INSTITUTIONAL COMPLIANCE AGREEMENT

BETWEEN THE

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

THE MOUNT SINAI SCHOOL OF MEDICINE

I. PREAMBLE

The Mount Sinai School of Medicine ("Mount Sinai") hereby enters into this Institutional Compliance Agreement (the "Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure compliance with the reimbursement 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") as they relate to the submission of claims for physician services claimed by Mount Sinai, The Mount Sinai School of Medicine Faculty Practice Associates ("FPA"), and their respective employees. Mount Sinai and FPA shall be hereinafter referred to as "Mount Sinai/FPA."

For purposes of this Agreement, the term "employee" shall mean: (1) physicians (including faculty) and ancillary health providers who are employed by Mount Sinai/FPA and for whom reimbursement claims are submitted on behalf of Mount Sinai/FPA; and (2) all other individuals who are employed by Mount Sinai/FPA who are involved in the generation and submission of reimbursement claims for physician services on behalf of Mount Sinai/FPA. To the extent provided in this Agreement, the obligations herein shall also apply to all third parties Mount Sinai/FPA may choose to engage as its billing agents for the generation and/or submission of reimbursement claims for physician services to the federal health care programs (hereinafter "billing agents"). Finally, this Agreement applies to Mount Sinai/FPA's medical residents (hereinafter referred to a "residents") as set forth in Section III below.

Prior to the execution of this Agreement, Mount Sinai/FPA voluntarily established a compliance plan, also known as the "Compliance Program," which provides for integrity policies and procedures and which, as represented by Mount Sinai/FPA in this Agreement, is aimed at ensuring that its participation in the federal health care programs (which includes any requests for payments) is in conformity with the statutes, regulations and other directives applicable to the federal health care programs. Therefore, pursuant to this Agreement, Mount Sinai/FPA hereby agrees to maintain in full operation the Compliance Program as it relates to the submission of claims for physician services for the term of this Agreement. The Compliance Program may be modified by Mount Sinai/FPA as appropriate, but at a minimum, shall always comply with the integrity obligations enumerated in this Agreement.

II. TERM AND SCOPE OF THE AGREEMENT

The period of the integrity obligations assumed by Mount Sinai/FPA under this Agreement shall be five (5) years from the effective date of this Agreement. The effective date of this Agreement shall be November 1, 1999. The obligations imposed upon Mount Sinai/FPA pursuant to this Agreement relate solely to the provision of, and reimbursement claims for, physician services in connection with federal health care program patients.

III. INTEGRITY OBLIGATIONS

Pursuant to this Agreement, and for its duration, Mount Sinai/FPA will make the following integrity obligations permanent features of its Compliance Program, which shall be established in accordance with the provisions below:

A. <u>COMPLIANCE COMMITTEE</u>

Mount Sinai/FPA has represented to OIG that, pursuant to its Compliance Program, it has created a compliance committee known as The Mount Sinai School of Medicine FPA Billing Compliance Committee (hereinafter the "Compliance Committee") to monitor Mount Sinai/FPA's compliance activities. Pursuant to this Agreement, Mount Sinai/FPA agrees to charge the Compliance Committee with responsibility for overseeing compliance with the integrity obligations in this Agreement. Accordingly, Mount Sinai/FPA 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 Agreement. Mount Sinai/FPA shall ensure that the Compliance Committee continuously consists of the following: at least five (5) medical staff chairpersons or vice chairpersons, the Associate Dean of Operations of the Mount Sinai, the Vice President of FPA, The Mount Sinai Corporate Compliance Officer and the Clinical Director of the FPA Office of Billing Compliance. The Compliance Committee shall receive periodic reports on Mount Sinai/FPA's compliance activities from the FPA Office of Billing Compliance. The Compliance Committee must be able to make reports directly to the Board of Trustees of Mount Sinai/FPA. Any changes in the positions that comprise the Compliance Committee must be reported to OIG within thirty (30) days of the effective date of the action.

B. COMPLIANCE OFFICER

Mount Sinai/FPA has represented to OIG that, pursuant to its Compliance Program, it has created a compliance officer position (known as "Corporate Compliance Officer") and appointed an individual to serve in that capacity. Accordingly, Mount Sinai/FPA shall formally maintain the appointment of an individual to serve as the Corporate Compliance Officer. In addition, Mount Sinai/FPA has created the position of Clinical Director of the FPA Billing Compliance Office (hereinafter the "Clinical Director") who shall report to the Corporate Compliance Officer. At a minimum, the Clinical Director 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 Agreement. Both the Corporate Compliance Officer and the Clinical Director must have the authority and ability to report directly to the Board of Trustees of Mount Sinai/FPA on any matter involving compliance or that otherwise arises from the obligations in this Agreement. Any changes in the identity or position description of the Corporate Compliance Officer or the Clinical Director (including voluntary or involuntary personnel changes) or any actions or changes that would affect their ability to perform the duties necessary to meet the obligations in this Agreement must be reported to OIG within thirty (30) days of the effective date of the action.

C. WRITTEN STANDARDS

1. CODE OF CONDUCT. Mount Sinai/FPA has represented to OIG that it has developed a Code of Conduct by which all employees are expected to abide in connection with the services they render to patients of the federal health care programs. Accordingly, to the extent it has not already done so, Mount Sinai/FPA shall distribute the Code of Conduct to all employees and billing agents within sixty (60) days of the effective date of this Agreement. Mount Sinai/FPA shall maintain the Code of Conduct in effect for the duration of this Agreement. The Code of Conduct shall also be readily accessible to employees, billing agents and residents through means that Mount Sinai/FPA considers effective. New employees shall receive the Code of Conduct within forty-five (45) days after the commencement of their employment. New billing agents shall receive the Code of Conduct prior to the commencement of the billing agent's engagement or contract. Mount Sinai/FPA shall coordinate with The Mount Sinai Hospital, Inc. to make the Code of Conduct available to all residents.

Mount Sinai/FPA shall document the actions taken to distribute the Code of Conduct to all employees. Such documents shall be produced to OIG upon request.

Mount Sinai/FPA will annually review the Code of Conduct and will make any necessary revisions. Any material revisions shall be distributed to all employees within thirty (30) days of initiating such a change, unless the nature of the revision is such that it warrants earlier notice.

Mount Sinai/FPA shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees and billing agents. At all times, the Code of Conduct shall, at a minimum, set forth:

- a. Mount Sinai/FPA's commitment to full compliance with all statutes, regulations, and guidance applicable to the federal health care programs, including its commitment to prepare and submit accurate reimbursement claims consistent with the federal health care program statutes and regulations, as well as guidance otherwise communicated by the Health Care Financing Administration ("HCFA") (or other regulatory agencies that administer the federal health care programs) and/or its agents;
- b. Mount Sinai/FPA's requirement that all of its employees and billing agents comply with all statutes, regulations, and guidance applicable to federal health care programs and with Mount Sinai/FPA's own policies and procedures (including the requirements arising from this Agreement);
- c. The requirement that Mount Sinai/FPA employees and billing agents (as it relates to its contract or engagement with Mount Sinai/FPA) are expected to report through the Compliance Program any suspected violations of any statute, regulation, or guidelines applicable to the federal health care programs or of Mount Sinai/FPA's own policies and procedures;
- d. The potential consequences to both Mount Sinai/FPA and to any employee and billing agent as a result of any failure to comply with the applicable federal health care program requirements and/or with Mount Sinai/FPA's own policies and procedures or any failure to report such non-compliance; and
- e. The right of all employees and billing agents to use Mount Sinai/FPA's confidential disclosure mechanisms, as well as Mount Sinai/FPA's commitment to confidentiality and non-retaliation policy with respect to good faith disclosures.
- 2. POLICIES AND PROCEDURES. Mount Sinai/FPA has represented to OIG that it has developed and placed into effect written policies and procedures regarding the operation of its Compliance Program and its overall compliance with all federal health care program statutes, regulations, and guidance issued by the agency in charge of administering the program and its agents. Within ninety (90) days of the effective date of this Agreement, Mount Sinai/FPA shall distribute to all employees and billing agents the aforementioned written policies and procedures. Mount Sinai/FPA shall take actions that it considers reasonable and effective to ensure that these policies are communicated to, and understood by, its employees and billing

agents. Compliance staff and/or supervisors should be duly identified and made continuously available to explain any and all policies and procedures.

Mount Sinai/FPA hereby agrees to maintain its policies and procedures, which at all times shall specifically address: (1) the need for compliance in connection with all submissions for reimbursement for professional services; (2) documentation requirements; and (3) a process for reasonable verification of compliance with these requirements. In addition, the policies and procedures shall include disciplinary guidelines and methods for employees and billing agents to disclose or otherwise report on compliance issues to management and/or supervisors, and through the Confidential Disclosure mechanisms required by Section III.F. Mount Sinai/FPA shall assess and update the policies and procedures at least annually or more frequently, as appropriate. At a minimum, summary of the policies and procedures will be provided to OIG in the Implementation Report, as provided in Section V.A. The policies and procedures shall be available to OIG upon request.

D. TRAINING AND EDUCATION.

- 1. <u>GENERAL TRAINING</u>. Within one-hundred and twenty (120) days of the effective date of this Agreement, Mount Sinai/FPA shall provide general compliance training to its employees. This general training shall explain Mount Sinai/FPA's:
 - a. Institutional Compliance Agreement requirements;
 - b. Compliance Program (including the policies and procedures established pursuant to Subsection C.2 above).

The training materials (including attendance logs) shall be maintained by Mount Sinai/FPA and made available to OIG, upon request. New employees shall receive the general training described above within forty-five (45) days of commencing employment with Mount Sinai/FPA. Mount Sinai/FPA shall also make the general training sessions and materials available to all billing agents and shall encourage their attendance.

2. <u>SPECIFIC TRAINING</u>. Within one-hundred and fifty (150) days of the effective date of this Agreement, Mount Sinai/FPA shall provide to all its employees more intensive training, in addition to the general training required above. At a minimum, this training shall include a discussion of:

- a. The submission of accurate requests for reimbursement for physician services rendered to patients of the federal health care programs;
- b. The policies, procedures and other requirements applicable to the documentation of medical records as it pertains to the rendering of physician services;
- 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 health care program requirements and Mount Sinai/FPA's policies;
- d. Reimbursement rules and statutes applicable to Mount Sinai/FPA's participation in the federal health care programs;
- e. The legal sanctions for improper reimbursement submissions (including the submission of false or inaccurate information); and
- f. Relevant examples of proper and improper billing practices, as it pertains to the rendering of physician services.

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

Within forty-five (45) days of the beginning of employment, Mount Sinai/FPA shall provide all new employees with specific training. If the new employee has any responsibility for the delivery of patient care, the preparation or submission of claims and/or the assignment of procedure codes prior to completing this specific training, a Mount Sinai/FPA employee who has completed the substantive training shall conduct periodic reviews of the untrained person's work regarding the documentation of services and/or the assignment of billing codes until such time as the new employee is duly trained.

Every employee shall receive refresher sessions on this specific training each year for the duration of this Agreement. The substance of the training and the identity of the individuals must be documented in accordance with Subsection D.3 below. All specific training sessions and materials shall be made available to billing agents. Mount Sinai/FPA shall encourage its

billing agents' attendance at such training sessions.

Mount Sinai/FPA recognizes the importance of educating residents concerning the reimbursement requirements of the federal health care programs and the importance of compliance. To further these objectives, Mount Sinai/FPA shall include residents in the specific training described in this subsection III.D.2. Residents will not otherwise be treated as new employees for purposes of this Agreement, but will be required to attend the specific training session during the first year of the their residency program. Residents will be instructed to include their attendance at the training sessions in their activity logs.

3. <u>CERTIFICATION</u>. Mount Sinai/FPA has represented to OIG that it maintains documents that reflect attendance at education and training sessions by employees and billing agents, and the topics covered at each session. Mount Sinai/FPA hereby agrees to continue the maintenance of such records, including those relating to both the general and specific training sessions pursuant to this Agreement. Mount Sinai/FPA may choose the exact format of these documents, but it is expected that the materials will include sheets with the signatures of the persons who attended. The Clinical Director shall retain the attendance logs as well as the course materials. All of these documents shall be available to OIG upon request.

Mount Sinai/FPA shall certify that such training has been provided in its Implementation and Annual Reports to OIG, in accordance with Section V below. Information concerning the format, dates, and copies of the materials provided will 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 Agreement, OIG shall consider Mount Sinai/FPA's training and education activities carried out pursuant to the Compliance Plan since January 1, 1999.

E. ANNUAL REVIEWS OF BILLING POLICIES, PROCEDURES AND PRACTICES

1. ANNUAL REVIEWS. Mount Sinai/FPA has developed a protocol, attached hereto as Attachment 1, for reviewing, on an annual basis, a sample of claims for professional services rendered through Mount Sinai/FPA and/or for which Mount Sinai/FPA submits reimbursement claims. An objective of the annual review is to evidence compliance with the reimbursement and billing requirements of the federal health care programs. Implementation of the agreed-upon procedures set forth in the protocol shall be an element of this Agreement.

For the fiscal year ending October 31, 2000, and annually thereafter, Mount Sinai/FPA shall contract with an independent entity (the "Independent Review Organization" or "IRO"), with expertise in the reimbursement requirements of the federal health care programs applicable to physician services, to perform agreed upon procedures to verify that Mount Sinai/FPA has followed the protocol. The IRO shall be required to issue a report explaining its procedures and findings.

If any of these annual reviews uncovers overpayments that were not already addressed in connection with Mount Sinai/FPA's routine monitoring, Mount Sinai/FPA shall notify the entity in charge of processing the claim or reimbursement (such as the Medicare Part B carrier or similar federal health care program payor) within sixty (60) days of determining the existence of the overpayment (or such additional time as may be agreed to by the payor in writing) and, within ninety (90) of such a determination, take remedial steps to correct the problem, including preventing the deficiency from recurring, calculating the amount of overpayment and make any appropriate refunds.

The notice to the payor shall include: (i) a statement that the refund is being made pursuant to this Agreement; (ii) a statement describing Mount Sinai/FPA's basis for the overpayment; (iii) the methodology by which the overpayment was determined; (iv) the amount of the overpayment; (v) any claim-specific information relating to the overpayment (e.g., beneficiary health insurance numbers, claim numbers, dates of service, amounts claimed, amounts paid and dates of payment, unless the methodology used to determine the overpayment is based on an extrapolation—in which case Mount Sinai/FPA shall exert good faith efforts to provide the necessary information to enable the appropriate processing of refunds); and (vi) the provider billing number under which the refund is being made.

If any annual review or monitoring reveals that there may be a material billing deficiency, Mount Sinai/FPA shall take reasonable steps to determine the extent of the problem, including the amount of overpayments made by any federal health care program. To determine the amount of potential overpayment, Mount Sinai/FPA shall conduct a special review, as set forth in Subsection E.2 below. For purposes of this Agreement, a material billing deficiency shall mean credible evidence of a substantial overpayment affecting a federal health care program resulting from Mount Sinai/FPA's conduct or policies that constitute violations of federal health care program statutes or regulations or directives issued by agency that administers the federal health care program and/or its agents. Mount Sinai/FPA shall notify OIG within sixty (60) days of determining that a

material billing deficiency exists.

Mount Sinai/FPA's notice to OIG shall include: (i) a detailed description of the material billing deficiency and the amount of overpayment resulting therefrom; (ii) Mount Sinai/FPA's actions to correct the deficiency and prevent recurrences; (iii) the name of the third-party payor (e.g., Medicare Part B carrier) to whom any refunds relating to the matter have been sent, its address and the names of representatives contacted, if any; (iv) the date of the check or electronic transfer and the identification number (or electronic transfer number) with which all refunds have been made; and (v) a report on the calculation of the overpayment amounts, as provided in Subsection E.2 below.

- 2. <u>SPECIAL REVIEWS</u>. In the event that a material billing deficiency is identified, Mount Sinai/FPA shall conduct a special review in accordance with the guidelines set forth in Attachment 2.
 - a. <u>REPORTING RESULTS</u>. Upon completion of each special review, Mount Sinai/FPA shall prepare a report reflecting adherence to the guidelines set forth in Attachment 2.

F. CONFIDENTIAL DISCLOSURE

Mount Sinai/FPA has represented to OIG that it has established a confidential disclosure mechanism through its Mount Sinai Corporate Compliance Hotline, a toll-free telephone line, as a means to enable employees, residents, staff and patients to report instances of noncompliance and/or make inquiries on compliance issues. Pursuant to this Agreement, Mount Sinai/FPA shall maintain a confidential disclosure mechanism such as the Hotline, which shall be available to all employees, residents, staff and patients for the purpose of reporting or inquiring on matters of compliance with federal health care program standards and the obligations in this Agreement.

In turn, Mount Sinai/FPA shall require the internal inquiry of any disclosure or inquiry regarding practices or billing procedures involving Mount Sinai/FPA that is sufficiently specific so that it: (i) permits a determination of the appropriateness of the practice alleged to be implicated; and (ii) permits corrective action to be taken and ensures that proper follow-up is conducted. In an effort to address each disclosure and inquiry received Mount Sinai/FPA shall, in good faith, make a preliminary inquiry for every disclosure to ensure it has obtained all of the necessary information that is required to determine whether an internal inquiry, in accordance with the language above, should be conducted. Mount Sinai/FPA shall maintain an internal tracking system to record, and follow up on, all disclosures and inquiries received. Mount Sinai/FPA shall ensure that it continuously provides

sufficient notice of its disclosure mechanism to all employees, residents, staff and patients.

Mount Sinai/FPA shall include in each Annual Report to OIG a summary of each communication received under its confidential disclosure mechanism concerning Mount Sinai/FPA's billing practices as they relate to the federal health care programs that is reported as, and found to be, inappropriate. Each summary shall include: (i) a description of the conduct or practice; (ii) a description of Mount Sinai/FPA's internal inquiry; (iii) results of its internal inquiry; and (iv) any follow-up activities on the matter (including corrective action). Mount Sinai/FPA hereby agrees to maintain the full reports on these matters in a manner consistent with Section VII of this Agreement.

Mount Sinai/FPA shall select the manner in which disclosures and inquiries are received, processed and resolved. The disclosing or inquiring individual's identity may be requested, but shall not be required. Anonymity shall not be discouraged.

G. INELIGIBLE PERSONS

- DEFINITIONS. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the federal health care programs after a period of exclusion, suspension, debarment, or ineligibility. A "contractor," as used in this subsection, shall mean an individual or entity engaged by Mount Sinai/FPA or its agents for the purpose of rendering health care items or services or for the processing, generation and/or submission of reimbursement claims to the federal health care programs.
- 2. SCREENING REQUIREMENTS. Mount Sinai/FPA shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Mount Sinai/FPA shall screen all prospective employees and staff and prospective contractors prior to engaging their services by: (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

- REVIEW AND REMOVAL REQUIREMENT. Within ninety (90) days of the effective date of this Agreement, Mount Sinai/FPA will review its list of current employees, staff and contractors against the Exclusion Lists. Thereafter, Mount Sinai/FPA will review the list every six months. If Mount Sinai/FPA has notice that an employee, staff or agent has become an Ineligible Person, Mount Sinai/FPA will remove such person from responsibility for, or involvement with, Mount Sinai/FPA'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 EXCLUSION. If Mount Sinai/FPA has information that an employee, staff or contractor is charged with a criminal offense related to any federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Mount Sinai/FPA on grounds of patient abuse, neglect or any other conduct that has jeopardized or may have jeopardized the health and/or safety of any patient (whether or not it involves patients of Mount Sinai/FPA and regardless of payor status), then within ten (10) days of receiving such information, Mount Sinai/FPA will remove such an individual during the pendency of the matter from responsibility for, or involvement with, Mount Sinai/FPA's business operations (including the provision of health care services to patients) as it relates to the federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion. For all other grounds, Mount Sinai/FPA shall periodically review the individual's work (including documentation of services and claim information) during the pendency of the matter to ensure that reimbursement claims made based upon, or pursuant to, the individual's services are appropriate under the federal health care program requirements.

Mount Sinai/FPA's obligations in this subsection may also be subject to federal, state and/or local laws. Should any such laws impede Mount Sinai/FPA's ability to act in accordance with this subsection, Mount Sinai/FPA shall defer taking action pursuant to this subsection and immediately notify OIG.

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Mount

Sinai/FPA's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (i) Mount Sinai/FPA's compliance with the terms of this Agreement; and (ii) Mount Sinai/FPA's compliance with the requirements of the federal health care programs. The documentation described above shall be maintained and made available by Mount Sinai/FPA at all reasonable times for inspection, review and reproduction by OIG. OIG's inspection and review activities pursuant to this section may include on-site visits.

Furthermore, for purposes of this provision, OIG or its authorized representative(s) may interview any of Mount Sinai/FPA's employees, residents and staff who consents 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. Mount Sinai/FPA agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request.

V. <u>IMPLEMENTATION AND ANNUAL REPORTS</u>

A. <u>IMPLEMENTATION REPORT</u>

On or before April 1, 2000, Mount Sinai/FPA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This Implementation Report shall include:

- 1. The names and positions of the members of the Compliance Committee required by Section III.A.
- 2. The name, address, phone number and position description of the Corporate Compliance Officer and the Clinical Director required by Section III.B.
- 3. A copy of Mount Sinai/FPA's Code of Conduct required by Section III.C.1.
- 4. A summary of the policies and procedures required by Section III.C.2 or a copy of the policies and procedures.
- 5. A description of the training programs required by Section III.D, including a description of the targeted audiences and a schedule of the dates on which the training sessions were held.
- 6. A certification by the Corporate Compliance Officer that, to the best of the her/his knowledge and, upon reasonable efforts and inquiry, the actions described in Sections III.C and III.D.1 of this Agreement have taken place.
- 7. A description of the confidential disclosure mechanisms required by Section III.F.

B. ANNUAL REPORT

Mount Sinai/FPA shall make annual reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures Mount Sinai/FPA has taken to ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include the following information:

- In the first Annual Report, copies of the document or documents that comprise Mount Sinai/FPA's Compliance Program, as adopted by Mount Sinai/FPA and implemented by the Compliance Committee and the Corporate Compliance Officer and the Clinical Director. For subsequent years, Mount Sinai/FPA shall note in the Annual Report any amendments or revisions to the Compliance Program documents made during the period covered by the Annual Report.
- 2. Any change in the identity, position or duties of the Corporate Compliance Officer and/or the Clinical Director, and/or any changes in the positions that comprise the Compliance Committee, as set forth in Sections III.A and III.B.
- 3. Copies of any revisions or amendments made to the Code of Conduct or the policies and procedures used or followed in the generation of claims submitted to the federal health care programs during the period covered by the Annual Report pursuant to Section III.C.
- 4. A description of the Training and Education activities engaged in pursuant to Section III.D of this Agreement and a summary of the activities undertaken to implement this program, including schedules, topic outlines of the training sessions, and lists of the participants organized by department or division. Additionally, Mount Sinai/FPA shall include a certification by the Corporate Compliance Officer that, to the best of her/his knowledge and, upon reasonable efforts and inquiry, the education and training activities required under this Agreement have taken place.
- 5. A summary of the findings made during the reviews conducted pursuant to Section III.E.1 of this Agreement relating to the year covered by the Annual Report; copies of any disclosures or notice documents prepared by Mount Sinai/FPA pursuant to that section; a copy of the IRO's report required under Section III.E.1; a copy of any special review reports described in Section III.E.2; and a description of the corrective steps and proof of refund to the pertinent payor (where applicable).
- 6. A summary of all material billing deficiencies reported during the period of the Annual Report pursuant to III.E.

- 7. A summary of communications (including the number of disclosures by employees and the dates of disclosure) received through the mechanisms established pursuant to Section III.F, as well as any follow up on such disclosures.
- 8. A written description of any personnel action (other than hiring) and/or any activity carried out by Mount Sinai/FPA as a result of the requirements in Section III.G and the identities of the individuals subjected to such an action or activity.
- 9. A summary describing any ongoing investigation, audit or legal proceeding conducted or brought by a governmental entity where Mount Sinai/FPA (including its employees and billing agents) is the subject or target on allegations of fraud or abuse, to the extent Mount Sinai/FPA is aware of such an investigation, audit or legal proceeding. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such an inquiry, legal proceeding or requests for information.

The period covered by the Annual Report shall be twelve (12) months commencing on November 1 and ending on October 31 of the following calendar year. All Annual Reports shall be due on December 31 following the end of the applicable period.

C. <u>CERTIFICATIONS</u>

The Implementation Report and Annual Reports shall include a certification by the Corporate Compliance Officer that: (1) to the best of her/his belief and, upon reasonable inquiry, Mount Sinai/FPA is in compliance with all of the requirements of this Agreement; and (2) the Corporate Compliance Officer has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that, upon such an inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

ATTENTION:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General

Office of Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW Cohen Building, Room 5527 Washington, DC 20201

Ph. 202.619.2078 Fax 202.205.0604

ATTENTION:

Jane Whitney Clinical Director

Office of Billing Compliance/Faculty Practice Associates

Mount Sinai School of Medicine 5 East 98th Street, Box 1061

New York, NY 10029 Ph. 212.241.7715 Fax 212.987.7733

VII. DOCUMENT AND RECORD RETENTION

Mount Sinai/FPA shall maintain for inspection documents and records relating to its compliance with the obligations in this Agreement, as well as those relating to the reimbursement claims submitted to the federal health care programs, for a period of six (6) years following the execution of this Agreement or one (1) year longer than the duration of this Agreement.

VIII. BREACH AND DEFAULT

Mount Sinai/FPA's compliance with the terms and conditions in this Agreement shall constitute an element of Mount Sinai/FPA's present responsibility with regard to participation in the federal health care programs. Full and timely compliance by Mount Sinai/FPA shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Mount Sinai/FPA. As stated below in Section X of this Agreement, any and all modifications to this Agreement (including changes to dates on which an obligation is due to be met) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, Mount Sinai/FPA and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of specific monetary penalties (hereinafter referred to as "stipulated penalties") in accordance with the following provisions.

1. A stipulated penalty of \$2,500 for each day Mount Sinai/FPA fails to comply with any of the following, which stipulated penalty shall begin to

accrue one day after the date the obligation becomes due:

- a. Submission of the complete Annual Report, in accordance with the requirements in Section V.B, by the due date established in Section V.B;
- b. Confirmation of the existence of a Corporate Compliance Officer and a Clinical Director in the Implementation Report as required under Section V.A;
- c. Confirmation of the existence of a Compliance Committee in the Implementation Report as required under Section V.A;
- d. Maintenance of a toll-free telephone line pursuant to Section III.F.
- A stipulated penalty of \$2,500 for each day Mount Sinai/FPA fails to comply by having in force during the term of this Agreement any of the following, which stipulated penalty shall begin to accrue on the date of receipt of OIG's notice of noncompliance, in accordance with Section VIII.B below:
 - a. the Compliance Program adopted pursuant to Section III of this Agreement;
 - b. the Compliance Committee, the Corporate Compliance Officer and the Clinical Director, discharging their respective duties, as required under Sections III.A and III.B of this Agreement;
 - c. the Training and Education activities required under Section III.D of this Agreement;
 - d. the Confidential Disclosure requirements under Section III.F of this Agreement.
- 3. A stipulated penalty of \$2,500 for each day Mount Sinai/FPA fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review rights set forth in Section IV of this Agreement, which stipulated penalty shall begin to accrue on the date Mount Sinai/FPA fails to grant access.
- 4. A stipulated penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began unless otherwise noted) for each day Mount Sinai/FPA:

- a. hires or enters into a contract with an Ineligible Person after the date upon which that person has been listed on the Exclusion Lists by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the federal health care program; this stipulated penalty shall not be demanded for any time period during which Mount Sinai/FPA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G) as to the status of the person;
- b. continues to employ or contract with a person who becomes an Ineligible Person and that person: (i) has responsibility for, or involvement with, Mount Sinai/FPA's business operations related to the federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by federal health care programs or otherwise with federal funds; this stipulated penalty shall not be demanded for any time period during which Mount Sinai/FPA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G) as to the status of the person; or
- c. fails to take action or engage in the required activities in accordance with subsection III.G.4 above, unless such an action is deferred pursuant to that subsection; this stipulated penalty shall not be demanded for any period before ten (10) days after Mount Sinai/FPA's receipt of OIG's notice of noncompliance.
- A stipulated penalty of \$1,000 (which shall begin to accrue five (5) days after the date of receipt of OIG's notice of noncompliance in accordance with Section VIII.B) for each day Mount Sinai/FPA fails to comply with any other requirement in this Agreement, which is not covered by provisions 1, 2, 3 and 4 of this Section VIII.A. In its notice to Mount Sinai/FPA, OIG shall state the specific grounds for its determination of noncompliance.

B. PAYMENT OF STIPULATED PENALTIES

Upon finding that Mount Sinai/FPA has failed to comply with any of the above-enumerated obligations, OIG may choose to enforce the obligation and demand payment of the stipulated penalties above. To effectuate the demand, OIG shall notify Mount Sinai/FPA by certified mail of: (i) Mount Sinai/FPA's failure to

comply; (ii) the specific grounds for its determination of noncompliance; and (iii) OIG's decision to exercise its contractual right to demand payment of the stipulated penalties payable under this Agreement. This notification is hereinafter referred to as the "Demand Letter."

Within ten (10) days of receipt of the Demand Letter, Mount Sinai/FPA shall respond by either: (i) curing the breach to OIG's reasonable satisfaction, paying the applicable stipulated penalties, if any, and notifying OIG of its corrective actions; or (ii) sending in writing to OIG a request for a hearing before an HHS administrative law judge to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth in Section VIII.D of this Agreement. Mount Sinai/FPA's election of the contractual right herein to seek review of OIG's noncompliance determination shall not preclude Mount Sinai/FPA from also choosing to pay the applicable stipulated penalties at any time after receiving the Demand Letter. Failure to respond to the Demand Letter shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section VIII.C below.

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 of this Agreement.

C. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Mount Sinai/FPA engages in conduct that OIG reasonably considers to be a material breach of this Agreement, OIG may seek the exclusion of Mount Sinai/FPA from participation in the federal health care programs. Upon making its determination, OIG shall notify Mount Sinai/FPA of the alleged material breach by certified mail, stating the specific grounds for its determination, and expressing its intent to exclude as a result thereof. This letter shall be referred to hereinafter as the "Notice of Material Breach and Intent to Exclude." Mount Sinai/FPA shall have thirty (30) days from the date of receipt of the letter to:

- 1. demonstrate to OIG's reasonable satisfaction that Mount Sinai/FPA is in full compliance with this Agreement;
- 2. cure the alleged material breach; or
- demonstrate to OIG's reasonable satisfaction that the alleged material breach cannot be cured within the thirty (30) day period, but that Mount Sinai/FPA has begun to take action to cure the material breach and that it shall pursue such an action with due diligence. Mount Sinai/FPA shall, at this time, submit a timetable for curing the material breach for OIG's approval.

If at the conclusion of the thirty-day period (or such other specific period as subsequently agreed to by OIG and Mount Sinai/FPA), Mount Sinai/FPA fails to meet the requirements of provisions 1, 2 or 3 above, OIG may exclude Mount Sinai/FPA from participation in the federal health care programs. OIG shall notify Mount Sinai/FPA by certified mail of its determination to exclude Mount Sinai/FPA. This letter shall be referred to hereinafter as the "Exclusion Letter."

Notwithstanding any provisions in Chapter 42 of the Code of Federal Regulations, the exclusion pursuant to this Agreement shall take effect thirty (30) days from the date of the Exclusion Letter unless, during such a period, Mount Sinai/FPA exercises its contractual right to seek review of OIG's exclusion determination by requesting a hearing before an administrative law judge as provided in Section VIII.D below. In the event Mount Sinai/FPA requests such a hearing, the exclusion shall not be effective unless and until an administrative law judge issues a decision supporting OIG's exclusion determination. The exclusion of Mount Sinai/FPA shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Mount Sinai/FPA is excluded pursuant to this Agreement, it may seek reinstatement in accordance with 42 C.F.R. §§ 1001.3001-1001.3004.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material billing deficiency, take corrective action and pay the appropriate refunds, as provided in Section III.E of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section VIII.A of this Agreement; or (iii) failure to respond to a Demand Letter concerning the payment of stipulated penalties in accordance with Section VIII.B above.

In connection with OIG's determination to exclude Mount Sinai/FPA pursuant to this provision, Mount Sinai/FPA shall have the right to dispute OIG's determination in accordance with the agreed-upon provisions set forth in Section VIII.D of this Agreement.

D. <u>DISPUTE RESOLUTION</u>

Upon OIG's delivery to Mount Sinai/FPA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Mount Sinai/FPA shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005 as if they applied to the stipulated penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of stipulated penalties or to seek exclusion shall be subject to review by an HHS administrative law judge in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. With respect to disputes regarding OIG's determination to

demand payment of stipulated penalties, Mount Sinai/FPA and OIG agree that the administrative law judge's decision shall be considered final for purposes of this Agreement. With respect to OIG's determination to seek exclusion, Mount Sinai/FPA and/or OIG may appeal the administrative law judge's decision to HHS's Departmental Appeals Board ("DAB") in a manner consistent with the provisions in the above-referenced regulations. For purposes of the parties' contractual remedies herein, the decision of the DAB shall be considered final. Neither the review by the administrative law judge nor the review by the DAB provided for above shall be considered to be appeal rights arising under any statutes or regulations.

Notwithstanding the language in 42 C.F.R. § 1005.2(c), requests for hearings involving stipulated penalties shall be made within ten (10) days of the date of receipt of the Demand Letter and requests for hearings involving exclusion shall be made within thirty (30) days of the date of receipt of the Exclusion Letter.

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 section shall be: (i) whether, on the date of the Demand Letter, Mount Sinai/FPA was in compliance with the obligations in this Agreement for which OIG demands payment; (ii) whether Mount Sinai/FPA failed to cure; (iii) whether the alleged noncompliance could have been cured within the ten-day period or such other period as previously agreed to in writing between OIG and Mount Sinai/FPA; and (iv) the period of noncompliance. For purposes of paying stipulated penalties under this Agreement, and if Mount Sinai/FPA chooses to seek review in lieu of curing the breach and paying the stipulated penalties as set forth above, the administrative law judge's decision shall give rise to Mount Sinai/FPA's obligation to pay the stipulated penalties determined therein. In such an instance, payment will be due fifteen (15) days from the day the administrative law judge's decision is received.

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 Agreement shall be: (i) whether Mount Sinai/FPA was in material breach of one or more of its obligations under this Agreement as set forth in the Exclusion Letter; (ii) whether the alleged material breach was continuing on the date of the Exclusion Letter; (iii) whether the alleged material breach could have been cured within the thirty-day period, or such other period as agreed to in writing between Mount Sinai/FPA and OIG; (iv) whether Mount Sinai/FPA began to take action to cure the alleged material breach with due diligence; and (v) whether Mount Sinai/FPA provided OIG a timetable for curing the alleged material breach. For purposes of the exclusion procedure herein agreed to, in the event of a material breach of this Agreement, an administrative law judge's decision finding in favor of OIG shall be deemed to make the exclusion effective, at which time OIG may proceed with its exclusion of Mount Sinai/FPA.

Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, OIG shall have the burden of going forward and the burden of persuasion with respect to the issue of whether Mount Sinai/FPA was out of compliance (for stipulated penalties) or in material breach (for exclusion) and with respect to the period of noncompliance or material breach. Mount Sinai/FPA shall bear the burden of going forward and the burden of persuasion with respect to the issue of whether, during the specified period, Mount Sinai/FPA cured the alleged noncompliance or material breach, and with respect to the issue of whether the alleged noncompliance or material breach could have been cured during the specified period. The burden of persuasion will be judged by a preponderance of the evidence.

All notices required under any of the aforementioned proceedings shall be given to OIG and Mount Sinai/FPA in accordance with Section VI of this Agreement.

IX. PRIVILEGES AND DISCLOSURES

Nothing in this Agreement shall constitute or be construed as a waiver by Mount Sinai/FPA of its attorney-client or other applicable privileges. The existence of any such privileges does not excuse or otherwise affect Mount Sinai/FPA's obligation to comply with the provisions in this Agreement.

Subject to HHS's Freedom of Information Act ("FOIA") procedures and definitions set forth in 45 C.F.R. Part 5, OIG shall make reasonable efforts to notify Mount Sinai/FPA prior to any release by OIG of information submitted by Mount Sinai/FPA pursuant to its obligations under this Agreement and identified upon submission by Mount Sinai/FPA as: (i) trade secrets; or (ii) commercial or financial information that is privileged or confidential under applicable FOIA requirements. Mount Sinai/FPA will make a good faith effort to designate as trade secrets, commercial or financial information that is privileged or confidential only materials that meet recognized criteria for exemption from disclosure under FOIA.

This Agreement shall not constitute or be construed as a waiver by Mount Sinai/FPA of any applicable claim of protection under a self-evaluative privilege theory as against third-party, non-governmental entities or persons in connection with the information provided to OIG pursuant to this Agreement.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the settlement agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated by reference, Mount Sinai/FPA and OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Mount Sinai/FPA that assume responsibility for submitting claims to the federal

health care programs for professional services rendered by physicians and other health care providers who, for purposes of providing such professional services, are employed by Mount Sinai/FPA or who are independent contractors with Mount Sinai/FPA. This Agreement shall also be binding on any entity owned or controlled by Mount Sinai/FPA that assumes responsibility for billing for professional services rendered by Mount Sinai/FPA's physician faculty members.

- 2. This Agreement shall become final and binding only upon signing by each respective party hereto;
- 3. Any modifications to this Agreement may be made only by a writing signed by the parties to this Agreement; and
- 4. The undersigned Mount Sinai/FPA signatories represent and warrant that they are authorized to execute this Agreement on behalf of The Mount Sinai Medical Center and The Mount Sinai School of Medicine Faculty Practice Associates. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement on behalf of OIG.

7-380 P. 24/20 F-370

On Behalf of The Mount Sinai School of Medicine

ARTHUR RUBENSTEIN, MBBCh

Dean and Chief Executive Officer

Mount Sinai School of Medicine

9/30/99

LORRAINE EGAN

Vice President and Corporate Compliance Officer

Mount Sinai School of Medicine

9/30/99

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 Counsel to the Inspector General

Office of Inspector General

U. S. Department of Health and Human Services

The Mount Sinai Medical Center

Faculty Practice Associates

The Mount Sinai Hospital Mount Sinai School of Medicine Box 1061

One Gustave L. Levy Place New York, NY 10029-6574 Tel (212) 241-6228 Fax (212) 534-2907

Attachment 1

The Mount Sinai/FPA Office of Billing Compliance Monitoring Program is designed to review departmental compliance with the Mount Sinai/FPA Compliance Plan. Selecting departments for review is based on several factors including dollar/volume, number of physicians, and potential issues in relation to the OIG work plan. Every physician within each department is reviewed as part of the departmental review. Departments are reviewed on a cyclical basis (18-24 months).

In order to verify departmental compliance the following occurs during the course of a review:

- ⇒ A random sample of services is selected. Selection is based on departmental and/or individual physician CPT code utilization.
- ⇒ Medical records (inpatient and/or outpatient) are reviewed and CPT codes are reassessed and compared with billing information.

Once the departmental monitoring is completed, a summary of the monitoring results will be distributed to the Administrator, the Departmental Chairman of the Department, and to the individual providers. The Office of Billing Compliance will meet with each provider individually or as a group to discuss the results of the monitoring and to give the provider the opportunity to respond to the findings. If, following the meeting, the provider continues to be found in "non-compliance", he/she will be required to attend an individualized training session and will be monitored following the session for subsequent dates of services.

If the monitoring reveals that the billing issues have not been addressed, the provider will be referred to the Clinical Director of the Office of Billing Compliance for further corrective action and the provider billing privileges are suspended. All billing for services rendered by the provider will be subject to a pre-billing review until such time that the Clinical Director of the Office of Billing Compliance is satisfied with the accuracy of the documentation and coding selection for billing. Any overpayment identified during the monitoring process will be refunded to the appropriate agency.



ATTACHMENT 2: SPECIAL REVIEW GUIDELINES

- A. <u>BASIC INFORMATION</u>. In documenting the special reviews pursuant to Section III.E. of the Institutional Compliance Agreement, Mount Sinai/FPA shall provide for the following:
 - Review Objective: A statement clearly articulating the objective of the review and the review procedure or combination of procedures applied to achieve the objective.
 - 2. Review Population: A statement identifying 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.
 - 3. <u>Sources of Data</u>: 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, compensation packages or formulae).
 - 4. <u>Personnel Qualifications</u>: The names and titles of those individuals involved in any aspect of the review, including statisticians, accountants, auditors, consultants and medical reviewers, and their qualifications.
- B. <u>SAMPLE ELEMENTS</u>. In documenting the selection and use of samples in the special reviews, Mount Sinai/FPA shall provide for the following:
 - 1. <u>Sampling Unit</u>: A definition of the sampling unit, which is any of the designated elements that comprise the population of interest.
 - 2. <u>Sampling Frame</u>: Identification of the sampling frame, which is the totality of the sampling units from which the sample will be selected. In addition, the plan should 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.
 - 3. <u>Sample Size</u>: A description of both the probe sample (if one is used) and the full sample, including the sample's level of confidence and precision.
 - 4. Random Numbers: Written assurance that all probe samples and samples used were selected through random numbers. The source of the random numbers used must be described. For this task, OIG strongly recommends the use of its Office of Audit Services's Statistical Sampling Software, also known as "RAT-STATS," which is currently available through the "internet" at http://www.hhs.gov/progorg/oas/ratstat.html, free of charge.

- 5. <u>Sample Design</u>: Unless Mount Sinai/FPA demonstrates the need to use a different sample design, the review should use simple random sampling. If necessitated, Mount Sinai/FPA may use stratified or multistage sampling. Details about the strata, stages and clusters should be included.
- 6. Characteristics Measured by the Sample: A statement identifying 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. This description 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.
- 7. <u>Missing Sample Items</u>: An explanation of how missing sample items were handled and the rationale.
- 8. <u>Other Evidence</u>: 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.
- 9. <u>Estimation Methodology</u>: Because the general purpose of the 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 matter discovered, Mount Sinai/FPA must use the mean point estimate. The use of RAT-STATS to calculate the estimates is strongly recommended.