# CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
DOUGLAS M. COLKITT, M.D. ("Dr. COLKITT")
AND
CERTAIN PARTIES RELATED TO Dr. COLKITT

## I. PARTIES

The individuals and entities listed on Appendix A hereto, who are also named defendants in the suit captioned United States *ex rel.* Rahman v. Oncology Associates, P.C., *et al.*, Civil Action No. H-95-2241 (D. MD) (hereinafter collectively referred to as "Colkitt defendants"), hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"). This CIA applies to all entities listed in Appendix A as Colkitt defendants, and all subsidiaries and affiliates in which any of the Colkitt defendants or a member of their immediate families or households (as defined by 42 U.S.C. § 1320a-7(j)) has an ownership or control interest (as defined by 42 U.S.C. § 1320a-3(a)(3)) or is a managing employee (as defined by 42 U.S.C. § 1320a-5(b)) (The Colkitt defendants and other entities described in this paragraph are hereinafter collectively referred to as "the Colkitt-related parties." The remaining named defendants in the Rahman case not listed on Appendix A, other than Jerome Derdel, shall be referred to hereinafter as the "Exempt defendants." Jerome Derdel shall be referred to as "Derdel.")

Derdel understands and agrees that, in the event he becomes an employee of or otherwise affiliated with a Colkitt-related party, this CIA will apply to him as if he were a Colkitt-related party, and he shall be required to take all measures within his authority to ensure compliance with this CIA, but only to the extent of such employment or affiliation.

The Colkitt-related parties' compliance with the terms and conditions in this CIA shall constitute an element of the Colkitt-related parties' present responsibility with regard to participation in Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs").

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## II. TERM OF THE CIA

The period of the compliance obligations assumed by the Colkitt-related parties under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the approval date of the Settlement Agreement Agreements pursuant to which this CIA is entered (the "effective date").

## III. CORPORATE INTEGRITY OBLIGATIONS

The Colkitt-related parties shall establish and maintain for the period of this CIA a compliance program that includes the following elements.

A. Compliance Officer. Within sixty (60) days of the effective date of this CIA, the Colkitt-related parties shall appoint an individual to serve as Compliance Officer, who 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 the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of a Colkitt-related entity, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of its Colkitt-related entity and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by the Colkitt-related parties to further their compliance objectives. The Compliance Officer shall be responsible for any reporting obligations created under this CIA.

In the event a new Compliance Officer is appointed during the term of this CIA, the Colkitt-related parties shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Compliance Committee. The Colkitt-related parties shall also appoint a Compliance Committee within ninety (90) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within the Colkitt-related parties' corporate structure (*e.g.*, senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his or her responsibilities.

C. Independent Coding Officer. Within sixty (60) days after the effective date of this CIA, the Colkitt-related parties engaged in furnishing radiation oncology items or services shall appoint an appropriately qualified Independent Coding Officer ("ICO") who has expertise in the rules governing submissions of claims to Federal health care programs for radiation oncology items and services. The ICO may retain additional personnel, including, but not limited to consultants, if needed to help meet the ICO's obligations under this CIA. The Colkitt-related parties shall be responsible for all costs reasonably incurred by the ICO in carrying out the responsibilities specified in this CIA, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel.

The ICO shall have the sole authority and responsibility to determine which claims for reimbursement for radiation oncology items and services furnished by the Colkitt-related parties will be submitted to Federal health care programs. The policies, procedures, and rules developed by the ICO shall be consistent with the final New York Local Medical Review Policy on Radiation Oncology and any subsequently adopted revisions. The Colkitt-related parties shall be informed in writing of the policies, procedures, and guidelines developed by the ICO.

The Colkitt-related parties furnishing radiation oncology items and services shall bill Federal health care programs for items and services solely in accordance with the ICO's policies, procedures and guidelines. Neither the Colkitt-related parties nor any of the individual defendants will participate in the ICO's development of these policies, procedures, and guidelines; their sole role will be to implement the policies, procedures, and guidelines developed by the ICO.

The ICO shall also be responsible for monitoring the day-to-day activities engaged in by the Colkitt-related parties to implement the ICO's policies, procedures, and guidelines. As part of that monitoring, the ICO shall at least twice per year conduct audits of the Colkitt-related parties' compliance with the coding policies, procedures, and guidelines. In the event an ICO audit detects that a claim submitted to a Federal health care program was at variance with the ICO's coding policies and procedures, the ICO shall investigate the discrepancy and require withdrawal of the claim or refund of payment as appropriate. The Colkitt-related parties shall comply with the ICO's findings. The ICO shall keep documentation of his or her investigations for submission as part of the Annual Report.

To facilitate performance of the ICO's responsibilities, the Colkitt-related parties shall give the ICO:

i. immediate access to the Colkitt-related parties' facilities, at any time and without prior notice, to assess compliance with this CIA;

ii. prompt access to any of the Colkitt-related parties' documents and data requested by the ICO to perform the duties required under this CIA; and

iii. prompt access to the Colkitt-related parties' staff for interviews outside the presence of supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals.

If the ICO resigns for any reason prior to expiration of the CIA, the Colkitt-related parties shall appoint a replacement within forty-five (45) days of the resignation and shall notify OIG of the identity of the new ICO within fifteen (15) days of such change.

D. Written Standards.

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, the Colkitt-related parties shall establish a Code of Conduct. The Code of Conduct shall be distributed within ninety (90) days of the effective date of this CIA to all employees, and to all contractors and agents who are involved directly or indirectly in the delivery of patient care and/or in the preparation, coding or submission of claims for reimbursement of such care to any Federal health program. (Those employees, contractors, and agents who are involved directly or indirectly in the delivery of patient care and/or in the preparation, coding or submission of claims for reimbursement of such care to any Federal health program shall hereinafter be referred to collectively as "Program Staff.") The Colkitt-related parties shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees and Program Staff. The Code of Conduct shall, at a minimum, set forth:

a. The Colkitt-related parties' commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including their commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;

b. The Colkitt-related parties' requirement that all of their employees and Program Staff shall comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with the Colkitt-related parties' own policies and procedures (including the requirements of this CIA);

c. The Colkitt-related parties' requirement that all of their employees and Program Staff shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of the Colkitt-related parties' own policies and procedures;

d. the possible consequences to both the Colkitt-related parties, and to employees and Program Staff, of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with the Colkitt-related parties' own policies and procedures or of failure to report such non-compliance; and

e. the right of all employees and Program Staff to use the confidential disclosure program, as well as the Colkitt-related parties' commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred twenty (120) days of the effective date of the CIA, each employee and Program Staff member shall certify, in writing, that he or she has received, read, understands, and will abide by the Colkitt-related parties' Code of Conduct.

New employees and members of Program Staff shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or contract or within one hundred twenty (120) days of the effective date of the CIA, whichever is later.

The Colkitt-related parties will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a change. Employees and Program Staff shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. *Policies and Procedures*. Within ninety (90) days of the effective date of this CIA, the Colkitt-related parties shall develop and put into effect written Policies

and Procedures regarding the operation of the Colkitt-related parties' compliance program and their compliance with all Federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for employees and Program Staff to make disclosures or otherwise report on compliance issues to the Colkitt-related parties' management through the Confidential Disclosure Program required by section III.E. The Colkitt-related parties shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

Within ninety (90) days of the effective date of the CIA, the Colkitt-related parties shall distribute the relevant portions of the Policies and Procedures to all Program Staff. The Colkitt-related parties will makes their compliance staff or supervisors available to explain any and all policies and procedures.

E. Training and Education.

1. *General Training*. Within one hundred twenty (120) days of the effective date of this CIA, the Colkitt-related parties shall provide at least two (2) hours of training to each employee and Program Staff member. This general training shall explain the Colkitt-related parties':

a. Corporate Integrity Agreement requirements;

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

c. Code of Conduct.

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

New employees and Program Staff members shall receive the general training described above within thirty (30) days of the beginning of their employment or within one hundred twenty (120) days after the effective date of this CIA, whichever is later. Employees and Program Staff shall receive such general training on an annual basis.

2. *Specific Training*. Within one hundred fifty (150) days of the effective date of this CIA, all Program Staff shall receive at least four (4) hours of training in addition to the general training required above. This training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;

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

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

d. applicable reimbursement rules and statutes;

e. the legal sanctions for improper billings and codings; and

f. examples of proper and improper billing and coding practices.

These training materials shall be made available to OIG, upon request. Persons providing the training must have expertise in the subject area.

New Program Staff shall receive this training within thirty (30) days of the beginning of their employment or within one hundred fifty (150) days of the effective date of this CIA, whichever is later. If a new Program Staff member has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Program Staff member who has completed the substantive training shall review all of the untrained person's work.

Program Staff members shall receive such specific training on an annual basis.

3. *Certification*. Each employee and Program Staff member shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.

F. Review Procedures. The Colkitt-related parties shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization") to perform review procedures to assist the Colkitt-related parties in assessing the adequacy of their billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which the Colkitt-related parties seek reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements. One will be an analysis of the Colkitt-related parties' billings to the Federal health care programs to assist the Colkitt-related parties and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether the Colkitt-related parties are in compliance with this CIA ("compliance engagement").

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. The Colkitt-related parties shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

Each annual billing engagement analysis shall include the following components in its methodology:

a. Billing Engagement Objective: A statement stating clearly the objective intended to be achieved by the billing engagement and the procedure or combination of procedures that will be applied to achieve the objective.

b. Billing Engagement Population: Identify the population, which is the group about which information is needed. Explain the

methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: Provide a full description of the source of the information upon which the billing engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.

d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.

e. Sampling Frame: Identify the sampling frame, which is the totality of the sampling units from which the sample will be selected.

As part of the billing engagement, the Independent Review Organization shall report in writing its findings regarding:

a. the Colkitt-related parties' billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, and effectiveness of the system);

b. whether the Colkitt-related parties are submitting accurate claims for services billed to the Federal health care programs.

c. the Colkitt-related parties' procedures to correct inaccurate billings or codings to the Federal health care programs; and

d. the steps the Colkitt-related parties are taking to bring their operations into compliance or to correct problems identified by the review.

2. *Compliance Engagement.* As part of the compliance engagement, the Independent Review Organization shall report in writing its findings regarding whether the Colkitt-related parties' program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include findings regarding the status of the Colkitt-related parties' compliance with each section of this CIA. In making its findings, the Independent Review Organization may interview appropriate employees and other

individuals, inspect appropriate documents, and take such other actions as are necessary to ascertain the facts.

A complete copy of the Independent Review Organization's billing and compliance engagement shall be included in the Colkitt-related parties' Annual Reports to OIG.

3. *Verification/Validation.* If the OIG has reason to believe that the billing engagement or compliance engagement fails to conform to the requirements of the CIA or indicates improper submissions not otherwise adequately addressed in the Independent Review Organization's report, it may conduct an independent review to determine whether or the extent to which the Colkitt-related parties are complying with their obligations under this CIA. Upon identifying the need for an independent review, OIG will notify the Colkitt-related parties of the basis for its determination and the expected parameters of the review, and will give the Colkitt-related parties an opportunity to respond to the problems that the OIG found with the IRO's report. The OIG may thereafter permit correction of the IRO report or, in its sole discretion, determine that an independent review is required. The Colkitt-related parties agree to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

G. Confidential Disclosure Program. Within ninety (90) days of the effective date of this CIA, the Colkitt-related parties shall establish a Confidential Disclosure Program, which must include measures (*e.g.*, a toll-free compliance telephone line) to enable Program Staff or other individuals to disclose, to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any suspected violation or irregularity associated with the Colkitt-related parties' policies, practices or procedures related to any Federal health care program. The Colkitt-related parties shall publicize the existence of the hotline by means calculated to reach all employees, contractors, agents, and other affected persons (*e.g.*, e-mail to employees or posting the hotline number prominently in common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. 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, the Colkitt-related parties 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 shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

H. Ineligible Persons.

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

2. *Screening Requirements.* The Colkitt-related parties shall not hire or engage as employees or Program Staff any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, the Colkitt-related parties shall screen all prospective employees and prospective Program Staff members prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within ninety (90) days of the effective date of this CIA, the Colkitt-related parties will review their list of current employees and Program Staff members against the Exclusion Lists. Thereafter, the Colkitt-related parties will review the list semi-annually. If a Colkitt-related party has notice that an employee or Program Staff member has become an Ineligible Person, the Colkitt-related party will remove such person from responsibility for, or involvement with, its business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until

such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If a Colkitt-related party has notice that an employee or Program Staff member is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion, the Colkitt-related party shall take all appropriate actions to ensure that the responsibilities of that employee or Program Staff member have not and will not adversely affect the quality of care rendered to any patient or resident, or the accuracy of any claims submitted to any Federal health care program.

I. Notification of Government Proceedings. Within thirty (30) days of discovery, the Colkitt-related parties shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that a Colkitt-related party 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. The Colkitt-related parties shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

J. Reporting.

1. *Overpayments*

*a. Definition of Overpayments.* For purposes of this CIA, an "overpayment" shall mean the amount of money the Colkitt-related parties have received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions. The Colkitt-related parties may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

*b. Reporting of Overpayments.* If, at any time, the Colkitt-related parties identify or learn of any billing, coding or other policies, procedures and/or practices that result in overpayments, the Colkitt-related parties shall notify the payor (*e.g.*, Medicare fiscal intermediary or carrier) and repay any overpayments within thirty (30) days of discovery (or such additional time as may be agreed to by the payor) and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying

problem and the overpayments from recurring. Notification of overpayment may be done pursuant to a form similar to the Overpayment Refund Form, provided as Appendix B to this CIA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment to the Colkitt-related parties relating to any Federal healthcare program; OR

(ii) a matter that a reasonable person would consider a non-de minimis violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized.

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

*b. Reporting of Material Deficiencies.* If the Colkitt-related parties have reason to believe that there is a material deficiency, the Colkitt-related parties shall notify OIG within thirty (30) days of 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 the OIG shall be made at the same time as the notification to the payor required in section H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(a) the payor's name, address, and contact person to whom the overpayment was sent; and

(b) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and program authorities implicated;

(iii) a description the Colkitt-related parties' actions to correct the Material Deficiency; and

(iv) any further steps the Colkitt-related parties plan to take to address such Material Deficiency and prevent it from recurring.

## IV. NEW BUSINESS UNITS OR LOCATIONS

In the event any of the Colkitt-related parties purchase or establish new business units or obtain new provider numbers after the effective date of this CIA, the Colkitt-related parties shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees and Program Staff members at such locations shall be subject to the requirements in this CIA that apply to new employees and Program Staff members (*e.g.*, completing certifications and undergoing training).

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred fifty (150) days of the effective date of this CIA, the Colkitt-related parties shall submit a written report to OIG summarizing the status of implementation of the requirements of this CIA. This Implementation Report shall include:

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

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

3. a copy of the Colkitt-related parties' Code of Conduct required by section III.D.1;

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

5. a description of the training programs required by section III.E including a description of the targeted audiences 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.D.2 have been developed, are being implemented, and have been distributed to all Program Staff;

b. all employees and Program Staff have completed the Code of Conduct certification required by section III.D.1; and

c. all employees and Program Staff have completed the training and executed the certification required by section III.E;

7. a description of the confidential disclosure program required by section III.G;

8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit;

9. a summary of personnel actions, other than hiring, taken pursuant to section III.H;

10. the name, address, phone number and position description of the Independent Coding Officer required by section III.C;

11. a copy of any policies, procedures, and guidelines developed by the ICO in accordance with section III.C;

12. a list of all locations (including locations and mailing addresses) of the Colkitt-related parties, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and

13. a certification by the Independent Coding Officer that the policies, procedures, and guidelines required by section III.C have been developed and implemented, that the Colkitt-related parties did not participate in or interfere with the development of these policies, procedures, and guidelines, and that the Colkitt-related parties have cooperated fully with the ICO in implementing these policies, procedures, and guidelines.

B. Annual Reports. The Colkitt-related parties shall submit to OIG an Annual Report with respect to the status and findings of the Colkitt-related parties' compliance activities. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee and/or the Independent Coding Officer described in sections III.A-C;

2. a certification by the Compliance Officer that:

a. all employees and Program Staff have completed the annual Code of Conduct certification required by section III.D.1; and

b. all Program Staff have completed the training and executed the certification required by section III.E;

3. notification of any changes or amendments to the Policies and Procedures required by section III.D and the reasons for such changes (*e.g.*, change in contractor policy);

4. a complete copy of any and all reports prepared pursuant to the Independent Review Organization's billing and compliance engagements, including a copy of the methodology used;

5. the Colkitt-related parties' response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of Material Deficiencies (as defined in III.J) identified during the reporting period and the status of any corrective and preventative actions relating to the Material Deficiency;

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

8. a copy of the confidential disclosure log required by section III.G;

9. a description of any personnel action (other than hiring) taken by the Colkitt-related parties as a result of the obligations in section III.F;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that a Colkitt-related party has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information;

11. a description of all changes to the most recently provided list (as updated) of the Colkitt-related parties' business units and 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 Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number;

12. copies of any revisions to the policies, procedures and guidelines developed by the ICO pursuant to section III.C;

13. copies of audit findings of the ICO pursuant to section III.C;

14. a certification by the ICO that the Colkitt-related parties did not participate in or interfere with the development of any revisions to the policies, procedures, and guidelines required by section III.C, and that the Colkitt-related parties have cooperated fully with the ICO in implementing these policies, procedures, and guidelines.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted 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 defendant Douglas R. Colkitt, MD, that: (1) the Colkitt-related parties are in compliance with all of the requirements of this CIA, to the best of his knowledge; and (2) Dr. Colkitt has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

The Colkitt-related parties:

Douglas Colkitt, M.D.

Phone:
Fax:

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 the Colkitt-related parties' books, records, and other documents and supporting materials and/or conduct onsite reviews of the Colkitt-related parties' operations as reasonably necessary for the purpose of verifying and evaluating: (a) the Colkitt-related parties' compliance with the terms of this CIA; and (b) the Colkitt-related parties' compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by the Colkitt-related parties to OIG or its duly authorized representative(s) at reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of the Colkitt-related parties' employees or Program Staff who consent to be interviewed at the person's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the person and OIG. The Colkitt-related parties agree to assist OIG in contacting and arranging interviews with such persons upon OIG's request. The Colkitt-related parties' employees and Program Staff members may elect to be interviewed with or without a representative of the Colkitt-related parties present.

## VIII. DOCUMENT AND RECORD RETENTION

The Colkitt-related parties shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

## IX. DISCLOSURES

Subject to HHS' Freedom of Information Act ("FOIA") procedures set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify the Colkitt-related parties prior to any release by OIG of information submitted by the Colkitt-related parties pursuant to its obligations under this CIA and identified upon submission by the Colkitt-related parties as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. The Colkitt-related parties shall refrain from identifying any information as trade secrets, commercial or financial information and

privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

## X. BREACH AND DEFAULT PROVISIONS

The Colkitt-related parties are expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Colkitt-related parties 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"). Such Stipulated Penalties shall be imposed only against such breaching party or parties in accordance with the following provisions.

1. A Stipulated Penalty of $2,000 (which shall begin to accrue on the day after the date the obligation became due) for each day, beginning 120 days (150 days regarding requirements in Paragraph III.E.2) after the effective date of this CIA and concluding at the end of the term of this CIA, such breaching Colkitt-related party or parties fail to have in place any of the following:

a. a Compliance Officer required by section III.A;
b. a Compliance Committee required by section III.B;
c. written Code of Conduct required by section III.D.1;
d. written Policies and Procedures required by section III.D.2;
e. training and education programs required by section III.E;
f. a Confidential Disclosure Program required by section III.G;
g. an Independent Coding Officer required by section III.C.

2. A Stipulated Penalty of $2,000 (which shall begin to accrue on the day after the date the obligation became due) for each day such breaching Colkitt-related party or parties fail to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day such breaching Colkitt-related party or parties employ or contract with an Ineligible Person and that person: (i) has responsibility for, or involvement with, such Colkitt-related party's or parties' business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or

the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds. (This Stipulated Penalty shall not be demanded for any time period during which such breaching Colkitt-related party or parties can demonstrate that they did not discover the person's exclusion or other ineligibility after making a reasonable inquiry as to the status of the person.)

4. A Stipulated Penalty of $1,000 (which shall begin to accrue on the date such Colkitt-related party or parties fail to grant access) for each day such breaching Colkitt-related party or parties fail to grant access to the information or documentation as required in section V of this CIA.

5. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to such breaching Colkitt-related party or parties of the failure to comply) for each day such breaching Colkitt-related party or parties fail to comply with any other obligation of this CIA. In its notice to such breaching Colkitt-related party or parties, OIG shall state the specific grounds for its determination that such breaching Colkitt-related party or parties have failed to comply with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that a Colkitt-related party or parties have failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify such Colkitt-related party or parties of (a) such Colkitt-related party or parties' 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").

Within fifteen (15) days of the date of the Demand Letter, the breaching Colkitt-related party or parties 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.D. In the event the breaching Colkitt-related party or parties elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until such Colkitt-related party or parties cure, to OIG's satisfaction, the alleged breach in dispute; provided, however, that no Stipulated Penalties shall be warranted if the ALJ overrules, reverses or vacates the OIG's determination of noncompliance. 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.C.

2. *Timely Written Requests for Extensions.* The breaching Colkitt-related party or parties may 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 such Colkitt-related party or parties fail to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two (2) business days after the Colkitt-related parties receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

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 otherwise noted, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for OIG's determination that a Colkitt-related party or parties have materially breached this CIA, which decision shall be made at OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Dr. Colkitt or any other Colkitt-related parties shall constitute an independent basis for the breaching party's or parties' exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that Dr. Colkitt or a Colkitt-related party or parties have materially breached this CIA and that exclusion should be imposed, OIG shall notify the party or parties alleged to be in breach of (a) the facts alleged to constitute the 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").

2. *Opportunity to Cure*. The party or parties alleged to be in material breach of the CIA shall have thirty-five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

a. the allegedly breaching party or parties are in full compliance with this CIA;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 35-day period, but that: (i) the breaching party or parties have initiated action to cure the material breach, (ii) the breaching party or parties are pursuing such action with due diligence, and (iii) the breaching party or parties have provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter*. If, at the conclusion of the thirty five (35) day period, the party or parties alleged to be in breach fail to satisfy the requirements of section X.C.2, OIG may exclude such party or parties from participation in the Federal health care programs. OIG will notify the party or parties in writing of its determination to exclude ( hereinafter the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. Any party or parties excluded under the provisions of this CIA may seek reinstatement pursuant to the provisions at 42 C.F.R. §§1001.3001-.3004.

4. *Material Breach*. A material breach of this CIA means:

a. a failure by a Colkitt-related party or parties to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.F;

b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above;

d. a failure to retain and use an Independent Review Organization for review purposes in accordance with the requirements set forth in section III.F;

e. a failure to retain and use an Independent Coding Officer in accordance with the requirements set forth in section III.C.

D. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to a party of a Demand Letter or an Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, the party receiving such Letter shall be afforded certain review rights comparable to those provided in 42 U.S.C. §1320a-7(f) and 42 C.F.R. §1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§1005.2-1005.21. Notwithstanding the language in 42 C.F.R. §1005.2(c), the request for a hearing involving stipulated penalties shall be made within fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date 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 the party was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. The party assessed stipulated penalties shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for OIG with regard to a finding of a breach of this CIA and orders payment of stipulated penalties, such stipulated penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that the Colkitt-related parties may request review of the ALJ decision by the DAB.

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 the party sought to be excluded was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) where applicable, whether it has been shown that although the alleged material breach cannot be cured within the 35 day period, (i) action has been initiated to cure the material breach, (ii) such corrective action is being pursued with due diligence, and (iii) OIG has been provided a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to OIG. A party's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the party upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that a timely request is made for review of the ALJ decision by the DAB.

## XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreements pursuant to which this CIA is entered, the Colkitt-related parties and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns and transferees of the Colkitt-related parties. However, OIG shall waive this successor liability provision upon receipt of verified proof to the OIG's satisfaction that the Colkitt-related parties have wholly divested themselves of any interest or involvement, direct or indirect, in the transferred or assigned entity, that the successor is an independent entity unrelated in any manner to the Colkitt-related parties, that the successor has acquired its interest at fair market value in an arms' length transaction, and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs.

B. This CIA shall be binding upon all Colkitt-related parties and shall become final and binding on the date the final signature is obtained on the CIA.

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

D. The undersigned signatories for the Colkitt-related parties 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.

**COLKITT-RELATED PARTIES**

BY: _____ 7/07/00

DOUGLAS R. COLKITT, M.D., DATE
individually and on behalf of
all Colkit-Related Parties
except Jerome Derdel, M.D.

BY: _____ 7/03/00

JOANNE RUSSELL DATE

BY: Jerome Derdel MD
JEROME DERDEL.M.D.

7/6/00
DATE

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

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

7/10/00
DATE