EXHIBIT 4

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

I. PREAMBLE

The Medical University of South Carolina ("MUSC") 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 MUSC and all physicians, residents, staff, agents, and faculty associated with MUSC 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"). MUSC'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, MUSC is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement.

For the purposes of this ICA, unless otherwise specified herein, the term "Employee" shall mean: (1) all MUSC clinical personnel who render medical services as employees of MUSC, or pursuant to contracts between their employers and MUSC, for which reimbursement claims are submitted by MUSC; or (2) any individual who is involved in the generation, preparation, or submission of claims on behalf of MUSC. For purposes of this ICA, "MUSC Agent" means any person who provides clinical services for which MUSC submits claims for reimbursement to any Federal health care program. Finally, this ICA applies to the medical residents assigned to MUSC clinical departments and acting under the supervision of the providers at MUSC (hereinafter referred to as "Residents").

Prior to the execution of this ICA, MUSC 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 MUSC'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, MUSC agrees to continue the operation of its CP for MUSC in accordance with the provisions set forth below for the term of this ICA. The CP may be modified by MUSC as appropriate, but at a minimum, MUSC 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 MUSC 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 MUSC submits all information required by OIG as part of the final Annual Report.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Committee

MUSC has represented to OIG that, pursuant to its CP, it has created a Compliance Committee to monitor MUSC's compliance activities. Pursuant to this ICA, MUSC agrees to charge the Compliance Committee for ensuring compliance with the integrity obligations in this ICA. Accordingly, MUSC 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. MUSC shall ensure that the Compliance Committee is continuously composed of representatives of multiple disciplines and segments of MUSC's operations. At a minimum, the Compliance Committee shall include or shall receive reports from the Chief Compliance Officer, Administrator of Integrated Services, Director of Patient Access Services, Director of Laboratory Services, Director of Decision Support Services, and Director of Psychiatric Access. The Compliance Committee must be able to make reports to the MUSC President and Board of Trustees. 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

MUSC has represented to OIG that, pursuant to its CP, it has created a Compliance Officer position (known as the "Chief Compliance Officer") and it has appointed an individual to serve in that capacity. Accordingly, MUSC shall formally maintain the appointment of an individual to serve as the Chief Compliance Officer. At a minimum, the Chief Compliance Officer 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 Chief Compliance Officer must have the authority and ability to report directly to the MUSC President, MUSC Medical Center Chief Executive Officer and Board of Trustees. Any changes in the appointment of the Chief Compliance Officer (including voluntary or involuntary personnel changes) or any actions or changes that would affect the Chief Compliance Officer'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 Chief Compliance Officer shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. *Code of Conduct.* MUSC has represented to OIG that it developed and distributed to all Employees, Residents, and MUSC Agents a Code of Conduct by which all such individuals are expected to abide. MUSC shall maintain the Code of Conduct in effect for the duration of this ICA. MUSC 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. MUSC'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. MUSC's requirement that all of its Employees, Residents and MUSC Agents shall be expected to comply with all Federal health care program requirements and with MUSC'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 MUSC's Employees, Residents and MUSC Agents shall be expected to report to the Chief Compliance Officer or other individual designated by the MUSC's suspected violations of any Federal health care program requirements or of MUSC's own Policies and Procedures;

d. the possible consequences to both MUSC and Employees, Residents and MUSC Agents of failure to comply with all Federal health care program requirements and with MUSC'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 MUSC'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, Resident, and MUSC Agent shall certify, in writing, that he or she has received, read, understood, and will abide by MUSC's Code of Conduct. For purposes of meeting this obligation, OIG will consider any certifications completed by Employees, Residents and MUSC Agents after January 1, 1998 as satisfying this requirement.

New Employees and MUSC Agents shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming an Employee or MUSC Agent or within 90 days of the effective date of the ICA, whichever is later. New Residents shall receive the Code of Conduct and shall complete the required certification within four weeks after becoming a Resident 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.

MUSC shall maintain a written summary of the actions taken to distribute the Code of Conduct to all Employees, Residents, and MUSC 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 MUSC.

MUSC 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, Residents, and MUSC 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.* MUSC has represented to OIG that it has developed, distributed to its Employees, Residents and MUSC 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 clinical 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, MUSC shall distribute the relevant portions of the Policies

and Procedures to all individuals whose job functions are related to those 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), MUSC 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, MUSC, in conjunction with the University of Medical Associates of the Medical University of South Carolina ("UMA") shall provide at least two hours of general training to each Employee, Resident and MUSC Agent (except for Residents who will be leaving MUSC on or before August 1, 2000). This training shall explain MUSC's and UMA'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 MUSC Agents shall receive the general training described above within 30 days of becoming an Employee or MUSC Agent or within 90 days after the effective date of this ICA, whichever is later. New Residents shall receive the general training within 90 days after the commencement of their residency. After receiving the initial training described above, each Employee, Resident, and MUSC Agent shall receive at least one hour of general training annually.

2. *Billing Training*. For the first year of this ICA and annually thereafter, MUSC shall provide each Employee and MUSC 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 2 hours of more intensive training, in addition to

the general training required above. 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 MUSC's policies;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

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.

3. *Resident Billing Training.* MUSC shall provide Residents with Billing Training as described in Section III.D.2 for each year of their residency. New Residents shall receive Billing Training within 90 days of the commencement of their residency program. Residents who leave prior to August 1, 2000 will not be required to complete the Billing Training.

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 MUSC Agents shall receive this training within 30 days of the beginning of their employment or becoming Relevant Employee or MUSC Agent or within 90 days of the effective date of this ICA, whichever is later. A MUSC employee who has completed the billing training shall conduct reviews of the new Relevant Employee or MUSC 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 MUSC Agent completes applicable training.

4. *Certification.* MUSC shall maintain documents that reflect attendance at all training sessions by Employees, Residents, and MUSC's Agents, and the topics covered. MUSC 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. MUSC shall maintain information concerning the format, dates, and copies of the materials provided. The Chief Compliance Officer 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 MUSC'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. MUSC 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 MUSC to provide findings about whether MUSC's claims for reimbursement 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, 2000.

Each annual Billing Engagement shall focus on 5 DRG codes that will be selected by the OIG. The agreed upon procedures to be performed for each DRG code may be handled separately or combined into a single engagement. MUSC will conduct these

annual reviews so that they coordinate with each fiscal year. MUSC shall contact OIG in writing by January 1, 2001, and will provide OIG a list of MUSC's 30 most frequently billed DRG codes, the number of times each individual DRG code was billed to the Federal health care programs, and the dollar amount associated with each DRG code. The OIG will select the 5 DRG codes to be reviewed and will contact MUSC by February 15, 2001. The procedure described above to select the 5 DRG codes 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 MUSC's Billing Engagement including the preparation of the reports on the review findings. At a minimum, each annual Billing Engagement must be realized within the following parameters:

   a. APPROACH: The annual Billing Engagement for each DRG code should consist of a review of a statistically valid sample of the claims that can be projected to the population of claims submitted by MUSC 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. MUSC 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 MUSC demonstrates the need to use a different sample design, each review should use simple random sampling. If necessary, MUSC 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.

(viii) 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, MUSC 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 MUSC'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 MUSC is complying with its obligations under this ICA, MUSC 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 MUSC 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

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

MUSC 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.

MUSC 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, MUSC 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. MUSC shall maintain an internal tracking system to record all disclosures received and all follow-up conducted. MUSC shall ensure that it provides sufficient notice of its disclosure mechanism to all Employees, Residents, and MUSC Agents.

MUSC 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. MUSC 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.* MUSC shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, MUSC shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) 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, MUSC shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, MUSC shall review the list quarterly. In addition, MUSC shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person. If MUSC has notice that an employee, contractor and/or physician with staff privileges has become an Ineligible Person, MUSC shall remove such person from responsibility for, or involvement with, MUSC'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 MUSC 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 MUSC 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, MUSC 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 MUSC 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. MUSC 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 MUSC has received in excess of the amount due and payable under any Federal health care program requirements. MUSC may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, MUSC identifies or learns of any overpayments, MUSC 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 MUSC determines that there is a Material Deficiency, MUSC 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 MUSC's actions taken to correct the Material Deficiency; and

(iv) any further steps MUSC 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, MUSC purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, MUSC 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, Residents, and MUSC 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, MUSC 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 MUSC's Code of Conduct required by section III.C.1;

4. the summary of the Compliance 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 Compliance Policies and Procedures required by section III.C.2 have been distributed to all appropriate individuals;

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

c. all Employees, Residents, and MUSC 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 MUSC'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 MUSC's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business.

B. Annual Reports. MUSC shall submit to OIG Annual Reports with respect to the status of and findings regarding of MUSC'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, Residents, and MUSC Agents have completed the annual Code of Conduct certification required by section III.C.1;

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

c. MUSC 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. MUSC'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 MUSC 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 MUSC'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 MUSC'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, MUSC 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: MUSC 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. MUSC 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:

Reece Smith - Director of Compliance
Medical University of South Carolina
171 Ashley Ave.
Charleston, South Carolina 29425
(792) 843-6128 (telephone)
(792) 843-6682 (fax)

Copy to: Joseph C. Good, Jr. - MUSC General Counsel
Medical University of South Carolina
171 Ashley Ave.
Charleston, South Carolina 29425

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

VIII. DOCUMENT AND RECORD RETENTION

MUSC 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 MUSC prior to any release by OIG of information submitted by MUSC pursuant to its obligations under this ICA and identified upon submission by MUSC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, MUSC shall have the rights set forth at 45 C.F.R. § 5.65(d). MUSC 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 MUSC of MUSC's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privileges does not affect MUSC's obligation to comply with the provisions of this ICA.

X. BREACH AND DEFAULT PROVISIONS

MUSC 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, MUSC 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 MUSC 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, Residents, and MUSC 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 MUSC 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 MUSC 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 MUSC employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, MUSC'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 MUSC 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 MUSC 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 MUSC fails to grant access.)

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

B. Timely Written Requests for Extensions. MUSC 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 MUSC 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 MUSC 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 MUSC 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 MUSC of: (a) MUSC'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, MUSC 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 MUSC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until MUSC 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 MUSC 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 MUSC 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 MUSC constitutes an independent basis for MUSC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that MUSC has materially breached this ICA and that exclusion should be imposed, OIG shall notify MUSC of: (a) MUSC'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*. MUSC 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. MUSC 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) MUSC has begun to take action to cure the material breach; (ii) MUSC is pursuing such action with due diligence; and (iii) MUSC has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, MUSC fails to satisfy the requirements of section X.D.3, OIG may exclude MUSC from participation in the Federal health care programs. OIG will notify MUSC in writing of its determination to exclude MUSC (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, MUSC wishes to apply for reinstatement, MUSC

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 MUSC 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, MUSC 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 MUSC was in full and timely compliance with the obligations of this ICA for which the OIG demands payment; and (b) the period of noncompliance. MUSC 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 MUSC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless MUSC 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 MUSC 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) MUSC had begun to take action to cure the material breach within that period;

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

(iii) MUSC provided to OIG within that period a reasonable timetable for curing the material breach and MUSC 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 MUSC 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 MUSC 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, MUSC and OIG agree as follows:

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

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 MUSC 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 THE MEDICAL UNIVERSITY OF SOUTH CAROLINA

Raymond L. Greenberg

Raymond Greenberg, M.D.
President of the Medical
University of South Carolina

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