CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
LEO E. OBERMILLER, JR., M.D.

I. PREAMBLE

Leo E. Obermiller, Jr., M.D. ("Dr. Obermiller") hereby agrees to enter into this Corporate Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of a Corporate Integrity Program to ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Dr. Obermiller, by any corporation in which he is an owner or has a control interest as defined in 42 U.S.C. § 1320a-3(a)(3), his employees, and all third parties whom Dr. Obermiller may choose to engage to act as billing or coding consultants or agents for his practice. Dr. Obermiller's compliance with the terms and conditions in this Agreement shall constitute an element of his present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Dr. Obermiller is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Dr. Obermiller under this Agreement shall be five (5) years from the effective date of this Agreement. The effective date of this Agreement will be the date on which the final signatory of this Agreement executes this Agreement (the "effective date.")

III. CORPORATE INTEGRITY OBLIGATIONS

Within one-hundred and twenty (120) days of the effective date of this Agreement, Dr. Obermiller agrees to implement a Corporate Integrity Program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within thirty (30) days of the effective date of this Agreement, Dr. Obermiller shall designate a person to be the contact person for purposes of the obligations herein. Dr. Obermiller may serve as the Compliance Contact. In the event a new contact person is appointed during the term of this Agreement, Dr. Obermiller shall notify the OIG, in writing, within thirty (30) days of such a change.

B. POSTING OF NOTICE

Within the first thirty (30) days following the effective date of this Agreement, Dr. Obermiller shall post in a prominent place accessible to all patients and employees a notice detailing his commitment to comply with all applicable statutes, regulations and directives applicable to Medicare, Medicaid and all other Federal health care programs in the conduct of his business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct can be reported anonymously.

C. WRITTEN POLICIES AND PROCEDURES

Dr. Obermiller agrees to develop and implement written policies and procedures within ninety (90) days of the effective date of this Agreement that address the following:

a. The proper submission of claims to the Medicare, Medicaid, and other Federal health care programs;
b. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;
c. The commitment of Dr. Obermiller to adhere to honest and accurate billing practices; and
d. The commitment of Dr. Obermiller not to hire or engage as a contractor any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion,

suspension, debarment, or ineligibility.[1]

D. TRAINING AND CERTIFICATION

Within ninety (90) days following the effective date of this Agreement, Dr. Obermiller and all personnel involved in preparing or submitting to Medicare, Medicaid, and all other Federal health care program claims for services and items provided by Dr. Obermiller or any of his agents shall be trained in the proper billing standards, methods, and procedures to ensure accurate billing for services rendered to beneficiaries of these programs. The training shall be designed to ensure that Dr. Obermiller and all of his employees and agents are knowledgeable about all applicable health care statutes, regulations, and program guidelines and are familiar with the standards of business conduct that each is expected to follow and the consequences (i.e., exclusion, legal sanctions, etc.) both to the individual and Dr. Obermiller that will ensue from any violation of such requirements.

In addition, Dr. Obermiller will arrange for all new personnel involved in billing for services to participate in such training no later than sixty (60) days after they begin working for Dr. Obermiller. Until they have had the requisite training, such new employees will work under the direct supervision of an employee who has received such training.

This training program shall provide for no less than six (6) hours of training annually for each person. At a minimum, the training sessions shall cover the following topics:

1. The proper billing standards and procedures for the submission of accurate claims for services rendered and/or items provided to beneficiaries of Medicare, Medicaid, and all other Federal health care programs to which Dr. Obermiller submits claims; and

2. All applicable statutes, rules, regulations, and guidelines related to Medicare, Medicaid and other Federal health care programs' billing and reimbursement requirements, and the legal sanctions for improper billing

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[1] Dr. Obermiller may ascertain whether any person or entity is an Ineligible Person for purposes of this Agreement by reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/ Entities (available through the Internet at http://www.dhhs.gov/progorg/oig).

and violation of these laws.

Every employee, officer, and director of Dr. Obermiller's practice will sign certifications indicating attendance at the annual training sessions and further attesting to an understanding of the provisions in the written policies and procedures referenced in section III.C and all applicable Federal health care laws, including Medicare and Medicaid statutes, regulations and standards of business conduct. These certifications will be maintained by Dr. Obermiller and shall be made available for inspection by the OIG or its duly authorized representatives.

Certain of Dr. Obermiller's employees and agents attended training in April 1999. If Dr. Obermiller and those employees certify, in writing, that the April 1999 training covered the topics outlined in subsections 1 and 2 above, the April 1999 training shall satisfy the training requirement for those employees for the first year of the term of this CIA. Dr. Obermiller and any employee or agent who did not receive the training in April of 1999 shall receive appropriate training for the first year of the term of this CIA in accordance with the specifications above. During the second and each subsequent year in the term of this CIA, Dr. Obermiller, his employees and agents shall receive training in accordance with this Section D.

E. INDEPENDENT AUDITS

Within thirty (30) days of the effective date of this Agreement, Dr. Obermiller shall contract with a third party reviewer (e.g., audit, law or health care consulting firm) to undertake an annual review of a statistically valid sample of the claims submitted by Dr. Obermiller, and his agents and/or employees to Medicare, Medicaid, and all other Federal health care programs to determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care statutes, regulations, and program requirements, including those relating to billing policies and procedures. Each audit shall cover the preceding one (1) year period and shall seek to determine that the claims submitted to the Medicare, Medicaid and other Federal health care programs are for medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. A report of the results of each annual review shall be submitted with each Annual Report, and if any problems are detected, Dr. Obermiller shall also submit a corrective action plan for correcting the deficiencies found.

If any of these annual reviews uncovers claims processing and/or billing policies, procedures and/or practices that result in material deficiencies, Dr. Obermiller shall undertake certain obligations. Specifically, he shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare carrier or other payor), within thirty (30) days of discovering the deficiency and take remedial steps within sixty (60) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency from reoccurring.

Contemporaneous with Dr. Obermiller's notification regarding a material deficiency to the payor as provided above, Dr. Obermiller shall notify the OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Dr. Obermiller's findings concerning the material deficiency; (4) Dr. Obermiller's actions to correct such material deficiency; and (5) any further steps Dr. Obermiller plans to take to address such material deficiency and prevent it and similar billing deficiencies from reoccurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs; (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for Federal health care beneficiaries or recipients. A material deficiency may be the result of an isolated event or a series of occurrences.

If Dr. Obermiller learns of any overpayment (regardless of its size and regardless of whether it results from a material deficiency) received from a Federal health care program, Dr. Obermiller shall notify the appropriate payor, make appropriate refunds and take any steps necessary to prevent the reoccurrence.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Dr. Obermiller will report to the OIG any reliable evidence of actions involving Dr. Obermiller or his agents that constitute a probable violation of any state or Federal civil, criminal or administrative statute, regulation, or rule governing a Federal health care program. Dr. Obermiller must

make the required disclosure no later than thirty (30) calendar days after becoming aware of the existence of the probable violation. This disclosure shall apply to conduct by any of Dr. Obermiller's personnel and any person or entity with a financial interest in Dr. Obermiller's business.

Dr. Obermiller will certify to the OIG that any disclosures made under this paragraph have been fully investigated and that appropriate corrective actions have been taken to ensure that Dr. Obermiller and his personnel and agents are in compliance with all state and Federal civil, criminal, and administrative statutes, regulations and rules governing all Federal health care programs. Nothing in this paragraph waives the OIG's right to enforce any and all statutes and regulations governing any Federal health care program, subject to the release provisions of the Settlement Agreement signed this same date.

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right the OIG may have by statute, regulation, contract or pursuant to this Agreement, the OIG or its duly authorized representative(s) may examine Dr. Obermiller's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating: (i) Dr. Obermiller's compliance with the terms of this Agreement; and (ii) Dr. Obermiller's compliance with the requirements of the Medicare, Medicaid and other Federal health care programs. The OIG, HCFA, or any affected intermediary or carrier, may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Dr. Obermiller's compliance with the statutory and regulatory requirements of Medicare, Medicaid and all other Federal health care programs.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within one-hundred and twenty (120) days of the effective date of this Agreement, Dr. Obermiller shall provide the OIG with a written report demonstrating that he has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

(1) A copy of the notice Dr. Obermiller posted in his office as described in Section III.B.

(2) A certification signed by Dr. Obermiller attesting that he and all employees have completed the initial training required by Section III.D. as well as a summary of what the training included and the proposed training schedule for the next year. The training materials will be made available to the OIG upon request.

(3) A copy of the written policies and procedures required by section III.C. of this Agreement.

(4) An identification of the third party reviewer with whom Dr. Obermiller has contracted pursuant to section III.E of this Agreement.

(5) A certification from Dr. Obermiller stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

B. ANNUAL REPORTS

Dr. Obermiller shall make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to the OIG describing the measures he has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. The first Annual Report shall be due one (1) year and thirty (30) days after the effective date of this Agreement. Subsequent Annual Reports shall be due on the anniversary of the due date for the first Annual Report. In accordance with the provisions above, the Annual Report shall include:

(1) A description, schedule and topic outline of the training programs implemented pursuant to section III.D. of this Agreement, and a written certification from Dr. Obermiller and all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement.

(2) A copy of the reports from the reviews conducted pursuant to section III.E. relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; copies of the disclosure or notice documents submitted by Dr. Obermiller pursuant to section III.E; and

details regarding any future corrective actions that Dr. Obermiller plans to initiate.

(3) A statement signed by Dr. Obermiller certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon his inquiry, the information is accurate and truthful.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise agreed upon subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

To the OIG:

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

To Dr. Obermiller:

Dr. Leo Obermiller
801 West 5th Avenue
Suite 523
Deaconess Medical Building
Spokane, WA 99204

Dr. Obermiller may submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. A "timely written request" is defined as a request in writing received by the OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed. If the OIG grants the request for an extension, any penalties for failure to timely perform any action, or

file any notification or report shall not begin to accrue until one (1) day after Dr. Obermiller fails to meet the revised deadline as agreed to by the OIG-approved extension. If the OIG denies the request for extension, any penalties for failure to timely perform any action or file any notification or report shall not begin to accrue until two (2) business days after Dr. Obermiller receives OIG's written denial of such request.

VIII. BREACH AND DEFAULT PROVISIONS

Dr. Obermiller is expected to fully and timely comply, throughout the duration of this Agreement, with all of the obligations to which he herein agrees.

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Dr. Obermiller engages in conduct that the OIG considers to be a material breach of this Agreement as defined below, the OIG may seek exclusion of Dr. Obermiller from participation in the Medicare, Medicaid and any other Federal health care programs. Upon making such a determination, the OIG shall notify Dr. Obermiller of the alleged material breach by certified mail and of its intent to exclude him as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Dr. Obermiller shall have thirty-five (35) days from the date of the letter to:

(1) cure the alleged material breach; or

(2) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that Dr. Obermiller has begun to take action to cure the material breach and that Dr. Obermiller will pursue such action with due diligence. Dr. Obermiller shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by the OIG and Dr. Obermiller), Dr. Obermiller fails to act in accordance with provisions (1) or (2) above, the OIG may exclude Dr. Obermiller from participation in the Medicare, Medicaid and all other Federal health care programs. The OIG will notify Dr. Obermiller in writing of its determination to exclude Dr. Obermiller (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution procedures in Section VIII.B, the

exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Dr. Obermiller is excluded under the provisions of this Agreement, he may seek reinstatement pursuant to the provisions at 42 C.F.R. § 1001.3001-.3004.

B. DISPUTE RESOLUTION

Upon the OIG's delivery to Dr. Obermiller of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, Dr. Obermiller shall be entitled to certain due process rights comparable to the ones provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the exclusion sought pursuant to this CIA. Specifically, the OIG's determination to seek exclusion shall be subject to review by an HHS Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. However, Dr. Obermiller agrees that the decision by the DAB, if any, shall constitute the final decision and no appeal right shall be afforded to Federal court.

Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing before an ALJ shall be made within thirty (30) days of the date of the Exclusion Letter. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issue in a proceeding for exclusion based on a material breach of this Agreement shall be whether Dr. Obermiller was in material breach of this Agreement.

For purposes of this section VIII, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations set forth in sections VI.A and VI.B of this Agreement; or (iii) a failure to retain and use a third party reviewer for audit purposes in accordance with section III.E.

IX. EFFECTIVE AND BINDING AGREEMENT

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

(1) this Agreement shall be binding on the successors, assigns and transferees of Dr. Obermiller;

(2) this Agreement shall become final and binding only upon signing by each respective party hereto; and

(3) any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

LEO E. OBERMILLER, JR., M.D.

Date	Leo E. Obermiller, Jr., M.D.
Date	Counsel for Dr. Obermiller

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

11/26/99	
Date	Lewis Morris, Esquire Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General U. S. Department of Health and Human Services

IN WITNESS WHEREOF, the parties hereto affix their signatures:

LEO E. OBERMILLER, JR., M.D.

1-13-00
Date

Leo E. Obermiller, Jr., M.D.

1-17-99
Date

Counsel for Dr. Obermiller

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

Date

Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND LEO E. OBERMILLER, JR., M.D.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Leo E. Obermiller, Jr., M.D. ("Dr. Obermiller") entered into a Corporate Integrity Agreement ("CIA") on January 13, 2000.

1. Pursuant to section IX.3. of the CIA, modifications to the CIA may be made with the prior written consent of both the OIG and Dr. Obermiller. Therefore, the OIG and Dr. Obermiller hereby agree that Dr. Obermiller's CIA will be amended as follows:

   Section III.E., Review Procedures of the CIA is hereby superceded by the attached new section III.E., Review Procedures.

   The attached Appendix A is hereby added to Dr. Obermiller's CIA.

2. The OIG and Dr. Obermiller agree that all other sections of Dr. Obermiller's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Dr. Obermiller.

3. The undersigned Dr. Obermiller signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

4. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF LEO E. OBERMILLER, JR., M.D.

[Name] President NWI2
[Title]

11/15/02
DATE

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

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

4/29/02
DATE

E. Review Procedures.

1. General Description.

a. Retention of Third Party Reviewer. Within 30 days of the effective date of this CIA, Dr. Obermiller shall retain a Third Party Reviewer ("Reviewer") to perform reviews to assist Dr. Obermiller in assessing and evaluating his billing and coding practices and systems. The Reviewer retained by Dr. Obermiller 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 Federal health care program(s) from which Dr. Obermiller seeks reimbursement. The Reviewer shall assess, along with Dr. Obermiller, whether it can perform the review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The review shall address and analyze Dr. Obermiller's billing and coding to the Federal health care programs ("Claims Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the effective date of this CIA. The Reviewer shall perform all components of each annual Claims Review.

c. Retention of Records. The Reviewer and Dr. Obermiller shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the Reviewer and Dr. Obermiller related to the reviews.)

2. *Claims Review.* The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this CIA, which is incorporated by reference.

a. Discovery Sample. The Reviewer shall randomly select and review a sample of 50 Federal health care program Paid Claims submitted by or on behalf of Dr. Obermiller. The Paid Claims shall be reviewed based on the supporting documentation available at Dr. Obermiller or under Dr. Obermiller's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Dr. Obermiller should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Obermiller recognizes that the OIG or 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. If the Discovery Sample indicates that the Error Rate is 5% or greater, the Reviewer shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Paragraph III.E., the Reviewer shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) 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 (2) 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 Dr. Obermiller or under Dr. Obermiller'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 the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Dr. Obermiller may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if statistically appropriate. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. Obermiller 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 Dr. Obermiller's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Obermiller's Reviewer shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and

Full Sample that resulted in an Overpayment, the Reviewer should 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 Reviewer shall provide to Dr. Obermiller the Reviewer's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. Obermiller agrees to repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Dr. Obermiller agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

3. *Claims Review Report.* The Reviewer 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. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Obermiller's Claims Review fails to conform to the requirements of this Agreement; or (b) the Reviewer's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. Obermiller agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Dr. Obermiller's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Obermiller of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Dr. Obermiller may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. Dr. Obermiller agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review issues with Dr. Obermiller prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

5. *Independence Certification*. The Reviewer shall include in its report(s) to Dr. Obermiller a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review, and that it has concluded that it is, in fact, independent.

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 Dr. Obermiller 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 Dr. Obermiller and for which Dr. Obermiller has received reimbursement from any Federal health care program.

d. Population: All Items for which Dr. Obermiller has submitted a code or line item and for which Dr. Obermiller has received reimbursement from the any Federal health care programs (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 Dr. Obermiller cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Obermiller 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. In most circumstances, the sampling frame will be identical to the Population.

e. Source of Data. A description of the specific documentation relied upon by the Reviewer 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 Reviewer.

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 Dr. Obermiller'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 Reviewer'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.

b. Quantitative Results.

i. Total number and percentage of instances in which the Reviewer determined that the Paid Claims submitted by Dr. Obermiller ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Dr. Obermiller.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample(s).

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the Reviewer), correct allowed amount (as determined by the Reviewer), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.