INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
KENNETH H. WILLIAMS, M.D.

I. PREAMBLE

WHEREAS, Kenneth H. Williams, M.D. ("Dr. Williams") is a physician employed by Mercy FamilyCare, Inc., a Maryland not-for-profit corporation;

WHEREAS, as an employee of Mercy FamilyCare, Inc., Dr. Williams represents that he does not own or maintain clinical or business records pertaining to the services he provides;

WHEREAS, as of the time of the execution of this Integrity Agreement ("the Agreement"), Dr. Williams represents that he does not own or have a control interest in any health care practice or entity, and that he does not employ any employee, agent, or contractor in performing health care services or providing coding or billing services;

WHEREAS, contemporaneously with this Agreement, Dr. Williams is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement;

WHEREAS, the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") and Dr. Williams desire to ensure Dr. Williams's compliance with the statutes, regulations, program requirements 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") ,

THEREFORE, Dr. Williams and the OIG ("the Parties") enter into this Agreement.

II. TERM OF THE AGREEMENT

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

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Dr. Williams pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

Dr. Williams hereby agrees to establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

If, at any time during the term of this Agreement, Dr. Williams owns part or all of a health care practice, within 30 days of assuming such ownership, Dr. Williams shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. In the event a new Compliance Contact is appointed during the term of this Agreement, Dr. Williams shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

If, at any time during the term of this Agreement, Dr. Williams owns part or all of a health care practice, within 30 days of assuming such ownership, Dr. Williams shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements 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. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

If, at any time during the term of this Agreement, Dr. Williams owns part or all of a health care practice, within 90 days of assuming such ownership, Dr. Williams agrees to develop, implement, and make available to all employees, agents, contractors and all third parties with whom Dr. Williams may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs ("Covered Persons"), written policies that address the following:

1. Dr. Williams's commitment to operate his business in full compliance with all Federal health care program requirements;

2. The proper procedures for the honest and accurate submission of claims in accordance with Federal health care program requirements;

3. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;

4. The requirement that all of Dr. Williams's Covered Persons shall be expected to report to Dr. Williams and the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Williams's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with medical practice standards or Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect;

5. The requirement that Dr. Williams not hire, employ or engage as contractors 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 in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Dr. Williams shall check all prospective employees or contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available

through the Internet at http://epls.arnet.gov).

6. The commitment of Dr. Williams to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the Fiscal Intermediary or carrier related to Federal health care program requirements.

7. The commitment of Dr. Williams to bill Federal health care programs for resident services only in accordance with the applicable Federal health care program rules.

8. The commitment of Dr. Williams to bill Federal health care programs for services provided by certified registered nurse practitioners only in accordance with the applicable Federal health care program rules.

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

If, at any time during the term of this Agreement, Dr. Williams owns part or all of a health care practice, within 90 days of the assuming such ownership and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Dr. Williams's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the Agreement, whichever is later.

Copies of the written policies and procedures shall be made available to the OIG or its duly authorized representatives, upon request.

D. Training and Certification

Within 90 days following the effective date of this Agreement and at least once each year thereafter, Dr. Williams and any Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least four hours of training from an individual or entity, other than Dr. Williams or another Covered Person, who has expertise in the topics listed below.

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 90 days after the effective date of this Agreement, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions shall cover the following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;

2. Federal health care program requirements related to proper documentation;

3. All other applicable Federal health care program requirements;

4. Federal health care program requirements related to the proper billing for physicians' supervision of certified registered nurse practitioners services;

5. Federal health care program requirements related to the proper billing for services involving the use of residents;

6. The legal sanctions for improper billings; and

7. Examples of proper and improper billing practices.

Each Covered Person 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. Dr. Williams shall retain the certifications, along with the training course materials. These shall be made available to the OIG or its duly authorized representatives, upon request.

E. Third Party Billing

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

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days of the effective date of this Agreement, Dr. Williams shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a billing review to assess Dr. Williams's billing and coding practices ("Billing Engagement"). The Independent Review Organization retained by Dr. Williams shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this Agreement and in the Federal health care program requirements.

2. *Frequency of the Billing Engagement.* The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The IRO shall perform all components of each annual Billing Engagement in accordance with the procedures detailed in **Appendix A**.

3. *Retention of Records*. The IRO and Dr. Williams shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Williams's Billing Engagement fails to conform to the requirements of this Agreement or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complies with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate. Dr. Williams agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after the final report is submitted and received by the OIG.

G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money Dr. Williams or Dr. Williams's employer has received for services billed as provided by Dr. Williams in excess of the amount due and payable under any Federal health care program requirements for such services. Dr. Williams may not subtract any underpayments for purposes of determining the amount of relevant "overpayments", provided that nothing in this Agreement shall be construed to prevent Dr. Williams or his employer from submitting timely corrected claims for any services for which they were underpaid.

b. Reporting of Overpayments. If, at any time, Dr. Williams identifies or learns of any overpayments, Dr. Williams shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this

Agreement.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this Agreement, a "Material Deficiency" means anything that involves:

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or 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 Dr. Williams determines that there is a Material Deficiency with respect to his practices or services, Dr. Williams 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.F.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 Dr. Williams's actions taken to correct the Material Deficiency; and

(iv) any further steps Dr. Williams plans to take to address the Material Deficiency and prevent it from recurring.

H. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, Dr. Williams shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Dr. Williams 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. Dr. Williams shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV NEW BUSINESS UNITS OR LOCATIONS

If, at any time during the term of this Agreement, Dr. Williams owns all or part of a health care practice or entity that furnishes items or services that may be reimbursed by Federal health care programs, Dr. Williams shall notify the OIG of this fact as soon as possible, but no later than 30 days of the date he becomes an owner. Such notification shall include the address(es) such practice(s) or entity, phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider or supplier number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

V. REPORTS

A. Implementation Report

Within 120 days after the effective date of this Agreement, or, within 120 days of the date Dr. Williams becomes an owner of part or all of a health care practice, whichever is applicable, Dr. Williams shall submit a written report to OIG summarizing the status of his implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. A copy of the notice Dr. Williams posted in his office as described in Section III.B;

2. A copy of the written policies and procedures required by section III.C. of this Agreement;

3. A certification signed by Dr. Williams attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;

4. A description of the training required by Section III.D., including a summary of the topics covered and a schedule of when the training session(s) were held;

5. A certification signed by Dr. Williams attesting that he and all other Covered Persons have completed the initial training required by Section III.D. and have executed the required certifications;

6. A copy of the certification from any third party billing company engaged by Dr. Williams, if required by section III.E of the Agreement;

7. The name of the person or entity Dr. Williams has retained to conduct the billing engagement and the proposed start and completion dates of the first annual review;

8. A list of all Dr. Williams'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 number(s) and the contractor's name and address that issued each provider identification number; and

9. A certification from Dr. Williams 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. Williams shall submit to OIG Annual Reports with respect to the status of and findings regarding Dr. Williams's compliance activities for each of the 5 one-year periods beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). 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.

Each Annual Report shall include:

1. If revisions were made to the written policies and procedures developed pursuant to section III.C. of this Agreement, a copy of any policies and procedures that were revised;

2. A certification by Dr. Williams that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C.;

3. A description, schedule and topic outline of the training programs attended in accordance with section III.D. of this Agreement;

4. A certification signed by Dr. Williams certifying that he is maintaining written certifications from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement;

5. A complete copy of all reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;

6. Dr. Williams's response and corrective action plan(s) related to any issues raised by the IRO;

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

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

9. A certification signed by Dr. Williams certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and

10. A certification signed by Dr. Williams 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.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in this Agreement or changed by notice under this section, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

ATTN: Civil Recoveries Branch - 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

All correspondence to Dr. Williams shall be sent to:

Kenneth H. Williams, M.D.
606 South Montford Avenue
Baltimore, Maryland 21224
Ph. 410.675.5789

Unless otherwise specified, all notifications and reports required by this Agreement 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 Dr. Williams's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Dr. Williams's compliance with the terms of this Agreement; and (b) Dr. Williams's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Dr. Williams to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. If, during the term of the Agreement, Dr. Williams owns or has a control interest in a health care practice, then Dr. Williams will permit OIG or its duly authorized representative(s) to conduct on-site reviews of any of Dr. Williams's locations and/or to interview any of Dr. Williams'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. Dr. Williams agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dr. Williams's employees may elect to be interviewed with or without a representative of Dr. Williams present.

VIII. DOCUMENT AND RECORD RETENTION

If, during the term of the Agreement, Dr. Williams obtains an ownership or control interest in a health care practice, he shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Dr. Williams prior to any release by OIG of information submitted by Dr. Williams pursuant to its obligations under this Agreement and identified upon submission by Dr. Williams as trade secrets, or information that is

commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Williams shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. Williams shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Dr. Williams shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Williams.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Williams and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement 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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Williams or any applicable Covered Person fails to have in place any of the following:

   a. a Compliance Contact to the extent required by section III.A;

   b. a Posting of Notice to the extent required by section III.B;

   c. written Policies and Procedures to the extent required by section III.C;

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Williams or any applicable Covered Person fails to attend the training required by section III.D. of the Agreement.

3. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Williams fails to submit an annual review report by an IRO, as required in section III.F.

4. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day

after the date the obligation became due) for each day Dr. Williams fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

5. A Stipulated Penalty of $750 (which shall begin to accrue on the date the failure to comply began) for each day Dr. Williams employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Williams's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Dr. Williams can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.C.5.) as to the status of the person).

6. A Stipulated Penalty of $750 for each day Dr. Williams fails to grant access to the information or documentation as required in section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Dr. Williams fails to grant access.)

7. A Stipulated Penalty of $750 for each day Dr. Williams fails to comply fully and adequately with any obligation of this Agreement not already covered in paragraphs 1-5. In its notice to Dr. Williams, OIG shall state the specific grounds for its determination that Dr. Williams has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Williams must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Dr. Williams of the failure to comply.)

B. <u>Timely Written Requests for Extensions</u>

Dr. Williams 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 Agreement. 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 Dr. Williams fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report

shall not begin to accrue until two business days after Dr. Williams 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 Dr. Williams 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 Dr. Williams of: (a) Dr. Williams's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Dr. Williams shall respond by either: (a) curing the breach to OIG's satisfaction, paying the applicable Stipulated Penalties and notifying OIG of his corrective actions; or (b) sending in writing to the OIG a request for 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 Dr. Williams elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Williams 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 Agreement 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 Dr. Williams has materially breached this Agreement, 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 Agreement

1. *Definition of Material Breach.* A material breach of this Agreement

means:

a. a failure by Dr. Williams to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.G;

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

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

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this Agreement by Dr. Williams constitutes an independent basis for Dr. Williams's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Williams has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Dr. Williams of: (a) Dr. Williams'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*. Dr. Williams 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. Dr. Williams is in full compliance with this Agreement;

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) Dr. Williams has begun to take action to cure the material breach; (ii) Dr. Williams is pursuing such action with due diligence; and (iii) Dr. Williams has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If at the conclusion of the 30-day period, Dr. Williams fails to satisfy the requirements of section X.D.3, OIG may exclude Dr. Williams from participation in the Federal health care programs. OIG will notify Dr. Williams in writing

of its determination to exclude Dr. Williams (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 non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dr. Williams wishes to apply for reinstatement, Dr. Williams must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Dr. Williams of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Dr. Williams 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 Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Dr. Williams was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. Dr. Williams shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Dr. Williams to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Williams 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 Agreement shall be:

a. whether Dr. Williams was in material breach of this Agreement;

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) Dr. Williams had begun to take action to cure the material breach within that period;

(ii) Dr. Williams has pursued and is pursuing such action with due diligence; and

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

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

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 Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

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. Williams and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Dr. Williams;

2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;

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

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

KENNETH H. WILLIAMS, MD

_____	_____
Date	Kenneth H. Williams, MD
_____	_____
Date	Counsel for Dr. Williams

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

8/18/00	
Date	Lewis Morris 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:

KENNETH H. WILLIAMS, MD

8-21-00
Date

Kenneth H. Williams, MD

8/17/00
Date

Counsel for Dr. Williams

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

Date

Lewis Morris
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

APPENDIX A

A. Billing Engagement

The Billing Engagement shall be composed of a "Claims Review" and, in the event that Dr. Williams obtains an ownership or control interest in a health care practice during the term of this Agreement, a "Systems Review." The IRO shall prepare a report (or reports, if applicable) to report the findings of the reviews.

1. ***Claims Review.*** The IRO shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by Dr. Williams to the Medicare program.

2. ***Claims Review Report.*** The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be submitted to the OIG in the Annual Report.

3. ***Systems Review.*** If, during the term of this Agreement, Dr. Williams obtains an ownership or control interest in a health care practice, then the IRO shall review Dr. Williams's billing and coding systems and/or operations (the "Systems Review"). This review shall examine the coding and claim submission process (e.g., reviewing the process, reviewing the systems edits).

4. ***Systems Review Report.*** If the IRO conducts a Systems Review, it shall prepare a report based upon the Systems Review ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding the strengths and weaknesses in Dr. Williams's coding systems and/or operations and claims submission process. This report shall also include any recommendations the IRO may have to improve any of these systems, operations, and processes. The Systems Review Report shall be submitted to the OIG in the Annual Report.

B. Claims Review

1. ***Definitions.*** For the purposes of the Claims Review, the following definitions

shall be used:

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Overpayment: For purposes of this Agreement, an Overpayment shall mean the amount of money Dr. Williams or Dr. Williams's employer has received for services billed as provided by Dr. Williams in excess of the amount due and payable under any Federal health care program requirements for such services. Dr. Williams may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" but nothing in this Agreement shall prevent or be construed to prevent Dr. Williams or Dr. Williams's employer, as applicable from filing a revised timely claim in the event and underpayment is determined.

d. Paid Claim: A code or line item submitted under Dr. Williams' UPIN and for which Dr. Williams or Dr. Williams's employer has received reimbursement from the Medicare program.

e. Population: All Items for which a code or line item was submitted under Dr. Williams's UPIN and for which Dr. Williams or his employer 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.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

2. ***Description of Claims Review.*** The Claims Review shall consist of an

appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Claims Review Sample Size Options.

Option 1: Review a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate.

To determine how many Items must be included in the Claims Review Sample, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall include at least 30 Items and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Dr. Williams or his employer for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment.

After the estimated mean and standard deviation of the population has been calculated the number of Items that must be included in the Claims Review Sample (in order to meet the 90% confidence and 25% precision requirement) shall be determined. This determination shall be made using RAT-STAT' "Sample Size Estimators" (located under the "Utility Program" file). The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population

including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

If no Overpayments are found in this Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample. The results of the Probe Sample shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section C, below); or

Option 2: Review a minimum 100 Items Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All 100 Paid Claims shall be reviewed and reported on in the Claims Review Report (See Section B, below).

d. Item Appraisal. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

e. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which Dr. Williams cannot produce documentation sufficient to support the Paid Claim shall be considered an error, and the total reimbursement received for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample and Claims Review Sample) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

C. **Claims Review Report.** The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have 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. Sources of Data: A description of the 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, HCFA 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. Documentation Required Under Option 1:

i. The number of Items appraised in the Probe Sample and in the Claims Review Sample.

ii. A copy of the RAT-STATS printout of the random numbers

generated by the "Random Numbers" function for the Probe Sample and the Claims Review Sample.

iii. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

iv. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.

v. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample shall be available to the OIG upon request.

b. Documentation Required Under Option 2:

i. The number of Items appraised in the Claims Review Sample.

ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for the Claims Review Sample.

iii. The Sampling Frame used in the Claims Review Sample shall be available to the OIG upon request.

3. ***Claims Review Results***

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

b. 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. Williams.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its

report to Dr. Williams, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments for the purpose of reporting these amounts in the Claims Review Report to the OIG.

d. 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 IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. ***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.