers' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

      ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

   b. Quantitative Results

      i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by the Providers (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

      ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to the Providers.

iii. Total dollar amount of all Overpayments in the Discovery Sample and the Full Sample (if applicable).

iv. Total dollar amount of Paid Claims included in the Discovery Sample and the Full Sample and the net Overpayment associated with the Discovery Sample and the Full Sample.

v. Error Rate in the Discovery Sample and the Full Sample.

vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, Medicaid managed care organization billed, beneficiary health insurance claim number, date of service, code submitted (e.g., CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct 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.

vii. If a Full Sample is performed, the methodology used by the IRO to estimate the actual Overpayment in the Population and the amount of such Overpayment.

c. Recommendations. The IRO's report shall include any recommendations for improvements to the Providers' billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in the Providers' billing systems and processes;

b. the strengths and weaknesses in the Providers' coding systems and processes; and

c. possible improvements to the Providers' billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *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.