CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
REGIONAL DEVELOPMENT BEHAVIORAL HEALTH CENTERS, INC.

I. PREAMBLE

Regional Development Behavioral Health Centers, Inc. hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its officers, directors, employees, and contractors, and by all entities for whom it performs Federal health care program billing or coding functions and such entities' owners, officers, directors, employees, contractors and agents, and by all other individuals responsible for the provision and documentation of items and services reimbursable by Federal health care programs or for the preparation of claims for reimbursement of such items and services billed by Regional Development Behavioral Health Centers, Inc. (hereinafter collectively referred to as "RDBHC"), 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"). To further this commitment to promote compliance, RDBHC and its officers and directors agree to ensure that any entity owned, operated, or managed by RDBHC or by any of its present or future officers or directors or in which they have a controlling interest, as defined in 42 U.S.C. §§ 1320a-3(a)(3), shall have RDBHC administer all of their billing of federal health care programs.

Contemporaneously with this CIA, RDBHC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by RDBHC under this CIA shall be five years from the effective date of this CIA ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this CIA executes 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, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) RDBHC's final annual report; or (2) any additional materials submitted by RDBHC pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. The definition of "Covered Persons" who fall within the scope of this CIA includes:

a. all owners, officers, directors, and employees of RDBHC;

b. all contractors, agents, and other individuals and entities that provide patient care items or services or that perform billing or coding functions on behalf of RDBHC with respect to items or services reimbursable by Federal health care programs; and

c. all entities for whom RDBHC performs Federal health care program billing or coding functions and such entities' owners, officers, directors, employees, contractors and agents.

2. The definition of "Relevant Covered Persons" who fall within the scope of this CIA includes each Covered Person who is involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program.

III. CORPORATE INTEGRITY OBLIGATIONS

RDBHC represents that it has an existing compliance program ("Compliance Program") that includes a compliance officer, written policies and procedures, internal monitoring, training and education, and other components. RDBHC shall maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Pursuant to its Compliance Program referenced in Section I, RDBHC represents that it has appointed an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of RDBHC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of RDBHC, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by RDBHC as well as for any reporting obligations created under this CIA.

RDBHC 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 15 days after such a change.

B. Written Standards.

1. *Code of Conduct.* RDBHC represents that it has established a written Code of Conduct that, at a minimum, sets forth:

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

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

d. the possible consequences to both RDBHC and Covered Persons of failure to comply with Federal health care program requirements and with RDBHC's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.E, and RDBHC's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

Within 90 days of the Effective Date of this CIA, the Compliance Officer shall review the Code of Conduct to ensure they meet the requirements set forth in the CIA. To the extent not already done, the Code of Conduct shall be distributed to all Covered Persons within 90 days after the Effective Date. RDBHC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by RDBHC's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

RDBHC shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of such revisions.

2. *Policies and Procedures*. RDBHC represents that it has implemented written Policies and Procedures regarding the operation of RDBHC's compliance program and its compliance with Federal health care program requirements. Within 90 days of the Effective Date of this CIA, the Compliance Officer shall review the Policies and Procedures to ensure they meet the requirements set forth in the CIA. 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. measures designed to ensure that RDBHC and its Covered Persons fully comply with all Medicare, Medicaid and other Federal

health care programs' statutes, regulations and guidelines applicable to RDBHC; and

c. measures designed to ensure that RDBHC and all of its Covered Persons meet all standards of the Medicare and Medicaid programs with respect to the quality of care (*e.g.*, staff to patient ratios, patient eligibility, treatment plans) and with respect to the credentials and sufficiency of the providers of that care.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), RDBHC shall assess and update as necessary the Policies and Procedures. Within 30 days after 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 relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 90 days after the Effective Date, RDBHC shall provide at least two hours of general training to each Covered Person. This training, at a minimum, shall explain RDBHC's:

a. CIA requirements; and

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

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

2. *Specific Training.* Within 90 days after the Effective Date, each Relevant Covered Person 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 claims for services rendered to Federal health care program beneficiaries;

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

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

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

e. the legal sanctions for improper claims; and

f. examples of proper and improper claims submission practices.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. A RDBHC employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, each Relevant Covered Person shall receive at least two hours of specific training annually. RDBHC shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or 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 after the Effective Date, RDBHC shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist RDBHC in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by RDBHC shall have expertise in the billing, coding, reporting, and other requirements related to RDBHC's federal health care business and in the general requirements of the Federal health care program(s) from which RDBHC seeks reimbursement. Each IRO shall assess, along with RDBHC, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist. The IRO(s) review shall address and analyze RDBHC's billing and coding to the Federal health care programs ("Claims Review") and, if applicable, shall analyze whether RDBHC sought payment for certain unallowable costs ("Unallowable Cost Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Unallowable Cost Review. If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

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

2. *Claims Review.* The Claims Review shall include a Discovery Sample of Paid Claims for each Federal health care program to which RDBHC submits bills, and, if necessary, a Full Sample for each such Federal health care program. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of RDBHC to each Federal health care program. The Paid Claims shall be reviewed based on the supporting documentation available at RDBHC or under RDBHC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, RDBHC should, as appropriate, further analyze any errors identified in the Discovery Sample. RDBHC recognizes 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.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on

supporting documentation available at RDBHC or under RDBHC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted 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, RDBHC may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from RDBHC to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If RDBHC's Discovery Sample identifies an Error Rate of 5% or greater, RDBHC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to 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 process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.H.1, RDBHC shall repay any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. RDBHC shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review.* If applicable, the IRO shall conduct a review of RDBHC's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether RDBHC has complied with its obligations

not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to 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 RDBHC or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. *Unallowable Cost Review Report.* If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether RDBHC 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.

6. *Validation Review.* In the event OIG has reason to believe that: (a) RDBHC's Claims Review or Unallowable Cost 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 or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). RDBHC 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 RDBHC's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify RDBHC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, RDBHC may request a meeting with OIG to discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Claims Review; or propose alternatives to the proposed Validation Review. RDBHC shall provide any

additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Unallowable Cost Review with RDBHC 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.

7. *Independence/Objectivity Certification.* The IRO shall include in its report(s) to RDBHC a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

Within 90 days after the Effective Date, RDBHC shall establish a Disclosure Program which shall 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 RDBHC's policies, conduct, practices, or procedures with respect to a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. RDBHC shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. 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, RDBHC 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 designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not),

the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements.* RDBHC shall ensure that all Covered Persons are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, RDBHC shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying 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://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) RDBHC to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days after the Effective Date, RDBHC shall review its list of the persons identified in Section F.2 against the Exclusion Lists. Thereafter, RDBHC shall review its list of such persons against the Exclusion Lists annually. In addition, RDBHC shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If RDBHC has actual notice that such person has become an Ineligible Person, RDBHC shall remove such person from responsibility for, or involvement with, RDBHC's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation 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 RDBHC has actual notice that a person identified in Section F.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, RDBHC shall take all appropriate actions to ensure that the responsibilities of that 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 to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, RDBHC shall notify OIG, in writing, of any ongoing investigation known to RDBHC or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that RDBHC 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. RDBHC 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. Reporting.

1. *Overpayments*

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

b. Reporting of Overpayments. If, at any time, RDBHC identifies or learns of any Overpayment, RDBHC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, RDBHC shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, RDBHC shall notify the payor of its efforts to quantify the Overpayment amount along with a

schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

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 probable 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 RDBHC determines through any means that there is a Material Deficiency, RDBHC shall notify OIG, in writing, within 30 days after making the determination that the Material Deficiency exists. The report to OIG shall include the following information:

i. If the Material Deficiency results in an Overpayment, the report to 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) by 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 RDBHC's actions taken to correct the Material Deficiency; and

iv. any further steps RDBHC 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, RDBHC changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, RDBHC shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at each such business unit or location 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, RDBHC 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, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. a copy of RDBHC's Code of Conduct required by Section III.B.1;

3. a copy of all Policies and Procedures required by Section III.B.2;

4. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a certification by the Compliance Officer that:

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

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

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

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

6. a description of the Disclosure Program required by Section III.E;

7. the identity of the IRO(s), a summary/description of all engagements between RDBHC and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion dates of the Claims Review, Unallowable Cost Review, or Systems Review;

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

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

10. a list of all of RDBHC'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 name and address of the Medicare contractor to which RDBHC currently submits claims;

11. A list of all entities and individuals for whom RDBHC performs the billing of their Federal health care program claims (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 name and address of the Medicare contractor to which RDBHC currently submits claims;

12. a description of RDBHC'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. RDBHC shall submit to OIG Annual Reports with respect to the status of, and findings regarding, RDBHC's compliance activities for each of the five Reporting Periods.

Each Annual Report shall 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 certification by the Compliance Officer that:

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

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

c. RDBHC has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct

addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek 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) and copies of any compliance-related Policies and Procedures;

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

5. a complete copy of all reports prepared pursuant to the IRO's claims review, unallowable cost review, and systems review, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

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

7. a revised summary/description of all engagements between RDBHC 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;

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

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

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

;

12. a description of any personnel actions (other than hiring) taken by RDBHC as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F., and the actions taken in response to the obligations set forth in that Section;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.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;

14. a description of all changes to the most recently provided list (as updated) of RDBHC's locations (including 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 Medicare provider identification number(s), and the contractor name and address that issued each Medicare provider number;

15. a description of all changes to the most recently provided list (as updated) of the locations (including addresses) of all entities and individuals for whom RDBHC performs the billing of their Federal health care program claims, 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 name and address that issued each Medicare provider number; and

16. the certification required by Section V.C.

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. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her knowledge, except as otherwise described in the applicable report, RDBHC is in compliance with all of the requirements of this CIA; 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. RDBHC shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. RDBHC 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, S.W.
Washington, D.C. 20201
Telephone: 202.619.2078
Facsimile: 202.205.0604

RDBHC:

Virginia Schenk
Compliance Officer
Regional Development Behavioral Health Centers, Inc.
210 South Centre Street
Pottsville, PA 17901
Telephone: 570.628.5215
Facsimile: 570.622.7864

Christopher L. White, Esq.
Morgan, Lewis & Bockius
1111 Pennsylvania Ave., NW
Washington, DC 20004
Telephone: 202.739.5240
Facsimile: 202.739.3001

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

RDBHC 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, RDBHC 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 RDBHC fails to have in place any of the obligations described in Section III:

    a. a Compliance Officer;

    b. a written Code of Conduct;

    c. written Policies and Procedures;

    d. a requirement that Covered Persons be trained; and

    e. a Disclosure Program.

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 RDBHC 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 RDBHC 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 RDBHC employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, RDBHC's business operations related to the Federal health care programs; or (b) 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 Subsection shall not be demanded for any time period during which RDBHC 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 RDBHC fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date RDBHC fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of RDBHC as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day RDBHC fails to comply fully and adequately with any obligation of this CIA. In its notice to RDBHC, OIG shall state the specific grounds for its determination that RDBHC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps RDBHC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after RDBHC receives 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 1-6 of this Section.

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

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If, at the conclusion of the 30-day period, RDBHC fails to satisfy the requirements of Section X.D.3, OIG may exclude RDBHC from participation in the Federal health care programs. OIG shall notify RDBHC in writing of its determination to exclude RDBHC (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 nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, RDBHC 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 RDBHC 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, RDBHC 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 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.

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 RDBHC was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. RDBHC shall have the burden of proving its 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 RDBHC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless RDBHC 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 RDBHC 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) RDBHC had begun to take action to cure the material breach within that period; (ii) RDBHC has pursued and is pursuing such action with due diligence; and (iii) RDBHC provided to OIG within that period a reasonable timetable for curing the material breach and RDBHC 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 RDBHC, only after a DAB decision in favor of OIG. RDBHC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RDBHC 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 RDBHC 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. RDBHC shall waive its 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 RDBHC, RDBHC shall be reinstated effective on 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

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

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

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

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

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

E. The undersigned RDBHC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

REGIONAL DEVELOPMENT BEHAVIORAL HEALTH CENTERS, INC.:

JOHN J. CANTWELL, individually and in his capacity as co-owner, Chief Operating Officer, and Secretary of the Board of RDBHC

8/13/03
DATE

FRANK C. MILEWSKI, individually and in his capacity as co-owner, Chief Executive Officer, and President of the Board of RDBHC

8/13/03
DATE

JOSEPH MCGINLEY, individually and in his capacity as co-owner, Chief Financial Officer, and Treasurer of RDBHC

8/13/03
DATE

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

Larry J. Goldberg

LARRY J. GOLDBERG
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

8/13/03
DATE

APPENDIX A

A. Claims Review.

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

a. Overpayment: The amount of money RDBHC has received in excess of the amount due and payable under any Federal health care program requirements.

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

c. Paid Claim: A code or line item submitted by RDBHC and for which RDBHC has received reimbursement from any Federal health care program.

d. Population: All Items for which RDBHC has submitted a code or line item and for which RDBHC has received reimbursement from any Federal health care 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.

e. 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 or Full Sample (as applicable) 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 Items in the sample.

2. Other Requirements.

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

b. 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 associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, 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.

B. Claims Review Report. 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. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

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

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

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has 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. Source 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, CMS 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 Discovery Sample and, if applicable, in the Full Sample.

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

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

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of RDBHC's 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) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by RDBHC ("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 RDBHC.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. 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), and dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. *Systems Review.* Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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

Attachment 1

Claim Review Results

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

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 Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

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 Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt