CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
REHABILICARE INC. AND STAODYN, INC.

I. PREAMBLE

Rehabilicare Inc. and Staodyn, Inc., (collectively "Rehabilicare") hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by Rehabilicare's (1) officers, directors, and employees, and (2) contractors and agents that are involved in Rehabilicare's sales, marketing, billing, collection or the submission of claims for reimbursement (collectively, "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"). Contemporaneously with this CIA, Rehabilicare is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Rehabilicare voluntarily established its own corporate compliance program (known as the "Rehabilicare Corporate Compliance Program" or the "Program"). In addition to corporate integrity policies and procedures, the Program provides for a Compliance Officer and a compliance committee, a training and educational program, ongoing compliance reviews and a compliance hotline. Rehabilicare represents that the Program is aimed, in part, at ensuring that Rehabilicare's activities are in conformity with all applicable statutes, regulations and guidelines of the Federal health care programs. Rehabilicare agrees to continue the operation of its Corporate Compliance Program in accordance with the provisions set forth below for the term of this CIA. Rehabilicare may modify the Corporate Compliance Program as appropriate, but, at a minimum, Rehabilicare shall ensure that during the term of this CIA, it shall comply with the integrity obligations that are enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Rehabilicare under this CIA shall be five 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) Rehabilicare's final Annual Report or (2) any additional materials submitted by Rehabilicare pursuant to the OIG's request (provided the request is made no later than 120 days after the OIG's receipt of the final Annual Report), whichever is later.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Rehabilicare has appointed an individual to serve as its Compliance Officer and Rehabilicare shall continue to have a Compliance Officer for the duration of the term of this CIA. The Compliance Officer is and shall continue to 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 continue to be a member of senior management of Rehabilicare, make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Rehabilicare, and be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by Rehabilicare as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* To the extent not already accomplished, within 90 days of the effective date of this CIA, Rehabilicare 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 marketing, 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 (i.e., the positions represented on the 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.* To the extent not already accomplished, within 90 days of the effective date of this CIA, Rehabilicare shall establish a Code of Conduct. To the extent not already accomplished, the Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. Rehabilicare 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. Rehabilicare'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. Rehabilicare's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with Rehabilicare's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

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

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

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

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

Rehabilicare 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 45 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 45 days of the distribution of such revisions.

2. *Policies and Procedures*. To the extent not already accomplished, within 90 days of the effective date of this CIA, Rehabilicare shall implement written Policies and Procedures regarding the operation of Rehabilicare's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.B.1;

b. the requirements of the Federal health care programs as they relate to documentation, billing and reimbursement for items or services furnished by Rehabilicare including, but not limited to, the requirements relating to medical necessity and all applicable demonstrations of medical necessity (e.g. - Certificates of Medical Necessity, and appropriate orders for such items and services from physicians or other medical personnel);

c. the requirements that Covered Persons not engage in any improper alterations to documentation supporting any claims submitted (e.g. - patient records and certificates of medical necessity); and

d. all applicable requirements of the Federal health care programs relating to the marketing and sales of Rehabilicare products (including, but not limited to, the Federal Anti-Kickback Statute, 42 U.S.C. § 1302a-7b).

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

Within 90 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training.* Within 90 days of the effective date of this CIA, Rehabilicare shall provide at least two hours of general training to each Covered Person. This training shall explain Rehabilicare's:

a. CIA requirements; and

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

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

To the extent that Rehabilicare provided training on its Code of Conduct to certain Covered Persons within 120 days prior to the effective date of this CIA, OIG shall credit that training for purposes of satisfying, in part, Rehabilicare's general training obligations for the first year of this CIA.

New Covered Persons shall receive the general training described above within 45 days of becoming a Covered Person or within 105 days after the effective date of

this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training*. Within 120 days of the effective date of this CIA, each Covered Person who is involved in the preparation or submission of claims for reimbursement for any Rehabilicare items or services to any Federal health care program (hereinafter referred to as "Relevant Covered Billing Persons") shall receive at least six hours of specific training in addition to the general training required above. Within 120 days of the effective date of this CIA, each Covered Person who is involved in contracting for, marketing or sales of any Rehabilicare items or services (hereinafter referred to as "Relevant Covered Sales Persons")[1] shall receive at least four hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

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

b. policies, procedures and other requirements applicable to the documentation of medical records, including, but not limited to, requirements for appropriate physician authorizations and certificates of medical necessity;

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate and that appropriate documentation of the medical necessity of the items and services exists to support the billings;

d. the personal obligation of each individual involved in contracting for, marketing, or sales of Rehabilicare items or services to comply with all applicable Federal health care program requirements;

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

f. the legal sanctions for improper billings; and

g. examples of proper and improper billing practices.

[1] The Relevant Covered Sales Persons and Relevant Covered Billing Persons shall be referred to collectively as "Relevant Covered Persons."

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject areas in which they are providing training.

Relevant Covered Persons shall receive this training within 45 days of the beginning of their employment or becoming Relevant Covered Persons or within 105 days of the effective date of this CIA, whichever is later. A Rehabilicare 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 sales of patient care items or services and/or 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.

If Rehabilicare has provided specific training that satisfies the requirements set forth above in Section III.C.2 to Relevant Covered Persons within 160 days prior to the effective date of this CIA, OIG shall credit that training for purposes of satisfying Rehabilicare's specific training obligations for the first year of this CIA.

After receiving the initial training described in this section, every Relevant Covered Billing Person shall receive at least six hours of specific training annually and every Relevant Covered Sales Person shall receive at least four hours of specific training annually.

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

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Rehabilicare shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist Rehabilicare in evaluating its billing and coding practices and its compliance

obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by Rehabilicare shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Rehabilicare seeks reimbursement. Each IRO shall assess, along with Rehabilicare, whether it can perform the IRO engagements in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

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

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

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

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

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of a statistically valid sample of Paid Claims submitted by Rehabilicare to the

Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

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 Appendix A to this CIA.

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

i. Rehabilicare'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, controls designed to ensure proper claim submission and billing, and procedures to correct inaccurate billing);

ii. Rehabilicare'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, controls designed 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 Rehabilicare's billing systems and/or operations;

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

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

3. *Compliance Engagement.*

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

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

ii. Unallowable Costs Review. The IRO shall determine whether Rehabilicare 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 any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Rehabilicare or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year of the Settlement Agreement, as well as from previous years.

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

i. the IRO's findings and supporting rationale regarding Rehabilicare's compliance with the terms of Sections I through VIII of the CIA; and

ii. the IRO's findings and supporting rationale regarding whether Rehabilicare 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

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Rehabilicare's Billing or Compliance Engagement fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. Rehabilicare 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 Rehabilicare 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, Rehabilicare 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 Engagements or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. The OIG will attempt in good faith to resolve any Billing or Compliance Engagement and/or Claims Review issues with Rehabilicare 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.

5. *Independence Certification.* Within 120 days from the effective date of this CIA, the IRO shall provide to Rehabilicare a certification or sworn affidavit that it has evaluated its professional independence with regard to the Billing and Compliance Engagements and that it has concluded that it was, in fact, independent. Such certification shall be included in Rehabilicare's Implementation Report submission.

E. Confidential Disclosure Program.

To the extent not already accomplished, within 90 days after the effective date of this CIA, Rehabilicare shall establish a Confidential Disclosure Program, which

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 Rehabilicare's policies, practices or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil or administrative law, rule or regulation. Rehabilicare shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Confidential Disclosure Program shall 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, Rehabilicare shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received regardless of whether the disclosure was made through the toll-free compliance telephone line, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The confidential disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements*. Rehabilicare shall not hire any Ineligible Person, nor shall it engage as a contractor to perform sales, marketing, billing, collection, or claims submission activities any Ineligible Person. To prevent hiring or

contracting with any Ineligible Person, Rehabilicare 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, Rehabilicare shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, Rehabilicare shall review the Exclusion Lists semi-annually. In addition, Rehabilicare shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee or contractor an Ineligible Person.

If Rehabilicare has notice that an employee or contractor has become an Ineligible Person, Rehabilicare shall remove such person from responsibility for, or involvement with, Rehabilicare'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 Rehabilicare 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, the Rehabilicare 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 any items or services rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

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

H. Reporting.

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, Rehabilicare identifies or learns of any overpayments, Rehabilicare shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

b. Reporting of Material Deficiencies. If Rehabilicare determines that there is a Material Deficiency, Rehabilicare 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 Rehabilicare's actions taken to correct the Material Deficiency; and

(iv) any further steps Rehabilicare 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, Rehabilicare 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, Rehabilicare 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 120 days after the effective date of this CIA, Rehabilicare shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

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

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

3. a copy of Rehabilicare's Code of Conduct required by section III.B.1;

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

5. a description of the training required by section III.C, 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 except as otherwise noted:

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

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

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

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

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

8. the identity of the IRO(s), a summary/description of all engagements between Rehabilicare and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;

9. a certification from the IRO regarding its professional independence from Rehabilicare;

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

11. a list of all of Rehabilicare'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;

12. to the extent not already furnished to OIG, or if modified, a description of Rehabilicare's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by section V.C.

B. Annual Reports. Rehabilicare shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Rehabilicare'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 or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that except as otherwise noted:

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

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

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

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

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

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

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

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

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

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

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

12. a description of all changes to the most recently provided list (as updated) of Rehabilicare's locations (including locations and mailing addresses) as required by section V.A.11, 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;

13. a revised summary/description of all engagements between Rehabilicare and the 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; and

14. 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, Rehabilicare 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: Rehabilicare shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Rehabilicare 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

Rehabilicare:

Gretchen Dacey
Corporate Compliance Officer
Rehabilicare, Inc.

701 U.S. Highway 301 South
Tampa, FL 33619
Phone: 888-895-6024
Fax: 813-246-3021

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

VIII. DOCUMENT AND RECORD RETENTION

_____Rehabilicare 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 Rehabilicare prior to any release by OIG of information submitted by Rehabilicare pursuant to its obligations under this CIA and

identified upon submission by Rehabilicare as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Rehabilicare shall have the rights set forth at 45 C.F.R. § 5.65(d). Rehabilicare 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

Rehabilicare 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, Rehabilicare and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rehabilicare fails to have in place any of the following:

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

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

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

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

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

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

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

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Rehabilicare fails to meet

any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Rehabilicare employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Rehabilicare'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 Rehabilicare 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 Rehabilicare 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 Rehabilicare fails to grant access.)

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

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Rehabilicare fails to satisfy the requirements of section X.D.3, OIG may exclude Rehabilicare from participation in the Federal health care programs. OIG will notify Rehabilicare in writing of its determination to exclude Rehabilicare (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, Rehabilicare wishes to apply for reinstatement, Rehabilicare 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 Rehabilicare 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, Rehabilicare shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Rehabilicare was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Rehabilicare 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 Rehabilicare to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Rehabilicare 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 Rehabilicare 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) Rehabilicare had begun to take action to cure the material breach within that period;

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

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

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

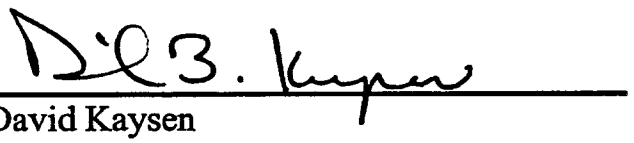
A. This CIA shall be binding on the successors, assigns, and transferees of Rehabilicare;

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

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

D. The undersigned Rehabilicare signatory represents and warrants that he is 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 REHABILICARE INC. AND STAODYN, INC.



David Kaysen
Chief Executive Officer
Rehabilicare Inc.

JAN. 16, 2001
DATE

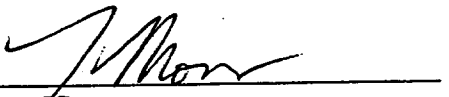
ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

SEE PAGE 29

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

—
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

1/19/07
DATE

APPENDIX A

A. Claims Review.

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

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

b. Item: Any discrete unit that can be sampled (e.g., 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 Rehabilicare 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, Rehabilicare shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

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

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

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

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

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

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

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

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

Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Rehabilicare for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

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

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file)

shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

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

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

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

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

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit

that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review 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" function results for the Probe Sample.

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

3. ***Claims Review Results***

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

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 Rehabilicare, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

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

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

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

REFUND INFORMATION

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

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

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

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

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

Reason Codes:

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

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

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

Attachment 1

Claim Review Results

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