

INSTITUTIONAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNIVERSITY PHYSICIANS, INC. (“UPI”) AND THE
CLINICAL PRACTICE GROUPS ASSOCIATED WITH UPI

I. PREAMBLE

University Physicians, Inc., (“UPI”) and the clinical practice groups (“CPGs”) who are signatory hereto (UPI and the CPGs are collectively referred to as “UPMD”) hereby enter 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 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 by UPMD with regard to professional services rendered by its providers.

UPI is the administrative organization for the CPGs. Prior to the execution of this ICA, UPI established a compliance plan (known as the “Compliance Program”) which provides for integrity policies and procedures and which, as represented by UPI in this ICA, 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 those programs. The CPGs and all physicians or other appropriate health care providers and staff participate in the compliance program (“Compliance Program”). For the purposes of this ICA, the term “provider” shall mean all physician faculty of the University of Maryland School of Medicine (“SOM”) or ancillary health providers who provide professional medical services as employees of the CPGs or UPI, or pursuant to contracts between their employers and the CPGs or UPI. For the purposes of this ICA, the term “employee” shall mean: all UPMD employees who are involved in the generation and submission of reimbursement claims for physician services, including, but not limited to, coders and billing personnel. UPMD’s use of billing agents to handle billing of professional services by some or all of its employees shall not affect or limit UPMD’s obligations or responsibilities under this ICA. This ICA also applies to all third parties UPMD may choose to engage as its billing agents. Finally, this ICA applies to the medical residents assigned to the SOM clinical departments and acting under the supervision of the providers at the University of Maryland Medical Center (“UMMC”) campus in Baltimore, Maryland (hereinafter referred to as “residents”) to the extent specifically set forth herein. The CPGs agree to be bound by the terms of this ICA, and they authorize the undertakings of UPI as set forth in this ICA.

Pursuant to this ICA, UPI hereby agrees to maintain in full operation, or adapt as required by this ICA, the Compliance Program as it relates to the submission of claims for physician services for the term of this ICA. The Compliance Program may be modified by UPI as appropriate, but at a minimum, shall comply with the integrity obligations enumerated in this ICA.

II. TERM AND SCOPE OF THE ICA

The period of the compliance obligations assumed by UPMD under this ICA shall be 5 years from the effective date of this ICA (unless otherwise specified). The effective date of this ICA shall be the date on which the final signatory of this ICA executes this ICA.

Sections IV, VII, VIII, IX and XI shall expire no later than 120 days from OIG's receipt of: (1) UPMD's final annual report; or (2) any additional materials submitted by UPMD pursuant to OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

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

A. COMPLIANCE COMMITTEE

UPI represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Committee to monitor the implementation of the Compliance Program and to provide advice and recommendations to the UPI Compliance Officer and the Board of Trustees of UPI on compliance issues, policies and procedures, and changes to the Compliance Program. The composition of the Compliance Committee includes a chairperson, who is a member of the Board of Trustees, and such other provider members and administrative staff of the CPGs and UPI administrative staff as the President of UPI shall designate from time to time. The Compliance Committee must be able to make reports directly to UPI's management and its board of directors. Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this ICA, must be reported to OIG, in writing, within 30 days of such a change.

B. COMPLIANCE OFFICER

UPI represents to OIG that, pursuant to its Compliance Program, it has created a Compliance Officer position and appointed an individual to serve in that capacity. Accordingly, UPI shall formally maintain the appointment of an individual to

serve as the Compliance Officer throughout the term of this ICA. At a minimum, the 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 Compliance Officer shall be a member of senior management of UPI, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Trustees of UPI, and shall be authorized to report on such matters to the President of UPI, the Executive Director of UPI and the Board of Trustees at any time. Any changes in the identity or position description of the Compliance Officer (including voluntary or involuntary personnel changes) or any actions or changes that would materially affect his or her ability to perform the duties necessary to meet the obligations in this ICA must be reported to OIG within 30 days of the effective date of the change or action.

C. WRITTEN STANDARDS

1. CODE OF CONDUCT. Unless UPI has already done so, within ninety (90) days after the effective date of this ICA, UPI shall develop and distribute to all employees and providers a written Code of Conduct as part of its Compliance Program, and shall maintain it in effect for the duration of this ICA. The Code of Conduct shall also be readily accessible to employees and providers through means that UPI considers effective. New employees and providers shall receive the Code of Conduct within thirty (30) days after the commencement of their employment, or within ninety (90) days after the effective date of this ICA, whichever is later.

UPI shall document the actions taken to distribute the Code of Conduct to all employees and providers. Such documents shall be produced to OIG upon request.

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

UPI shall make the promotion of, and adherence to, the Code of Conduct an element (1) in evaluating the performance of all employees and (2) in determining whether to continue to contract for the provision of a provider's services to UPMD patients. The Code of Conduct shall be amended and, at a minimum, set forth:

- a. UPI'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 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. UPI’s requirement that all of its employees and providers comply with all statutes, regulations, and guidance applicable to the Federal health care programs and with UPI’s own policies and procedures (including the requirements arising from this ICA);
- c. The requirement that UPI employees and providers 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 UPI’s own policies and procedures;
- d. The potential consequences to both UPI and to any of its employees or providers as a result of any failure to comply with the applicable Federal health care program requirements and/or with UPI’s own Policies and Procedures or any failure to report such non-compliance; and
- e. The right of all employees and providers to use UPI’s confidential disclosure mechanisms, as well as UPI’s commitment to confidentiality and non-retaliation policy with respect to good faith disclosures.

Within 120 days of the effective date of this ICA, all employees and providers shall certify, in writing, that they have received, read, understand and will abide by UPI’s amended Code of Conduct. New employees and providers shall receive the Code of Conduct and shall complete the required certification within 30 days after the commencement of their employment or contract, or within 90 days after the effective date of this ICA, whichever is later.

The provisions of this subsection III.C.1 shall not apply to employees who terminate their relationship with UPMD within 90 days after the effective date of this ICA.

2. POLICIES AND PROCEDURES. Within 120 days of the effective date of this ICA, UPI shall implement (to the extent it has not already done so) written policies and procedures (hereinafter the “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. Accordingly, UPI 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 medical services; (2) documentation requirements as it pertains to the physician services rendered and/or claimed for reimbursement by or through UPI; and (3) a process for reasonable verification of compliance with these requirements. In addition, the Policies and Procedures shall include guidelines and methods for employees and providers to make disclosures or otherwise report on compliance issues to management and/or supervisors, and through the Confidential Disclosure mechanisms required by Section III.F. UPI shall assess and update the Policies and Procedures at least annually or more frequently, as appropriate. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures. A 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 will be made available to OIG upon request.

Within one-hundred and twenty (120) days of the effective date of this ICA, UPI shall provide to all of its employees and providers the Policies and Procedures relevant to their tasks and responsibilities in connection with UPI's participation in the Federal health care programs. UPI shall take actions that it considers reasonable and effective to ensure that these Policies and Procedures are communicated and readily available to employees and providers, and understood by them. Compliance staff or supervisors should be duly identified and made continuously available to explain any and all Policies and Procedures.

D. TRAINING AND EDUCATION.

1. GENERAL INITIAL TRAINING. Within 120 days of the effective date of this ICA, UPI shall provide general compliance training to its employees and providers. This general training shall explain UPI's:
 - a. Institutional Compliance Agreement requirements;
 - b. Compliance Program (including the Policies and Procedures established pursuant to Subsection C.2, above), except that OIG shall consider training conducted by UPI under the Compliance Program since July 1, 2001 to meet this obligation; and

c. Code of Conduct.

The training materials (including attendance logs) shall be maintained by UPI and made available to OIG, upon request.

New employees and providers shall receive the general training described above within 45 days of beginning their employment with UPI or within 120 days after the effective date of this ICA, whichever is later. All employees and providers shall receive such general training on an annual basis.

2. SPECIFIC TRAINING. Within one-hundred and twenty (120) days of the effective date of this ICA, UPI shall provide to all its employees who perform CPT coding and providers additional training to supplement 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 and 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 health care program's requirements and UPI's policies;
- d. Reimbursement rules and statutes applicable to the services for which UPI seeks reimbursement from 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 45 days of the beginning of employment, or within 120 days of the effective date of this ICA, whichever is later, UPI shall provide all such new employees and providers with specific training using internal or external resources. If the new employee or provider has any responsibility for the delivery of patient care, and/or the assignment of procedure codes prior to completing this specific training, a UPI employee who has completed the substantive training shall conduct sporadic 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 or provider is duly trained.

All employees and providers shall receive refresher sessions on this specific training each year for the duration of this ICA. The substance of the training and the identity of the individuals must be documented in accordance with subsection D.3, below.

UPI recognizes the importance of educating medical trainees concerning billing requirements and the importance of compliance. To further that objective, UPI will include residents in the training described in this section IV.D.2. Residents will not otherwise be treated as new employees for the purposes of this ICA, but they will be required to attend compliance training during the first year after they become residents. Residents will be instructed to include their attendance at compliance training sessions in their logs of activities.

3. CERTIFICATION. UPI shall maintain documents that reflect attendance at both general and specific training sessions by employees and providers, and the topics covered. UPI may choose the format of these documents, but it is expected that the materials will include sheets with the signatures of the persons who attended. The Compliance Officer shall retain the attendance logs as well as the course materials. All of these documents shall be made available to OIG, upon request.

UPI 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 made available, upon request, for review by OIG.

For the purposes of meeting the obligations under this subsection D, for the term of the first Annual Report under this Agreement, OIG shall consider UPI's training and educational activities carried out pursuant to the Compliance Program since July 1, 2001.

4. DEPARTING PERSONS. The provisions of this subsection III.D shall not apply to providers, employees or residents who terminate their relationship with UPMD or UMMC prior to April 1, 2002, or residents/fellows who are with UPMD or UMMC for 60 days or less.

E. ANNUAL REVIEWS OF BILLING POLICIES, PROCEDURES AND PRACTICES

1. ANNUAL REVIEWS. UPI has developed a protocol, attached hereto as Attachment A, for reviewing a sample of claims for each provider who submits claims for professional services through UPMD. An objective of the review is to verify 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 commence on March 1, 2002 and shall end on February 29, 2003, and shall be an element of this ICA throughout its term.. UPI shall, on an annual basis, contract with an Independent Review Organization (the "IRO") with expertise in the reimbursement and billing requirements of the Federal health care programs to verify whether UPI is implementing the agreed upon procedures for the CPGs. UPI will request the Annual Reviewer to produce a report on its work, which report shall be included in the Annual Reports to OIG.

If any of these annual reviews uncovers overpayments that were not already addressed in connection with UPI's routine monitoring, UPI 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 that there has been an overpayment and take remedial steps within ninety (90) days of such determination (or such additional time as may be agreed to by the payor in writing) to correct the problem, including preventing the deficiency from recurring, and make any appropriate refunds. The notice to the payor shall include:

- a. a statement that the refund is being made pursuant to this ICA;
- b. a description of the circumstances surrounding the overpayment;
- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and

- f. the provider identification number under which the repayment is being made.

If any annual review or monitoring reveals that there may be a material billing deficiency, UPI shall take reasonable steps to determine the extent of the problem, including the amount of overpayments by any Federal health care program. To determine the amount of potential overpayment, UPI shall conduct a special review, as set forth in subsection E.2 below. For the purposes of this Agreement, a “material billing deficiency” shall mean credible evidence of: (i) a substantial overpayment affecting a Federal health care program; or (ii) conduct or policies that constitute violations of Federal health care program statutes, regulations or directives issued by CMMS and/or its agents. UPI shall notify OIG within sixty (60) days of discovering that a material billing deficiency exists.

UPI’s notice to OIG shall include: (i) a detailed description of the material billing deficiency and the amount of overpayment resulting therefrom; (ii) UPI’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. SPECIAL REVIEWS. In the event that a material deficiency has been identified, UPI shall conduct a special review in accordance with the review guidelines as set forth in Attachment B. Upon completion of any special review, UPI shall prepare a report reflecting adherence to the guidelines set forth in Attachment B.

F. CONFIDENTIAL DISCLOSURE

UPI has represented to OIG that it has established a confidential disclosure mechanism through a compliance hotline as a means to enable employees, providers and residents to report instances of noncompliance and/or make inquiries on compliance issues. Pursuant to this ICA, UPI shall maintain this confidential disclosure mechanism, which shall be available to all employees, providers and residents for the purpose of reporting or inquiring on matters of compliance with Federal health care program standards and the obligations in this ICA.

The confidential disclosure mechanism shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous,

confidential communication. Upon receipt of a disclosure, the Compliance Officer shall gather all relevant information from the disclosing individual. UPI shall require the internal inquiry of any disclosure or inquiry that is sufficiently specific so that it: (i) permits a determination of the appropriateness of the practice alleged to be implicated; and (ii) reasonably permits corrective action to be taken and ensures that proper follow-up is conducted. In an effort to address each disclosure and inquiry received UPI 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. UPI shall maintain an internal tracking system to record, and follow up on, all disclosures and inquiries received. UPI shall appropriately publicize the existence of the disclosure mechanism (e.g., by reviewing at the annual training, by notation in monthly Compliance Newsletters, and on UPI's Compliance website).

UPI 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) concerning UPI's billing practices reported as, and found to be, inappropriate. UPI shall also report the results of its internal inquiries and any follow-up activities on such matters.

G. INELIGIBLE PERSONS

1. DEFINITION. For the 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 (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. A "contractor," as used in this subsection, shall mean an individual or entity engaged by UPI 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; provided that this term shall not include any individual or entity employed or engaged by a contractor. However, UPI shall demand assurances from its prospective contractors, or from contractors with which it renews contracts, that such contractors will not utilize any Ineligible Person related to its engagement with UPI.

2. SCREENING REQUIREMENTS. UPI shall not knowingly hire as an employee or engage as a provider or contractor any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, UPI shall screen all prospective employees, providers and 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.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 120 days of the effective date of this ICA, UPI shall review its list of current employees, providers and contractors against the Exclusion Lists. Thereafter, UPI shall review the list every six (6) months. In addition, UPI shall require employees, providers and new contractors or contractors with which UPI renews contracts, to disclose immediately any debarment, exclusion or other event that makes any such individual an Ineligible Person.

If UPI has notice that an employee, provider or contractor has become an Ineligible Person, UPI shall remove such person from responsibility for, or involvement with, UPI’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. For the purposes of this ICA, UPI shall be considered to have “notice” of only verified information that is within the actual current knowledge of any member of the Compliance Committee or which such persons should have known through the exercise of reasonable diligence.

4. PENDING CHARGES AND PROPOSED EXCLUSION. If UPI has notice that an employee, provider 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, UPI shall take all appropriate actions to ensure that the responsibilities of that individual do 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, UPI 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 UPI 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. UPI 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.

IV. 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 UPI's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UPI's locations for the purpose of verifying and evaluating: (a) UPI's compliance with the terms of this ICA; and (b) UPI's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by UPI to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. UPI shall have the right to have representatives present at the time of OIG's onsite examination of documents. Nothing in this section requires UPI to provide OIG or its agents with any legally privileged documents. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UPI'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. UPI agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UPI's employees may elect to be interviewed with or without a representative of UPI present.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. IMPLEMENTATION REPORT

Within one hundred and eighty (180) days after the effective date of this ICA, UPI shall submit a written report to OIG summarizing the status of its implementation of the requirements of this ICA. To the extent the following information has not been provided to OIG, 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 Compliance Officer required by section III.B;
3. a copy of UPI'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 Compliance Officer that, to the best of his or her knowledge and upon reasonable efforts and inquiry, the actions described in sections III.C and III.D.1 of this ICA have taken place;
7. a description of the confidential disclosure mechanisms required by section III.F;
8. a summary of personnel actions taken pursuant to section III.G; and
9. a list of all of UPI's locations at which providers regularly render professional medical services to patients for which UPI bills (including locations and mailing addresses), the corresponding name under which UPI is doing business at each location, the corresponding phone numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. ANNUAL REPORTS

UPI shall submit to OIG Annual Reports with respect to the status of, and findings regarding, UPI's compliance activities for each of the 5 one-year periods beginning on the effective date of the ICA. In accordance with the provisions above, the Annual Reports shall include the following information:

1. in the first Annual Report, copies of the document or documents that comprise UPI's Compliance Program, as adopted by UPI and implemented by the Compliance Committee and the Compliance Officer. For subsequent years, UPI 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 Compliance Officer and/or the positions that comprise the Compliance Committee, as set forth in sections III.A and III.B;
3. copies of any revisions or amendments (including the reason(s) for the change(s)) 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 ICA and a summary of the activities undertaken to implement this program, including schedules, topic outlines of the training sessions, and lists of the participants. Additionally, UPI shall include a certification by the Compliance Officer that the education and training

activities required under this ICA have taken place;

5. a summary of the findings made during the reviews conducted pursuant to section III.E. of this ICA relating to the year covered by the Annual Report; a copy of the report prepared by the Annual Reviewer concerning UPI's performance of the agreed upon procedures; copies of any disclosures or notice documents prepared by UPI pursuant to that section; 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 section III.E;
7. a summary of communications (including the number of disclosures by employees and the dates of disclosure) received through the Confidential Disclosure Program established pursuant to section III.F that alleged possible improper billing in such detail as to allow further inquiry, and the results of all investigations, internal reviews, and any follow up on such disclosures;
8. a written description of any personnel action (other than hiring) and/or any activity carried out by UPI as a result of the requirements in section III.G and the identities of the individuals subjected to such an action or activity; and
9. a summary describing any ongoing investigation, audit or legal proceeding conducted or brought by a governmental entity involving an allegation, made known to UPI by such entity, that UPI has committed a crime or has engaged in fraudulent activities. The statement shall include a description of UPI's understanding of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or requests for information.
10. a description of all changes to the most recently provided list (as updated) of UPI's locations at which providers regularly render professional medical services to patients for which UPI bills (including locations and mailing addresses), the corresponding name under which UPI is doing business at each location, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by OIG no later than May 1, 2003. Subsequent Annual Reports shall be received no later than the anniversary date of the due date of the first Annual Report. Each Annual Report shall cover the complete prior fiscal year.

C. CERTIFICATIONS

The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) to the best of his or her belief and, upon reasonable inquiry, UPI is in compliance with all of the requirements of this ICA; and (2) the 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.

D. DESIGNATION OF INFORMATION

UPI 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 potentially exempt from disclosure under the Freedom of Information of Act ("FOIA"), 5 U.S.C. § 552. UPI shall make a good faith effort to refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this ICA, all notifications and reports required under the terms of this ICA shall be submitted 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: Jerome D. Carr, Compliance Officer
University Physicians, Inc.
419 W. Redwood Street, Suite 220
Baltimore, MD 21201
Ph. 410-328-2678
Fax 410-328-6191

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 the purposes of this requirement,

internal facsimile confirmation sheets do not constitute proof of receipt.

VII. DOCUMENT AND RECORD RETENTION

UPI shall maintain for inspection all documents and records relating to its compliance with the obligations in this ICA, as well as those relating to the reimbursement claims submitted to the Federal health care programs during the term of this ICA for a period of six (6) years following the execution of this ICA (or longer if otherwise required by law).

VIII. BREACH AND DEFAULT

UPI's compliance with the terms and conditions in this ICA shall constitute an element of UPI's present responsibility with regard to participation in the Federal health care programs. Full and timely compliance by UPI shall be expected throughout the duration of this ICA with respect to all of the obligations herein agreed to by UPI.

A. STIPULATED PENALTIES FOR FAILURE TO COMPLY WITH CERTAIN OBLIGATIONS

As a contractual remedy, UPI and OIG hereby agree that failure to comply with certain obligations set forth in this ICA 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 UPI 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 Compliance Officer in the Implementation Report as required under section V.A; and
 - c. Confirmation of the existence of a Compliance Committee in the Implementation Report as required under section V.A.
2. A Stipulated Penalty of \$2,500 for each day UPI fails to comply by having in force during the term of this ICA any of the following, which Stipulated Penalty shall begin to accrue on the date of OIG's notice of noncompliance, in accordance with section VIII.B below:

- a. the Compliance Program adopted pursuant to section III of this ICA;
 - b. the Compliance Committee and the Compliance Officer, discharging their respective duties, as required under sections III.A and III.B of this ICA;
 - c. the training and education activities required under section III.D of this ICA; and
 - d. the Confidential Disclosure requirements under section III.F of this ICA.
3. A Stipulated Penalty of \$1,500 for each day UPI 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 ICA, which Stipulated Penalty shall begin to accrue on the date UPI 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 UPI:
 - 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 programs, and UPI had or should have had notice, as defined in section III.G.3, of such exclusion, debarment or suspension; this Stipulated Penalty shall not be demanded for any time period during which UPI 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, after UPI had notice, as defined in section III.G.3, that such person had become an Ineligible Person and that person: (i) has responsibility for, or involvement with, UPI'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

UPI 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; this Stipulated Penalty shall not be demanded for any period before ten (10) days after UPI's receipt of OIG's notice of noncompliance.

5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date of receipt of OIG's notice of noncompliance in accordance with section VIII.C) for each day UPI fails to comply with any other requirement in this ICA, which is not covered by provisions 1, 2, 3 and 4 of this section VIII.A. In its notice to UPI, OIG shall state the specific grounds for its determination of noncompliance.

B. TIMELY WRITTEN REQUESTS FOR EXTENSIONS. UPI 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, UPI shall not be in default under this ICA and Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after UPI fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, UPI shall not be in default under this ICA and Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until 2 business days after UPI 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 5 business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. PAYMENT OF STIPULATED PENALTIES

Upon finding that UPI has failed to comply with any of the above-enumerated obligations, OIG may choose to demand payment of the Stipulated Penalties above. To effectuate the demand, OIG shall notify UPI in writing of: (i) UPI'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 ICA. This notification is hereinafter referred to as the "Demand Letter."

Within ten (10) days of receipt of the Demand Letter, UPI 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 ICA. UPI's election of the contractual right herein to seek review of OIG's noncompliance determination shall not preclude UPI 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 ICA and shall be grounds for exclusion under section VIII.D, 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 ICA.

Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's determination that UPI has materially breached this ICA, which decision shall be made at OIG's discretion and governed by the provisions in section VIII.D, below.

D. REMEDIES FOR MATERIAL BREACH OF THIS ICA

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

1. demonstrate to OIG's satisfaction that UPI is in full compliance with this ICA;
2. cure the alleged material breach; or
3. demonstrate to OIG's reasonable satisfaction that the alleged material breach cannot be cured within the thirty (30) day period, but that UPI has begun to take action to cure the material breach and that it shall pursue such an action with due diligence. UPI 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 UPI), UPI fails to meet the requirements of provisions 1, 2 or 3 above, OIG may exclude UPI from participation in the

Federal health care programs. OIG shall notify UPI by certified mail of its determination to exclude UPI. 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 ICA shall take effect thirty (30) days following the date of the Exclusion Letter unless, during such a period, UPI 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.E, below. In the event UPI 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 UPI shall have national effect and will also apply to all other federal procurement and non-procurement programs. If UPI is excluded pursuant to this ICA, 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 ICA; (ii) repeated or flagrant violations of the obligations under this ICA, including, but not limited to, the obligations addressed in section VIII.A of this ICA; 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 UPI pursuant to this provision, UPI shall have the right to dispute OIG’s determination in accordance with the agreed-upon provisions set forth in section VIII.E of this ICA.

E. DISPUTE RESOLUTION

Upon OIG’s delivery to UPI 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, UPI 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 HHS administrative law judge and, in the event of an appeal, the HHS’ Departmental Appeals Board (“DAB”), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. UPI and/or OIG may appeal the administrative law judge’s decision to the DAB in a manner consistent with the provisions in the above-referenced regulations. For the 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 twenty-five (25) 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 ICA shall be: (i) whether UPI was in compliance with the obligations of this ICA for which OIG demands payment; (ii) whether UPI 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 UPI; and (iv) the period of noncompliance. For the purposes of paying Stipulated Penalties under this ICA, and if UPI chooses to seek review in lieu of curing the breach and paying the Stipulated Penalties as set forth above, if the administrative law judge agrees with OIG with regard to a finding of a breach of this ICA and orders UPI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the administrative law judge issues such a decision unless UPI requests DAB review of the administrative law judge's decision. If the administrative law judge's decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable twenty (20) days after the DAB issues its decision.

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: (i) whether UPI was in material breach of one or more of its obligations under this ICA 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 UPI and OIG; (iv) whether UPI began to take action to cure the alleged material breach with due diligence; and (v) whether UPI provided OIG a timetable for curing the alleged material breach. For the purposes of the exclusion procedure herein agreed to, in the event of a material breach of this ICA, 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 UPI; provided, however, that UPI may request a DAB review of the administrative law judge's decision.

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 UPI was out of compliance (for Stipulated Penalties) or in material breach (for exclusion) and with respect to the period of noncompliance or material breach. UPI shall bear the burden of going forward and the burden of persuasion with

respect to the issue of whether, during the specified period, UPI 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 UPI in accordance with section VI of this ICA.

IX. PRIVILEGES AND DISCLOSURES

Nothing in this ICA shall constitute or be construed as a waiver by UPI or the CPGs of their attorney-client or other applicable privileges. 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 UPI prior to any release by OIG of information submitted by UPI pursuant to its obligations under this ICA and identified upon submission by UPI as: (i) trade secrets; or (ii) commercial or financial information that is privileged or confidential under applicable FOIA requirements. UPI shall make a good faith effort to refrain from identifying any information as trade secrets, commercial or financial information, or privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

X. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the effective date of this ICA, UPI changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, UPI shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this ICA (e.g., completing certifications and undergoing training). This notification shall not include a location change within the campus area of the University of Maryland Baltimore except for a change in principal place of business.

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 by reference, UPI and OIG agree as follows:

- A. This ICA shall be binding on the successors, assigns and transferees of UPI that assume responsibility for submitting claims to the Federal health care programs for professional medical services rendered to UPI patients by physicians and other health care providers who, for purposes of providing such professional services,

are employed by UPI or who are independent contractors with UPI. This ICA shall also be binding on any entity owned or controlled by UPI that assumes responsibility for billing for professional services rendered by UPI's physician faculty members.

- B.** This ICA shall become final and binding only upon signing by each respective party hereto;
- C.** Any modifications to this ICA may be made only by a writing signed by the parties to this ICA; and
- D.** The undersigned UPI and CPG signatories represent and warrant that they are authorized to execute this ICA on behalf of UPI and the respective CPGs. The undersigned OIG signatory represents that he is signing this ICA in his official capacity and that he is authorized to execute this ICA on behalf of OIG.

ON BEHALF OF UNIVERSITY PHYSICIANS, INC.
AND THE CLINICAL PRACTICE GROUPS

University Physicians, Inc.

By: 

Donald E. Wilson, M.D.
President

12/20/01
DATE

University of Maryland Anesthesiology Associates, P.A.

By: 

12/20/01
DATE

University of Maryland Dermatologists, P.A.

By: 

12/20/01
DATE

University of Maryland Emergency Medicine Associates, P.A.

By: 

12/20/01
DATE

University of Maryland Family Medicine Associates, P.A.

By: 

12/20/01
DATE

University of Maryland Physicians, P.A.

By: 

12/20/01
DATE

University of Maryland Neurology Associates, P.A.

By: 

12/20/01
DATE

University of Maryland Obstetrical & Gynecological Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Eye Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Pathology Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Pediatric Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Psychiatry Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Radiation Oncology Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Diagnostic Imaging Specialists, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Surgical Associates, P.A.

By: Bruce E. Jurek

12/20/01
DATE

University of Maryland Neurosurgery Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Oncology Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Physical Therapy Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Shock Trauma Associates, P.A.

By: [Signature]

12/20/01
DATE

University of Maryland Orthopaedic Associates, P.A.

By: [Signature]

12/20/01
DATE

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

L Morris

LEWIS MORRIS

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

12/21/9
DATE

ATTACHMENT A
UNIVERSITY PHYSICIANS, INC. COMPLIANCE OFFICE

Protocol for Conducting Internal Audits

I. Introduction

Each physician and non-physician provider under whose name bills are submitted through University Physicians Faculty Practice Plan will be audited to assure compliance with all documentation, coding and billing requirements of the Federal health care programs. The audits will be conducted by the staff of the University Physicians, Inc. Compliance Office (“UPCO”). A minimum of six (6) encounters per provider will be audited representing a cross-section of outpatient and inpatient evaluation and management services and, where applicable, surgical procedures. All providers in the Medicare and Surgery Practice Groups shall be audited annually. At least half of the remaining practice groups shall be audited annually (those not audited one year shall be audited the next year).

II. Audit Staff

The individuals conducting the audits will be certified coders (CPC or CCS-P), have clinical backgrounds, (e.g., nurse, physician assistant, etc.) Or have a minimum of three (3) years experience in coding for physician billing. In addition, the work of each auditor will be monitored by the Director of Compliance/Training to assure accuracy and consistency of the audit results.

III. Audit Process

The audit process will be as follows:

- (1) Each Practice Group Administrator will be contacted and a date set to initiate the process. The Administrator will designate a contact person within the Practice Group that will be responsible for accumulating all the information needed for the audit.
- (2) The auditor will request a list of all patients seen by each provider, both inpatient and outpatient, during a specified period of time; usually one month, at least two to three months in the past. By dividing the total number of patients seen during that period by $6(T/10=N)$, and then selecting every Nth encounter, the auditors will randomly select 6 encounters (at least 4 for Federal health care program beneficiaries and at least 1 for non-Federal health care programs), and request the charts reflecting the documentation for each service. The services selected may be adjusted to substitute other randomly selected services in order to obtain an appropriate cross-section of services. The Practice Group will produce the charts for office services as well as a copy of the charge capture document or ledger reflecting the code(s) billed. Inpatient charts will be requested by the UPCO from Medical Records of the Hospital.
- (3) The audit tool that will be used combines the American Medical Association (AMA) and

the Center for Medicare and Medicaid Services (CMMS) 1995 and/or 1997 Documentation Guidelines. The elements that will be addressed include:

- documentation supporting the level of service and type of service being billed;
- documentation reflecting the attending physician's participation in the service;
- surgical unbundling;
- services provided but not billed.

(4) All documentation will be reviewed to determine compliance or non-compliance.

IV. Reporting

Once completed, a summary of the audit results will be distributed to the Chairman of the Practice Group and to the Administration and Compliance Liaisons of the Practice Group. The Chief Compliance Officer and/or the Director of Compliance/Training will meet with each provider individually or as a group to discuss the results of the audit 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 at a minimum, be re-audited in 4 weeks following the session for subsequent dates of service.

If the re-audit reveals that the billing issues have not been addressed, the provider will be referred to the Chief Compliance Officer for further corrective action. All billing for services rendered by the provider will be subject to a pre-billing review, at the provider's expense, until such time that the Chief Compliance Officer is satisfied that the billing, as identified by the provider, is consistently correct.

Any overpayment identified during the audit process will be refunded to the appropriate agency within 60 days of the completion of the audit. If, as a result of the audit, the UPCO identifies a possible material billing deficiency as defined in the Institutional Compliance Agreement, a broader review will be undertaken using the sampling protocol established by the OIG in order to ascertain the extent of the problem and to estimate overpayments attributable to the material billing deficiency. The results of that review will be reported to the OIG consistent with provisions of the Institutional Compliance Agreement.

ATTACHMENT B: SPECIAL REVIEW GUIDELINES

A. BASIC INFORMATION. In documenting the special reviews pursuant to Section III.E. of the Institutional Compliance Agreement, UPI shall provide for the following:

1. 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. Sources of Data: 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. Personnel Qualifications: 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. SAMPLE ELEMENTS. In documenting the selection and use of samples in the special reviews, UPI shall provide for the following:

1. Sampling Unit: A definition of the sampling unit, which is any of the designated elements that comprise the population of interest.
2. Sampling Frame: 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. Sample Size: 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' 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. Sample Design: Unless UPI demonstrates the need to use a different sample design, the review should use simple random sampling. If necessary, UPI 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. Missing Sample Items: An explanation of how missing sample items were handled and the rationale.
8. 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.
9. Estimation Methodology: 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, UPI must use the mean point estimate. The use of RAT-STATS to calculate the estimates is strongly recommended.