INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MARY ANNE MCDONALD, M.D.

I. PREAMBLE

Mary Anne McDonald, M.D. ("Dr. McDonald") hereby enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations, 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") by Dr. McDonald. This commitment to promote compliance applies to any entity that Dr. McDonald owns or in which Dr. McDonald has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. McDonald's and any such entity's employees, agents, contractors and all third parties with whom Dr. McDonald or such entity may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs ("Covered Persons").

On November 26, 1999, Dr. McDonald entered into a Corporate Integrity Agreement ("CIA") with HHS-OIG which was later incorporated by reference into the February 3, 2000 Settlement Agreement with the United States. Due to a change in Dr. McDonald's employment status, the parties have agreed to execute this new Agreement effective October 1, 2001. As of October 1, 2001, this Agreement will nullify and replace the November 26, 1999 CIA. Until such time as this Agreement becomes effective, Dr. McDonald agrees to adhere to the obligations and reporting requirements of the November 26, 1999 CIA. Although the November 26, 1999 CIA will be nullified and replaced effective on October 1, 2001, Dr. McDonald agrees to submit the Annual Report that was due under that CIA on November 26, 2001.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the compliance obligations assumed by Dr. McDonald under this Agreement shall begin on the effective date of this Agreement and run through November 26, 2004. The effective date of this Agreement shall be October

1, 2001.

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. McDonald pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days of execution of this Agreement, Dr. McDonald 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. McDonald shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

Within the first 30 days following the effective date of this Agreement, Dr. McDonald shall post in a prominent place accessible to all patients and Covered Persons a notice detailing her commitment to comply with all Federal health care program requirements in the conduct of her business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the first Annual Report.

C. Written Policies and Procedures

Within 90 days of the effective date of this Agreement, Dr. McDonald agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

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

2. The requirement that all claims for items and services billed to the

Federal health care programs are reviewed to ensure that the claims are: (1) coded to accurately reflect the level of service or item provided to patients; (2) sufficiently documented to establish medical necessity in accordance with the Federal health care program requirements; and (3) properly reimbursable and covered by the Federal health care programs.

3. The proper and accurate billing of CPT codes 90935, 90937, 90945, 90947 and modifier -25 (as defined in CPT 2000).

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

5. The requirement that Dr. McDonald 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, 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. McDonald shall check all prospective employees and 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) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

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

At least annually (and more frequently if appropriate), Dr. McDonald 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.

Within 90 days of the effective date of the Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Dr. McDonald'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 included in the first Annual Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 90 days following the effective date of this Agreement and at least once each year thereafter, Dr. McDonald and 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 training from an individual or entity other than Dr. McDonald on, at a minimum, the training topics outlined below. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by Dr. McDonald.

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 60 days after becoming a Covered Person or within 90 days of 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 coding, documentation and submission of accurate bills for services rendered and/or items provided to Federal health care program patients;

2. The written Policies and Procedures developed pursuant to Section III.C., above;

3. The legal sanctions for improper billing or other violations of the Federal health care program requirements; and

4. Examples of proper and improper billing practices.

Each Covered Person shall annually 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. McDonald shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Third-Party Billing

In the event that Dr. McDonald contracts with a third-party billing company to submit claims to the Federal health care programs on behalf of her practice, the following provisions of this Paragraph III.E shall apply. Dr. McDonald will certify to the OIG that she does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third-party billing company and is not employed by, and does not act as a consultant to, the third-party billing company. If Dr. McDonald intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third-party billing company during the term of this Agreement, Dr. McDonald shall notify OIG 30 days prior to any such proposed involvement.

Upon retention of a third-party billing company, Dr. McDonald shall obtain and include in the Annual Report a certification from the third-party billing company that (i) to the best of its knowledge, the company 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 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 the required training in accordance with section III.D. of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs. Each time Dr. McDonald contracts with a new third-party billing company during the term of this Agreement, Dr. McDonald shall obtain the required certification and include such certification in the Annual Report.

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days of the effective date of this Agreement, Dr. McDonald 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 Claims Review and a Process Review (collectively the "Reviews") to assess Dr. McDonald's billing and coding practices. The Independent Review Organization retained by Dr. McDonald 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. The IRO shall assess, along with Dr. McDonald, whether it can perform the IRO engagement in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

2. *Frequency of the Reviews.* The Claims Review shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this Agreement. The Process Review shall be performed for the first one year Reporting Period. The IRO shall perform all components of the Reviews and prepare the required reports in accordance with the procedures detailed in **Appendix A** to this Agreement, which is incorporated by reference into this Agreement.

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

4. *Independence Certification.* Within 120 days from the effective date of this Agreement, the IRO shall provide to Dr. McDonald a certification or sworn affidavit that it has evaluated its professional independence with regard to the Reviews and that it has concluded that it is, in fact, independent. Such certification shall be included in Dr. McDonald's Annual Report submission.

5. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. McDonald's Reviews fail to conform to the requirements of this Agreement or (b) the results of the Reviews are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Reviews comply with the requirements of the Agreement and/or the results of the Reviews are inaccurate. Dr. McDonald 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 submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. McDonald of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Dr. McDonald may request a meeting with the OIG to discuss the results of the Reviews; present any additional or relevant information to clarify the results of the Reviews or to correct the inaccuracy of the Reviews; and/or propose alternatives to the proposed Validation Review. Dr. McDonald 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 issues regarding the Reviews with Dr. McDonald 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.

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. McDonald has received in excess of the amount due and payable under any Federal health care program requirements. Dr. McDonald may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this Agreement.

b. Reporting of Overpayments. If, at any time, Dr. McDonald identifies or learns of any overpayments, Dr. McDonald shall notify the payor within 30 days of identification of the overpayment 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. Also, within 30 days of identification of the overpayment, Dr. McDonald shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, Dr. McDonald 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 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 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 Dr. McDonald determines, by any means, that there is a Material Deficiency, Dr. McDonald 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.G.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. McDonald's actions taken to correct the Material Deficiency; and

(iv) any further steps Dr. McDonald 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. McDonald 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. McDonald 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. McDonald 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

In the event that, of the effective date of this Agreement, Dr. McDonald changes locations or purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. McDonald 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 operation(s), phone number, fax number, Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider 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. Annual Reports

Dr. McDonald shall submit to OIG Annual Reports with respect to the status of and findings regarding Dr. McDonald's compliance activities for each of the 3 one-year periods following 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 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. A copy of the Policies and Procedures developed pursuant to section III.C. of this Agreement shall be included with the first Annual Report. For subsequent Annual Reports, a copy of any revised section III.C. Policies and Procedures;

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

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

4. A certification signed by Dr. McDonald certifying that she is maintaining written certifications from all Covered Persons 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 Engagement, including the Claims Review Report and Process Review Report, along with a copy of the IRO's engagement letter;

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

7. A summary/description of all engagements between Dr. McDonald and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;

8. A summary of any 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;

9. 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;

10. A certification signed by Dr. McDonald 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

11. A certification signed by Dr. McDonald certifying that she has reviewed the Annual Report, she has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

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

If to Dr. McDonald:
[Contact Person]
Address
City, State Zip
Ph.
Fax

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

VIII. DOCUMENT AND RECORD RETENTION

Dr. McDonald shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for 4 years (or longer if otherwise required).

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. McDonald prior to any release by OIG of information submitted by Dr. McDonald pursuant to her obligations under this Agreement and identified upon submission by Dr. McDonald as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. McDonald shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. McDonald 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. McDonald shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr.

McDonald.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. McDonald 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. McDonald:

a. Fails to have in place a Compliance Contact as required in section III.A;

b. Fails to post the notice required in section III.B;

c. Fails to have in place the Policies and Procedures required in section III.C;

d. Or each applicable Covered Person fails to attend the training required by section III.D. of the Agreement within the time frames required in that section;

e. Fails to retain an IRO within the timeframe required in section III.F.1, or annually submit the IRO's Claims Review Report and Process Review Report as required in section III.F. and Appendix A; or

f. Fails to meet any of the deadlines for the submission of the Annual Reports to OIG.

2. A Stipulated Penalty of $750 (which shall begin to accrue on the date the failure to comply began) for each day Dr. McDonald employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. McDonald'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. McDonald can demonstrate that Dr. McDonald 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).

3. A Stipulated Penalty of $750 for each day Dr. McDonald 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. McDonald fails to grant access.)

4. A Stipulated Penalty of $750 for each day Dr. McDonald fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. McDonald, OIG shall state the specific grounds for its determination that Dr. McDonald has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. McDonald 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. McDonald of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions

Dr. McDonald 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. McDonald 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 Dr. McDonald 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. McDonald 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. McDonald of: (a) Dr. McDonald'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 of the receipt of the Demand Letter, Dr. McDonald shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of her corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to 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. McDonald elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. McDonald 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. McDonald 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. McDonald 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;

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 Independent Review Organization in accordance with section III.F.

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

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. McDonald has begun to take action to cure the material breach; (ii) Dr. McDonald is pursuing such action with due diligence; and (iii) Dr. McDonald 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. McDonald fails to satisfy the requirements of section X.D.3, OIG may exclude Dr. McDonald from participation in the Federal health care programs. OIG will notify Dr. McDonald in writing of its determination to exclude Dr. McDonald (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. McDonald wishes to apply for reinstatement, Dr. McDonald 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. McDonald 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. McDonald 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 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 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. McDonald was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Dr. McDonald 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. McDonald to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. McDonald 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. McDonald 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. McDonald had begun to take action to cure the material breach within that period;

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

(iii) Dr. McDonald provided to OIG within that period a reasonable timetable for curing the material breach and Dr. McDonald 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 Dr. McDonald, only after a DAB decision in favor of OIG. Dr. McDonald's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. McDonald 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 Dr. McDonald 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. Dr. McDonald agrees to waive her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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.

XI. 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. McDonald and the OIG agree as follows:

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

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

3. OIG may agree to a suspension of Dr. McDonald's obligations under this Agreement in the event of Dr. McDonald's cessation of participation in Federal health care programs. If Dr. McDonald withdraws from participation in Federal health care programs and is relieved from her Agreement obligations by the OIG, Dr. McDonald agrees to notify the OIG

30 days in advance of Dr. McDonald's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.

4. The undersigned Dr. McDonald 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:

MARY ANNE MCDONALD, M.D.

10-24-01
Date

MAMcDonald MD
Mary Anne McDonald, M.D.
[Address]

10/22/01
Date

J. Ronald Sim
Counsel for Dr. McDonald

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

10/11/01
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

APPENDIX A

A. Overview of Required IRO Reviews

The IRO shall conduct two separate reviews, a "Claims Review" and a "Process Review." The IRO shall prepare a Claims Review Report and a Process Review Report to communicate 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. McDonald to the Medicare program. This review shall be performed annually.

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. ***Process Review.*** The IRO shall review Dr. McDonald's billing and coding systems and/or operations (the "Process Review"). This review shall examine the coding and claim submission process (e.g., reviewing the process, reviewing the systems edits, automated coding systems). This review shall only be conducted for the first Reporting Period.

4. ***Process Review Report.*** The IRO shall prepare a report based upon the Process Review ("Process Review Report"). The Process Review Report shall include the IRO's findings and supporting rationale regarding the strengths and weaknesses in Dr. McDonald'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, and a discussion of how Dr. McDonald can implement such recommendations. The Process Review Report shall be submitted to the OIG in the first 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. Paid Claim: A code or line item submitted by Dr. McDonald and for which Dr. McDonald has received reimbursement from the Medicare program.

d. Population: All Items for which Dr. McDonald has submitted a code or line item and for which Dr. McDonald 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.

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a randomly selected sample of Items (the Claims Review Sample).

a. Claims Review Sample. Review a minimum 100 Items Claims Review Sample. The 100 Items shall be randomly selected by the IRO. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report (See Section C., below).

b. Item Appraisal. For each Item appraised, only Paid Claims shall be evaluated. 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.

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

Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

d. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample 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 Claims Review Sample.

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

a. Claims Review Methodology

(i) *Claims Review Objective*: A clear statement of the objective intended to be achieved by the Claims Review.

(ii) *Sampling Unit*: A description of the Item as that term is utilized for the Claims Review. As noted in section A.3.b above, for purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

(iii) *Claims Review Population*: A description of the Population subject to the Claims Review.

(iv) *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).

(v) *Review Protocol*: A narrative description of how the Claims Review was conducted and what was evaluated.

b. Claims Review Results

(i) Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by Dr. McDonald ("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. McDonald;

(iii) 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. The IRO may, in its report to Dr. McDonald, 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 when reporting these amounts in the Claims Review Report to the OIG; and

(iv) 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.

c. Credentials.

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

AMENDMENT TO THE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MARY ANNE McDONALD, M.D.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Mary Anne McDonald, M.D. ("Dr. McDonald") entered into a Integrity Agreement ("IA") on October 24, 2001.

A. Pursuant to section XI.2. of Dr. McDonald's IA, modifications to the IA may be made with the prior written consent of both the OIG and Dr. McDonald. Therefore, the OIG and Dr. McDonald hereby agree that Dr. McDonald's IA will be amended as follows:

Section III.F., Review Procedures of the IA is hereby superceded by the attached new section III.F., Review Procedures.

Appendix A of Dr. McDonald's IA is hereby superceded by the attached new Appendix A.

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

C. The undersigned Dr. McDonald 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.

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

ON BEHALF OF MARY ANNE McDONALD, M.D.

Mary Anne McDonald, MD
[*Name*]
[*Title*]

4-16-02
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

DATE

F. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this IA, Dr. McDonald 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 assist Dr. McDonald in assessing and evaluating her billing and coding practices and systems, and her compliance obligations pursuant to this IA and the Settlement Agreement. The IRO retained by Dr. McDonald shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which Dr. McDonald seeks reimbursement. The IRO shall assess, along with Dr. McDonald, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO review shall address and analyze Dr. McDonald'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 IA beginning with the effective date of this IA. The IRO shall perform all components of each annual Claims Review.

c. Retention of Records. Dr. McDonald and the IRO shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between Dr. McDonald and the IRO 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 IA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare and other Federal health care programs Paid Claims submitted by or on behalf of Dr. McDonald. The Paid Claims shall be

reviewed based on the supporting documentation available to Dr. McDonald or under Dr. McDonald's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) 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. McDonald should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. McDonald 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 IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.F.2., the IRO 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 to Dr. McDonald or under Dr. McDonald'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. McDonald 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 appropriately. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. McDonald 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. McDonald's Discovery Sample identifies an Error Rate of 5% or greater, Dr. McDonald's IRO shall also conduct a Systems Review. Specifically, for each Item in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the Item to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Dr. McDonald observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with section III.G. of the IA, Dr. McDonald 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. McDonald agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

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. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. McDonald's Claims Review fails to conform to the requirements of this IA; or (b) the IRO'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 IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. McDonald 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. McDonald's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. McDonald 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. McDonald 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 proposed Validation Review. Dr. McDonald 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. McDonald 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 IRO shall include in its report to Dr. McDonald 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 was, 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. McDonald 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. McDonald and for which Dr. McDonald has received reimbursement from Medicare or other Federal health care programs.

d. Population: All Items for which Dr. McDonald has submitted a code or line item and for which Dr. McDonald has received reimbursement from the Medicare and other 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 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. McDonald cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. McDonald 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. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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 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. **Claims Review Findings.**

a. a description of Dr. McDonald's billing and coding system(s), including the identification, by position description, of the personnel involved in

coding and billing;

b. the IRO's findings, supporting rationale, and a summary of such findings and rationale 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. Note: for the purpose of this reporting, 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; and

c. the IRO's findings and recommendations concerning the Systems Review (if any).

3. **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.

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

4. **Claims Review Results.**

a. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Dr. McDonald ("Claims 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. McDonald.

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

d. Error Rate in the sample(s).

e. 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.)

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s) in the sample Population.

6. **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.