

CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
WESTERN MARYLAND HEALTH SYSTEM

**I. PREAMBLE**

Western Maryland Health System, for and on behalf of its component hospitals, Sacred Heart Hospital of the Sisters of Charity and Memorial Hospital and Medical Center of Cumberland (hereinafter collectively WMHS), hereby enters 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 by its officers, directors, employees, contractors and agents 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”). Contemporaneously with this CIA, WMHS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement. WMHS represents to the OIG that it adopted a voluntary compliance program (“Compliance Program”) in 1998. WMHS agrees that it shall modify its Compliance Program as necessary to meet the requirements of this CIA.

**II. TERM OF THE CIA**

A. The period of the compliance obligations assumed by WMHS under this CIA shall be three (3) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA shall be the date on which the final signatory of this CIA executes this CIA (Effective Date).

B. Sections VII, VIII, IX, X and XI shall expire no later than 90 days after the OIG’s receipt of: (i) WMHS’s final annual report; or (ii) any additional materials submitted by WMHS 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 officers, directors, and employees of WMHS, except for maintenance, housekeeping, laundry, and food service employees; and
- b. all contractors and agents that provide direct patient care services or that perform billing or coding functions on behalf of WMHS.

Notwithstanding the above, the term "Covered Persons" does not include part-time, temporary or *per diem* employees, contractors, agents or other individuals 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" includes each Covered Person who, directly or in a supervisory capacity, is involved in the preparation or submission of claims (including, but not limited, to coding or billing) for reimbursement from any Federal health care program.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

WMHS hereby agrees to maintain and adapt, as necessary, its current Compliance Program so that it includes the following elements during the term of this CIA:

A. Compliance Officer and Committee.

1. *Compliance Officer.* WMHS shall continue to have an individual serving as its Compliance Officer. The Compliance Officer shall continue to 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 shall continue to be a member of senior management of WMHS, shall continue to make periodic (at least quarterly) reports regarding compliance matters directly to the CEO and shall continue to be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall continue to be responsible for monitoring the day-to-day compliance activities engaged in by WMHS as well as for any reporting obligations created under this CIA.

Any substantive changes in the identity or position description of the Compliance Officer, 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, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* WMHS shall continue to have in place a Compliance Committee, which is known as the Corporate Responsibility Committee (CRC). The Compliance Committee shall continue, at a minimum, to include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall continue to chair the Compliance Committee and the Committee shall continue to support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall continue to assist in the analysis of the organization's risk areas and oversee monitoring of internal and external audits and investigations).

Any substantive changes in the composition of the Compliance Committee or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA must be reported to OIG, in writing, within 15 days of such a change.

#### B. Written Standards.

1. *Standards of Conduct.* WMHS shall continue to have in place its Standards of Conduct. The Standards of Conduct shall be distributed to all Covered Persons who have not already received it within 120 days after the Effective Date of this CIA. WMHS shall continue to make the promotion of, and adherence to, the Standards of Conduct an element in evaluating the performance of all employees. The Standards of Conduct shall continue, at a minimum, to set forth:

- a. WMHS'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;
- b. WMHS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with WMHS's own Policies and Procedures as implemented pursuant to section III.B.2 (including the requirements of this CIA);

- c. the requirement that all of WMHS's Covered Persons shall be expected to report to the Compliance Officer or other individual designated by the WMHS suspected violations of any Federal health care program requirements or of WMHS's own Policies and Procedures;
- d. the possible consequences to both WMHS and Covered Persons of failure to comply with all Federal health care program requirements and with WMHS's own Policies and Procedures or of failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in section III.E, and WMHS's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 120 days after the Effective Date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by WMHS's Standards of Conduct. Distributions of the Standards of Conduct by WMHS to and written certifications by Covered Persons that they have received, read, understood, and will abide by WMHS's Standards of Conduct made during calendar year 2003 prior to the execution of this CIA may be credited towards the Standards of Conduct requirements in this Section III.B.1. New Covered Persons shall receive the Standards of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date of the CIA, whichever is later.

WMHS shall continue periodically to review the Standards of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. If the Standards of Conduct are substantively revised following the Effective Date of this CIA, any such revised Standards of Conduct shall be distributed within 30 days of the effective date of such revision. Covered Persons shall certify that they have received, read, understood and will abide by the revised Standards of Conduct within 60 days of the effective date of such revisions.

2. *Policies and Procedures.* WMHS shall continue to have in place written Policies and Procedures regarding the operation of WMHS's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Standards of Conduct identified in section III.B.1;

- b. the accurate billing and coding of claims for treatment provided at WMHS.

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

Within 120 days after the Effective Date of the CIA, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures and who have not already received such Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), WMHS shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any substantive revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

### C. Training, and Education.

1. *General Training.* WMHS represents that since the inception of its Compliance Program, WMHS has trained on compliance with Federal health care program requirements and with the Standards of Conduct and Policies and Procedures as they relate to general compliance issues. WMHS further represents that all employees, regardless of their positions, receive training regarding WMHS' standards of conduct, its compliance program, and non-retaliatory disclosure policy. Within 120 days after the Effective Date of this CIA, WMHS shall provide at least one hour of reasonable and appropriate general training to each Covered Person. This training shall explain WMHS's:

- a. CIA requirements; and
- b. Compliance Program (including the Standards of Conduct and the Policies and Procedures as they pertain to general compliance issues).

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

New 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 of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive such reasonable and appropriate general training annually. WMHS shall identify within its Implementation Certification those Covered Persons who received general training during the six months immediately prior to the Effective Date of the CIA. WMHS may educate Covered Persons on the CIA via newsletter, personal letter, or other appropriate and effective means. General compliance training, as described above, provided by WMHS to Covered Persons during the six months immediately prior to the Effective Date of the CIA may be credited towards the training time requirements set forth in section III.C.1.

2. *Specific Training.* WMHS will continue to train its personnel involved in the claims preparation and submission process. Within 120 days of the Execution Date of this CIA, each Relevant Covered Person shall receive at least four hours of specific training in addition to the general training required above. Specific training provided by WMHS to Relevant Covered Persons during the six months immediately prior to the Effective Date of this CIA may be credited towards the training time requirements set forth in this section. WMHS shall identify within its Implementation Certification those Covered Persons who received specific training during the six months immediately prior to the Effective Date of the CIA. This specific training 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 are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

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

New Relevant Covered Persons shall receive this training within 60 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 WMHS 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 preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, and during the remainder of the CIA term thereafter, every Relevant Covered Person shall receive at least three hours of specific training annually. The specific training may be provided in periodic training sessions over the course of each calendar year during which this CIA is in effect.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, 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 his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Exception for Physicians with Privileges.* Notwithstanding any other provisions of this CIA, the following are WMHS's only obligations hereunder with respect to training and certifications for Covered Persons who are physicians with active staff privileges but not WMHS employees: WMHS shall make the Standards of Conduct available to all non-employee physicians with active staff privileges and shall make the general training and specific training, as appropriate, available to all physicians with active staff privileges and shall use its best efforts to encourage their attendance and participation. The Compliance Officer shall keep a record of the names and percentage of all physicians with active staff privileges who attend each such training.

#### D. Review Procedures.

WMHS represents that prior to the execution of this CIA, WMHS established an internal audit program to review medical record documentation and corresponding coding and charges as part of WMHS's ongoing compliance reviews. To supplement such periodic reviews, WMHS agrees to the following Review Procedures:

1. *General Description.*

- a. Retention of Independent Review Organization. Within 120 days of the Execution Date of this CIA, WMHS shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist WMHS in evaluating its billing and coding practices and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each Independent Review Organization retained by WMHS shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Medicare program. Each IRO shall assess, along with WMHS, 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 engagements that may exist. The IRO(s) review shall address and analyze WMHS's billing and coding to the Federal health care programs ("Claims Review") and shall analyze whether WMHS sought payment for certain unallowable costs ("Unallowable Cost Review").
- b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the calendar years 2004, 2005, and 2006. The IRO(s) shall perform all components of each annual Claims Review.
- c. Frequency of Unallowable Cost Review. The IRO shall perform the Unallowable Cost Review for the first Reporting Period.
- d. Retention of Records. The IRO and WMHS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and WMHS) related to the reviews.

2. *Claims Review.* The Claims Review shall consist of two separate components. Each component will include a Discovery Sample and, if necessary, a Full Sample. The first component of the Claims Review shall require the IRO to review and assess Medicare Paid Claims for outpatient radiology services submitted by or on behalf of WMHS. The



second component of the Claims Review shall require the IRO to review and assess Medicare Paid Claims for all non-radiology services submitted by or on behalf of WMHS. The applicable definitions, procedures, and reporting requirements for both components of the Claims Review are outlined in Appendix A to this CIA, which is incorporated by reference. For both components of the Claims Review, the Paid Claims shall be reviewed based on the supporting documentation available at WMHS or under WMHS's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

a. *Discovery Samples.* For the first component of the Claims Review, the IRO shall randomly select and review a sample of 50 Medicare Paid Claims for radiology services submitted by or on behalf of WMHS. For the second component of the Claims Review, the IRO shall randomly select and review a sample of 100 Medicare Paid Claims for all non-radiology services submitted by or on behalf of WMHS.

i. With respect to each component of the Claims Review, if the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling or Systems Review is required for that component, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, WMHS should, as appropriate, further analyze any errors identified in the Discovery Sample. WMHS recognizes that OIG or any other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. With respect to each component of the Claims Review, if the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review for that respective component, as described below.

b. Full Samples. If necessary, as determined by procedures set forth in Section III.D.2.a, with respect to each of the components of the Claims Review, the IRO shall perform an additional sample or samples of Paid Claims using commonly accepted sampling methods

and in accordance with Appendix A. Each Full Samples shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at WMHS or under WMHS's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of any Full Sample, the corresponding Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, WMHS may use the Items sampled as part of the corresponding Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. OIG, in its full discretion, may refer the findings of any Full Sample (and any related workpapers) received from WMHS to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If WMHS's Discovery Sample identifies an Error Rate of 5% or greater in either component of the Claims Review, WMHS's IRO shall also conduct a Systems Review. Specifically, for each claim in a Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.H.1, WMHS shall repay any Overpayment(s) identified in a Discovery Sample or Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. WMHS shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the “Claims Review Report”). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review.* The IRO shall conduct a review of WMHS’s compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether WMHS has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the 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 WMHS or any of its subsidiaries. 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.* 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 WMHS has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its 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) WMHS’s Claims Review or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) the IRO’s findings or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate (“Validation Review”). WMHS shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after WMHS’s final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify WMHS 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, WMHS may request a meeting with OIG to discuss the results of any Claims Review or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Unallowable Cost Review or to correct the inaccuracy of the Claims Review; or propose alternatives to the proposed Validation Review. WMHS shall 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 or Unallowable Cost Review with WMHS 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 WMHS 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 Claims Review or Unallowable Cost Review and that it has concluded that it is, in fact, independent and/or objective.

E. Disclosure Program.

WMHS represents that, pursuant to its ongoing compliance activities, it has an established a disclosure program which includes a toll-free anonymous compliance telephone line, as a means to enable individuals to report instances of non-compliance and/or make inquiries on compliance issues.

WMHS shall continue to maintain the Disclosure Program, which must 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 WMHS'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. WMHS shall 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 Program shall continue to emphasize a non-retribution, non-retaliation policy, and shall continue to include a reporting mechanism for anonymous, confidential communications. 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 whether the alleged improper practice is actually inappropriate; and (2) provides an opportunity for taking corrective action, WMHS shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall continue to maintain a disclosure log, which shall include a record and summary of each disclosure received, the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

#### F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an “Ineligible Person” shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) 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.

2. *Screening Requirements.* WMHS shall ensure that all owners, officers, directors, employees, contractors, physicians with staff privileges, and agents of WMHS are not Ineligible Persons. To ensure that such persons are not Ineligible Persons, WMHS shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying 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://oig.hhs.gov>) (these lists shall hereinafter be referred to as the “Exclusion Lists”). Nothing in this Section affects the responsibility of WMHS to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days after the Effective Date, WMHS shall review its list of the persons identified in Section III.F.2 against the Exclusion Lists. Thereafter, WMHS shall review its list of such persons against the Exclusion Lists annually. In addition, WMHS shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person.

If WMHS has actual notice that such person has become an Ineligible Person, WMHS shall remove such person from responsibility for, or involvement with, WMHS's 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 rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If WMHS has actual notice that a person identified in Section III.F.2 is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term or, in the case of a physician, during the term of the physician's medical staff privileges, WMHS 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, WMHS shall notify OIG, in writing, of any ongoing investigation known to WMHS or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that WMHS has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. WMHS 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 proceedings, if any.

H. Reporting.

1. *Overpayments*

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

- b. Reporting of Overpayments. If, at any time, WMHS identifies or learns of any Overpayment, WMHS 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, WMHS 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, WMHS 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 Appendix B 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. *Material Deficiencies*.

- a. *Definition of Material Deficiency*. For purposes of this CIA, a "Material Deficiency" 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 Material Deficiency may be the result of an isolated event or a series of occurrences.

- b. *Reporting of Material Deficiencies*. If WMHS determines that there is a Material Deficiency, WMHS shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

- (i) If the Material Deficiency results in an overpayment, the report to the 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) on which the overpayment was repaid/refunded;
- (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (iii) a description of WMHS's actions taken to correct the Material Deficiency; and
- (iv) any further steps WMHS plans to take to address the Material Deficiency and prevent it from recurring.



#### **IV. NEW BUSINESS UNITS OR LOCATIONS**

In the event that, after the Effective Date of this CIA, WMHS changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, WMHS shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operations), phone number, fax number, Medicare provider numbers) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations purchased by WMHS or at such locations which are WMHS new business units shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

#### **V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Compliance Officer's Implementation Certification. Within 150 days after the Effective Date of this CIA, WMHS's Compliance Officer shall be available to OIG, at a mutually agreeable time, to summarize the status of WMHS's implementation of the requirements of this CIA. The Compliance Officer shall also certify in writing by that date, to the extent not already submitted to the OIG:

1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
2. the names and positions of the members of the Compliance Committee required by section III.A;
3. a copy of WMHS's Standard of Conduct required by section III.B.1;
4. the summary of the Policies and Procedures required by section III.B.2;
5. a description of the training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
  - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons;
  - b. all Covered Persons have completed the Standards of Conduct certification required by section IILB.1; and

- c. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;

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

7. a description of the Disclosure Program required by section III.E;
8. the identity of the IRO(s), a summary/description of all engagements between WMHS and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
9. a summary of personnel actions taken pursuant to section III.F;
10. a certification from the IRO regarding its professional independence from WMHS;
11. a list of all of WMHS's 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 identification numbers) and the contractor's name and address that issued each;
12. to the extent not already furnished to OIG, or if modified, a description of WMHS's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business; and
13. the certification required by section V.C.

B. Annual Reports. WMHS shall submit to OIG Annual Reports with respect to the status of and findings regarding WMHS's compliance activities for each of the three one-year periods beginning on the Effective Date of the CIA. (The period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Reporting Period shall cover the time period from the Effective Date of the CIA through December 31, 2004. The second and third Reporting Periods shall cover calendar years 2005 and 2006 respectively.

Each Annual Report shall include:

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

2. a certification by the Compliance Officer that:
  - a. all Covered Persons have completed any Standards of Conduct certifications required by section III.B.1;
  - b. all Covered Persons have completed the applicable training and executed the certification(s) required by section III.C;
  - c. WMHS has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from Federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);
4. a copy of all training materials used for the training required by Section III.C, a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when, the training sessions were held;
5. a complete copy of all reports prepared pursuant to the IRO's Claims Review, Unallowable Cost Review, and Systems Review, if applicable, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
6. WMHS's response and corrective action plans) related to any issues raised by the IRO(s) or WMHS's Medical Auditor;
7. a summary of Material Deficiencies (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
8. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) and other

Federal health care programs. 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;

9. 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;
10. a description of any personnel actions (other than hiring) taken by WMHS as a result of the obligations in section III.F, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under section III.F, and the actions taken in response to the obligations set forth in that section;
11. 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;
12. a description of all changes to the most recently provided list (as updated) of WMHS's locations (including locations and mailing 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 Federal health care program provider identification numbers), and the contractor name and address that issued each provider identification number;
13. the certification required by section V.C; and
14. a revised summary/description of all engagements between WMHS and the IRO, 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 Certification.

The first Annual Report shall be received by the OIG no later than one year and 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 Report shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable certification or report, WMHS is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance

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

D. Designation of Information: WMHS shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. WMHS 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 of this CIA, 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, SW  
Washington, DC 20201  
Telephone (202) 619-2078  
Facsimile (202) 205-0604

WMHS:

Scott Borsuk  
Corporate Compliance Officer  
Western Maryland Health System  
P.O. Box 539  
Cumberland, MD 21501  
Telephone (301) 723-1407  
Facsimile (301) 723-6413

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 WMHS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of WMHS's locations for the purpose of verifying and evaluating: (a) WMHS's compliance with the terms of this CIA; and (b) WMHS's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by WMHS 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 WMHS'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. WMHS agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. WMHS's employees may elect to be interviewed with or without a representative of WMHS present following being informed that they have such a right.

## **VIII. DOCUMENT AND RECORD RETENTION**

WMHS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for four 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, the OIG shall make a reasonable effort to notify WMHS's Compliance Officer at the address listed in section VI prior to any release by OIG of information submitted by WMHS pursuant to its obligations under this CIA and identified upon submission by WMHS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, WMHS shall have the rights set forth at 45 C.F.R. § 5.65(d). WMHS shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA. Nothing in this CIA, or any communication or report made pursuant to this CIA,

shall constitute a waiver of, or be construed to require WMHS to waive, WMHS's attorney-client, work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect WMHS's obligation to comply with the provisions of this CIA, e.g., by providing all documents necessary to determine whether WMHS is in compliance with the terms of the CIA.

## **X. BREACH AND DEFAULT PROVISIONS**

WMHS is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, WMHS and OIG hereby agree that failure to comply with certain obligations 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 WMHS fails to have in place any of the obligations described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Standards of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

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 WMHS fails to retain an IRO, as required in Section III.D.

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 WMHS fails to meet any of the

deadlines for the submission of the Implementation Certification or the Annual Reports to OIG.

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

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of WMHS as part of its Implementation Certification, Annual Report, 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 WMHS fails to comply fully and adequately with any obligation of this CIA. In its notice to WMHS, OIG shall state the specific grounds for its determination that WMHS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps WMHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after WMHS receives 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 1-7 of this Section.

B. Timely Written Requests for Extensions. WMHS 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 WMHS 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 three business days after WMHS receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

### C. Payment of Stipulated Penalties.

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

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, WMHS 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 WMHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until WMHS 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 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 WMHS has 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 WMHS 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 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 retain 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 WMHS constitutes an independent basis for WMHS's exclusion from participation in the Federal health care programs. Upon a determination by OIG that WMHS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify WMHS of: (a) WMHS's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* WMHS 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. WMHS is 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) WMHS has begun to take action to cure the material breach; (ii) WMHS is pursuing such action with due diligence; and

(iii) WMHS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, WMHS fails to satisfy the requirements of Section X.D.3, OIG may exclude WMHS from participation in the Federal health care programs. OIG shall notify WMHS in writing of its determination to exclude WMHS (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 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, WMHS 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 WMHS 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, WMHS 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 Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether WMHS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. WMHS shall have the burden of proving its 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 WMHS to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless WMHS 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 CIA shall be:

- a. whether WMHS was 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) WMHS had begun to take action to cure the material breach within that period; (ii) WMHS has pursued and is pursuing such action with due diligence; and (iii) WMHS provided to OIG within that period a reasonable timetable for curing the material breach and WMHS has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for WMHS, only after a DAB decision in favor of OIG. WMHS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude WMHS 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 WMHS 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. WMHS shall waive its 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 WMHS, WMHS 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.

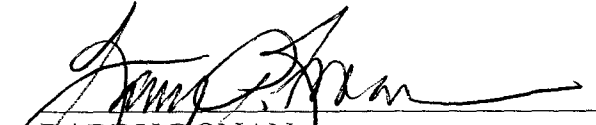
## **XI. EFFECTIVE AND BINDING AGREEMENT**

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

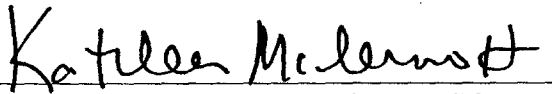
- A. This CIA shall be binding on the successors, assigns, and transferees of WMHS;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and
- D. OIG may agree to a suspension of WMHS's obligations under the CIA in the event of WMHS's cessation of participation in Federal health care programs. If WMHS withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, WMHS shall notify OIG at least 30 days in advance of WMHS's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

The undersigned WMHS signatories 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 WESTERN MARYLAND HEALTH SYSTEM

  
BARRY RONAN  
Chief Executive Officer  
Western Maryland Health System

11/6/03  
DATE

  
KATHLEEN McDERMOTT, ESQ.  
Counsel for Western Maryland Health System

11-5-03  
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

*10/29/03*

\_\_\_\_\_  
DATE

## APPENDIX A

### A. Claims Review.

1. *Definitions.* For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money WMHS has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).
- c. Paid Claim: A code or line item submitted by WMHS and for which WMHS has received reimbursement from the Medicare program.
- d. Population: All Items for which WMHS has submitted a code or line item and for which WMHS has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
- e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

### 2. *Other Requirements.*

- a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which WMHS cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by



WMHS for such Paid Claim shall be deemed an Overpayment.  
Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.

B. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology*.

a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review.

b. Claims Review Population. A description of the Population subject to the Claims Review.

c. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame.

e. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.

## 2. *Statistical Sampling Documentation.*

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

## 3. *Claims Review Findings.*

### a. Narrative Results.

i. A description of WMHS’s billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

### Claim Review Results

Federal Health Care Program Billed	Bene	HIC #	Date of Service	Procedure Code Submitted	Procedure Code	Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed	(IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt
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