CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KEYSTONE ONCOLOGY, LLC
AND
CENTRAL PENNSYLVANIA RADIATION, PC

I. PARTIES

Keystone Oncology, LLC, and Central Pennsylvania Radiation, PC (hereinafter collectively referred to as "Keystone"), hereby enter into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by Keystone, all of its subsidiaries and affiliates, its employees, physicians, and other health care professionals, as well as all third parties with whom it may choose to engage to act as billing or coding agents or consultants (hereinafter collectively referred to as "Keystone") 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"). Keystone's compliance with the terms and conditions in this CIA shall constitute an element of its present responsibility with regard to participation in the Federal health care programs.

Keystone agrees that throughout the duration of this CIA, neither it nor any of its subsidiaries or affiliates will maintain any ownership, employment, agency, consulting, financial, management, or contractual relationship, directly or indirectly, with Douglas R. Colkitt, M.D., or with any entity in which Dr. Colkitt or a member of his immediate family or household (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)) (hereinafter collectively referred to as "Colkitt"). Nor will Colkitt be involved in any way, directly or indirectly, with the ownership or operations of Keystone or its affiliates and subsidiaries.

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

II. TERM OF THE CIA

The period of the compliance obligations assumed by Keystone under this CIA shall be five (5) years from the effective date of the CIA (unless otherwise specified). The effective date of the CIA will be the approval date of the Settlement Agreement ("effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

Keystone 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, Keystone 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 Keystone or Central Pennsylvania Radiation, P.C. shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Keystone or Central Pennsylvania Radiation, P.C., and shall be authorized to report to the Board of Directors of either entity at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Keystone to further its 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, Keystone shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. Written Standards.

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, Keystone 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.") Keystone 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. Keystone's 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. Keystone's requirement that all of its employees and Program Staff shall comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Keystone's own policies and procedures (including the requirements of this CIA);

c. Keystone's requirement that all of its 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 Keystone's own policies and procedures;

d. the possible consequences to both Keystone, and to employees and Program Staff, of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Keystone's 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 Keystone's 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 Keystone's Code of Conduct.

New employees and Program Staff members 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.

Keystone 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, Keystone shall develop and put into effect written Policies and Procedures regarding the operation of Keystone's compliance program and its 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 Keystone's management through the Confidential Disclosure Program required by section III.E. Keystone 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, Keystone shall distribute the relevant portions of the Policies and Procedures to all Program Staff. Keystone will make its compliance staff or supervisors available to explain any and all policies and procedures.

C. Training and Education.

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

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.

D. Review Procedures. Keystone shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization") to perform review procedures to assist Keystone in assessing the adequacy of its 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 Keystone 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 Keystone's billings to the Federal health care programs to assist Keystone and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether Keystone is 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. Keystone 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".

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. Keystone's 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 Keystone is submitting accurate claims for services billed to the Federal health care programs.

c. Keystone's procedures to correct inaccurate billings or codings to the Federal health care programs; and

d. the steps Keystone is 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 Keystone's program, policies, procedures, and operations comply with the terms of this CIA. This engagement shall include findings regarding the status of Keystone's 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 Keystone's Annual Reports to OIG.

3. *Verification/Validation.* If the OIG has a good faith, reasonable belief 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 Keystone is complying with its obligations under this CIA. Upon identifying the need for an independent review, OIG will notify Keystone, in writing, of the basis for its good faith, reasonable determination and the expected parameters of the review, and will give Keystone reasonable opportunity to respond to the problems that OIG found with the Independent Review Organization's report prior to undertaking an independent review. OIG may thereafter permit correction of the Independent Review Organization's report or the problems described therein and thereafter, in its sole discretion, determine whether or not an independent review is required Keystone agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

E. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, Keystone shall establish a Confidential Disclosure Program, which must include measures (*e.g.*, a toll-free compliance telephone line, drop box, etc.) 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 Keystone's policies, practices or procedures related to any Federal health care program. Keystone shall publicize the existence of its confidential disclosure procedures by means calculated to reach all employees, contractors, agents, and other affected persons (*e.g.*, e-mail to employees or posting the disclosure procedures 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 seek to gather additional 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 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 merits of the allegations, and (2) provides an opportunity for taking corrective action, Keystone 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.

F. 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.* Keystone shall not hire or engage as employees or Program Staff any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Keystone 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, Keystone will review its list of current employees and Program Staff members against the Exclusion Lists. Thereafter, Keystone will

review the list semi-annually. If Keystone has notice that an employee or Program Staff member has become an Ineligible Person, Keystone 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 Keystone 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, Keystone 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.

G. Notification of Government Proceedings. Within thirty (30) days of discovery, Keystone 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 Keystone 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. Keystone 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.

H. Reporting.

1. *Overpayments*

a. Definition of Overpayments. For purposes of this CIA, an "overpayment" shall mean the amount of money Keystone 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. Keystone may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Keystone identifies or learns of any billing, coding or other policies, procedures or practices that result in overpayments, Keystone 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 Attachment # 1 to this CIA. Nothing contained herein shall preclude the filing of a Notice of Underpayment at any time, including simultaneously with the filing of a Notice of Overpayment

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 Keystone relating to any Federal healthcare program; OR

(ii) a matter that a reasonable person would consider a 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 Keystone has a good faith, reasonable belief that a Material Deficiency has occurred, Keystone shall notify OIG within thirty (30) days of making the determination. 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 Keystone's actions to correct the Material Deficiency; and

(iv) any further steps Keystone plans to take to address such Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event Keystone purchases or establishes new business units or obtains new provider numbers after the effective date of this CIA, Keystone 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 after the effective date of this CIA, Keystone 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. a copy of Keystone's 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 Program Staff;

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

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

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

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 taken pursuant to section III.F; and

10. a list of all locations (including locations and mailing addresses) of Keystone, 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.

B. Annual Reports. Keystone shall submit to OIG an Annual Report with respect to the status and findings of Keystone's compliance activities. The Annual Reports shall include:

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

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.B.1; and

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

3. notification 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 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. Keystone's response/corrective action plan to any issues raised by the Independent Review Organization;

6. a summary of Material Deficiencies (as defined in III.H) 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.E;

9. a description of any personnel action (other than hiring) taken by Keystone as a result of the obligations in section III.D;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that

Keystone has committed a crime or has engaged in fraudulent activities, which have been reported pursuant to section III.E. 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

11. a description of all changes to the most recently provided list (as updated) of Keystone's 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.

The first Annual Report shall be received by OIG no later than one year and forty-five (45) 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 that: (1) Keystone 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.

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

Keystone:

George Keister
Secretary Treasurer
Keystone Oncology, LLC
119 South Burrows Street, #705
State College, PA 16801
Business: (814) 867-2014
Fax: (814) 867-2015

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, upon prior written notice, examine Keystone's books, records, and other documents and supporting materials and/or conduct onsite reviews of Keystone's operations for the purpose of verifying and evaluating: (a) Keystone's compliance with the terms of this CIA; and (b) Keystone's compliance with the requirements of the Federal health care programs in which they participate. Keystone shall, upon prior written notice, make available the documentation described above 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 Keystone's 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. Keystone agrees to assist OIG in contacting and arranging interviews with such persons upon OIG's request. Keystone's employees and Program Staff members may elect to be interviewed with or without an attorney or a representative of Keystone present.

VIII. DOCUMENT AND RECORD RETENTION

Keystone 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 Keystone prior to any release by OIG of information submitted by Keystone pursuant to its obligations under this CIA and identified upon submission by Keystone as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Keystone 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

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

1. A Stipulated Penalty of $2,000 (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.D.2) after the effective date of this CIA and concluding at the end of the term of this CIA, Keystone fails to have in place any of the following:

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

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 Keystone fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG unless that deadline is otherwise extended pursuant to X.B.2., below.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Keystone employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Keystone's business operations related to the Federal health care programs or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds. (This Stipulated Penalty shall not be demanded for any time period during which Keystone can demonstrate that it 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 Keystone fails to grant access) for each day Keystone fails to grant access, upon prior written notice, 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 Keystone of the failure to comply) for each day Keystone fails to comply with any other obligation of this CIA. In its notice to Keystone, OIG shall state the specific grounds for its determination that Keystone has failed to comply with the CIA obligation(s) at issue.

B. Payment of Stipulated Penalties.

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

Within fifteen (15) days of the date of the Demand Letter, Keystone 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 Keystone elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Keystone cures, 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 initial 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.* Keystone 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 Keystone fails 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 Keystone 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 any 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 Keystone has 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 shall constitute an independent basis for Keystone's 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 Keystone has materially breached this CIA and that exclusion should be imposed, OIG shall notify Keystone by certified mail 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.* Keystone 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. Keystone 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) Keystone has initiated action to cure the material breach, (ii) Keystone is pursuing such action with due diligence, and (iii) Keystone has 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, Keystone fails to satisfy the requirements of section X.C.2, OIG may seek to exclude Keystone from participation in the Federal health care programs. OIG will notify Keystone 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. Keystone 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 Keystone to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.D;

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.D;

D. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Keystone 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, Keystone 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 Keystone was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Keystone 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, unless otherwise agreed to by the parties, become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Keystone 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 Keystone was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; (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. Keystone's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Keystone 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 Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, Keystone and OIG agree as follows:

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

B. This CIA shall be binding upon Keystone 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 Keystone 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 the Office of Inspector General
of the U.S. 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

Date

D. The undersigned signatories for Keystone 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 KEYSTONE ONCOLOGY, LLC

GEORGE KEISTER
Secretary & Treasurer

7/3/2000
DATE

ON BEHALF OF CENTRAL PENNSYLVANIA RADIATION, PC

George Keister
Secretary Treasurer

7/3/2000.
Date

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND KEYSTONE ONCOLOGY, LLC AND CENTRAL PENNSYLVANIA RADIATION, PC

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Keystone Oncology, LLC and Central Pennsylvania Radiation, PC (hereinafter, collectively referred to as "Keystone") entered into a Corporate Integrity Agreement ("CIA") on July 10, 2000.

A. Pursuant to section XI.C. Keystone's CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Keystone. Therefore, the OIG and Keystone hereby agree that Keystone's CIA will be amended as follows:

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures.

The attached Appendix A is hereby added to Keystone's CIA.

B. The OIG and Keystone agree that all other sections of Keystone's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Keystone.

C. The undersigned Keystone signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF KEYSTONE ONCOLOGY, LLC

George Keister
Secretary and Treasurer

1/10/02
DATE

ON BEHALF OF CENTRAL PENNSYLVANIA RADIATION, PC

George Keister
Secretary and Treasurer

1/10/02
DATE

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

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

1/17/02
DATE

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, Keystone shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Keystone in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by Keystone shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which Keystone seeks reimbursement. Each IRO shall assess, along with Keystone, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Keystone's billing and coding to the Federal health care programs ("Claims Review"), and shall analyze Keystone's compliance with the obligations assumed under this CIA and Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO **for the first one-year period beginning with the effective date of this CIA.**

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

2. *Claims Review.*

The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

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

i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Keystone should, as appropriate, further analyze any errors identified in the Discovery Sample. Keystone recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a., the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Keystone or under

Keystone's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Keystone may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Keystone to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If Keystone's Discovery Sample identifies an Error Rate of 5% or greater, Keystone's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Keystone observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.H.1 of the CIA, Keystone agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Keystone agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

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

4. *Compliance Review.* The IRO shall conduct a review of Keystone's compliance activities. The Compliance Review shall consist of a review of Keystone's compliance with the obligations set forth in each section of this CIA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings, supporting rationale, and a summary of such findings and rationale regarding Keystone's compliance with the terms of each section of the CIA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) Keystone's Claims Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Keystone agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Keystone's final submission is received by the OIG.

   Prior to initiating a Validation Review, the OIG shall notify Keystone of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Keystone may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Keystone agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with Keystone prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to Keystone a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and Compliance Review and that it has concluded that it was, in fact, independent.

APPENDIX A

A. Claims Review.

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

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

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

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

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

   e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

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

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

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. **Claims Review Methodology.**

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Claims Review Findings.**

a. A description of Keystone's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;

b. The IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation; and

c. The IRO's findings and recommendations concerning the Systems Review (if any).

3. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

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

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

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

4. **Claims Review Results.**

a. Total number and percentage of instances in which the IRO determined

that the Paid Claims submitted by Keystone ("Claims Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

b. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Keystone.

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

d. Error Rate in the sample.

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

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

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