

**CORPORATE COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE UNIVERSITY OF VIRGINIA MEDICAL CENTER**

I. PREAMBLE

The University of Virginia Medical Center (“UVA”) hereby enters into this Corporate Compliance Agreement (“CCA” or “Agreement”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to ensure compliance with the reimbursement requirements of Medicare, Medicaid and all other Federal Health Care Programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal Health Care Programs requirements”). Contemporaneously with this CCA, UVA is entering into a Release and Settlement Agreement with the United States, and this CCA is incorporated by reference into the Release and Settlement Agreement.

The scope of this CCA shall be governed by the following definitions and shall apply to the following individuals:

1. “Covered Persons”: includes all a) officers; b) Members of the Health Affairs Committee of the Board of Visitors; c) managers; d) administrators; and e) employees (including staff physicians of UVA and physicians who are voluntary members of the active medical staff and who have admitting privileges) of UVA; and

2. “Covered Contractors”: includes all contractors, agents, and other third parties engaged to bill/submit reimbursement claims, and all other individuals responsible for the provision, or documentation of items or services provided to beneficiaries reimbursable by Federal Health Care Programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services.

3. “Temporary Staff”: includes any staff retained to work at UVA on a contractual basis or otherwise for 100 hours or less out of any consecutive 52 week period during the term of this CCA. Temporary staff who work greater than 100 hours are required to

fulfill all obligations required of Covered Persons unless such persons are engaged to bill/submit reimbursement claims, or are responsible for the provision or documentation of items or services provided to beneficiaries reimbursable by Federal Health Care Programs, then such persons are required to fulfill all obligations required of Covered Contractors.

Prior to the execution of this CCA, UVA represents that it has voluntarily appointed a Corporate Compliance Officer (hereinafter the "Compliance Officer"), established a compliance committee known as "The University of Virginia Health System Corporate Compliance Steering Committee" (hereinafter the "Steering Committee"), implemented a Compliance Code of Conduct (hereinafter the "Code of Conduct") and established certain policies, procedures and disciplinary guidelines as part of its efforts to comply with all applicable local, state and federal laws. In furtherance of those efforts, UVA represents that its Board of Visitors ("BOV") has established a committee (the "BOV Audit Committee") that oversees compliance activities and that UVA has developed a compliance program that provides policies, procedures and training aimed at ensuring compliance with all applicable laws (the "Compliance Program"). Pursuant to this CCA, UVA agrees to maintain the full operation of its Compliance Program as it relates to the submission of claims to the Federal Health Care Programs for services for the term of this CCA as well as the aforementioned committees, codes, policies and individual appointments in accordance with this CCA. The Compliance Program may be modified by UVA as appropriate, but at a minimum, shall comply with the integrity obligations contained in this Agreement.

II. TERM OF THE CCA

The period of the compliance obligations assumed by UVA under this CCA shall be three (3) years from the Effective Date of this CCA. The Effective Date of this CCA shall be the date on which the final signatory of this CCA executes this CCA ("Effective Date").

8/11/01

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

III. INTEGRITY OBLIGATIONS

Pursuant to this CCA, and for its duration, UVA will maintain or make the following integrity obligations features of its Compliance Program, in accordance with the provisions below:

A. Board of Visitors Audit Committee.

UVA has represented to OIG that its Board of Visitors (“BOV”) have established an Audit Committee one of whose functions is to oversee UVA’s compliance activities on behalf of the BOV. Accordingly, UVA hereby agrees to maintain the BOV Audit Committee which will maintain and continue its compliance oversight duties on behalf of the BOV.

B. Steering Committee.

UVA has represented to OIG that it has previously established a Steering Committee to guide the development and implementation of a Compliance Program for the UVA Medical Center consistent with UVA’s values, mission and the guidelines of the OIG. Pursuant to this Agreement, UVA agrees to charge the Steering Committee with oversight and advisory responsibility for ensuring compliance with the integrity obligations in this Agreement. Accordingly, UVA hereby agrees to maintain the Steering Committee (or in the event that such committee ceases to exist, to create a committee) with overall responsibility for its Compliance Program. UVA shall ensure that the Steering Committee is continuously composed of representatives of UVA’s clinical departments, compliance department, and any other members of UVA’s senior management necessary to meet the requirements of this CCA (e.g., senior executives from each major functions, such as billing, clinical, human resources, and operations). One or more representatives from the Health Services Foundation (“HSF”) shall be invited to participate in UVA’s Steering Committee meetings when coordination of UVA’s and HSF’s compliance activities is necessary or as otherwise appropriate. All members of the Steering Committee shall be voting members. At a minimum, the Steering Committee shall receive periodic (at least quarterly) reports from the Compliance Officer on the compliance activities of UVA and on compliance with the integrity obligations in this Agreement. Further, all Steering Committee recommendations shall be included in the Compliance Officer’s quarterly reports to the UVA BOV Audit Committee.

Any material changes in the composition of the Steering Committee, or any actions or changes that would affect the Steering Committee's ability to perform the duties necessary to meet the obligations in this CCA, must be reported to OIG, in writing, within forty five (45) days of the effective date of such action or change. Any other matters affecting the membership or responsibilities of the Steering Committee shall be reported to the OIG in accordance with Section V below.

C. Compliance Officer.

UVA has represented to OIG that it has established a Compliance Officer position and that it has appointed an individual to serve in that capacity. Accordingly, UVA 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 of UVA and with overall responsibility for the obligations in this CCA. The Compliance Officer shall be a member of the senior management of UVA, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Steering Committee, the Executive Vice President & Chief Operating Officer (the "EVP&CEO") and to the BOV Audit Committee, and shall be authorized to report on any compliance related matters to the BOV at any time.

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 CCA, must be reported to OIG, in writing, within forty five (45) days of the effective date of such action or change. Changes in the position, or material changes in the duties, of the Compliance Officer shall be reported in accordance with Section V below. In the event that the Compliance Officer is no longer employed at UVA for any reason or has an extended absence, UVA may appoint an interim Compliance Officer while seeking to hire a new Compliance Officer.

D. Written Standards.

1. *Code of Conduct.* UVA has represented to the OIG that it has voluntarily developed and distributed a Code of Conduct that requires its Covered Persons to certify in writing that they have received, read, and received training on the Code of Conduct. UVA shall maintain its existing Code of Conduct and shall incorporate

the minimum requirements set forth below, if necessary, in all future distributions of its Code of Conduct for the duration of this Agreement consistent with section III.D.1.b, below.

- a. *Contents.* At all times, the Code of Conduct shall, at a minimum set forth:
 - i) UVA's commitment to full compliance with all Federal Health Care Program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
 - ii) UVA's requirement that all of its Covered Persons shall be expected to comply with UVA's policies and procedures, with the requirements of this CCA, and with all Federal Health Care Program requirements;
 - iii) the requirement that all of UVA's Covered Persons shall be expected to report to the Compliance Officer (or his/her designee), suspected violations of any Federal Health Care Program requirements or of UVA's own policies and procedures either by reporting such violations directly to the Compliance Officer (or his/her designee) or through the Confidential Disclosure Mechanism implemented pursuant to this Agreement;
 - iv) the possible consequences to both UVA and Covered Persons for failing to comply with all of UVA's policies and procedures, with the requirements of this CCA, and with all Federal Health Care Program requirements or of failure to report such non-compliance; and the Code of Conduct will inform employees that violations will subject the employee to sanctions up to termination of employment; and
 - v) the right of all individuals to use UVA's confidential disclosure mechanisms, and UVA's commitment to maintain confidentiality, and non-retaliation policy with respect to disclosures.

b. *Distribution and Certification.* Within 120 days of the Effective Date, for all Covered Persons who have received UVA's existing Code of Conduct prior to 30 days after the Effective Date, UVA shall send notice that it expects all Covered Persons to understand and abide by the minimum requirements set forth above and with its Code of Conduct. All other Covered Persons who receive the Code of Conduct 30 days after the Effective Date or later shall certify in writing that they have received, read, understood and will abide by UVA's Code of Conduct that incorporates the minimum requirements set forth above. New Covered Persons shall receive the Code of Conduct within thirty (30) days of the commencement of their employment or relationship with UVA and shall complete the required certification within sixty (60) days of the commencement of their employment or relationship with UVA or within one hundred twenty (120) days of the Effective Date of the CCA, whichever is later. Notwithstanding the foregoing, UVA shall have 180 days from the Effective Date to distribute the Code of Conduct and obtain required certifications from all members of UVA's active medical staff. UVA shall maintain a written summary of the actions taken to distribute the Code of Conduct to all Covered Persons and such summaries shall be produced to OIG upon request. For purposes of this CCA, OIG may request access to, or copies of, any underlying documents summarized by UVA.

UVA 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 thirty (30) days of finalizing such changes. Covered Persons shall certify that they have received, read, received training on and understood the revised Code of Conduct within sixty (60) days of the finalization of such revisions. UVA shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons.

c. *Covered Contractor Requirements.* For each of its Covered Contractors, UVA shall: i) require in its contract that the Covered Contractor acknowledge UVA's Compliance Program and Code of Conduct; ii) obtain from each Covered Contractor within sixty (60) days of becoming a Covered Contractor written certification that the Covered Contractor has received, read, received training on and understands that UVA's Compliance Program and Code of Conduct applies to the Covered Contractor; and iii) for any Covered Contractor with whom UVA has an existing contract, UVA shall in good faith seek to reform the contract to require the Covered Contractor to acknowledge the Compliance Program and Code of Conduct, and obtain from each Covered Contractor written certification that the Covered Contractor has received, read, received training on

and understood that UVA's Compliance Program and Code of Conduct applies to the Covered Contractor. UVA shall ensure that the Code of Conduct is provided to all of its Covered Contractors whether or not they have pre-existing contracts.

2. *Policies and Procedures.* Within ninety (90) days of the Effective Date of this CCA, and to the extent such policies and procedures have not already been implemented, UVA shall implement, written policies and procedures regarding the operation of UVA's Compliance Program and its compliance with Federal Health Care Program requirements. At a minimum, the policies and procedures shall address: (1) the need for compliance in connection with all submissions for claims to Federal Health Care Programs; (2) the documentation requirements of the Federal Health Care Programs; (3) a process for reasonable verification of compliance with these requirements; and (4) create a written policy governing the creation and submission of UVA's cost reports (or equivalent reporting mechanisms) to the Federal Health Care Programs that includes:

- i.) Guidelines for UVA's staff to enable them to properly identify allowable and unallowable costs; and
- ii.) Internal policies and Health Care Financing Administration ("HCFA") guidance regarding the characterization of its clinics as "provider-based."

For the duration of this Agreement, UVA shall maintain its Compliance Auditing & Monitoring Program, Coding Compliance Plan and Internal Audit policy and controls. Additionally, to the extent not already implemented, within one hundred fifty (150) days of the Effective Date of this CCA, UVA shall implement policies and procedures that include disciplinary guidelines for failure to adhere to the Federal Health Care Program requirements, the Code of Conduct, UVA's policies and procedures, and the requirements of this CCA. UVA shall also formally adopt and implement a written policy for identifying Ineligible Persons as required and described in Section III.J herein. Further, UVA shall formally adopt and implement written policies and procedures that outline UVA's billing policies and procedures for both inpatients and outpatients (collectively, hereinafter the "Policies and Procedures").

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

Within one hundred fifty (150) days of the Effective Date of the CCA, the relevant portions of the Policies and Procedures shall be communicated to all individuals

(including Covered Persons and Covered Contractors) whose job functions are related to those Policies and Procedures and UVA shall take reasonable measures to ensure that these Policies and Procedures are understood by such individuals. Appropriate and knowledgeable staff shall be identified and made available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), UVA shall assess and update as necessary the Policies and Procedures. Within sixty (60) days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be communicated to all individuals whose job functions are related to those Policies and Procedures.

E. Training and Education.

1. *General Training.* Within one hundred twenty (120) days of the Effective Date of this CCA, UVA shall provide appropriate general training sufficient to satisfy the requirements of this CCA to each Covered Person and Covered Contractor. This training shall explain UVA's:

- a. CCA requirements, including the possible consequences to UVA for failing to comply with the terms of the CCA and with all applicable statutes and regulations, including the Federal Health Care Program requirements; and
- b. Compliance Program (including the Code of Conduct and Policies and Procedures).

The training materials (including attendance logs) shall be maintained by UVA and made available to OIG, upon request. New Covered Persons and new Covered Contractors shall receive the general training described above within sixty (60) days of becoming a Covered Person or Covered Contractor or within one hundred twenty (120) days after the Effective Date of this CCA, whichever is later. Notwithstanding the foregoing, UVA shall have 180 days from the Effective Date to provide appropriate general training and obtain required certifications from all members of UVA's active medical staff. After receiving the initial training described above, each Covered Person and Covered Contractor shall receive at least one hour of General Training annually.

2. *Specific Training.* Within one hundred twenty (120) days of the Effective Date of this CCA, each Covered Person or Covered Contractor who is involved in the preparation or submission claims for reimbursement (including but not limited to the preparation or submission of cost reports (or their equivalent)) from any Federal Health Care Program (hereinafter referred to as “Relevant Covered Persons” and “Relevant Covered Contractor”) shall receive more intensive training in addition to the General Training required above. This Specific Training, at a minimum, shall include a discussion of:

- a. the submission of accurate bills 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 involved in the billing process to ensure that such billings and cost reports (or their equivalent) are accurate;
- d. the reimbursement rules, regulations, statutes and program requirements applicable to UVA’s Federal Health Care Program business, including an explanation and discussion regarding UVA’s cost report submissions, its hospital-based clinics and physician-based practices, if applicable, and of the proper use of site of service billing codes, if applicable;
- 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.

All training materials shall be made available to OIG, upon request. Persons providing both the General and Specific Training must be knowledgeable about the subject area.

Relevant Covered Persons and Relevant Covered Contractors shall receive this training within sixty (60) days of the beginning of their employment or becoming

Relevant Covered Persons or Relevant Covered Contractors or within one hundred twenty (120) days of the Effective Date of this CCA, whichever is later. Notwithstanding the foregoing, UVA shall have 180 days from the Effective Date to provide appropriate Specific Training and obtain required certifications from all members of UVA's active medical staff. A UVA employee who has completed the specific training shall review the work of the new Relevant Covered Person or new Relevant Covered Contractor regarding the documentation of services and/or the assignment of billing codes until such time as the new Relevant Covered Person or new Relevant Covered Contractor completes applicable Specific Training.

Each year, for the term of this Agreement, every Covered Person and Covered Contractor shall receive training on the subjects described in this subsection as appropriate for their position (e.g., Relevant Covered Persons and Relevant Covered Contractors shall receive the General Training and the Specific Training each year). The substance of the training and the identity of the individuals must be documented in accordance with Subsection D.3 below. Relevant Covered Persons and Relevant Covered Contractors with responsibility for UVA's cost reports may receive appropriate specific training regarding cost reports by attendance at one or more appropriate seminars on Federal Health Care Program reimbursement if such specific training is concluded within one hundred and eighty (180) days of the Effective Date of this CCA and annually thereafter.

3. *Certification.* UVA shall maintain documents that reflect attendance at both general and specific training sessions. UVA may choose the format of such attendance records, provided that each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall also specify the type of training received and the date received. The Compliance Officer, or his/her designee, shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Contract Training.* UVA may contract with HSF to provide the required General and Specific Training required in Section III of this Agreement for its Covered Persons and Covered Contractors but must be responsible for obtaining and maintaining certifications from HSF that its Covered Persons and Covered Contractors have received all required training.

5. *Prior Training.* Training provided to affected Covered Persons and Covered Contractors on or after September 1, 2000 that satisfies the requirements of Section III.E shall be deemed to meet the time frame obligation imposed by this section, but does not obviate the requirements for attendance certifications.

F. Temporary Staff Requirements

Within 3 business days of commencing work for UVA, UVA shall obtain written documentation from its Temporary Staff showing:

1. *Code of Conduct.* That the Temporary Staff has received and read UVA's Code of Conduct and that the Temporary Staff understands that UVA's Code of Conduct also applies to the Temporary Staff.

2. *Policies and Procedures.* That the Temporary Staff has received and read all of UVA's Policies and Procedures, if any, applicable to the job functions for which the Temporary Staff has been engaged.

3. *Confidential Disclosure Program.* That the Temporary Staff has received notice of and education on the appropriate use of the Confidential Disclosure Program.

4. *General and Specific Training.* That the Temporary Staff has received appropriate training for the services for which the Temporary Staff has been engaged by UVA. Except as provided in Section I.3., Temporary Staff are not required to receive either General or Specific Training required by this CCA, provided UVA obtains and maintains all documentation evidencing compliance with this section III.F.

G. Third Party Billing

If during the term of this Agreement, UVA has an engagement with a third party billing company to submit claims to the Federal Health Care Programs, it shall notify OIG within 30 days of entering into such engagement or within 30 days of the Effective Date, whichever is later. If UVA intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become a consultant to, any third party

billing company during the term of this Agreement, UVA shall notify OIG at least 30 days prior to any such proposed involvement.

In the event UVA engages a third party billing company it shall, prior to such engagement, obtain a certification from the third party billing company that (i) it is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal Health Care Programs; (ii) it has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to participate in Medicare or other Federal Health Care Programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides at least 6 hours of training per year in billing and coding related to the Medicare and other Federal Health Care Programs for those employees involved in the preparation and submission of claims to those programs. UVA shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

H. Periodic Reviews of Billing Policies, Procedures and Practices.

1. *Internal Billing Reviews and Implementation.* UVA represents that it has voluntarily developed internal review processes, including, among others, the Compliance Auditing & Monitoring Program, Coding Compliance Plan and Internal Audit policies and controls which are aimed at improving UVA's internal processes including its process for billing and submitting claims to the Federal Health Care Programs.

For the duration of this Agreement, UVA agrees to maintain and annually review the above-listed internal policies, procedures and plans, and shall conduct an internal review on an annual basis of all clinics whose services are billed as hospital services to determine if they meet the applicable criteria for being "provider-based."

2. *Annual Reviewer.* Within 120 days of the Effective Date of this CCA, UVA shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Annual Reviewer") that are sufficiently independent, to annually review UVA's obligations under this Agreement ("Compliance Review"). The Annual Reviewer shall be capable of monitoring UVA's performance under this Agreement and shall be qualified and experienced in accepted auditing and control processes and possess expertise in billing, coding and the reimbursement requirements of the Federal Health Care Programs. UVA agrees that for each Annual Reporting Period (as defined in

Section IV) following the Effective Date of this Agreement (“Engagement Period”), UVA will engage the Annual Reviewer to conduct its Compliance Review. The Annual Reviewer shall assess, along with UVA, whether it can perform the Compliance Engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

As part of the Compliance Review, the Annual Reviewer shall conduct a review of UVA’s Compliance Auditing & Monitoring Program, Coding Compliance Plan and Internal Audit policies and controls to ensure that UVA is following its own internal processes including its process for billing and submitting claims to the Federal Health Care Programs. In addition, during the first Engagement Period, the Annual Reviewer shall conduct a review of all of UVA’s compliance obligations under this Agreement. This one-time review shall consist of a review of UVA’s compliance with the obligations set forth in each section of this Agreement, and a review of UVA’s Settlement Agreement obligation not to charge to, or otherwise seek payment from, Federal or State payors for any unallowable costs (as defined in paragraph 16 of the Release and Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program.

This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by UVA or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the Annual Reviewer may need to review cost reports and/or financial statements from the year of the Settlement Agreement, as well as from previous years.

The Annual Reviewer shall be required to issue a report concerning its work, including its findings, conclusions and recommendations after each annual review (“Annual Reviewer’s Report”). This report shall be provided to the OIG with the Annual Report.

If any of these annual reviews uncover overpayments, UVA shall notify the entity responsible for processing its claims for reimbursement from the Federal Health Care Programs (such as the Medicare Part A fiscal intermediary, Part B carrier or similar

Federal Health Care Program payors) within sixty (60) days of verifying an overpayment and take remedial steps within ninety (90) days of verifying the overpayment (or such additional time as may be agreed by the payor in writing) to correct the problem, including preventing similar overpayments from recurring, calculating the amount of overpayment and making any appropriate refunds to the extent such overpayment has been quantified. The routine submission of corrected bills in conformance with payor policy within 30 days fulfills this requirement. The notice to the payor shall include: (i) a statement that the refund is being made pursuant to this CCA; (ii) a statement describing UVA's basis concluding it was overpaid; (iii) the methodology by which the amount of overpayment was determined; (iv) the amount of the overpayment; (v) any claim-specific information relating to the overpayments (e.g., beneficiary health insurance numbers, claim numbers, dates of service, amounts claimed, amounts paid and dates of payment); and (vi) the provider billing number under which the refund is being made.

If UVA determines that there is a Material Billing Deficiency (as defined below), UVA shall take reasonable steps to determine the extent of the problem, including the amount of any overpayments made by any Federal Health Care Program. To determine the amount of potential overpayment, UVA shall conduct a special review, as set forth below in Subsection III.H.3.

For the purposes of this Agreement, a Material Billing Deficiency shall mean a substantial overpayment or a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal Health Care Program for which penalties or exclusions are authorized. A Material Billing Deficiency may be the result of an isolated event or a series of occurrences.

UVA shall notify OIG within sixty (60) days of verifying that a Material Billing Deficiency exists. UVA's notice to OIG shall include: (i) a detailed description of the Material Billing Deficiency and the amount of any overpayment resulting therefrom; (ii) UVA's actions and/or plans to correct the deficiency and prevent recurrences; (iii) the name of the third-party payor (e.g., Medicare Part A fiscal intermediary or 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 check number (or electronic transfer number) with which any refunds have been made; and (v) a report on the calculation of any overpayment amounts, as provided in Subsection III.H.3 below. To the extent the UVA 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.

3. *Special Reviews.* In the event that a Material Billing Deficiency is identified, UVA shall conduct a special review in accordance with the guidelines set forth in Attachment 1. Upon completion of each such special review, UVA shall prepare a report reflecting adherence to the guidelines set forth in Attachment 1 (“Special Review Report”) or such other methodology that may be agreed upon by UVA and the OIG.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) UVA’s Compliance Review or Special Review fails to conform to the requirements of this Agreement; or (b) the Annual Reviewer’s Report, Compliance Review, or Special Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Compliance Review or Special Review complies with the requirements of the CCA and/or whether the Annual Reviewer’s Report, Compliance Review, or Special Review results are inaccurate. UVA agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the submission of UVA’s final Annual Report (as described in Section IV) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify UVA of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, UVA may request a meeting with the OIG to discuss the results of any engagement submissions or any review findings; present any additional or relevant information to clarify the results of the engagements or to correct the inaccuracy of the reviews; and/or propose alternatives to the proposed Validation Review. The OIG will attempt in good faith to resolve any issues with UVA prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

I. Confidential Disclosure Program.

UVA has represented that it has established a “Compliance Help Line” (currently identified by the phone number 800.235.8700, but subject to change by UVA from time to time) (hereinafter “Compliance Help Line”) and that it has established policies and procedures for investigating and following up on calls and confidential disclosures received through the Compliance Help Line. UVA hereby agrees to maintain its

Compliance Help Line for the duration of this Agreement. UVA shall ensure that it provides sufficient notice of its disclosure mechanism to all Covered Persons and Covered Contractors. At a minimum, the Compliance Help Line shall at all times include a mechanism to enable individuals to anonymously disclose, to UVA's Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with UVA's policies, practices or procedures with respect to a Federal Health Care Program, believed by the individual to be a potential violation of criminal, civil or administrative law.

In addition, the Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Within sixty (60) days of the Execution Date, UVA will develop a formal written policy for directing appropriate confidential and anonymous responses to all callers. Upon receipt of a disclosure, the Compliance Officer (or his/her designee) shall gather, to the extent possible, all relevant information from the disclosing individual. UVA shall require the internal inquiry of the allegations set forth in any specific disclosure or inquiry and ensure that proper follow-up is conducted, provided that such disclosure or inquiry is sufficiently specific so that it reasonably: (1) permits a determination of the inappropriateness of the alleged practice; and (2) permits corrective action to be taken.

Further, UVA shall permit the employees, physicians, providers, contractors and agents of the HSF to utilize the Compliance Help Line and shall develop a written formal policy for directing HSF related confidential disclosures, calls or inquiries to HSF's Manager of Audit and Compliance (or his/her designee).

The Compliance Officer (or his/her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, a summary of findings, and any corrective action taken in response to the internal reviews (the "Confidential Disclosure Log"). UVA shall ensure that it provides sufficient notice of its disclosure mechanism to all Covered Persons. The Confidential Disclosure Log shall be available to OIG, upon request.

J. Ineligible Persons.

1. *Definition.* For purposes of this CCA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible

to participate in the Federal Health Care Programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible under 42 U.S.C. § 1320a-7(a).

2. *Screening Requirements.* UVA has represented that it routinely and voluntarily screens all new employees to determine whether they are on OIG's published list of persons excluded from participation in the Federal Health Care Programs or on the General Services Administration's List of Parties Excluded from Federal Programs. In accordance with this voluntary measure, UVA agrees that for contracts executed after the Effective Date of this CCA, it shall not knowingly hire as employees, engage as contractors or grant staff privileges to any Ineligible Person for any position for which the Ineligible Person's salary or the items or services furnished, directed or prescribed by the Ineligible Person will be paid, in whole or in part, directly or indirectly, by a Federal Health Care Program. To prevent hiring or contracting with any Ineligible Person, UVA shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within one hundred twenty (120) days of the Effective Date of this CCA, UVA shall review its list of current employees and contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, UVA shall review the list every nine (9) months. In addition, UVA shall require employees, contractors with contracts executed or renewed after the Effective Date, and physicians with staff privileges to disclose immediately any debarment, exclusion or other event that makes the employee or contractor an Ineligible Person.

If UVA has notice that an employee, contractor or physician with staff privileges has become an Ineligible Person, UVA shall remove such person from responsibility for, or involvement with, UVA's business operations related to the Federal Health Care Programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Health Care Programs or otherwise with Federal

funds at least until such time as the person is reinstated into participation in the Federal Health Care Programs.

4. *Contractual Screening Option.* UVA may contract with HSF to perform its Screening and Review Requirements under this CCA for some or all of its employees, contractors and physicians with staff privileges but UVA is ultimately responsible for ensuring that it does not employ or contract with any Ineligible Persons. In the event UVA contracts with HSF to perform the Screening or Review Requirements of this CCA, UVA shall obtain a certification of completion from HSF that details the dates of screening and/or review and identifies any ineligible persons within 15 days of each screening and/or review required by this CCA.

5. *Pending Charges and Proposed Exclusions.* If UVA 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, UVA shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal Health Care Program.

K. Notification of Government Investigation or Legal Proceedings.

Within thirty (30) days of learning of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that UVA has committed a crime or has engaged in fraudulent activities, UVA shall notify OIG in writing of such investigation or legal proceeding. 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 to the extent known. UVA shall also provide written notice to OIG within thirty (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 CERTIFICATION AND ANNUAL REPORTS

A. Implementation Certification. Within one hundred fifty (150) days after the Effective Date of this Agreement, UVA's Compliance Officer shall certify in writing that UVA has complied with the obligations contained in this CCA that are due to be

performed on or before the implementation certification date, including but not limited to the obligation to maintain a person in the position of Corporate Compliance Officer and Corporate Compliance Steering Committee as described in Section III and shall certify that UVA has:

- a. developed and implemented all applicable Policies and Procedures;
- b. implemented all General and Specific Training requirements;
- c. distributed UVA's Code of Conduct to all appropriate individuals; and
- d. obtained all required certifications.

UVA shall also submit as part of its Implementation Certification the names and positions of the members of the BOV Audit Committee and the Steering Committee required by sections III.A. and III.B., all training materials described in Section III.E, a summary of any personnel actions (other than hiring) taken pursuant to Section III.J and the proposed start and completion dates of the first annual review identified in Section III.H.

B. Annual Reports. UVA shall make three annual reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the matters set forth below. The one (1) year period beginning with January 31, 2001 and ending January 31, 2002, and each Annual Report period thereafter shall be referred to as the "Annual Reporting Period."

Each Annual Report shall include:

1. Any change in the identity or position description of the Compliance Officer and/or the individuals that comprise the BOV Audit Committee and the Steering Committee as described in Section III.A, III.B and III.C.
2. Copies of any revisions or amendments made to the Code of Conduct or the Policies and Procedures used or followed in the generation of claims submitted to the Federal Health Care Programs during the period covered by the Annual Report pursuant to Section III.D and the reasons for such changes (e.g., change in contractor policy).
3. All training and education materials for the activities engaged in pursuant to Section III.E of this Agreement and a summary of the activities

undertaken to implement this training and education program, including a schedules, topic outlines of the training sessions, and lists of the participants organized by department or division at the time the person received the training. Additionally, UVA shall include certification by the Compliance Officer that, to the best of the Compliance Officer's knowledge and, upon reasonable efforts and inquiry, the education and training activities required under this Agreement have taken place.

4. A summary of the findings made during the reviews conducted pursuant to Section III.H of this Agreement relating to the year covered by the Annual Report; copies of any disclosures or notice documents prepared by UVA pursuant to that section; a complete copy of all reports prepared pursuant to the Annual Reviewer's review required under Section III.H; a copy of any special review reports described in Section III.H.3; and a description of the corrective steps and proof of refund to the pertinent payor (where applicable).

5. A summary of any Material Billing Deficiencies identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

6. A summary of the communications (including the number of disclosures by employees, contractors, or beneficiaries and the dates of disclosure) and a summary of the Confidential Disclosure Log received through the mechanisms established pursuant to Section III.D. UVA shall maintain its actual Confidential Disclosure Log and shall make such records available to OIG upon request.

7. A description of any personnel actions (other than hiring) taken by UVA as a result of the obligations in Section III.J. With respect to personnel actions taken pursuant to Section III.J.3 and III.J.5, UVA shall provide a description of the responsibilities of the person affected by any such actions. UVA shall maintain records concerning all such personnel actions and shall make such records available to OIG upon request.

8. A summary describing any corrective measures taken in response to any ongoing investigation or legal proceeding conducted or brought by a

governmental entity or its agents involving an allegation that UVA has committed a crime or has engaged in fraudulent activities.

The first Annual Report shall be received by the OIG no later than sixty (60) days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Certification and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, UVA is in compliance with all of the requirements of this CCA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the applicable report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: UVA 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. UVA 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 CCA, all notifications and reports required under this CCA 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

UVA:

Ralph Traylor
Interim Compliance Officer
UVa Health System
P.O. Box 800788
Charlottesville, VA 22908-0788
Phone: 804.924.5024
Fax: 804.982.3759
e-mail: rwt6t@virginia.edu

Unless otherwise specified, all notifications and reports required by this CCA 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, contract, or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine UVA's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UVA's locations for the purpose of verifying and evaluating: (a) UVA's compliance with the terms of this CCA; and (b) UVA's compliance with the requirements of the Federal Health Care Programs. The documentation described above shall be made available by UVA 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 UVA'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. UVA agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UVA's employees may elect to be interviewed with or without a representative of UVA present.

VII. DOCUMENT AND RECORD RETENTION

UVA shall maintain for inspection, to the greatest extent possible, all documents and records maintained in the ordinary course of business relating to reimbursement from the Federal Health Care Programs, and records demonstrating compliance with this CCA, for a period of four (4) years (or longer if otherwise required by law).

VIII. BREACH AND DEFAULT PROVISIONS

UVA's compliance with the terms and conditions of this Agreement shall constitute an element of UVA's present responsibility with regard to participation in the Federal Health Care Programs. Full and timely compliance by UVA shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by UVA. As stated below in Section X of this Agreement, any and all modifications to this Agreement (including changes to the dates on which an obligation is due to be met or a submission or response is due to be made) shall be requested in writing and agreed to by OIG in writing prior to the date on which the modification is expected to take effect.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, UVA and OIG hereby agree that failure to comply with certain obligations set forth in this CCA 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 UVA 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 Implementation Certification and complete Annual Reports, in accordance with the requirements in Section IV.;
- b. Maintenance of the Confidential Disclosure Program as required by Section III.D.

2. A Stipulated Penalty of \$2,500 for each day UVA fails to comply by having in force during the term of this Agreement any of the following, which stipulated

penalty shall begin to accrue on the date of receipt of OIG's notice of noncompliance or as otherwise indicated in OIG's notice:

- a. The Compliance Program adopted pursuant to Section III of this Agreement;
- b. The BOV Audit Committee, the Steering Committee and the Compliance Officer, discharging their respective duties, as required under Sections III.A, III.B and III.C of this Agreement;
- c. The Training and Education activities required under Section III.E of this Agreement;
- d. The Confidential Disclosure requirements under Section III.I of this Agreement.
- e. The retention and identification of an Annual Reviewer as required under Section III.F.

3. A Stipulated Penalty of \$2,500 for each day UVA fails to grant reasonable access to the information or documentation necessary to exercise OIG's inspection, audit and review and rights set forth in Section VI of this Agreement, which Stipulated Penalty shall begin to accrue on the date UVA fails to grant access.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day UVA employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, UVA'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, directed, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Health Care Programs; (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which UVA can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.J) as to the status of the person).

5. A Stipulated Penalty of \$1,000 for each day UVA fails to comply materially with any requirement of this CCA after receiving notice from the OIG of such

failure to comply. In its notice to UVA, OIG shall state the specific grounds for its determination that UVA has failed to comply materially with the CCA's obligation(s) at issue and steps UVA must take to comply with the CCA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to UVA of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-4 of this section.

B. Timely Written Requests for Extensions. UVA 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 CCA. 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 (1) day after UVA 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 (2) business days after UVA 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 (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. Notwithstanding UVA's right to file a timely written request for extension, UVA's obligations under this Agreement shall be suspended by acts of God, fires or any other casualty or occurrence, condition, event or circumstance not reasonably within UVA's control which could not have been avoided by reasonable measures provided that (i) the suspension of performance is of no greater scope and of no longer duration than is necessarily caused by such unavoidable acts and required by any remedial measures; and (ii) UVA uses its reasonable efforts to remedy the inability to perform.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. Upon a finding that UVA has failed to comply with any of the above-enumerated obligations, and after determining that Stipulated Penalties are appropriate, OIG shall notify UVA of: (a) UVA'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 ten (10) days of the receipt of the Demand Letter, UVA shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties, if any; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section VIII.E. In the event UVA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UVA cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for exclusion under Section VIII.D.

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.

D. Remedies for Material Breach of this CCA

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CCA by UVA constitutes an independent basis for UVA's exclusion from participation in the Federal Health Care Programs. Upon a determination by OIG that UVA has materially breached this CCA and that exclusion should be imposed, OIG shall notify UVA of: (a) UVA'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").

2. *Opportunity to Cure.* UVA shall have thirty (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. UVA is in compliance with the obligations of this CCA cited by the OIG as being the basis for the material breach;
- 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) UVA has begun to take action to cure the material breach; (ii) UVA is pursuing such action with due diligence; and (iii) UVA has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the 30-day period, UVA fails to satisfy the requirements of Section VIII.D.2, OIG may exclude UVA from participation in the Federal Health Care Programs. OIG will notify UVA in writing of its determination to exclude UVA (this letter shall be referred to hereinafter as the “Exclusion Letter”).

Notwithstanding any provisions in Chapter 42 of the Code of Federal Regulations, the exclusion pursuant to this Agreement shall take effect thirty (30) days from the date of receipt of the Exclusion Letter unless UVA exercises its contractual right to seek review of OIG’s exclusion determination by requesting a hearing before an ALJ as provided in Section VIII.E below. In the event UVA seeks such a hearing, the exclusion shall not be effective until the issuance of an ALJ’s decision and order supporting OIG’s exclusion determination. The exclusion of UVA shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. If UVA is excluded pursuant to this Agreement, it may seek reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Definition of Material Breach.* A material breach of this CCA means:

a. a failure by UVA to report a material deficiency, take corrective action and make the appropriate refunds, as required in Section III.H;

b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section VIII.A.;

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

d. a failure to retain, identify and use an Annual Reviewer in accordance with Section III.D.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to UVA of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, UVA 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 CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. With respect to OIG's determination to seek exclusion, UVA and/or OIG may appeal the ALJ's decision to HHS's Departmental Appeals Board ("DAB"), in a manner consistent with the above referenced regulations. Neither the review by the ALJ or the decision of 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) or the language in Section II of this CCA, the request for a hearing involving Stipulated Penalties shall be made within ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty-five (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 CCA shall be: (a) whether on the date of the Demand Letter, UVA was in full and timely compliance with the obligations of this CCA for which the OIG demands payment; (b) whether UVA failed to cure; and (c) the period of noncompliance, if any; and (d) with respect to a Stipulated Penalty authorized under section VIII.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) UVA had begun to take action to cure the failure to comply, (ii) UVA was and is pursuing such action with

due diligence, and (iii) UVA had provided to OIG a reasonable timetable for curing the material breach which is being followed. UVA shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders UVA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UVA 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 CCA shall be: (a) whether UVA was in material breach of one or more obligations in this CCA; (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 thirty (30) day period, or such other period as agreed to in writing between UVA and OIG, despite UVA's actions and efforts to (i) cure the material breach within that period; (ii) pursue a cure with due diligence; and (iii) provide the OIG, within that period, a reasonable timetable for curing the material breach and a showing that UVA has followed the timetable. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that UVA 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 twenty (20) days after the DAB decision.

IX. PRIVILEGES AND DISCLOSURES

The OIG will follow all applicable Federal laws concerning privacy and confidentiality, including the Federal Privacy Act, 5 U.S.C. § 552a, to the greatest extent allowed by law.

Consistent with HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify UVA prior to any release by OIG of information submitted by UVA pursuant to its obligations under this CIA and identified upon submission by UVA as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. UVA shall refrain from identifying any information as trade secrets, commercial, or financial

information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA. With respect to the disclosure of information, UVA shall have the rights set forth in 45 C.F.R. § 5.65(d). OIG shall protect confidential information under the FOIA rules to the greatest extent allowed by law. When required, the OIG shall provide the pre-disclosure notice required pursuant to 45 C.F.R. § 5.65(d) to the Compliance Officer at the address provided in Section V.

Nothing in this CCA, or any communication or report made pursuant to this CCA, shall constitute or be construed as a waiver by UVA of UVA's attorney-client, work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect UVA's obligation to comply with the provisions of this CCA.

X. EFFECTIVE AND BINDING AGREEMENT

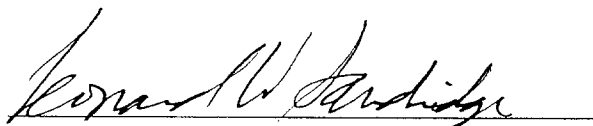
Consistent with the provisions in the Settlement Agreement pursuant to which this CCA is entered, and into which this CCA is incorporated by reference, UVA and OIG agree as follows:

A. This CCA shall be binding on the successors, assigns, and transferees of UVA that assume responsibility for submitting claims to the Federal Health Care Programs for services billed to the Federal Health Care Programs by UVA. UVA shall also require that any entity owned or controlled by UVA that assumes responsibility for billing for services rendered by UVA employees or contractors comply with this Agreement.

B. Any modifications to this CCA shall be made only with the prior written consent of the parties to this CCA; and

C. The undersigned UVA signatories represent and warrant that they are authorized to execute this CCA on behalf of UVA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he or is authorized to execute this CCA.


ON BEHALF OF UVA



LEONARD W. SANDRIDGE
Executive Vice President and
Chief Operating Officer
University of Virginia
Charlottesville, VA 22903

8/1/01
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

3/2/01
DATE

ATTACHMENT 1

Special Review Guidelines

A. *Basic Information.* A special review pursuant to Section III.H.3 of the CCA shall consist of a review of either: (1) all of the claims or items affected by the Material Billing Deficiency, or (2) a statistically valid sample of the claims or items that can be projected to the population of claims or items affected by the Material Billing Deficiency for the relevant period. In documenting the special reviews pursuant to Section III.F. of the CCA, UVA 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 the payment data and the documents that will be relied upon (e.g., cost reports, claim forms, 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, UVA 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.