EXHIBIT A

INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ROBERT MEDAGLIO, D.P.M.

I. PREAMBLE

Robert Medaglio, D.P.M. ("Dr. Medaglio") hereby agrees to enter into this Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Dr. Medaglio, Dr. Medaglio's employees and any entity which participates in the Federal health care programs in which Dr. Medaglio has an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)). Dr. Medaglio's compliance with the terms and conditions of this Agreement shall constitute an element of Dr. Medaglio's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Dr. Medaglio is entering into a Settlement Agreement with the United States. This Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

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

III. INTEGRITY OBLIGATIONS

Within ninety (90) days of the date of the effective date of this Agreement, Dr. Medaglio agrees to implement an Integrity Program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Agreement, Dr. Medaglio shall designate a person to be the contact person for purposes of the obligations herein. At all times during the term of this Agreement, there shall be a contact person who shall have operational responsibility for ensuring compliance with the integrity obligations in this Agreement. If a new contact person is designated during the term of this Agreement, Dr. Medaglio shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this agreement, Dr. Medaglio shall post, in a prominent place accessible to all patients and employees, a notice detailing his commitment to comply with applicable statutes, regulations and written directives applicable to the Medicare, Medicaid and other Federal health care programs in the conduct of his medical practice and in seeking reimbursement for services and items furnished to patients of the Federal health care programs. This notice shall identify a means (*i.e.*, telephone number, address) through which matters of concern can be reported anonymously.

C. WRITTEN COMPLIANCE POLICIES AND PROCEDURES

Within sixty (60) days of the effective date of this Agreement Dr. Medaglio agrees to develop and implement written compliance policies and procedures , which shall, at a minimum, address the following:

1. Dr. Medaglio's commitment to adhere to honest and accurate billing practices;

2. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards and coverage requirements;

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

4. A mechanism for employees and agents to make inquiries regarding compliance with medical practice standards and Federal health care program reimbursement standards and coverage requirements

without risk of retaliation or other adverse effect.

D. INELIGIBLE PERSONS

1. *Definition*. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) 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.

2. *Screening Requirements*. Dr. Medaglio shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Dr. Medaglio shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement*. Within 90 days of the effective date of this CIA, Dr. Medaglio shall review his list of current employees and contractors against the Exclusion Lists. Thereafter, Dr. Medaglio shall review the list semi-annually. In addition, Dr. Medaglio shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If Dr. Medaglio has notice that an employee or contractor has become an Ineligible Person, Dr. Medaglio shall remove such person from responsibility for, or involvement with, Dr. Medaglio's business operations related to the Federal health care programs and shall remove such person from any 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 at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Dr. Medaglio has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, the Dr. Medaglio shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

E. TRAINING AND CERTIFICATION

Within ninety (90) days of the effective date of this Agreement, Dr. Medaglio and Dr. Medaglio's employees who are directly or indirectly involved in the preparation or submission of claims for reimbursement to the Federal health care programs ("Covered Employees') shall be trained in the proper reimbursement standards, program policies, verification and compliance procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal health care program beneficiaries. The training shall be designed to ensure that Dr. Medaglio and all Covered Employees are aware of all applicable Federal health care program statutes, regulations and written directives and the consequences (*e.g.*, criminal, civil and administrative liability, including overpayment demands, restitution, penalties and exclusion from the Federal health care programs) both to the Covered Employee and to Dr. Medaglio that may ensue from any violation of such statutes, regulations and written directives.

Dr. Medaglio agrees to arrange for each new Covered Employee to participate in such training no later than fifteen (15) days after the person begins to work for Dr. Medaglio. Until the person has received the requisite training, such new Covered Employee shall work under the direct supervision of a Covered Employee who has received the required training.

This training program shall provide for no less than four (4) hours of training annually for Dr. Medaglio and each Covered Employee.

At a minimum, the training session shall cover the following topics:

1. Dr. Medaglio's obligations under this Agreement;

2. All applicable Federal health care program statutes, regulations and written directives related to reimbursement, and the legal sanctions for improper

billing or other violations of these standards; and

3. The written compliance policies and procedures developed pursuant to section III. C. above, including the proper billing standards and procedures for the submission of accurate claims to the Medicare, Medicaid and other Federal health care programs.

Dr. Medaglio and each Covered Employee shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the compliance policies and procedures developed in accordance with section III. C. and all applicable Federal health care program statutes, regulations and written directives addressed in the training. These certifications will be maintained by Dr. Medaglio and shall be made available for inspection by OIG or its duly authorized representative(s). At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

F. THIRD PARTY BILLING

Dr. Medaglio presently contracts with a third party billing company to submit claims to the Federal health care programs. Dr. Medaglio represents that he 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. Medaglio 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. Medaglio shall notify OIG 30 days prior to any such proposed involvement.

Within 120 days of the effective date of this Agreement, Dr. Medaglio shall obtain and include in the Implementation Report 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 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.E. of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs. If Dr. Medaglio contracts with a new third party billing company during the term of this

Agreement, Dr. Medaglio shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

G. INDEPENDENT REVIEWS

On at least an annual basis and for the duration of this Agreement, Dr. Medaglio agrees to contract with an independent third-party reviewer (*e.g.*, a health care billing auditor or a consultant) (hereinafter the "independent reviewer") to undertake a review of a statistically valid random sample of claims submitted to Medicare and other Federal health care programs by Dr. Medaglio or by any third party billing company on behalf of Dr. Medaglio. The purpose of this review is to determine whether the claims are in compliance with the appropriate billing and coverage requirements. This review will be conducted by an independent reviewer who is an appropriately trained person or entity with knowledge of Federal health care program statutes, regulations, written directives and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the Federal health care programs are medically necessary and covered services under applicable statutes, regulations and written directives and that the claims are appropriately coded and billed. At the conclusion of each review, the independent reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as presenting the independent reviewer's findings, conclusions and recommendations. A copy of this report shall be included in Dr. Medaglio's Annual Report to OIG. If OIG determines that an additional review is necessary, Dr. Medaglio agrees to pay for the reasonable costs of such review which will be performed by OIG or its authorized representative(s).

H. REPORTING

1. *Overpayments*

a. Definition of Overpayment. For purposes of this CIA, an "overpayment" shall mean the amount of money Dr. Medaglio has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or written directives, including carrier and intermediary instructions. Dr. Medaglio may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, Dr. Medaglio

identifies or learns of any billing, coding or other policies, procedures and/or practices that result in overpayments, Dr. Medaglio shall notify the payor (*e.g.*, Medicare fiscal intermediary or carrier) and repay any overpayments within 30 (thirty) days of discovery and take remedial steps within 60 (sixty) 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 to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, can be done pursuant to a form similar to the Overpayment Refund Form, provided as Attachment 1 to this CIA.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this CIA, a "Material Deficiency" means an isolated event or a series of occurrences that involve:

(a) a substantial overpayment relating to any Federal health care program;

(b) 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; or

(c) a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care, where such violation has occurred in one or more instances, that presents an imminent danger to the health, safety or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

b. Reporting of Material Deficiencies. If Dr. Medaglio determines that there is a material deficiency, Dr. Medaglio shall notify OIG within 30 (thirty) days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(a) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III. H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

(ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;

(b) a complete description of the Material Deficiency, including the relevant facts, persons involved and legal and program authorities implicated;

(c) a description of Dr. Medaglio's actions taken to correct the Material Deficiency; and

(d) any further steps Dr. Medaglio plans to take to address such Material Deficiency and prevent it from recurring.

IV. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Dr. Medaglio's books, records, documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) Dr. Medaglio's compliance with the terms of this Agreement, and (ii) Dr. Medaglio's compliance with Federal health care programs statutes, regulations and written directives. OIG, or its duly authorized representative(s), may conduct unannounced on-site visits at Dr. Medaglio's place of business at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Dr. Medaglio's compliance with the statutory and regulatory requirements of the Federal health care programs and compliance with the terms of this Agreement. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s), may interview any of Dr. Medaglio'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. Medaglio

agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. Dr. Medaglio's employees, contractors and agents may elect to be interviewed with or without a representative of Dr. Medaglio present.

V. REPORTS

A. IMPLEMENTATION REPORT

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

1. A copy of the notice Dr. Medaglio posted in its office as described in Section III.B.

2. A certification signed by Dr. Medaglio attesting that Dr. Medaglio and all Covered Employees have completed the initial training required by Section III.E. as well as a summary of what the training included. The training materials will be made available to OIG upon request.

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

4. A certification from Dr. Medaglio stating that Dr. Medaglio has reviewed the Implementation Report, and believes that the information is accurate and truthful.

B. ANNUAL REPORTS

Dr. Medaglio agrees to provide annual written reports, each one of which is referred to throughout this Agreement as the "Annual Report", to OIG describing the measures he has taken to implement, maintain and ensure compliance with the terms of this Agreement. The Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented pursuant to Section III.E. of this Agreement, and a

written certification from Dr. Medaglio and all Covered Employees that they received training pursuant to the requirements set forth in Section III.E. of this Agreement.

2. A copy of the annual review conducted pursuant to Section III.G. of this Agreement relating to the year covered by the Annual Report; a complete description of the independent reviewer's findings and any corrective actions taken in response to the findings.

3. A summary of any changes or amendments to the Compliance Policies and Procedures required by section III.C and the reasons for such changes (*e.g.*, change in contractor policy).

4. A description of any changes to the training program.

5. A summary of Material Deficiencies (as defined in section III.H) identified during the reporting period and the status of any corrective and preventative action relating to the Material Deficiency.

6. A report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid and other Federal health care programs.

7. A certification signed by Dr. Medaglio certifying that he has reviewed the Annual Report and believes that the information is accurate and truthful.

The first Annual Report shall be submitted no later than one (1) year and sixty (60) days after the effective date of this Agreement. Subsequent Annual Reports will be submitted on the anniversary date of the date of submission of the first Annual Report.

VI. NOTIFICATION AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with section IX. below, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

To 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, D.C. 20201
Tel: (202) 619-2078
Fax: (202) 205-0604

To Dr. Medaglio:
Robert Medaglio, D.P.M.
459 Broadway
Everett, Massachusetts
Tel:
Fax:

VII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Dr. Medaglio shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Medaglio. In the event of Dr. Medaglio's failure to comply with any of the obligations in this Agreement, the Agreement may be deemed in breach and the parties shall proceed in the appropriate manner as described below.

A. DEFINITION OF MATERIAL BREACH

For purposes of this section, a "material breach" is defined as: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III. H. of this Agreement; (ii) repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in sections IV., V.A and V.B of this Agreement; or (iii) a failure to retain and use an independent reviewer for the annual review described in section III.G.

B. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

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

1. cure the alleged material breach; or

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

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and Dr. Medaglio), Dr. Medaglio fails to act in accordance with sections VII.B.1.or 2. above, OIG may initiate steps to exclude Dr. Medaglio from participation in the Federal health care programs. OIG will notify Dr. Medaglio in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter").

C. DISPUTE RESOLUTION

Upon OIG's delivery to Dr. Medaglio of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, the OIG may initiate steps to exclude Dr. Medaglio from participation in the Federal health care programs. Dr. Medaglio shall be entitled to certain due process rights similar to those afforded under 42 U.S.C. § 1320a-7(f) and 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. OIG and Dr. Medaglio agree that the decision by the DAB, if any, shall constitute the final decision for purposes of the exclusion under this Agreement.

The review by an ALJ or the DAB provided for above shall not be considered to

be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Dr. Medaglio agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise, or to seek review by any court or other adjudicative form.

VIII. NEW ENTITIES OR LOCATIONS

In the event that Dr. Medaglio purchases or establishes new business units, that participate in the Federal health care programs, after the effective date of this Agreement, Dr. Medaglio shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider identification number(s) and the corresponding payor(s) (contractor specific) that has issued each provider number. Dr. Medaglio and all Covered Employees at such locations shall be subject to the requirements in this Agreement that apply to new employees (*e.g.*, completing certifications and undergoing training).

IX. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement to which this Integrity Agreement is incorporated by reference, Dr. Medaglio and OIG agree as follows:

A. this Agreement shall be binding on the successors, assigns and transferees of Dr. Medaglio;

B. this Agreement shall become final and binding only upon signing by each respective party hereto; and

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

ROBERT MEDAGLIO, D.P.M.

Robert Medaglio, D.P.M. — Date: 1-7-01

COUNSEL FOR ROBERT MEDAGLIO, D.P.M.

Robert Griffith, Esq. — Date: 1/15/01
30 Federal Street
Boston, Massachusetts 02110

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

Lewis Morris, Esq. — Date
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:

ROBERT MEDAGLIO, D.P.M.

Robert Medaglio, D.P.M. Date

COUNSEL FOR ROBERT MEDAGLIO, D.P.M.

Robert Griffith, Esq. Date
30 Federal Street
Boston, Massachusetts 02110

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

Lewis Morris, Esq. Date 1/22/01
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ROBERT MEDAGLIO, D.P.M.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Robert Medaglio, D.P.M., ("Dr. Medaglio") entered into an Integrity Agreement ("IA") on January 22, 2001.

A. Pursuant to Section IX.C., Effective and Binding Agreement, of Dr. Medaglio's IA, modifications to the IA may be made with the prior written consent of both the OIG and Dr. Medaglio. Therefore, the OIG and Dr. Medaglio hereby agree that Dr. Medaglio's IA will be amended as follows:

   Section III.G., Independent Reviews, of the IA is hereby superceded by the attached new Section III.G., Review Procedures.

   The attached Appendix A is hereby added to Dr. Medaglio's IA.

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

C. Dr. Medaglio's signature represents and warrants that he is 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. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF ROBERT MEDAGLIO, D.P.M.

Robert Medaglio, D.P.M.

Robert B Medaglio DPM

2-2-02
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

1/28/02
DATE

G. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this Agreement, Dr. Medaglio shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Dr. Medaglio in assessing and evaluating his billing and coding practices and systems pursuant to this Agreement and the Settlement Agreement. Each IRO retained by Dr. Medaglio 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 general requirements of the Federal health care program(s) from which Dr. Medaglio seeks reimbursement. Each IRO shall assess, along with Dr. Medaglio, 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(s) review shall address and analyze Dr. Medaglio's billing and coding of claims submitted to 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 Agreement beginning with the effective date of this Agreement. The IRO(s) shall perform all components of each annual Claims Review.

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

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of Dr. Medaglio to Medicare

or any other Federal health care programs. The Paid Claims shall be reviewed based on the supporting documentation available at Dr. Medaglio's office(s) or under Dr. Medaglio'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. Medaglio should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Medaglio 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.G.2.a, 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 at Dr. Medaglio office(s) or under Dr. Medaglio'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. Medaglio 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. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. Medaglio 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. Medaglio's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Medaglio's IRO shall also conduct a Systems Review. Specifically, for each claim 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 claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Dr. Medaglio 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.H of the Agreement, Dr. Medaglio 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. Medaglio 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. Medaglio's Claims Review fails to conform to the requirements of this Agreement; 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 CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. Medaglio 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. Medaglio's final submission is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Medaglio 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. Medaglio 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. Medaglio 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. Medaglio 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(s) to Dr. Medaglio 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. Medaglio 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. Medaglio and for which Dr. Medaglio has received reimbursement from the Medicare program.

d. Population: All Items for which Dr. Medaglio has submitted a code or line item and for which Dr. Medaglio has received reimbursement from the Medicare and any other Federal health care program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

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

2. **Other Requirements.**

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

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

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

1. **Claims Review Methodology.**

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical

records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

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

b. Quantitative Results.

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

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

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the 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. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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