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

I. PREAMBLE

The University of Florida College of Medicine, Gainesville Campus (hereinafter referred to as "UOFCOM") hereby enters into this Institutional Compliance Agreement ("ICA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS"). This ICA is intended to ensure compliance by UOFCOM with the billing 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 professional services provided by UOFCOM faculty, physicians, residents and other health care professionals. Contemporaneously with this ICA, the University of Florida ("University") is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement.

For the purposes of this ICA, unless otherwise specified herein, the term "Employee" shall mean: (1) all physician faculty, or ancillary health providers who are: (i) employees of UOFCOM or (ii) leased to UOFCOM pursuant to a contract that provides UOFCOM with responsibility for supervision and control of these ancillary health providers, and for whom reimbursement claims for the delivery of patient care services are submitted through UOFCOM; and (2) all individuals who are: (i) employees of UOFCOM or (ii) leased to UOFCOM pursuant to a contract that provides UOFCOM with responsibility for supervision and control of these individuals, and who are involved in the generation and submission of reimbursement claims for physician services. This ICA also applies to the medical residents and fellows assigned to the UOFCOM clinical departments and acting under the supervision of the UOFCOM faculty at the University of Florida Health Sciences Center in Gainesville, Florida (hereafter referred to as "Residents.") UOFCOM's use of billing agents to handle billing of professional services by some or all of its Employees shall not affect or limit its obligations and responsibilities under this ICA.

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

II. TERM OF THE ICA

The period of the integrity obligations assumed by the University 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 VII, VIII, IX, X and XI shall remain in effect until UOFCOM submits all information required by OIG as part of the final Annual Report.

III. INTEGRITY OBLIGATIONS

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

A. OFFICE OF COMPLIANCE AND COMPLIANCE COMMITTEE

UOFCOM has represented to OIG that, pursuant to the BCP, it has created an Office of Compliance and a Compliance Committee. Accordingly, UOFCOM shall formally maintain an Office of Compliance and a Compliance Committee, which, at a minimum, shall be collectively responsible for compliance with the integrity obligations in this Agreement. As a function of the Office of Compliance, the Compliance Committee shall meet regularly to address billing compliance issues and, at a minimum, shall consist

of: (a) appointed representatives from the Dean's office; (b) the Director of Compliance; (c) the Compliance Leaders of each UOFCOM clinical department; and (d) any appointed representatives of UOFCOM billing entities. The Compliance Committee must be able to make reports to the Dean of the College of Medicine and the President of the University of Florida.

Any changes in the positions that comprise the Compliance Committee must be reported to OIG, in writing, within thirty (30) days of the effective date of the action. Any other matters affecting the membership or responsibilities of the Compliance Committee shall be reported to OIG in accordance with Section V below.

B. COMPLIANCE OFFICER

UOFCOM has represented to OIG that, pursuant to its BCP, it has created and funded a Compliance Officer position (known as the "Compliance Officer") and it has appointed an individual to serve in that capacity. Accordingly, UOFCOM shall formally maintain the appointment of an individual to serve as the Compliance Officer. 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 must have the authority and ability to report directly to the Dean of the College of Medicine and the President of the University of Florida. Any changes in the appointment of the Compliance Officer (including voluntary or involuntary personnel changes) or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this ICA must be reported to OIG, in writing, within thirty (30) days of the effective date of the action. Changes in the position, or material changes in the duties, of the Compliance Officer shall be reported in accordance with Section V below.

C. WRITTEN STANDARDS

1. *Code of Conduct.* UOFCOM has represented to OIG that, pursuant to its BCP, it has established a Code of Conduct that will be maintained for

the duration of this ICA. To the extent not already distributed, the Code of Conduct shall be distributed to all Employees and Residents within 120 days of the effective date of this ICA. Adherence to the Code of Conduct shall be an element in evaluating the performance of all Employees. The Code of Conduct shall, at a minimum, set forth:

a. UOFCOM's commitment to full compliance with the Regulations, including its commitment to prepare and submit accurate claims consistent with such requirements;

b. UOFCOM's requirement that all of its Employees and Residents shall be expected to comply with all Regulations and with UOFCOM's own Policies and Procedures as implemented pursuant to section III.C.2 (including the requirements of this ICA);

c. the requirement that all Employees and Residents shall be expected to report to the Office of Compliance or other individual designated by UOFCOM, suspected violations of any Regulation or of UOFCOM's own Policies and Procedures;

d. the possible consequences to both UOFCOM and Employees and Residents of failure to comply with all Regulations and with UOFCOM's own Policies and Procedures or of failure to report such non-compliance; and

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

Within 120 days of the effective date of the ICA, each Employee and Resident shall certify, in writing, that he or she has received, read, understood, and will abide by UOFCOM's Code of Conduct. New Employees shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming an Employee or within 120 days of the effective date of the ICA, whichever is later. New Residents shall receive the Code of Conduct and shall complete the required certification within six weeks after becoming a Resident or within

90 days of the effective date of the ICA, whichever is later. Copies of the certifications shall be available to OIG, upon request.

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

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

Employees and Residents shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 60 days of the finalization of such revisions.

The provisions of this section III.C.1 shall not apply to Employees or Residents who terminate their relationship with UOFCOM before November 1, 2001.

2. *Policies and Procedures*. UOFCOM has represented to OIG that it has developed, distributed to its Employees and Residents and placed into effect written policies and procedures regarding the operation of its BCP.

At a minimum, the Policies and Procedures shall address:

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

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

c. The final rule of the Centers for Medicare & Medicaid Services ("CMS") (formerly the Health Care Financing Administration) with respect to Medicare billing by teaching physicians and any relevant

memorandum or other correspondence issued by the Medicare Part B carrier;

d. documentation requirements; and

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

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

Within 120 days of the effective date of this ICA, to the extent it has not already done so, UOFCOM shall distribute the relevant portions of the Policies and Procedures to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), UOFCOM shall assess and update as necessary the Policies and Procedures. Within 60 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.

D. TRAINING AND EDUCATION

1. *General Training*. Within 120 days of the effective date of this ICA, UOFCOM shall provide general training to each Employee and Resident. This training shall explain UOFCOM's:

a. ICA requirements; and

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

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

New Employees shall receive the general training described above within 30 days of becoming an Employee or within 120 days after the effective date of this ICA, whichever is later. New Residents shall receive the general training within 90 days after the commencement of their residency.

After receiving the initial general training described above, each Employee and Resident shall receive general training annually.

2. *Specific Training*. Within 120 days of the effective date of this ICA, UOFCOM shall provide each Employee responsible for generating, preparing and/or submitting claims for reimbursement from the Federal health care programs for professional services (a "Relevant Employee") with more intensive training, in addition to the general training required above. This training shall include a discussion of:

a. the submission of accurate claims for reimbursement for services rendered to Federal health care program patients;

b. policies, procedures and other requirements applicable to the documentation of medical records;

c. the personal obligation of each individual to ensure that the information documented by the individual, whether relating to actual patient care, the type of services or items delivered, or the coding of such services or items is accurate and meets the federal and state requirements for the Federal health care programs, as well as UOFCOM's policies;

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

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

f. relevant examples of proper and improper billing practices.

All training materials shall be made available to OIG upon request. Persons providing the training must be knowledgeable about the subject area. New Relevant Employees shall receive this training within 30 days of the beginning of their employment or becoming a Relevant Employee or within 120 days of the effective date of this ICA, whichever is later. An employee who has completed the specific training shall conduct reviews of the new Relevant Employee's work, to the extent the work relates to the preparation or submission of claims for reimbursement from any Federal

health care program, until such time as the new Relevant Employee completes applicable training.

3. *Resident Billing Training.* UOFCOM recognizes the importance of educating physician trainees concerning billing requirements and the importance of compliance. To further that objective, UOFCOM will include Residents in the Specific Training described in this Section III.D.2. Residents will not be treated as new employees for purposes of the Specific Training requirement of this ICA, but they will be required to attend specific training during each year of their residency. Residents will be instructed to include their attendance at compliance training sessions in their logs of activities.

4. *Certification.* UOFCOM shall maintain documents that reflect attendance at both general and specific training sessions by Employees and Residents, and the topics covered. UOFCOM may choose the exact format of these documents, but the materials must include sheets with the signatures of the persons who attended or other reliable means (including electronic means) of verifying attendance and participation. UOFCOM shall maintain information concerning the format, dates, length of each training session, and copies of the materials provided. The Compliance Officer shall retain the attendance logs as well as the course materials. All of these documents shall be available to OIG upon request.

For purposes of meeting the obligations under this subsection III.D, for the term of the first Annual Report under this ICA, OIG shall credit UOFCOM's training and education activities carried out pursuant to the BCP on or after July 1, 2000, to the extent such training satisfies the requirements set forth above.

5. *Departing Persons.* The provisions of this subsection III.D shall not apply to Employees who terminate their relationship with UOFCOM prior to November 1, 2001 and Residents who terminate their relationship with UOFCOM prior to November 1, 2001.

E. ANNUAL REVIEWS OF BILLING POLICIES, PROCEDURES AND PRACTICES

1. *Internal Review.* UOFCOM has developed a protocol, attached hereto as Attachment 1, for reviewing, on an annual basis, a sample of claims for professional services rendered by Employees (the "Internal Review"). An objective of the Internal Review process is to verify compliance with the Regulations. Implementation of the agreed-upon procedures set forth in the protocol shall be a required element of this Agreement. The calendar year period covered by each Internal Review shall be referred to as the "Review Year."

2. *External Review.* For the calendar year ending December 31, 2001 and annually thereafter, UOFCOM shall contract with an independent review organization (the "IRO") with expertise in the reimbursement requirements of the Federal health care programs to verify whether UOFCOM is implementing the agreed-upon procedures set forth in Attachment 1 (the "External Review"). The IRO shall issue a report concerning its work, including its findings, conclusions and recommendations. The calendar year period covered by each External Review shall also be referred to as the "Review Year."

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

   If any of the Internal or External Reviews uncover Overpayments, UOFCOM shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare Part B carrier, the Agency for Health Care Administration of the State of Florida or similar Federal health care program payors) within 60 days of verifying the overpayment and take remedial steps within 90 days of verifying the overpayment (or such additional time as may be agreed to by the payor in writing) to correct the problem, including preventing the deficiency from reoccurring, calculate the amount of the 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 UOFCOM's basis for the overpayment; (iii) the methodology by which the overpayment was determined; (iv) the amount of 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 payments); and (vi) the provider billing number under which the refund is being made.

4. *Reporting of Material Deficiencies.* For purposes of this Agreement, a "Material Billing Deficiency" means anything that involves:

   (i) a substantial overpayment received from a Federal health care program; or

   (ii) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

If any of the Internal or External Audits or any other event reveal that a Material Billing Deficiency has occurred, UOFCOM shall take remedial steps within 60 days of the deficiency determination and conduct a special review in accordance with the guidelines set forth in Attachment 2 within 90 days in order to ascertain the extent of the deficiency, correct the cause of the deficiency, and implement safeguards to prevent the deficiency from reoccurring (the "Review Period"). Any overpayment identified during the Review Period will be refunded to the appropriate agency within 30 days of the end of the Review Period.

UOFCOM shall notify OIG within 120 days of determining that a Material Billing Deficiency exists. UOFCOM's notice to OIG shall include: (i) a detailed description of the Material Billing Deficiency and the amount of any overpayment resulting therefrom; (ii)

UOFCOM's actions and /or plans to correct the deficiency and prevent reoccurrences; (iii) the name of the third-party payor (e.g. Medicare Part B carrier) to whom any refunds relating to the matter have been or will be 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 any refunds have been made; and (v) a report on the calculation of any overpayment amounts. To the extent UOFCOM has not completed its corrective actions and/or made any refund payments at the time of a notice pursuant to this subsection, it shall notify OIG in writing once such corrective actions are undertaken and/or any refunds are paid.

F. CONFIDENTIAL DISCLOSURE PROGRAM

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

UOFCOM shall publicize the existence of the confidential disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas). The confidential disclosure program shall emphasize a non-retribution, non-retaliation policy.

UOFCOM shall conduct an internal inquiry of any disclosure provided whereby such disclosure is sufficiently specific so that it: (i) reasonably permits a determination of the appropriateness of the practice alleged to be implicated; and (ii) reasonably permits corrective action including but not limited to repayment of an identified overpayment, to be taken and ensure that proper follow-up is conducted. In an effort to address each disclosure received, UOFCOM shall, in good faith, make a preliminary inquiry for every disclosure to ensure it has obtained all of the necessary information that is reasonably required to determine whether an internal

inquiry, in accordance with the language above, should be conducted. UOFCOM shall maintain an internal tracking system to record all disclosures received and all follow-up conducted.

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

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

G. INELIGIBLE PERSONS

1. *Definition*. For purposes of this ICA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, and has not been reinstated in the Federal health care programs after a period of exclusion, debarment or ineligibility. The term "contractor," as used by this subsection, shall mean an individual or entity engaged by UOFCOM 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, UOFCOM 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 UOFCOM.

2. *Screening Requirements*. UOFCOM shall not knowingly hire or engage as contractors any Ineligible Person. To prevent hiring or

contracting with any Ineligible Person, UOFCOM shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 120 days of the effective date of this ICA, UOFCOM shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, UOFCOM shall review the list semi-annually. In addition, UOFCOM shall require employees and new contractors (or contractors whose contracts are being renewed) to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person. If UOFCOM has notice that an employee or contractor has become an Ineligible Person, UOFCOM shall remove such person from responsibility for, or involvement with, UOFCOM'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, UOFCOM 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 Exclusions.* If UOFCOM has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, UOFCOM shall take all appropriate actions to ensure that the responsibilities of that employee or contractor 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, UOFCOM 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 UOFCOM has committed a crime or has engaged in fraudulent activities involving health care programs. 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. UOFCOM 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. IMPLEMENTATION AND ANNUAL REPORTS

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

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

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

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

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

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

6. a certification by the Compliance Officer that:

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

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

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

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

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

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

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

10. a list of all of UOFCOM Federal health care programs' provider identification number(s) and the contractor's name and address that issued each provider identification number.

B. Annual Reports. UOFCOM shall submit to OIG Annual Reports with respect to the status of and findings regarding UOFCOM's compliance activities for each of the five Reporting Periods and corresponding Review Years set forth below.

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:

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

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

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

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

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

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

5. a summary of the findings made during the reviews conducted pursuant to Section III.E of this ICA relating to the Review Period covered by the Annual Report; copies of any disclosures or notices prepared by UOFCOM pursuant to that section; a copy of any special review reports; and a description of the corrective steps and proof of refund to the pertinent payor (where applicable);

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

7. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid, (report each applicable state separately), and other Federal health care programs;

8. a summary of the disclosures in the confidential disclosure log required by section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

9. a description of any personnel actions (other than hiring) taken by UOFCOM as a result of the obligations in section III.G, and the name, title, and responsibilities of any person that falls within the ambit of section III.G.4, and the actions taken in response to the obligations set forth in that section;

10. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding; and

11. a list of any new UOFCOM Federal health care programs' provider identification number(s), and the contractor name and address that issued each provider identification number.

The following represents the scope of the Review Years, Reporting Periods, and the due dates of the Annual Reports:

Review Year	Reporting Period	Annual Report Due
January 1, 2001 to December 31, 2001	July 1, 2001 – December 31, 2001	April 1, 2002
January 1, 2002 to December 31, 2002	January 1, 2002 – December 31, 2002	April 1, 2003
January 1, 2003 to December 31, 2003	January 1, 2003 – December 31, 2003	April 1, 2004
January 1, 2004 to December 31, 2004	January 1, 2004 – December 31, 2004	April 1, 2005
January 1, 2005 to December 31, 2005	January 1, 2005 – June 30, 2006	October 1, 2006

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, UOFCOM is in compliance with all of the requirements of this ICA, to the best of his or her knowledge; and (2) the Compliance Officer has

reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: UOFCOM shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. UOFCOM shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

UOFCOM:

Pamela J. Bernard, Esq.
General Counsel
University of Florida
123 Tigert Hall
P.O. Box 113125
Gainesville, Florida 32611-3125
Phone 352.392.1358
Fax 352.392.4387

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

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

Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UOFCOM's Employees or Residents 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. The University agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Employees or Residents shall have the right to request the presence of a University representative during such interviews.

VII. DOCUMENT AND RECORD RETENTION

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

VIII. DISCLOSURES AND PRIVILEGES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify UOFCOM prior to any release by OIG of

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

IX. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the University and OIG hereby agree that failure to comply with certain obligations set forth in this ICA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UOFCOM fails to have in place any of the following:

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

b. Compliance Officer as described by section III.B.;

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

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

e. a program for training Employees and Residents as described in section III.D; and

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

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UOFCOM fails to retain an IRO, as required in section III.E.

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

4. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day UOFCOM employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, UOFCOM's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which UOFCOM can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

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

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

B. Timely Written Requests for Extensions. UOFCOM may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this ICA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after the UOFCOM fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the

notification or report shall not begin to accrue until two business days after the UOFCOM receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

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

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, the University shall either: (a) demonstrate to OIG's satisfaction that no breach has occurred; (b) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (c) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section IX.E. Failure to respond to the Demand Letter in one of these three manners within the allowed time period shall be considered a material breach of this ICA and shall be grounds for exclusion under section IX.D. In the event the University elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UOFCOM cures, to OIG's satisfaction, the alleged breach in dispute.

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

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

D. Exclusion for Material Breach of this ICA

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

a. a failure by the UOFCOM to report a Material Billing Deficiency, take corrective action and make the appropriate refunds, as required in section III.E;

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

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

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

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

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

a. there is no material breach of this ICA;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, the UOFCOM fails to satisfy the requirements of section IX.D.3, OIG may exclude the

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

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to UOFCOM 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, UOFCOM shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this ICA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this ICA shall be (a) whether UOFCOM was in full and timely compliance with the obligations of this ICA for which OIG demands payment; (b) the period of noncompliance and (c) with respect to a Stipulated Penalty authorized under section X.A.6 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) UOFCOM had begun to take action to cure the failure to comply, (ii) UOFCOM was and is pursuing such action with due diligence, and (iii) UOFCOM had provided to OIG a reasonable timetable for curing the material breach which is being followed. UOFCOM shall have the burden of proving that stipulated penalties should not be imposed or that there was no material breach and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this ICA and orders the University to pay Stipulated Penalties, such Stipulated Penalties shall become due and

payable 20 days after the ALJ issues such a decision unless the University requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

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

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

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

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

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

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This ICA shall be binding on the successors, assigns and transferees of UOFCOM that assume responsibility for submitting claims to the Federal health care programs for professional medical services rendered to UOFCOM patients by physicians and other health care providers who, for purposes of providing such professional services, are employed by UOFCOM or who are independent contractors with UOFCOM. This ICA shall also be binding on any entity owned or controlled by UOFCOM that assumes responsibility for billing for professional services rendered by UOFCOM's physician faculty members;

B. This ICA shall become final and binding on the date the final signature is obtained on the ICA;

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

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

ON BEHALF OF THE UNIVERSITY OF FLORIDA

CHARLES E. YOUNG
President

7/26/01
DATE

KENNETH I. BERNS, M.D., Ph.D.
Vice President for Health Affairs
Dean, College of Medicine

7/26/01
DATE

ROBERT C. NEWMAN, M.D.
Director of Compliance , College of Medicine

7/25/01
DATE

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

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

7/27/01
DATE

ATTACHMENT 1
Review Guidelines

I. Policy

The University of Florida College of Medicine will utilize reliable and effective methods to monitor and review clinical documentation in an effort to verify the accuracy of reimbursement claims. The Office of Compliance compiles the outcomes of billing and documentation reviews. Based on the results of these reviews, corrective action may be initiated, including, where appropriate, mandatory education on specific documentation deficiencies and, in all instances, repayment of any identified overpayments and refunds for services that lack sufficient documentation to support reimbursement claim submissions or are otherwise non-reimbursable. The repayment of any overpayments or other refunds will be made in accordance with the provisions of Section III.E. of the Institutional Compliance Agreement.

II. Procedures for Conducting Chart Reviews

A. Introduction

The Office of Compliance, under the direction of the Director of Compliance, shall review billing and reimbursement support documentation and medical record documentation of all physician faculty or ancillary health providers (the "Provider") to ensure compliance with the billing requirements of the Federal health care programs (the "Review"). The Review shall be designed and implemented so as to maximize the effectiveness of the Review and minimize the risk of undetected billing errors. At present, the Review consists of a minimum of 12 encounters per provider over a 24 month period representing outpatient, inpatient and surgical billing, - appropriate to the Provider's practice and as detailed below.

B. Review Schedule

The Office of Compliance will prepare a work plan outlining the order in which the Reviews will be conducted along with the scheduled completion dates. The work plan shall be reviewed and approved by the Director of Compliance who will guide the routine Review process.

C. Sample Selection Process

1. Data sources for selection of encounters to be included in the Review include accounts receivable, billing software for the Group Practice and/or any other billing services used by Providers.

2. Selection of the encounters to be included in the Review will be taken from the total pool of services billed to Federal health care programs for bills exceeding one dollar ($1) for professional services rendered during the relevant Review period.

3. The encounters will be selected to target representative aspects of the individual Provider's practice, as well as the inclusion of other encounters for the purpose of making the overall sample selection more complete and effective. Selection may include inpatient, outpatient and surgical procedures as is pertinent to the segment selected for audit.

   i. In order to ensure that the Review is completed and to measure performance by specific clinical units, the Review will be conducted in units of clinical divisions within each Department. The Review and the corresponding reporting will be completed on a unit basis. Smaller departments without division will be completed as a unit.

   ii. The Review will be conducted to target specific areas of billing by risk or Review effectiveness. The selection of the review sample is not random, but rather judgmental, based on several factors including a review of billing records.

   iii. In order to determine the Review sample, the Office of Compliance shall query the appropriate billing database to review specific categories of billing as they may pertain to the specific Provider's practice areas. This process shall assist in identifying the subset of encounters or procedures from which the Review sample shall be selected. For example, billing for certain departments may have a higher percentage of surgical procedures than clinical visits, while other departments may have more clinical visits selected.

   iv. The selection process shall be guided by current directives applicable to billing the Federal healthcare programs, including but not limited to the OIG Work Plan, changes in CPT and ICD-9 coding and HCFA correct coding initiatives. In addition, a significant factor in the selection of the Review

sample shall be any previous recommendations or findings from the Review process for the individual provider or within the provider's division.

v. The Review sample is selected without the knowledge of the Departments or the physicians.

III. Review Procedure

Claims for E&M services will be reviewed using specific audit tools for the scoring of E&M services. Claims for both E&M and non-E&M services will be reviewed based upon the standard accepted principles for coding based on CPT and ICD-9 guidelines. Medicare claims for both E&M and non-E&M services will be reviewed based on the documentation criteria for teaching physicians as outlined in the applicable Medicare Documentation Guidelines for Teaching Physicians. Copies of these audit tools shall be available to OIG upon request

IV. Follow-Up and Corrective Action Plan

A. Evaluation of Review Results

The Office of Compliance shall evaluate the Review results to determine whether the Provider's documentation is acceptable or whether follow-up education of the Provider is necessary.

B. Notice to Providers

The Office of Compliance will provide written notification to each Provider of the results of the Review. Notification also shall be provided to the appropriate Chair (or designee). Each Provider will be given the opportunity to provide additional documentation for further consideration by the Office of Compliance, which materials will be included in the Review work papers.

C. Refunds

When results of the Review reveal that any bills have been submitted in error, the Office of Compliance will promptly notify the billing department so that a refund can be processed.

D. Follow-up Review

1. In the event that any Review reveals billing or coding deficiencies that require additional analysis, the Office of Compliance will notify the Departmental Chair (or designee) and the involved Provider. A

more focused review of billing for the involved Provider will be completed under the direction of the Office of Compliance.

2. When results of any Follow-up Review reveal that any bills have been submitted in error, the Office of Compliance will promptly notify the billing department so that a refund can be processed.

3. In the event that any Follow-up Review identifies a Material Billing Deficiency (as defined in Section III.E.2 of the Institutional Compliance Agreement) the Office of Compliance shall conduct a special review in accordance with the provisions set forth in Attachment 2 (Special Review Guidelines) of the Institutional Compliance Agreement.

E. Corrective Action

When compliance issues are identified with respect to Providers, the Department Chair, in consultation with the Director of Compliance, is responsible for imposing the appropriate remedies and sanctions pursuant to University rules. The University's existing remedial and disciplinary mechanisms for violations of billing compliance policies and procedures include letters of counseling, letters of reprimand, suspension without pay and termination.

F. Education

When compliance issues are identified with respect to Providers, the Office of Compliance shall be responsible for arranging the appropriate mandatory education that will focus on these specific issues. Providers who require such mandatory follow-up education shall receive written notification of this requirement from the Office of Compliance.

G. Internal Reliability Validation

In order to ensure accuracy in the Review process, and as part of the Review process, the Office of Compliance has established an internal control structure that provides for systematic supervisory review of each auditor's non-compliant Review findings and for periodic confirmation of each auditor's compliant Review findings.

H. Reports

The Office of Compliance will oversee the Review process and will prepare a full and timely report detailing the results of the Reviews to be provided to the Director of Compliance. The Office of Compliance will maintain a

detailed and summary record of Review outcomes by provider, division and Department.

ATTACHMENT 2
Special Review Guidelines

I. Basic Information

A special review pursuant to Section III.E of the Institutional Compliance Agreement (ICA") shall consist of a review of either: (1) all the claims affected by the Material Billing Deficiency, or (2) a statistically valid sample of the claims that can be projected to the population of claims affected by the Material Billing Deficiency for the relevant period. In documenting the special reviews pursuant to Section III.E of the ICA, UOFCOM shall provide for the following:

A. Review Objective

A statement clearly articulating the objective of the review and the review procedure or combination of procedures applied to achieve the objective.

B. Review Population

A statement identifying the population (i.e., 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.

C. 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 source of payment data and the documents that will be relied upon (e.g., employment contracts, compensation packages or formulae).

D. 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.

II. Sample Elements

In documenting the selection and use of samples in the special reviews, UOFCOM shall provide for the following:

A. Sampling Unit

A definition of the sampling unit, which is any of the designated elements that comprise the population of interest.

B. Sampling Frame

Identification of the sampling frame, which is the totality of the sampling unit from which the sample will be selected. In addition, the plan should document how the review population differs from the sampling frame and what effects this difference has on conclusions reached as a result of this review.

C. 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.

D. Random Numbers

Written assurance that all probe samples and full samples used were selected through random numbers. The source of the random numbers used must be described. For this task, OIG 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.

E. Sample Design

Unless UOFCOM demonstrates the need to use a different sample design, the review should use simple random sampling. If necessitated, UOFCOM may use stratified or multistage sampling. Details about the strata and clusters should be included.

F. 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.

G. Missing Sample Items

An explanation of how missing sample items were handled and the rationale.

H. 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.

I. 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 unless UOFCOM demonstrates the need to use a different methodology. To estimate the amount implicated in the matter discovered, UOFCOM must use the mean point estimate, unless UOFCOM demonstrates the need to use a different methodology. The statistical estimates must be reported using the mean point estimate. The use of RAT-STATS to calculate the estimates is recommended.