CORPORATE INTEGRITY AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

RAPID CITY REGIONAL HOSPITAL

I. PREAMBLE

Rapid City Regional Hospital ("RCRH") 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, contractors, and agents 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, RCRH is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

RCRH represents that prior to the execution of this CIA, RCRH voluntarily established a Corporate Compliance Program which provides for a Corporate Compliance Officer, a compliance training and education program, a confidential reporting hotline, a screening methodology for prospective employees, and which includes various policies and procedures aimed at ensuring that RCRH's participation in the Federal health care programs conforms to all applicable statutes, regulations and other legal requirements contained in any formal program directives issued by appropriate governmental agencies, e.g., the Centers for Medicare and Medicaid Services ("CMS") and/or their contractors.

Pursuant to this CIA, RCRH agrees to operate its Corporate Compliance Program consistent with the requirements of this CIA and to adopt or modify any components of RCRH's existing Corporate Compliance Program in order to be in compliance with all of the corporate integrity obligations under this CIA.

II. TERM AND SCOPE OF THE CLA

A. The period of the compliance obligations assumed by RCRH under this CIA shall be five (5) years from the effective date of this CIA ("Effective Date") (unless

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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: (A) RCRH's final annual report; or (B) any additional materials submitted by RCRH pursuant to OIG's request, whichever is later.
 - C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" includes:
 - a. all officers, directors, and employees;
 - b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of RCRH;
 - 2. "Relevant Covered Persons" includes any Covered Persons who are medical staff with staff privileges, or Covered Persons involved directly or in a supervisory role in the marketing, sales, contracting process, preparation, medical staff with staff privileges or submission of claims for items or services (including, but not limited to, coding or billing) to any Federal health care program.

For the purposes of this CIA, the definition of "Covered Persons" excludes housekeeping staff, dietary employees, maintenance workers, construction workers, plant operations workers, grounds keeping workers, security staff, gift shop employees and mailroom employees.

III. CORPORATE INTEGRITY OBLIGATIONS

RCRH shall establish, as appropriate, a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. Compliance Officer. RCRH has represented 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 make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of RCRH, 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 RCRH as well as for any reporting obligations created under this CIA.

RCRH 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.

2. Compliance Committee. Within 90 days after the Effective Date, RCRH shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

RCRH shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

1. Code of Conduct. Within 120 days after the Effective Date, RCRH shall establish a written Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within 120 days after the Effective Date. RCRH 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. RCRH'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. RCRH's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with RCRH's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of RCRH's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by RCRH suspected violations of any Federal health care program requirements or of RCRH's own Policies and Procedures:
- d. the possible consequences to both RCRH and Covered Persons of failure to comply with Federal health care program requirements and with RCRH'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.D, and RCRH's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by RCRH'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 120 days after the Effective Date, whichever is later.

RCRH 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. Within 120 days after the Effective Date, RCRH shall implement written Policies and Procedures regarding the operation of RCRH'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. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute or the Stark Law.
 - c. the requirements set forth in Section III.D.

Within 120 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), RCRH 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 120 days after the Effective Date, RCRH shall provide at least two (2) hours of general training to each Covered Person. This training, at a minimum, shall explain RCRH's:
 - a. CIA requirements;

- b. RCRH's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).
- c. the legal sanctions and consequences for improper contracting or financial arrangements;
- d. examples of violations of the Anti-Kickback Statute and Stark Law;
- e. applicable reimbursement statutes, regulations, and program requirements and directives; and
- f. a review of RCRH's contracting Policies and Procedures related to Arrangements, as defined in Section III.D. below, as developed pursuant to specific contracting sections of the Policies and Procedures, Section ____ and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and RCRH's Policies and Procedures.

New Covered Persons shall receive the general training described above within 30 days after becoming a Covered Person or within 120 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 120 days after the Effective Date, each Relevant Covered Person shall receive at least three (3) hours of specific training in addition to the general training required above. This specific training shall include a discussion of:
 - a. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes;
 - b. policies, procedures and other requirements applicable to the Federal health care program requirements of medical necessity;

- c. the personal obligation of each individual involved in the billing process to make appropriate and accurate representations regarding coverage and billing for Items and Services;
- d. the legal sanctions for improper sales, marketing, physician recruitment and contracting strategies or arrangements; and
- e. examples of proper and improper marketing and physician recruitment strategies or arrangements.

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 120 days after the Effective Date, whichever is later. An RCRH employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to sales, marketing, and physician contracting 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. RCRH 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 or external 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: Contractual Compliance with the Anti-Kickback
 Statute and the Stark Law.
 - 1. General Description.
 - a. <u>Scope</u>. This Section shall apply to every arrangement or transaction that: (1)(a) involves, directly or indirectly, the offer,

payment, solicitation, or receipt of anything of value; and (b) is between RCRH and any actual or potential source of health care business or referrals to RCRH or any actual or potential recipient of health care business or referrals from RCRH. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or (2)(a) is between RCRH and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)); and (b) where the physician makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to RCRH for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)), collectively, "Arrangements." The other party to an Arrangement shall be referred to herein as a "contractor."

- b. Retention of Independent Review Organization. Within 90 days after the Effective Date, RCRH 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 RCRH in assessing and evaluating its specified other obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by RCRH 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 RCRH seeks reimbursement. Each IRO shall assess, along with RCRH, 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 whether RCRH sought payment for certain unallowable costs ("Unallowable Cost Review").
- c. <u>Frequency of Unallowable Cost Review</u>. The IRO shall perform the Unallowable Cost Review for the first Reporting Period.

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

2. Arrangements Review

- a. <u>Implementation</u>. Within 120 days after the Effective Date, RCRH shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or the Stark Law. RCRH shall summarize all Arrangements in the form provided at Appendix B. RCRH shall update the summary at Appendix B annually and shall submit the summary with each Annual Report.
 - b. Requirements. RCRH shall ensure that all new and/or renewed (i.e., at renewal date) Arrangements are in compliance with the Anti-Kickback Statute and Stark Law, and the regulations, directives, and guidance related to these statutes, and comply with the following requirements:
 - 1. The Arrangement shall include a provision that all Covered Persons shall comply with RCRH's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, RCRH will provide each contractor with a copy of its Code of Conduct and Stark and Anti-Kickback Policies and Procedures;
 - 2. RCRH shall certify and shall require the contractor to certify, at the time of signing the Arrangement and annually thereafter, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and

- 3. RCRH shall require the contractor to certify, at the time of signing the Arrangement, that the contractor shall comply with RCRH's compliance program and with the Anti-Kickback Statute and the Stark Law.
- 4. RCRH shall retain and make available to OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this CIA or any other communication or report made pursuant to this CIA, shall constitute a waiver by RCRH of its attorney-client, attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by RCRH to avoid its obligations to comply with the provisions of this CIA.
- 3. Unallowable Cost Review. The IRO shall conduct a review of RCRH's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether RCRH 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 RCRH 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.
- 4. Unallowable Cost Review Report. 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 RCRH 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.

5. Validation Review. In the event OIG has reason to believe that:

(a) RCRH's Arrangements Review or Unallowable Cost Review fails to conform to the requirements of this CIA, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Arrangements Review results are inaccurate ("Validation Review"). RCRH 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 RCRH's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify RCRH 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, RCRH may request a meeting with OIG to discuss the results of any Arrangements Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Arrangements Review or Unallowable Cost Review or to correct the inaccuracy of the Arrangements Review, or propose alternatives to the proposed Validation Review. RCRH 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 Arrangements Review or Unallowable Cost Review with RCRH 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.

6. Independence/Objectivity Certification. The IRO shall include in its report(s) to RCRH 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 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, RCRH 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 RCRH's policies, conduct, practices, or procedures with respect to a

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Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law. RCRH 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, RCRH 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. RCRH shall not hire as employees or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, RCRH shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants 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) RCRH 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, RCRH shall review its list of current employees, contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, RCRH shall review its list of current employees, contractors and physicians with staff privileges against the Exclusion Lists annually. In addition, RCRH shall require employees, contractors and physicians with staff privileges to disclose immediately any debarment, exclusion, suspension, or other event that makes the employee, contractor or physician with staff privileges an Ineligible Person.

If RCRH has actual notice that an employee, contractor or physician with staff privileges has become an Ineligible Person, RCRH shall remove such person from responsibility for, or involvement with, RCRH'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 RCRH has actual notice that an employee, contractor or physician with staff privileges 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 term or, in the case of a physician, during the term of the physician's medical staff privileges, RCRH shall take all appropriate actions to ensure that the responsibilities of that employee, contractor or physician with staff privileges 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, RCRH shall notify OIG, in writing, of any ongoing

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investigation known to RCRH or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that RCRH 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. RCRH 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. <u>Definition of Overpayments</u>. For purposes of this CIA, an "Overpayment" shall mean the amount of money RCRH 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, RCRH identifies or learns of any Overpayment, RCRH 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, RCRH 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, RCRH 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. <u>Definition of Material Deficiency</u>. 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 RCRH determines through any means that there is a Material Deficiency, RCRH 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 RCRH's actions taken to correct the Material Deficiency; and

iv. any further steps RCRH 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, RCRH 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, RCRH 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. <u>Implementation Report</u>. Within 120 days after the Effective Date, RCRH 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. the names and positions of the members of the Compliance Committee required by Section III.A;
 - 3. a copy of RCRH's Code of Conduct required by Section III.B.1;
 - 4. a copy of all Policies and Procedures required by Section III.B.2;
 - 5. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted

audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

- 6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
 - b. all Covered Persons have completed the Code of Conduct certification required by Section III.B.1; and
 - c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

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

- 7. a description of the Disclosure Program required by Section III.E;
- 8. the identity of the IRO(s), a summary/description of all engagements between RCRH and the IRO, including, but not limited to, any outside financial audits or reimbursement consulting, and the proposed start and completion date of the Unallowable Cost Review;
- 9. a certification from the IRO regarding its professional independence and/or objectivity from RCRH;
- 10. a summary of personnel actions (other than hiring) taken pursuant to Section III.F.;
- 11. a list of all of RCRH'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 RCRH currently submits claims;

- 12. a description of RCRH'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. RCRH shall submit to OIG Annual Reports with respect to the status of, and findings regarding, RCRH's compliance activities for each of the five (5) Reporting Periods.

Each Annual Report shall include:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications required by Section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C;
 - c. RCRH 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 unallowable cost review, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
- 6. RCRH'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 RCRH 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 from RCRH;
- 9. a completed copy of Appendix B, including copies of work papers or methodologies used in the Arrangements Review to determine conclusions conveyed in Appendix B.
- 10. 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;
- 11. 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;

- 12. 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;
- 13. a description of any personnel actions (other than hiring) taken by RCRH 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;
- 14. 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;
- 15. a description of all changes to the most recently provided list (as updated) of RCRH'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; 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. <u>Certifications</u>. 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, RCRH 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. <u>Designation of Information</u>. RCRH 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. RCRH 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

RCRH

Rapid City Regional Hospital, Inc. 353 Fairmont Blvd.
Rapid City, SD 57701
Telephone: 605.719.1000
Facsimile: 605.719.8053

Facsimile: 202.205.0604

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

VIII. DOCUMENT AND RECORD RETENTION

RCRH shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 6 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 RCRH prior to any release by OIG of information submitted by RCRH pursuant to its obligations under this CIA and identified upon submission by RCRH as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, RCRH shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. Breach and Default Provisions

RCRH is expected to fully and timely comply with all of its CIA obligations.

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, RCRH 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 RCRH fails to have in place any of the obligations described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. a requirement that Covered Persons be trained; and
 - f. a Disclosure Program.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RCRH 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 RCRH 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 RCRH employs, contracts with or grants staff privileges to an Ineligible Person and that person: (a) has responsibility for, or involvement with, RCRH'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 RCRH 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 RCRH fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date RCRH fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 for each day RCRH fails to comply fully and adequately with any obligation of this CIA. In its notice to RCRH, OIG shall state the specific grounds for its determination that RCRH has failed to comply fully and adequately with the CIA obligation(s) at issue and steps RCRH shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after RCRH 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 1-5 of this Section.
- B. Timely Written Requests for Extensions. RCRH 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 RCRH 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 RCRH 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 RCRH 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 RCRH of: (a) RCRH'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, RCRH 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 RCRH elects to request an AIJ hearing, the Stipulated Penalties shall continue to accrue until RCRH 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 RCRH 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 RCRH 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 RCRH constitutes an independent basis for RCRH's exclusion from participation in the Federal health care programs. Upon a determination

by OIG that RCRH has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify RCRH of: (a) RCRH'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. RCRH 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. RCRH 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) RCRH has begun to take action to cure the material breach; (ii) RCRH is pursuing such action with due diligence; and (iii) RCRH has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, RCRH fails to satisfy the requirements of Section X.D.3, OIG may exclude RCRH from participation in the Federal health care programs. OIG shall notify RCRH in writing of its determination to exclude RCRH (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. If at the end of the period of exclusion, RCRH wishes to apply for reinstatement, RCRH shall submit a written request for reinstatement in accordance with the provisions at 42 CER. §§ 1001.3001-3004.

E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to RCRH 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, RCRH 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 RCRH was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. RCRH 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 RCRH to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless RCRH 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 RCRH 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) RCRH had begun to take action to cure the material breach within that period; (ii) RCRH has pursued and is pursuing such action with due diligence; and (iii) RCRH provided to OIG within that period a reasonable timetable for curing the material breach and RCRH has followed the timetable.

XI

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for RCRH, only after a DAB decision in favor of OIG. RCRH's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RCRH 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 RCRH 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. RCRH shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALL or DAB. If the DAB finds in favor of RCRH, RCRH 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.

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, RCRH and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of RCRH;
- 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 RCRH's obligations under the CIA in the event of RCRH's cessation of participation in Federal health care programs. If RCRH withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, RCRH shall notify OIG at least 30 days in advance of RCRH'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 RCRH 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.

12/18/02 17:11 FAX 6053304405 12/17/02 TUE 15:21 FAX 612 340 8800 DEC-17-2002 14:45 DURSEY & DEC-17-2002 1:41PM RCRH LEGAL **Ø** 048 DORSEY WHITNEY LLP DORSEY & WHITHEY LLP P.03/05 RCRH LEGAL SERVICES NO.373 ON BEHALF OF RAPID CITY REGIONAL HOSPITAL Fresident/CEO DATE December 17, 2002 DATE DATE RCRH Corporate Integrity Agreement October 2002

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12/18/02 17:11 FAX 6053304405 ☑ 049 12-18-02 04:14pm T-535 P.34/36 From-DHHS

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

Chief Counsel to the Inspector General
Office of Inspector General

U. S. Department of Health and Human Services

RCRH Corporate Integrity Agreement December 2002

APPENDIX A

OVERPAYMENT REFUND

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