EXHIBIT 5

INSTITUTIONAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNIVERSITY MEDICAL ASSOCIATES

I. PREAMBLE

University Medical Associates of The Medical University of South Carolina ("UMA") hereby enters into this Institutional Compliance Agreement ("ICA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance by UMA and all physicians, residents, faculty, staff, and agents, associated with UMA 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"). UMA's compliance with the terms and conditions in this ICA shall constitute an element of its present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this ICA, UMA is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement.

UMA is a non-profit, non-stock membership corporation organized under the laws of the State of South Carolina. The membership of the organization consists of (i) all full-time faculty of the College of Medicine of The Medical University of South Carolina ("MUSC") who are individuals possessing M.D., D.D.S., D.M.D., D.O. and Ph.D. degrees and (ii) other clinical professionals who are on the MUSC faculty.

For the purposes of this ICA, unless otherwise specified herein, the term "Employee" shall mean: (1) all UMA members (including faculty) or ancillary health providers who provide professional medical services as employees of UMA, or pursuant to contracts between their employers and UMA, and for whom reimbursement claims are submitted through UMA; or (2) individuals who are involved in the generation, preparation, or submission of claims on behalf of UMA. For purposes of this ICA, "UMA Agent" means any person who provides professional services for which UMA

submits claims for reimbursement to any Federal health care program. For purposes of this ICA, the term "Residents" shall mean medical residents assigned to MUSC clinical departments and acting under the supervision of the providers at MUSC.

Prior to the execution of this ICA, UMA voluntarily established a compliance program (known as the "Compliance Program" and hereinafter referred to as "CP"). The CP establishes institutional compliance policies and procedures and, as represented by UMA, is aimed at ensuring that UMA's participation in Federal health care programs is in conformity with the statutes, regulations and other directives applicable to the programs. Pursuant to this ICA, UMA agrees to continue the operation of its CP for UMA in accordance with the provisions set forth below for the term of this ICA. The CP may be modified by UMA as appropriate, but at a minimum, UMA shall ensure that it complies with the integrity obligations that are enumerated in this ICA.

II. TERM OF THE ICA

The period of the integrity obligations assumed by UMA under this ICA shall be from the effective date of this ICA through June 30, 2005 (unless otherwise specified). The effective date of this ICA shall be the date this ICA is approved by the Court.

Sections VII, VIII, IX, X and XI shall remain in effect until UMA submits all information required by OIG as part of the final Annual Report.

III. INTEGRITY OBLIGATIONS

Pursuant to this ICA, and for its duration, UMA will make the following integrity obligations permanent features of its CP, which shall be established in accordance with the provisions below:

A. Compliance Committee

UMA has represented to OIG that, pursuant to its CP, it has created a Compliance Committee to monitor UMA's compliance activities. Pursuant to this ICA, UMA agrees to charge the Compliance Committee for ensuring compliance with the integrity obligations in this ICA. Accordingly, UMA hereby agrees to maintain the Compliance Committee (or in the event that such a committee ceases to exist, to create a committee) with overall responsibility for the obligations in the ICA. UMA shall ensure that the Compliance Committee is continuously composed of representatives of

multiple disciplines and segments of UMA's operations. At a minimum, the Compliance Committee shall include or shall receive reports from the Director of Compliance, all Departmental Compliance Managers, Compliance Liaison, Compliance Analysts, Compliance Reviewer, Compliance Assistant and representatives from UMA's patient accounting and ambulatory care divisions. The Compliance Committee must be able to make reports to UMA's Board of Directors. Any changes in the positions that comprise the Compliance Committee must be reported to OIG, in writing, within thirty (30) days of the effective date of the action. Any other matters affecting the membership or responsibilities of the Compliance Committee shall be reported to OIG in accordance with Section VI below.

B. COMPLIANCE OFFICER

UMA has represented to OIG that, pursuant to its CP, it has created a Compliance Officer position (known as the "Director of Compliance") and it has appointed an individual to serve in that capacity. Accordingly, UMA shall formally maintain the appointment of an individual to serve as the Director of Compliance. At a minimum, the Director of Compliance must continuously be charged with the responsibility for the day-to-day compliance activities in furtherance of the integrity obligations assumed herein, as well as for any reporting obligations established under this ICA. The Director of Compliance must have the authority and ability to report directly to UMA's Board of Directors. Any changes in the appointment of the Director of Compliance (including voluntary or involuntary personnel changes) or any actions or changes that would affect the Director of Compliance's ability to perform the duties necessary to meet the obligations in this ICA must be reported to OIG, in writing, within thirty (30) days of the effective date of the action. Changes in the position, or material changes in the duties, of the Director of Compliance shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. *Code of Conduct.* UMA has represented to OIG that it developed and distributed to all Employees a Code of Conduct by which all such individuals are expected to abide. UMA shall maintain the Code of Conduct in effect for the duration of this ICA. UMA shall make the

promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. UMA's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. UMA's requirement that all of its Employees and UMA Agents shall be expected to comply with all Federal health care program requirements and with UMA's own Policies and Procedures as implemented pursuant to section III.C.2 (including the requirements of this ICA);

c. the requirement that all of UMA's Employees and UMA Agents shall be expected to report to the Director of Compliance or other individual designated by the UMA's suspected violations of any Federal health care program requirements or of UMA's own Policies and Procedures;

d. the possible consequences to both UMA and Employees and UMA Agents of failure to comply with all Federal health care program requirements and with UMA's own Policies and Procedures or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in section III.F, and UMA's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the ICA, to the extent is has not already been done, each Employee and UMA Agent shall certify, in writing, that he or she has received, read, understood, and will abide by UMA's Code of Conduct. For purposes of satisfying this requirement, OIG will consider any certifications completed by Employees and UMA Agents after January 1, 1998.

New Employees and UMA Agents shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming an Employee or UMA Agent or within 90 days of the effective date of the ICA, whichever is later. Copies of the certifications shall be available to OIG, upon request.

UMA shall maintain a written summary of the actions taken to distribute the Code of Conduct to all Employees and UMA Agents. Such summaries shall be produced to OIG upon request. For purposes of this ICA, OIG may request access to, or copies of, any underlying documents summarized by UMA.

UMA shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes, unless the nature of the revision is such that it warrants earlier notice.

Employees and UMA Agents shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the finalization of such revisions.

2. *Compliance Policies and Procedures*. UMA has represented to OIG that it has developed, distributed to its Employees and UMA Agents, and placed into effect written policies and procedures regarding the operation of its CP.

At a minimum, the Compliance Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in section III.C.1;

b. the need for compliance in connection with all submissions for reimbursement for professional services;

c. documentation requirements; and

d. a process for reasonable verification of compliance with those requirements.

The Compliance Policies and Procedures shall be available to OIG upon request.

Within 90 days of the effective date of this ICA, to the extent it has not already done so, UMA shall distribute the relevant portions of the Compliance Policies and Procedures to all individuals whose job functions are related to those Compliance Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Compliance Policies and Procedures.

At least annually (and more frequently if appropriate), UMA shall assess and update as necessary the Compliance Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Compliance Policies and Procedures shall be distributed to all individuals whose job functions are related to those Compliance Policies and Procedures.

D. TRAINING AND EDUCATION

1. *General Training.* Within 90 days of the effective date of this ICA, UMA in conjunction with the Medical University of South Carolina ("MUSC") shall provide at least two hours of general training to each Employee, and UMA Agent. This training shall explain UMA's and MUSC's:

a. ICAs requirements; and

b. CP (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

All training materials shall be made available to OIG upon request.

New Employees and UMA Agents shall receive the general training described above within 30 days of becoming an Employee or UMA Agent or within 90 days after the effective date of this ICA, whichever is later. After receiving the initial training described above, each Employee, and UMA Agent shall receive at least one hour of general training annually.

2. *Department Chair and Compliance Manager Training.* During the initial year, UMA shall provide to all UMA Department Chairs and Compliance Managers at least 4 hours of additional training on supervising and reviewing the submission of accurate requests for reimbursement for services rendered to Federal health care program patients as well as other compliance leadership issues. During subsequent years of this ICA, at least 2 hours of such training shall be provided.

3. *The Department of Psychiatry Training.* Within 90 days of this ICA and annually thereafter, UMA shall provide to all Employees and UMA Agents within the Department of Psychiatry at least 4 hours of additional training on the submission of accurate requests for reimbursement for services rendered to Federal health care program patients. The Department Chair and Compliance Manager of MUSC's Psychiatry Department shall also be required to complete the additional training described in this subparagraph III.C.3.

4. *Billing Training.* Within 120 days of the effective date of this ICA and annually thereafter, UMA shall provide each Employee and UMA Agent responsible for generating, preparing and/or submitting requests for reimbursement from the Federal health care programs for professional services (a "relevant" individual) with at least 3 hours of more intensive training, in addition to the general training required above. UMA Departmental Chairs and Compliance Managers, and Employees and UMA Agents of MUSC's Department of Psychiatry shall also be required to complete the training described in this subparagraph III.C.4. This training shall include a discussion of:

a. the submission of accurate requests for reimbursement 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 to ensure that the information documented by the individual, whether relating to actual patient care, the type of services or items delivered, or the coding of such services or items is accurate and meets the federal and state

requirements for the Federal health care programs, as well as UMA's policies;

d. applicable reimbursement statutes, regulations, and program requirements and directives including the types of services an ancillary provider can provide to Federal health care program patients and whether and how such services may be billed to Federal health care programs;

e. the legal sanctions for improper reimbursement submissions (including the submission of false and inaccurate information); and

f. relevant examples of proper and improper billing practices.

All training materials shall be made available to OIG upon request. Persons providing the training must be knowledgeable about the subject area. Relevant Employees and UMA Agents shall receive this training within 30 days of the beginning of their employment or becoming a Relevant Employee or a UMA Agent or within 90 days of the effective date of this ICA, whichever is later. A UMA employee who has completed the billing training shall conduct reviews of the new Relevant Employee or UMA Agent's work, to the extent the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Employee or UMA Agent completes applicable training.

6. *Certification.* UMA shall maintain documents that reflect attendance at all training sessions by Employees and UMA's Agents, and the topics covered. UMA may choose the exact format of these documents, but the materials must include sheets with the signatures of the persons who attended or other reliable means (including electronic means) of verifying attendance and participation. UMA shall maintain information concerning the format, dates, and copies of the materials provided. The Director of Compliance shall retain the attendance logs as well as the course materials. All of these documents shall be available to OIG upon request.

For purposes of meeting the obligations under this Subsection D, for the term of the first Annual Report under this ICA, OIG shall credit UMA's training and education activities carried out pursuant to the CP on or after

October 1, 1999, to the extent such training satisfies the requirements set forth above.

E. ANNUAL REVIEWS OF BILLING POLICIES, PROCEDURES AND PRACTICES

1. GENERAL REVIEW PROVISIONS. UMA shall contract with an entity such as an accounting, auditing or consulting firm (hereinafter the "Independent Review Organization" or "IRO"), with expertise in the reimbursement and billing requirements of the Federal health care programs, to perform procedures on an annual basis concerning the billing practices of 5 UMA departments, as selected by the OIG, in order to provide findings about whether UMA's claims for reimbursement submitted by those departments comply with all applicable Federal health care program statutes, regulations, program and carrier directives and to identify instances where claims fail to meet these standards ("Billing Engagement"). The IRO must be retained to conduct the agreed upon procedures for the first year by April 1, 2001. The billing reviews of each department may be handled separately or combined into a single engagement.

UMA will conduct these annual engagements so that they coordinate with each UMA fiscal year. UMA shall contact OIG in writing by January 1, 2001, and will provide to OIG a list of all UMA departments, the number of physicians in each department, and the amount of money each department billed to each Federal health care program. The OIG will select the 5 UMA departments to be reviewed and will contact UMA by February 15, 2001. The procedure described above to select the 5 UMA departments shall be repeated for fiscal year 2002, 2003, 2004, and 2005.

Prior to each Billing Engagement, the IRO shall prepare a work plan describing the protocol it proposes to follow in conducting the review. At a minimum, the work plan must show that the review is designed to determine the accuracy, validity and appropriateness of claims submitted for reimbursement to the Federal health care programs and to identify patterns or significant single occurrences where claims are filed in contravention of applicable Federal health care program standards. The engagement shall include a valid statistical sample of claims that can be projected to the universe of

claims being audited. See Section E.2, below, for Review Guidelines.

2. REVIEW GUIDELINES. The following guidelines are intended to provide a basis for UMA's Billing Engagements including the preparation of the reports on the review findings. At a minimum, each annual Billing Engagement must include the following features:

a. APPROACH: The annual Billing Engagement for each department should consist of a review of a statistically valid sample of the claims that can be projected to the population of claims submitted by that UMA department to the Federal health care programs during the relevant period.

b. BASIC INFORMATION: Each annual Billing Engagement shall include the following components in its work plan:

(i) Review Objective: There should be a statement clearly articulating the objective of the review and the review procedure or combination of procedures applied to achieve the objective.

(ii) Review Population: The plan should identify the population, which is the group about which the information is needed. In addition, there should be an explanation of the methodology used to develop the population and the basis for this determination.

(iii) Sources of Data: The plan should provide a full description of the source of the information upon which the review will be based, including the legal or other standards to be applied, the sources of payment data and the documents that will be relied upon (e.g., employment contracts, rental agreements, etc.).

(iv) Personnel Qualifications: The plan should identify the names and titles of those individuals involved in any aspect of the review, including statisticians,

accountants, auditors, consultants and medical reviewers, and describe their qualifications.

c. SAMPLE ELEMENTS: The work plan shall also include the sampling plan as follows:

(i) Sampling Unit: The plan must define the sampling unit, which is any of the designated elements that comprise the population of interest.

(ii) Sampling Frame: The plan must identify the sampling frame, which is the totality of the sampling units from which the sample will be selected. In addition, the plan must document how the review population differs from the sampling frame and what effect this difference has on conclusions reached as a result of this review.

(iii) Sample Size: The size of the sample must be determined through the use of a probe sample. Accordingly, the plan should include a description of both the probe sample and the full sample. At a minimum, the full sample must be designed to generate an estimate with a ninety (90) percent level of confidence and a precision of at least 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.

(iv) Random Numbers: Both the probe sample and the full sample must be selected through random numbers. The source of the random numbers used must be shown in the sampling plans. UMA 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/oas/ratstat.html*".

(v) Sample Design: Unless UMA demonstrates the need to use a different sample design, each review should use simple random sampling. If necessary, UMA may use stratified or multistage sampling. Details about the strata, stages and clusters should be included in the description of the audit plan.

(vi) Characteristics Measured by the Sample: The sampling plan should identify the characteristics used for testing each sample item. For example, in a sample drawn to estimate the value of overpayments due to duplicate payments, the characteristics under consideration are the conditions that must exist for a sample item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. The sampling plan must also contain the decision rules for determining whether a sample item entirely meets the criterion for having characteristics or only partially meets the criterion.

(vii) Missing Sample Items: The sampling plan must include a discussion of how missing sample items were handled and the rationale.

(vii) Other Evidence: Although sample results should stand on their own in terms of validity, sample results may be combined with other evidence in arriving at specific conclusions. If appropriate, indicate what other substantiating or corroborating evidence was developed.

(ix) Estimation Methodology: Because the general purpose of each review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling using the difference estimator. To estimate the amount implicated in the disclosed matter, UMA must use the mean point estimate. The statistical estimates must be reported using a ninety (90) percent confidence level.

(x) Reporting Results: The sampling plan shall indicate how the results will be reported at the conclusion of the review. In preparing the report, enough details must be provided to clearly indicate what estimates are reported.

3. COMPLIANCE ENGAGEMENT. An IRO shall also conduct a Compliance Engagement, that shall provide findings regarding whether UMA's CP and operations comply with the terms of this ICA. This engagement shall include section by section findings regarding the requirements of this ICA.

4. VERIFICATION/VALIDATION. In the event that OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which UMA is complying with its obligations under this ICA, UMA agrees to pay for the reasonable cost of any such review or engagement by OIG or any of its designated agents.

After the completion of the Billing Engagements for fiscal year 2001, OIG will consider whether it is appropriate to allow UMA to perform some of the functions of the IRO in subsequent years. This decision will be within the sole discretion of the OIG.

F. CONFIDENTIAL DISCLOSURE PROGRAM

UMA has represented to OIG that it has established a confidential disclosure mechanism through its Confidential Compliance HotLine, a toll-free telephone line, as a means to enable Employees, Residents and UMA Agents to report instances of noncompliance and/or make inquiries on compliance issues. Pursuant to this ICA, UMA shall maintain a confidential disclosure mechanism such as the Confidential Compliance HotLine, which shall be available to all Employees, Residents, Staff, and UMA Agents for the purpose of reporting or inquiring on matters of UMA's compliance with Federal health care program standards and the obligations in this ICA.

UMA shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent

common areas). The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy.

UMA shall conduct an internal inquiry of any disclosure provided that such disclosure is sufficiently specific so that it: (i) reasonably permits a determination of the appropriateness of the practice alleged to be implicated; and (ii) reasonably permits corrective action to be taken and ensure that proper follow-up is conducted. In an effort to address each disclosure received, UMA shall, in good faith, make a preliminary inquiry for every disclosure to ensure it has obtained all of the necessary information that is reasonably required to determine whether an internal inquiry, in accordance with the language above, should be conducted. UMA shall maintain an internal tracking system to record all disclosures received and all follow-up conducted. UMA shall ensure that it provides sufficient notice of its disclosure mechanism to all Employees, Residents and UMA Agents.

UMA shall include in each Annual Report to OIG a summary of the communications received under its confidential disclosure mechanism (including the number of disclosures received and the dates of such disclosures). The reports shall also summarize the results of its internal inquiries and any follow-up activities on such matters. UMA hereby agrees to maintain all documents supporting the Annual Report summaries and make these documents available to the OIG upon request.

The disclosing or inquiring individual's identity may be requested, but shall not be required. Anonymity shall not be discouraged.

G. INELIGIBLE PERSONS

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

2. *Screening Requirements.* UMA shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, UMA shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to

disclose whether they are Ineligible Persons; and (b) 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 90 days of the effective date of this ICA, UMA shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, UMA shall review the list quarterly. In addition, UMA shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person. If UMA has notice that an employee or contractor has become an Ineligible Person, UMA shall remove such person from responsibility for, or involvement with, UMA's 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 UMA 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, the UMA shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

H. NOTIFICATION OF GOVERNMENT INVESTIGATION OR LEGAL PROCEEDINGS

Within 30 days of discovery, UMA 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 UMA has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. UMA shall also provide written notice to

OIG within 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.

I. REPORTING

1. *Overpayments*

a. Definition of Overpayments. For purposes of this ICA, an "overpayment" shall mean the amount of money UMA has received in excess of the amount due and payable under any Federal health care program requirements. UMA may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, UMA identifies or learns of any overpayments, UMA shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 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 and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Exhibit 1 to this ICA.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

(ii) 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 may be authorized.

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

b. Reporting of Material Deficiencies. If UMA determines that there is a Material Deficiency, UMA shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the 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 III.I.1.b, 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 Federal health care program authorities implicated;
(iii) a description of UMA's actions taken to correct the Material Deficiency; and

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this ICA, UMA purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, UMA shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care provider number(s) (if any), and the corresponding contractor's name and address that has issued each Federal health care provider number. All Employees and UMA Agents at such locations shall be subject to the applicable requirements in this ICA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the effective date of this ICA, UMA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this ICA. This Implementation Report shall include:

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

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

3. a copy of UMA's Code of Conduct required by section III.C.1;

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

5. a description of the training required by section III.D, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.C.2 have been distributed to all appropriate individuals;

   b. all Employees and UMA Agents have completed the Code of Conduct certification required by section III.C.1; and

   c. all Employees and UMA Agents have completed the applicable training and executed the certification(s) required by section III.D.;

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

7. a description of the confidential disclosure mechanisms required by section III.F;

8. the identity of the IRO(s) and the proposed start and completion dates of the first annual review;

9. a summary of personnel actions taken pursuant to section III.G.;

10. a list of all of UMA's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care provider identification number(s) and the contractor's name and address that issued each provider identification number; and

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

B. Annual Reports. UMA shall submit to OIG Annual Reports with respect to the status of and findings regarding of UMA's compliance activities for each of the five one-year periods beginning on the effective date of the ICA (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The initial Annual Report shall cover the period July 1, 2000 through June 30, 2001. Subsequent Annual Reports will correspond to succeeding fiscal years.

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

a. all Employees and UMA Agents have completed the annual Code of Conduct certification required by section III.C.1;

b. all Employees and UMA Agents have completed the applicable training and executed the certification(s) required by section III.D;

c. UMA has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; 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 to identify and adjust any past charges or claims for unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.C.2 and the reasons for such changes (e.g., change in contractor policy);

4. a description of the training required by section III.D conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;

5. a complete copy of all reports prepared pursuant to the IRO's Billing, and Compliance Engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

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

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

8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient 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.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by UMA as a result of the obligations in section III.G, and the name, title, and responsibilities of any person that falls within the ambit of section III.G.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.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

12. a description of all changes to the most recently provided list (as updated) of UMA's locations (including locations and mailing addresses) as required by section V.A.10, 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 contractor name and address that issued each provider identification number; and

13. a list of all of UMA's unlicensed physicians, other than residents and fellows. Any documentation related to any services performed by any of these unlicensed physicians to Federal health care program beneficiaries and billing for such services shall be made available to OIG upon request.

The first Annual Report shall be received by the OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, UMA is in compliance with all of the requirements of this ICA, 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 the information is accurate and truthful.

D. Designation of Information: UMA 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. UMA shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the effective date of this ICA, all notifications and reports required under this ICA shall be submitted to the following entities:

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

MUSC:

Julie Acker - Director of Compliance
University Medical Associates
135 Rutledge Ave.
P.O. Box 250576
Charleston, South Carolina 29425
Phone 803.876.1325
Fax 803.876.1322

Unless otherwise specified, all notifications and reports required by this ICA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of UMA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UMA's locations for the purpose of verifying and evaluating: (a) UMA's compliance with the terms of this ICA; and (b) UMA's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by UMA to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction.

Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UMA's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. UMA agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UMA's employees may elect to be interviewed with or without a representative of UMA present.

VIII. DOCUMENT AND RECORD RETENTION

UMA shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this ICA, for 6 years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify UMA prior to any release by OIG of information submitted by UMA pursuant to its obligations under this ICA and identified upon submission by UMA as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, UMA shall have the rights set forth at 45 C.F.R. § 5.65(d). UMA shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA. Nothing in this ICA, or any communication or report made pursuant to this ICA, shall constitute or be construed as any waiver by UMA of UMA's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privileges does not affect UMA's obligation to comply with the provisions of this ICA.

X. BREACH AND DEFAULT PROVISIONS

UMA is expected to fully and timely comply with all of terms and conditions of this ICA.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, UMA and OIG hereby agree that failure to comply with certain obligations set forth in this ICA 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 UMA fails to have in place any of the following:

a. a Compliance Officer as described by section III.A.;

b. a Compliance Committee as described by section III.B

c. a written Code of Conduct as described by section III.C.1;

d. written Compliance Policies and Procedures as described by section III.C.2;

e. a requirement that Employees and UMA Agents be trained as described in section III.D; and

f. a Confidential Disclosure Program as described in section III.F.

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

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UMA fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day UMA employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, UMA'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 (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which UMA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

5. A Stipulated Penalty of $1,500 for each day UMA fails to grant access to the information or documentation as required in section VII of this ICA. (This Stipulated Penalty shall begin to accrue on the date UMA fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day UMA fails to comply fully and adequately with any obligation of this ICA not already covered in paragraphs 1-5. In its notice to UMA, OIG shall state the specific grounds for its determination that UMA has failed to comply fully and adequately with the ICA obligation(s) at issue and steps UMA must take to comply with the ICA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to UMA of the failure to comply.)

B. Timely Written Requests for Extensions. UMA may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this ICA. 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 UMA fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after UMA receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that UMA has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify UMA of: (a) UMA's 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").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, UMA shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. 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 ICA and shall be grounds for exclusion under section X.D. In the event UMA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UMA cures, to OIG's satisfaction, the alleged breach in dispute.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in section VI.

4. *Independence from Material Breach Determination.* Except as set forth in section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that UMA has materially breached this ICA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this ICA

1. *Definition of Material Breach.* A material breach of this ICA means:

a. a failure by UMA to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.I;

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

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

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this ICA by UMA constitutes an independent basis for UMA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that UMA has materially breached this ICA and that exclusion should be imposed, OIG shall notify UMA of: (a) UMA's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* UMA shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. UMA is in full compliance with this ICA;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, UMA fails to satisfy the requirements of section X.D.3, OIG may exclude UMA from participation in the Federal health care programs. OIG will notify UMA in writing of its determination to exclude UMA (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, UMA wishes to apply for reinstatement, UMA must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to UMA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this ICA, UMA shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this ICA. 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 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this ICA shall be: (a) whether UMA was in full and timely compliance with the obligations of this ICA for which the OIG demands payment; and (b) the period of noncompliance. UMA shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if

any. If the ALJ agrees with OIG with regard to a finding of a breach of this ICA and orders UMA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UMA requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this ICA shall be:

a. whether UMA was in material breach of this ICA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) UMA had begun to take action to cure the material breach within that period;

(ii) UMA has pursued and is pursuing such action with due diligence; and

(iii) UMA provided to OIG within that period a reasonable timetable for curing the material breach and UMA has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the MUSC, only after a DAB decision in favor of OIG. MUSC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude UMA upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that UMA may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This ICA shall be binding on the successors, assigns, and transferees of UMA;

B. This ICA shall become final and binding on the date this ICA is approved by the Court;

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

D. The undersigned UMA signatories represent and warrant that they are authorized to execute this ICA. The undersigned OIG signatory represents that he is signing this ICA in his official capacity and that he is authorized to execute this ICA; and

E. This ICA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

ON BEHALF OF UNIVERSITY MEDICAL ASSOCIATES

Marion E Woodbury

Marion E. Woodbury
Chief Executive Officer
University Medical Associates
(843) 792-9600

april 4, 2000
DATE

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

Lewis Morris

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

April 4, 2000
DATE

EXHIBIT
1

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)
(Please list all claim numbers involved. Attach separate sheet, if necessary)
*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____
For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Comorate Integrity Agreement with OIG? _____Yes_____No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____

AMENDMENT TO THE INSTITUTIONAL COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND UNIVERSITY MEDICAL ASSOCIATES

The Office of Inspector General ("OIG") of the Department of Health and Human Services and University Medical Associates ("UMA") entered into an Institutional Compliance Agreement ("ICA") on April 4, 2000.

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

Section III.E., Review Procedures of the ICA is hereby superceded by the attached new section III.E., Review Procedures and Appendix A.

The attached Appendix A is hereby added to UMA's ICA.

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

C. The undersigned UMA signatory represent and warrant that he is 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.

E. Annual Reviews of Billing Policies, Procedures and Practices

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this ICA, UMA 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 UMA in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this ICA and the Settlement Agreement. Each IRO retained by UMA shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this ICA and in the general requirements of the Federal health care program(s) from which UMA seeks reimbursement. Each IRO shall assess, along with UMA, 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 UMA's billing and coding to the Federal health care programs ("Claims Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the ICA which shall coordinate with each UMA fiscal year. UMA shall contact OIG in writing by January 1, 2002, and will provide to OIG a list of all UMA departments, the number of physicians in each department, and the amount of money each department billed to each Federal health care program. The OIG will select 5 UMA departments to be reviewed and will contact UMA by February 15, 2002. The procedure described above to select the 5 UMA departments shall be repeated for fiscal years 2003, 2004, and 2005.

c. Retention of Records. The IRO and UMA 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 UMA 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 ICA, 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 UMA. The sample shall be selected from a universe of Paid Claims from five UMA departments. The Paid Claims shall be reviewed based on the supporting documentation available at UMA or under UMA'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, UMA should, as appropriate, further analyze any errors identified in the Discovery Sample. UMA 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.E.2, 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 UMA or under UMA'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, UMA 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 UMA 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 UMA's Discovery Sample identifies an Error Rate of 5% or greater, UMA'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 UMA 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.I.1 of the ICA, UMA 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. UMA 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. *Validation Review.* In the event the OIG has reason to believe that: (a) UMA's Claims Review fails to conform to the requirements of this ICA; 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 complied with the requirements of the ICA and/or the findings or Claims Review results are inaccurate ("Validation Review"). UMA 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 UMA's final submission (as described in section II) is received by the OIG.

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

5. *Independence Certification.* The IRO shall include in its report(s) to UMA a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims 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 UMA 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 UMA and for which UMA has received reimbursement from the Medicare program.

d. Population: All Items for which UMA has submitted a code or line item and for which UMA has received reimbursement from the Federal health care programs (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.

f. Net Overpayment: The Difference between the gross Overpayments and gross Underpayments where Overpayments exceed Underpayments.

g. Underpayment: The difference between actual payments UMA received from Federal payors and the correct amount which should have been received, where the error resulted in an Underpayment to UMA.

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

UMA cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by UMA 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 UMA'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 UMA ("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 UMA.

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.

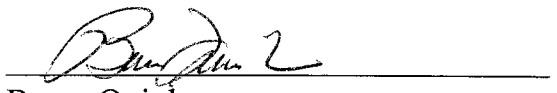
6. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment 1

Claim Review Results

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

ON BEHALF OF UNIVERSITY MEDICAL ASSOCIATES



Bruce Quinlan
Chief Executive Officer
University Medical Associates
(843) 792-9600

5/16/02
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

DATE