CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RADIOLOGY CONSULTANTS, P.A.

I. PREAMBLE

Radiology Consultants, P.A. ("Radiology Consultants") 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 ensure compliance by its member physicians, employees, and other health care professionals, as well as all staff and third parties whom Radiology Consultants may choose to engage to act as its billing or coding agents or consultants, including but not limited to, Interstate Radiology Management, Inc., ("Covered Persons") with the requirements of 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."). Radiology Consultants' compliance with the terms and conditions in this CIA shall constitute an element of Radiology Consultants' present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Radiology Consultants is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

Prior to the execution of this CIA, Radiology Consultants voluntarily established its own corporate compliance program. The program, as represented Radiology Consultants, is aimed at ensuring that Radiology Consultants' activities are in conformity with all applicable statutes, regulations and guidelines of the Federal health care programs. Radiology Consultants agrees to continue the operation of its compliance program in accordance with the provisions set forth below for the term of this CIA. Radiology Consultants may modify its compliance program as appropriate, but at a minimum, Radiology Consultants shall comply with the integrity obligations that are enumerated in this CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by Radiology Consultants under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

Radiology Consultants shall maintain or establish a compliance program that includes the following elements.

A. Compliance Officer.

To the extent not already accomplished, within one hundred and twenty (120) days after the effective date of this CIA, Radiology Consultants shall appoint an individual to serve as its 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 Radiology Consultants, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors 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 Radiology Consultants to further its compliance objectives as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, Radiology Consultants shall notify the OIG, in writing, within forty-five (45) days of such a change.

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, within ninety (90) days of the effective date of this CIA, Radiology Consultants shall establish a Code of Conduct. The Code of Conduct shall be distributed to all Covered Persons within ninety (90) days of the effective date of this CIA. Radiology Consultants shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the

performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. Radiology Consultants' commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its 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. Radiology Consultants' requirement that all Covered Persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Radiology Consultants' own policies and procedures (including the requirements of this CIA);

c. the requirement that all Covered Persons shall be expected to report to the Compliance Officer or other individual designated by Radiology Consultants suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Radiology Consultants' own policies and procedures;

d. the possible consequences to both Radiology Consultants and to any Covered Person of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Radiology Consultants' own policies and procedures or of failure to report such non-compliance; and

e. the right of individuals to use the Confidential Disclosure Program described in Section III.E, as well as Radiology Consultants' commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by Radiology Consultants' Code of Conduct. New Covered Persons 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 ninety (90) days of the effective date of the CIA, whichever is later.

Radiology Consultants will annually review the Code of Conduct and will make any necessary revisions. Any such revised Code of Conduct shall be distributed within

thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, understand and will abide by the revised Conduct within thirty days of the finalization of such revisions.

2. *Policies and Procedures*. Within one hundred and twenty (120) days of the effective date of this CIA, Radiology Consultants shall develop and initiate implementation of written Policies and Procedures regarding the operation of Radiology Consultants' compliance program and its compliance with the requirements of the Federal health care programs. At a minimum, the Policies and Procedures shall specifically address appropriate and proper billing of all radiology services to the Federal health care programs and the subjects relating to the Code of Conduct. Radiology Consultants 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 the OIG in the Implementation Report. The Policies and Procedures will be available to the OIG upon request.

Within one hundred and twenty (120) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate Covered Persons. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. <u>Training and Education</u>.

1. *General Training*. Within ninety (90) days of the effective date of this CIA, Radiology Consultants shall provide at least two (2) hours of training to each Covered Person. This general training shall explain Radiology Consultants':

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.

The training materials for this general training shall be made available to the OIG, upon request.

New Covered Persons shall receive the general training described above within thirty (30) days of the beginning of their employment or engagement by Radiology Consultants or within ninety (90) days after the effective date of this CIA, whichever is

later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training on an annual basis.

2. *Specific Training*. Within ninety (90) days of the effective date of this CIA, each Covered Person who is involved directly or indirectly in the coding or billing process for claims for reimbursement submitted to any Federal health care programs ("Relevant Covered Persons") shall receive at least four (4) hours of specific 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 Federal health care program patients;
b. policies, procedures and other requirements applicable to the documentation of medical records;
c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
d. applicable reimbursement rules and statutes;
e. the legal sanctions for improper billings; and
f. examples of proper and improper billing practices.

These training materials shall be made available to the OIG, upon request. Persons providing the training must be knowledgeable about the subject area.

New Relevant Covered Persons shall receive this training within thirty (30) days of the beginning of their employment or engagement by Radiology Consultants or within ninety (90) days of the effective date of this CIA, whichever is later. If a new Relevant Covered Person has any responsibility for the preparation or submission of claims and/or the assignment of procedure or billing codes prior to completing this specific training, a Relevant Covered Person who has completed the specific training shall review all of the untrained person's work regarding the submission of claims and/or the assignment of procedure or billing codes.

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

3. *Certification*. Each individual required to receive training as specified above 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 the OIG upon request.

D. Review Procedures.

Radiology Consultants shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist Radiology Consultants in assessing the adequacy of its billing and compliance practices pursuant to this CIA, including those performed by Interstate Radiology Management, Inc. or any other billing entity retained by Radiology Consultants. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Radiology Consultants seeks 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 Radiology Consultants' billing to the Federal health care programs to assist Radiology Consultants and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The billing engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of the CIA. The second engagement will determine whether Radiology Consultants is in compliance with this CIA ("compliance engagement"). The compliance engagement shall be performed by the Independent Review Organization for the first one-year period beginning with the effective date of this CIA.

1. *Billing Engagement.* The billing engagement shall consist of a review of a statistically valid sample of claims for services rendered by Radiology Consultants 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. Radiology Consultants 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/progorg/ratstat.html .

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

a. Billing Engagement Objective: a clear statement of 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: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination.

c. Sources of Data: 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: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest.

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

The billing engagement shall provide:

a. findings regarding billing and coding operations for services rendered by Radiology Consultants (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);

b. findings regarding whether Radiology Consultants is submitting accurate claims for services billed to the Federal health care programs.

c. findings regarding Radiology Consultants' procedures to correct inaccurate billings or codings to the Federal health care program; and

d. findings regarding the steps Radiology Consultants is taking to bring its operations into compliance or to correct problems identified by the audit.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether Radiology Consultants' program, policies, procedures, and operations comply with the terms of this regarding the requirements of this CIA.

Complete copies of the Independent Review Organization's billing and compliance engagement report(s) shall be included in each of Radiology Consultants' Annual Reports to OIG.

E. Confidential Disclosure Program.

Radiology Consultants has established and will maintain a Confidential Disclosure Program that includes measures such as a toll-free compliance telephone line to enable Covered Persons 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 identified issues or questions associated with Radiology Consultants' policies, practices or procedures with respect to the Federal health care programs, believed by the individual to be inappropriate. Radiology Consultants shall continue to publicize the existence of the hotline (e.g., e-mail to employees or post hotline number in prominent common areas).

The Confidential Disclosure Program shall continue to 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, Radiology Consultants 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. The confidential disclosure log shall be available to the OIG upon request.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, 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 and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements.* Radiology Consultants shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Radiology Consultants shall screen all prospective employees and prospective contractors 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://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.dhhs.gov/oig) (these lists and reports 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, Radiology Consultants will compare its list of current employees and contractors against the Exclusion Lists. Thereafter, Radiology Consultants will review the list once annually. If Radiology Consultants has notice that an employee or contractor has become an Ineligible Person, Radiology Consultants will remove such person from responsibility for, or involvement with, Radiology Consultants' 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 Radiology Consultants has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, Radiology Consultants shall take all appropriate actions to ensure that the responsibilities of that individual have not and will not adversely affect the quality of care

rendered to any patient, or the accuracy of any claims submitted to the Federal health care programs.

G. Notification of Government Proceedings. Within thirty (30) days of discovery, Radiology Consultants shall notify the OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Radiology Consultants has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. Radiology Consultants shall also provide written notice to the OIG within thirty (30) days of the resolution of the matter, and shall provide the OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Reporting of Overpayments.* If, at any time, Radiology Consultants identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, Radiology Consultants shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayment within thirty (30) days of discovery 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 to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, can be done pursuant to a form similar to the Overpayment Refund Form, provided as Attachment A to this CIA.

2. *Reporting of Material Deficiencies.* If Radiology Consultants determines that there is a material deficiency as defined below, it shall notify the OIG within thirty (30) days of making the determination that the material deficiency exists. The report to the OIG shall include the following information:

(a) 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:

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

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

(b) a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities implicated;

(c) a description of Radiology Consultants's actions to correct the material deficiency; and

(d) a description of any further steps Radiology Consultants plans to take to address such material deficiency and prevent it from recurring.

3. *Definition of "Overpayment."* For purposes of this CIA, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or guidelines, including carrier and intermediary instructions. Radiology Consultants may not subtract any underpayments for purposes of determining the relevant overpayment amount.

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

(a) a substantial overpayment relating to any Federal health care program;
(b) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion are authorized.

A material deficiency may be the result of an isolated event or a series of occurrences.

IV. NEW LOCATIONS

In the event that Radiology Consultants changes locations or purchases or establishes new business units after the effective date of this CIA, Radiology Consultants shall notify the 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

Covered Persons at such locations shall be subject to the applicable requirements of this CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and twenty (120) days after the effective date of this CIA, Radiology Consultants shall submit a written report to the OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

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

2. a copy of Radiology Consultants' Code of Conduct required by section III.B.1;

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

4. a description of the training programs required by section III.C including a description of the targeted audiences and a schedule of when the training sessions were held;

5. a certification by the Compliance Officer that:
   a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all pertinent 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 training and executed the certification required by section III.C.

6. a description of the confidential disclosure program required by section III.E;

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

8. a summary of personnel actions taken pursuant to section III.F.

9. a list of all of Radiology Consultants' locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone 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.

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

B. Annual Reports. Radiology Consultants shall submit to the OIG an Annual Report with respect to the status and findings of Radiology Consultants' compliance activities for each of the one (1) year periods beginning on the effective date of the CIA. The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer described in section III.A;

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

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

   c. Radiology Consultants 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 conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims, and (ii) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify and adjust any past charges of unallowable costs;

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

4. a description of the training required by section III.C conducted during the prior year, 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 Independent Review Organization's billing and compliance engagements, including a copy of the methodology used;

6. Radiology Consultants' response/corrective action plan to any issues raised by the Independent Review Organization;

7. a summary of any material deficiencies as discovered in accordance with III.D.H. and reported throughout the course of the previous twelve (12) months and the status of any corrective and preventative actions relating to the material deficiencies;

8. 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;

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

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

11. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.G. The 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; and

12. a description of all changes to the most recently provided list (as updated) of Radiology Consultants' 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.

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 the Compliance Officer under penalty of perjury, that: (1) Radiology Consultants is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

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

Radiology Consultants:

Amanda Dittman, Compliance Officer
Radiology Consultants
306 Avenue C, N.E.
Winter Haven, FL 33881

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 the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s), may examine Radiology Consultants' books, records, and other documents and supporting materials and/or conduct an onsite review of Radiology Consultants' operations for the purpose of verifying and evaluating: (a) Radiology Consultants' compliance with the terms of this CIA; and (b) Radiology Consultants' compliance with the requirements of the Federal health care programs in which it participates.

The documentation described above shall be made available by Radiology Consultants to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Radiology Consultants' 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 the OIG. Radiology Consultants agrees to assist the OIG in contacting and arranging interviews with these individuals upon the OIG's request. Radiology Consultants' employee, contractors or agents may elect to be interviewed with or without a representative of Radiology Consultants present.

VIII. DOCUMENT AND RECORD RETENTION

Radiology Consultants shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one (1) year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Radiology Consultants prior to any release by the OIG of information submitted by Radiology Consultants pursuant to its obligations under this CIA and identified upon submission by Radiology Consultants as trade secrets, or information that is commercial or financial and privileged or confidential under the FOIA rules. With respect to such releases, Radiology Consultants shall have the rights set forth at 45 C.F.R. § 5.65(d). Radiology Consultants shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Radiology Consultants is 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, Radiology Consultants and the 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, beginning one hundred and twenty (120) days after the effective date of this CIA and concluding at the end of the term of this CIA, Radiology Consultants fails to have in place any of the following:

a. a Compliance Officer;
b. a written Code of Conduct;
c. written Policies and Procedures;

d. a training program; and
e. a Confidential 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 Radiology Consultants fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

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 Radiology Consultants fails to retain an IRO, as required in section III.D.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Radiology Consultants employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Radiology Consultants' 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 Radiology Consultants 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 (which shall begin to accrue on the date the Radiology Consultants fails to grant access) for each day Radiology Consultants fails to grant access to the information or documentation as required in section VII of this CIA.

6. A Stipulated Penalty of $1,000 (which shall begin to accrue ten (10) days after the date that the OIG provides notice to Radiology Consultants of the failure to comply) for each day Radiology Consultants fails to comply fully and adequately with any obligation of this CIA. In its notice to Radiology Consultants, the OIG shall state the specific grounds for its determination that the Radiology Consultants has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Radiology Consultants has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, the OIG shall notify Radiology Consultants by personal service or certified mail of (a) Radiology Consultants' failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

Within fifteen (15) days of the date of the Demand Letter, Radiology Consultants shall either (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event Radiology Consultants elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Radiology Consultants cures, to the 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.C.

2. *Timely Written Requests for Extensions.* Radiology Consultants 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 the 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 (1) day after Radiology Consultants fails to meet the revised deadline as agreed to by the OIG-approved extension. Notwithstanding any other provision in this section, if the 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 Radiology Consultants receives the OIG's written denial of such request. A "timely written request" is defined as a request in writing received by the 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 the 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 the OIG's determination that Radiology Consultants has materially breached this CIA, which decision shall be made at the 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 Radiology Consultants constitutes an independent basis for Radiology Consultants' exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by the OIG that Radiology Consultants has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Radiology Consultants by certified mail of (a) Radiology Consultants' material breach; and (b) the 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*. Radiology Consultants shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

a. Radiology Consultants is 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) Radiology Consultants has begun to take action to cure the material breach, (ii) Radiology Consultants is pursuing such action with due diligence, and (iii) Radiology Consultants has provided to the OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter*. If at the conclusion of the thirty five (35) day period, Radiology Consultants fails to satisfy the requirements of section X.C.2, the OIG may exclude Radiology Consultants from participation in the Federal health care programs. The OIG will notify Radiology Consultants in writing of its determination to exclude Radiology Consultants (this letter shall be referred to hereinafter as 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. If Radiology Consultants is excluded under the provisions of this CIA, Radiology Consultants may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

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

a. a failure by Radiology Consultants to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.H;
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; or
d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Radiology Consultants of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, Radiology Consultants 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. § 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, the 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 Radiology Consultants was in full and timely compliance with the obligations of this CIA

for which the OIG demands payment; and (b) the period of noncompliance. Radiology Consultants 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 the OIG with regard to a finding of a breach of this CIA and orders Radiology Consultants to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Radiology Consultants 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 Radiology Consultants 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 be cured within the 35 day period, but that (i) Radiology Consultants began to take action to cure the material breach, (ii) Radiology Consultants pursued such action with due diligence, and (iii) Radiology Consultants provided to the OIG 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 the OIG. Radiology Consultants' election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Radiology Consultants upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Radiology Consultants may request review of the ALJ decision by the DAB.

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 and Radiology Consultants agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

D. The undersigned Radiology Consultants 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.

ON BEHALF OF RADIOLOGY CONSULTANTS

Raymond Larue, M.D.
Acting President, Radiology Consultants, P.A.

8/10/00
Date

Gabriel L. Imperato, Esq.
Counsel for Radiology Consultants, P.A.

8/15/00
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

8/15/00
Date