INSTITUTIONAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNIVERSITY OF WASHINGTON PHYSICIANS AND CHILDREN'S UNIVERSITY MEDICAL GROUP

I. PREAMBLE

The Association of University Physicians d/b/a University of Washington Physicians (UWP) and the Association of CHMC and University Physicians d/b/a Children's University Medical Group (CUMG) (individually and/or collectively, the "Plans") hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). UWP and CUMG are individual parties to this CIA and, as such, shall be separately responsible for compliance with the obligations enumerated in this CIA and/or with respect to any breach thereof. Contemporaneously with this CIA, UWP and CUMG are entering into a Stipulation and Order of Settlement and Dismissal (the "Agreement") with the United States.

Prior to the execution of this CIA, the Plans established compliance plans (known as the "Compliance Programs") which provide for integrity policies and procedures and which, as represented by the Plans in this CIA, are aimed at ensuring that its participation in the Federal health care programs (which includes any requests for payments) is in conformity with the statutes, regulations and other directives applicable to those programs. The Plans' employees, and all physicians or other appropriate health care providers and staff participate in the Compliance Programs. For the purposes of this CIA, the term "provider" shall mean all physicians of the Plans or ancillary health providers who provide professional medical services as employees of the Plans, or pursuant to contracts between their employers and the Plans. For the purposes of this CIA, the term "employee" shall mean: all of the Plans' employees who are involved in the generation and submission of reimbursement claims for physician services, including, but not limited to, coders and billing personnel. The Plans' use of billing agents to handle billing of

professional services by some or all of its employees shall not affect or limit the Plans' obligations or responsibilities under this CIA. This CIA also applies to all third parties the Plans may choose to engage as billing agents.

Pursuant to this CIA, the Plans hereby agree to maintain in full operation, or adopt as required by this CIA, the Compliance Programs as they relate to the submission of claims for physician services for the term of this CIA. The Compliance Programs may be modified by the Plans as appropriate, but at a minimum, shall comply with the integrity obligations enumerated in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by the Plans under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

   a. all owners, officers, directors, and employees of the Plans; and

   b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of the Plans.

   Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" is a subset of Covered Persons consisting of:

a. all physicians of the Plans, or ancillary health care providers, who provide professional medical services as employees of the Plans, or pursuant to contracts between their employers and the Plans (hereafter, "Providers");

b. all of the Plans' employees who are involved in the generation and submission of reimbursement claims for physician services, including, but not limited to, coders and billing personnel. (The Plans' use of billing agents to handle billing of professional services by some or all of its employees shall not affect or limit the Plans' obligations or responsibilities under this CIA.); and

c. all third parties the Plans may choose to engage as billing agents.

III. CORPORATE INTEGRITY OBLIGATIONS

The Plans shall continue to implement and maintain its Compliance Program that includes, at a minimum, the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* The Plans represent to OIG that, pursuant to their Compliance Programs, they have created the position of Director of Regulatory Compliance (hereafter "Compliance Officer(s)") and appointed individuals to serve in that capacity. The Plans shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer(s) shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer(s) shall be a member of senior management of the Plans, shall make periodic (at least quarterly) reports regarding compliance matters directly to the UWP Board of Trustees and the CUMG Board of Directors (collectively hereafter the "governing boards"), and shall be authorized to report on such matters to the Dean of the University of Washington (UW) School of Medicine and the Plans' governing boards at any time. The Compliance Officer shall not be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-

to-day compliance activities engaged in by the Plans as well as for any reporting obligations created under this CIA.

The Plans shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer(s), or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

2. *Compliance Committee.* The Plans represent to OIG that, pursuant to their Compliance Programs, they have created the UWP Physician Education, Billing, and Compliance Council and the CUMG Physicians Education, Billing, and Compliance Committee (hereafter, the "Compliance Committees") to monitor the implementation of the Compliance Programs and to provide advice and recommendations to the Plans' Compliance Officer(s), the Dean of the UW School of Medicine, and the governing boards for the Plans, on compliance issues, policies and procedures, and changes to the Compliance Program. The Compliance Committees shall, at a minimum, include the Compliance Officer(s) and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments such as billing, clinical, audit, and operations, and members of the Plans' governing boards). The Plans' Chief Compliance Officers shall be *ex officio* members of the Compliance Committees, and the Compliance Committees shall support the Chief Compliance Officers in fulfilling their responsibilities (e.g., shall assist in the analysis of the organizations' risk areas and shall oversee monitoring of internal and external audits and investigations).

The Plans shall report to OIG, in writing, any changes in the composition of the Compliance Committee(s), or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 30 days after such a change.

B. Written Standards.

1. *Code of Conduct.* Unless the Plans have already done so, within 120 days after the Effective Date, the Plans shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. The Plans shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. The Plans' commitment to full compliance with all Federal health care program requirements, including their commitment to prepare and submit accurate claims consistent with such requirements;

b. The Plans' requirement that all of their Covered Persons shall be expected to comply with all Federal health care program requirements and with the Plans' own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);

c. The requirement that all of the Plans' Covered Persons shall be expected to report to the Compliance Officer(s) or other appropriate individual designated by the Plans suspected violations of any Federal health care program requirements or of the Plans' own Policies and Procedures;

d. The possible consequences to both the Plans and Covered Persons of failure to comply with Federal health care program requirements and with the Plans' own Policies and Procedures and the failure to report such noncompliance; and

e. The right of all individuals to use the Disclosure Program described in Section III.E, and the Plans' commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by the Plans' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

The Plans' current Code of Conduct, as submitted to the OIG, conforms with the requirements of this Subparagraph. The Plans shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or

she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

The provisions of this Section III.C.1 shall not apply to Covered Persons or Relevant Covered Persons who terminate their relationship with the Plans within 120 days after the Effective Date of this CIA.

2. *Policies and Procedures*. Within 120 days after the Effective Date, the Plans shall implement written Policies and Procedures (to the extent they have not already done so) regarding the operation of the Plans' Compliance Programs and their compliance with Federal health care program requirements. Accordingly, the Plans hereby agree to maintain their Policies and Procedures, which at all times shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

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

c. documentation requirements as they pertain to the physician services rendered and/or claimed for reimbursement by or through the Plans; and

d. a process for reasonable verification of compliance with these requirements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed (to the extent the Plans have not already done so) to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), the Plans shall assess and update as necessary the Policies and Procedures. Within 30 days after 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 relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date of this CIA, the Plans shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain the Plans':

a. CIA requirements; and

b. the Plans' Compliance Programs (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. the Federal health care program requirements regarding the accurate coding and submission of claims;

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

c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;

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

e. the legal sanctions for violations of the Federal health care program requirements; and

f. examples of proper and improper claims submission practices, as they pertain to the rendering of physician services.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date of this CIA, whichever is later. A Plan employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least three hours of Specific Training annually.

3. *Certification.* 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 specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* The Plans shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Claims Review, and any other relevant information.

6. *Computer-based Training.* The Plans may provide the training required under this CIA through appropriate computer-based training approaches. If the Plans choose to provide computer-based training, they shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

7. *Credit for Prior Training.* For the purposes of meeting the obligations under this Section III.C, for the term of the first Annual Report under this CIA, OIG shall

consider the Plans' training and educational activities carried out pursuant to the Compliance Programs since July 1, 2003.

D. Billing and Special Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization to Verify Billing Review Results.* The Plans have developed a protocol, attached hereto as Attachment A, for reviewing a sample of claims for each Provider (as defined above) who submits claims for professional services through the Plans (Billing Reviews). Within 90 days after the Effective Date, the Plans shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO") to verify whether the Plans are implementing these agreed upon procedures (Verification Review). The IRO(s) shall also, if applicable, analyze whether the Plans sought payment for certain unallowable costs (Unallowable Cost Review).

Each IRO engaged by the Plans shall have expertise in the billing, coding, reporting, and other requirements of physician billing and in the general requirements of the Federal health care program(s) from which the Plans seek reimbursement. Each IRO shall assess, along with the Plans, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

b. *Frequency of Verification Reviews.* The Verification Review shall be performed annually and shall cover each of the Reporting Periods.

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.

d. *Retention of Records.* The IRO and the Plans shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and the Plans) related to the reviews.

2. Special Review. If the IRO identifies a Reportable Event, as defined below in Section III.H.2, the Plans shall conduct a Special Review in accordance with the review guidelines as set forth in Attachment B, below. Upon completion of any Special Review, the Plans shall prepare a report reflecting adherence to the guidelines set forth in Attachment B.

3. Verification Review Report. The IRO shall prepare a report based upon the Verification Review performed (Verification Review Report).

4. Unallowable Cost Review. If applicable, the IRO shall conduct a review of the Plans' compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether the Plans have complied with their obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their 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 the Plans or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

5. Unallowable Cost Review Report. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether the Plans have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as

defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

6. Validation Review. In the event OIG has reason to believe that: (a) the Plans' Billing Reviews fail to conform to the requirements of this CIA; or (b) the IRO's findings or Verification Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Billing Review complied with the requirements of the CIA and/or the findings or Billing Review results are inaccurate (Validation Review). The Plan(s) shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of the Plans' final Annual Report must be initiated no later than one year after the Plans' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify the Plan(s) of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, the Plan(s) may request a meeting with OIG to: (a) discuss the results of any Billing Review submissions or findings; (b) present any additional information to clarify the results of the Billing Review or to correct the inaccuracy of the Billing Review; and/or (c) propose alternatives to the proposed Validation Review. The Plan(s) agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with the Plan(s) 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 OIG.

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to the Plans a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to the Billing Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

The Plans have represented to OIG that they have established Disclosure Programs that include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with the Plans' policies, conduct, 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. The Plans shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Programs shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, the Plans shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG, upon request.

F. Ineligible Persons.

1. *Definitions*. For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or

in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).

2. *Screening Requirements*. The Plans shall ensure that all prospective and current owners, officers, directors, employees, contractors, and agents of the Plans are not Ineligible Persons, by implementing the following screening requirements.

a. For all prospective owners, officers, directors, employees, contractors, and agents, the Plans shall screen such persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.

b. For all current owners, officers, directors, employees, contractors, and agents, the Plans shall screen all such persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. The Plans shall implement a policy requiring all owners, officers, directors, employees, contractors, and agents of the Plans to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) the Plans to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If the Plans have actual notice that an owner, officer, director, employee, contractor, or agent has become an Ineligible Person, the Plans shall remove such person from responsibility for, or involvement with, the Plans' business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If the Plans have actual notice that a person identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, the Plans shall take all appropriate actions to ensure that the responsibilities of that person 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.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, the Plans shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to the Plans conducted or brought by a governmental entity or its agents involving an allegation that the Plans have committed a crime or have engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. The Plans shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money the Plans have received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, the Plans identify or learn of any Overpayment, the Plans shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, the Plans shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, the Plans shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Attachment C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Reportable Events.*

a. Definition of Reportable Event. For purposes of this CIA, a "Reportable Event" means anything that involves:

i. a substantial Overpayment; 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 Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If the Plans determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Plans shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of the Plans' actions taken to correct the Reportable Event; and

iv. any further steps the Plans plan to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, the Plans change locations or sell, close, purchase, or establish a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, the Plans shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment, although this requirement does not apply to the May, 2004 move of UWP to 501 Eastlake Avenue East, Seattle, Washington. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, the Plans shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). To the extent the following information has not been provided to OIG, the Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer(s) required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer(s) may have;

2. the names and positions of the members of the Compliance Committees required by Section III.A;

3. a copy of the Plans' Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

7. a description of the Disclosure Program required by Section III.E;

8. the following information regarding the IRO(s): (a) identity, address and phone number; (b) a copy of the engagement letter; (c) a summary and description of all engagements between the Plans and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting; and (d) the proposed start and completion dates of the Verification Review;

9. a certification from the IRO regarding its professional independence and/or objectivity with respect to the Plans;

10. a description of the process by which the Plans fulfill the requirements of Section III.F regarding Ineligible Persons;

11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal

health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

12. a list of all of the Plans' locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which the Plans currently submit claims;

13. a description of the Plans' corporate structures, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

14. the certifications required by Section V.C.

B. Annual Reports. the Plans shall submit to OIG annually a report with respect to the status of, and findings regarding, the Plans' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

4. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);

6. the Plans' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;

7. a summary/description of all engagements between the Plans and the IRO(s), including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and/or objectivity with respect to the Plans;

9. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

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

12. any changes to the process by which the Plans fulfill the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by the Plans in response to the screening and removal obligations set forth in Section III.F; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. 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;

15. a description of all changes to the most recently provided list of the Plans' locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which the Plans currently submit claims; and

16. the certifications required by Section V.C.

The first Annual Report(s) shall be received by OIG no later than 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 Report and Annual Reports shall include a certification by the Compliance Officers that:

(1) to the best of his or her knowledge, except as otherwise described in the applicable report, the Plans are in compliance with all of the requirements of this CIA;

(2) he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and

(3) the Plans have complied with their obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) if applicable, to identify and adjust any past charges or claims for unallowable costs.

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
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, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

The Plans:

Rick Deese
Executive Director
University of Washington Physicians
501 Eastlake Avenue East, Suite 500
Box 359110
Seattle, Washington 98109
Telephone: (206) 616-1024
Facsimile: (206) 543-1600

Richard Nielsen
Executive Director
Children's University Medical Group
2345 Eastlake Avenue East, Suite 105
Seattle, Washington 98102
Telephone: (206) 987-5924
Facsimile: (206) 987-5022

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

VII. OIG Inspection, Audit, and Review Rights

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

VIII. Document and Record Retention

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

IX. Disclosures

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify the Plans prior to any release by OIG of information submitted by the Plans pursuant to their obligations under this CIA and identified upon submission by the Plans as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, the Plans shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

The Plans are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Plans and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA 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 the Plans fail to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;

e. the training of Covered Persons;

f. a Disclosure Program;

g. ineligible Persons screening and removal requirements; and

h. notification of Government investigations or legal proceedings.

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 the Plans fail to engage an IRO, as required in Section III.D and Appendix A.

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 the Plans fail to submit the

Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the Plans fail to submit the annual Claims Review Report in accordance with the requirements of Section III.D and Appendix B.

5. A Stipulated Penalty of $1,500 for each day the Plans fail to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date the Plans fail to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of the Plans as part of their Implementation Reports, Annual Reports, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day the Plans fail to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to the Plans, stating the specific grounds for its determination that the Plans have failed to comply fully and adequately with the CIA obligation(s) at issue and steps the Plans shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the Plans receive this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. The Plans 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 CIA. 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 Plans fail 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 three business days after the Plans receive 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 Plans have failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify the Plans of: (a) the Plans' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, the Plans shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event the Plans elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Plans cure, 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 CIA and shall be grounds for exclusion under Section X.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 VI.

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

D. Exclusion for Material Breach of this CIA.

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

a. a failure by the Plans to report a Reportable Event, 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 CIA, including, but not limited to, the obligations addressed in Section X.A;

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

d. a failure to engage and use an IRO in accordance with Section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by the Plans constitutes an independent basis for the Plans' exclusion from participation in the Federal health care programs. Upon a determination by OIG that the Plans have materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify the Plans of: (a) the Plans' 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.* the Plans 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. the Plans are in compliance with the obligations of the CIA cited by 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) the Plans have begun to take action to cure the material breach; (ii) the Plans are pursuing such action with due diligence; and (iii) the Plans have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, the Plans fail to satisfy the requirements of Section X.D.3, OIG may exclude the Plans from participation in the Federal health care programs. OIG shall notify the Plans in writing of its determination to exclude the Plans (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below,

the exclusion shall go into effect 30 days after the date of the Plans' receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, the Plans may apply for reinstatement by submitting 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 the Plans of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, the Plans 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 CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. 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 after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether the Plans were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. The Plans shall have the burden of proving their full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders the Plans to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Plans request 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether the Plans were in material breach of this CIA;

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) the Plans had begun to take action to cure the material breach within that period; (ii) the Plans have pursued and are pursuing such action with due diligence; and (iii) the Plans provided to OIG within that period a reasonable timetable for curing the material breach and the Plans have 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 Plans, only after a DAB decision in favor of OIG. The Plans' election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the Plans upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that the Plans 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. The Plans shall waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of the Plans, the Plans shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Order of Settlement and Dismissal pursuant to which this CIA is entered, and into which this CIA is incorporated, the Plans and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of the Plans;

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

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

D. OIG may agree to a suspension of the Plans' obligations under the CIA in the event of the Plans' cessation of participation in Federal health care programs. If the Plans withdraw from participation in Federal health care programs and are relieved of their CIA obligations by OIG, the Plans shall notify OIG at least 30 days in advance of the Plans' intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned signatories of the Plans represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF THE UNIVERSITY OF WASHINGTON PHYSICIANS

By: Rick Deese
Its Executive Director

4/30/04
DATE

ON BEHALF OF THE CHILDREN'S UNIVERSITY MEDICAL GROUP

By: Richard Nielsen
Its Executive Director

DATE

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

Larry J Goldberg

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

29 April 2004

DATE

ATTACHMENT A

Protocol for Conducting Internal Audits

I. Introduction

Each physician and non-physician provider ("Provider") under whose name bills are submitted through the Plans shall be audited to assure compliance with all documentation, coding and billing requirements of the Federal health care programs. The audits shall be conducted by the staff of the Plans' respective Offices of Regulatory Compliance (the "Compliance Offices"). A minimum of six (6) encounters per provider shall be audited representing a cross-section of outpatient and inpatient evaluation and management services and, where applicable, surgical procedures. For the purposes of this Attachment A, the term "encounter" shall mean an individual service rendered to a patient. All providers in the Nephrology Division and Neurosurgical Department shall be audited annually. At least half of the remaining practice groups shall be audited annually (those not audited one year shall be audited the next year, so that all Providers in each practice group shall be audited at least once every two years).

II. Audit Staff

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

III. Audit Process

The audit process shall be as follows:

(1) Each Department Chairperson or his or her designee shall be contacted and a date set to initiate the process. The Department Chairperson or his or her designee shall designate a contact person within the Department that shall be responsible for timely accumulating all information needed for the audit.

(2) The auditor shall request a list of all patients seen by each Provider, both inpatient and outpatient, during a specified time period; usually one month, at least two to

three months in the past. By dividing the total number of patients seen during that period by 6(T/6=N), and then selecting every Nth encounter, the auditors shall randomly select 6 encounters (at least 4 for Federal health care program beneficiaries), and request the charts reflecting the documentation for each service. The services selected may be adjusted to substitute other randomly selected services in order to obtain an appropriate cross-section of services. Each Department shall produce the charts for office services as well as a copy of the charge capture document or ledger reflecting the code(s) billed. Inpatient charts shall be requested by the Compliance Office(s) from Medical Records of the respective health care facilities served by the Plans' Providers.

(3) The audit tool that shall be used must reflect current Centers for Medicare and Medicaid Services (CMS) Documentation Guidelines for Physician Services. The elements that shall be addressed include:

(i) documentation supporting the level of service and type of service being billed;

(ii) documentation reflecting the attending physician's participation in the service;

(iii) surgical unbundling; and

(iv) services provided but not billed.

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

IV. Reporting

Once completed, a summary of the audit results will be distributed to each Department Chairperson or his or her designee. A member of the Compliance Office staff shall meet with each Provider to discuss the results of the audit and to give the Provider the opportunity to respond to the findings. If, following the meeting, the Provider continues to be found in "non-compliance," he/she shall be required to attend an individualized training session and shall at a minimum, be re-audited in four (4) weeks following the session for subsequent dates of service.

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

Any Overpayment identified during the audit process shall be reported and refunded as set forth in Section III.H of the CIA. If, as a result of the audit, the Compliance Officer identifies a Reportable Event as defined in the CIA, a broader review shall be undertaken using the sampling protocol established by the OIG in order to ascertain the extent of the problem and to estimate overpayments attributable to the Reportable Event. The results of that review shall be reported to the OIG consistent with provisions of the CIA.

ATTACHMENT B: SPECIAL REVIEW GUIDELINES

A. BASIC INFORMATION. In documenting the special reviews pursuant to Section III.D of the CIA, the Plans 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 shall be based, including the legal or other standards to be applied, the sources of payment data and the documents that shall be relied upon (e.g., employment contracts, compensation packages or formulae).

4. Personnel Qualifications: The names and titles of those individuals involved in any aspect of the review, including statisticians, accountants, auditors, consultants and medical reviewers, and their qualifications.

B. SAMPLE ELEMENTS. In documenting the selection and use of samples in the special reviews, the Plans shall provide for the following:

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

2. Sampling Frame: Identification of the sampling frame, which is the totality of the sampling units from which the sample shall be selected. In addition, the plan should document how the review population differs from the sampling frame and what effect this difference has on conclusions reached as a result of this review.

3. Sample Size: A description of both the probe sample (if one is used) and the full sample, including the sample's level of confidence and precision.

4. Random Numbers: Written assurance that all probe samples and samples used were selected through random numbers. The source of the random numbers used must be described. For this task, OIG strongly recommends the use of its Office of Audit Services' Statistical Sampling Software, also known as "RAT-STATS," which is currently available through the "internet" at *http://www.hhs.gov/progorg/oas/ratstat.html*, free of charge.

5. Sample Design: Unless the Plans demonstrate the need to use a different sample design, the review should use simple random sampling. If necessary, the Plans may use stratified or multistage sampling. Details about the strata, stages and clusters should be included.

6. Characteristics Measured by the Sample: A statement identifying the characteristics used for testing each sample item. For example, in a sample drawn to estimate the value of overpayments due to duplicate payments, the characteristics under consideration are the conditions that must exist for a sample item to be a duplicate. The amount of the duplicate payment is the measurement of the overpayment. This description must also contain the decision rules for determining whether a sample item entirely meets the criterion for having characteristics or only partially meets the criterion.

7. Missing Sample Items: An explanation of how missing sample items were handled and the rationale.

8. Other Evidence: Although sample results should stand on their own in terms of validity, sample results may be combined with other evidence in arriving at specific conclusions. If appropriate, indicate what other substantiating or corroborating evidence was developed.

9. Estimation Methodology: Because the general purpose of the review is to estimate the monetary losses to the Federal health care programs, the methodology to be used must be variables sampling using the difference estimator. To estimate the amount implicated in the matter discovered, UPI must use the mean point estimate. The use of RAT-STATS to calculate the estimates is strongly recommended.

ATTACHMENT C

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____ AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? _____ Yes _____ No

Reason Codes:

Billing/Clerical Error	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify)
06 - Billed in Error		_____
07 - Corrected CPT Code		