

EXHIBIT A

INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND DR. REMIGIO PALUMBO

I. PREAMBLE

Dr. Remigio Palumbo (Palumbo) hereby enters into this Integrity 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 Palumbo. This commitment to promote compliance applies to any entity that Palumbo owns or in which Palumbo has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's officers and directors, employees, agents, contractors and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons"). Contemporaneous with this Integrity Agreement, Palumbo is entering into a Settlement Agreement with the OIG. The Integrity Agreement is incorporated by reference into that Settlement Agreement.

II. TERM OF THE INTEGRITY AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Palumbo under this Integrity Agreement shall be 5 years from the effective date of this Integrity Agreement. The effective date of this Integrity Agreement shall be the date on which the final signatory of this Integrity Agreement executes this Integrity Agreement.

Sections VII, VIII, IX, X and XI shall expire no later than 120 days from the OIG's receipt of: (1) Palumbo's final annual report; or (2) any additional materials submitted by Palumbo pursuant to OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days of execution of this Integrity Agreement, Palumbo 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 Integrity Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Integrity Agreement, Palumbo 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 Integrity Agreement, Palumbo shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include a means (*i.e.*, telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

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

1. Palumbo's commitment to operate his business in full compliance with all Federal health care program requirements;
2. Palumbo's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Palumbo's own Policies and Procedures as implemented pursuant to Section III.C (including the requirements of this Integrity Agreement);
3. The requirement that all of Palumbo's Covered Persons shall be expected to report to Palumbo or the Compliance Contact suspected violations of any Federal health care program requirements or Palumbo'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;

4. The requirement that Palumbo shall not hire, employ, or engage as contractors any Ineligible Person. For purposes of this Integrity 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 that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Palumbo 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.oig.gov>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>). In addition to prospective checks, Palumbo shall conduct annual checks of all employees against each exclusion list;

5. The commitment of Palumbo to remain current with applicable Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from carriers or intermediaries related to Federal health care program requirements;

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

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

8. The requirement that any business or financial arrangements or contracts, including medical director contracts, shall not directly or indirectly induce the unlawful referral of Federal health care program beneficiaries, in violation of 42 U.S.C. § 1320a-7b (the Anti-Kickback Statute) or 42 U.S.C. § 1395nn (the Stark Law).

At least annually (and more frequently if appropriate), Palumbo 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 Integrity Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Palumbo'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 Integrity Agreement, whichever is later.

Copies of the written policies and procedures shall be included in the Implementation 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 Integrity Agreement and at least once each year thereafter, Palumbo 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 appropriate training from an individual or entity, other than Palumbo or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., fraud and abuse expertise regarding contractual arrangements.

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 90 days of the effective date of this Integrity 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. The written Policies and Procedures developed pursuant to Section III.C., above;
2. The Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes;
3. Applicable legal sanctions and consequences for improper financial arrangements or referrals;
4. Examples of violations of the Anti-Kickback Statute and the Stark Law that pertain to referral relationships with outside physicians and entities, including hospitals; and

5. A review of Palumbo's contracting policies and procedures related to contracts with potential referral sources as developed pursuant to Section III.E.

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. Palumbo shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Contracts for Professional or Administrative Services

Palumbo shall create procedures reasonably designed to prevent contractual or other arrangements with referral sources and recipients of referrals from violating the Anti-Kickback Statute and shall implement procedures to evaluate all existing contractual relationships and other relationships involving remuneration with contractors, vendors, and agents to the extent not already so evaluated. At a minimum, Palumbo shall ensure that all new and/or renewed (*i.e.*, at renewal date) independent contractor agreements: (1) related to the provision of its items or services, or (2) with parties in a position to recommend Federal health care program beneficiaries to Palumbo for the purchasing, leasing, or ordering of any items or services, or facility for which payment may be made in whole or in part from a Federal health care program, under which such parties are to provide sales related services to Palumbo, meet the following requirements:

1. The agreement shall be in writing and signed by the parties;
2. The agreement shall specify the actual services to be provided by the independent contractor to Palumbo;
3. The payment to the contracting entity under the agreement or compensation may be based on hours worked or other service-based criteria, paid to the contracting entity shall be set in advance, shall be consistent with fair market value in an arms-length transaction, and shall not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any Federal health care program;
4. The services performed under the agreement shall not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law; and

5. The contract shall include a provision that all Covered Persons shall comply with Palumbo's Corporate Compliance Program which includes training related to the Anti-Kickback Statute and the Stark Law. Additionally, Palumbo will provide to each entity with which Palumbo contracts that falls within the ambit of this Section a copy of its Standards of Conduct and Anti-Kickback policies and procedures.

F. Annual Review Procedures

1. *Legal Review.*

a. The Legal Review. The Legal Review shall consist of a review of all applicable independent contractor agreements and employment agreements that fall within the scope of Section III.F. to evaluate whether such agreements and relationships meet the applicable requirements and standards set forth in Section III.F. Palumbo shall retain an individual attorney or law firm with appropriate knowledge to analyze the sufficiency of Palumbo's contracts (Legal Reviewer) to conduct the Legal Review.

b. Legal Review Report. The Legal Reviewer shall certify that the Legal Review has occurred and the Legal Review Report shall include a summary of the findings of the Legal Review. Palumbo shall retain all agreements and policies that have been reviewed as well as all written reports generated by the Legal Reviewer relating to the Legal Review, including the Legal Review Report.

c. Frequency of Legal Review. The Legal Review shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this CIA.

d. Retention of Records.

(i). The Legal Reviewer and Palumbo shall retain and make available to the OIG, upon request, copies of contracts subject to the Legal Review required pursuant to Section III.F.1 and all nonprivileged communications, including work papers, supporting documentation, correspondence, draft reports, and contracts.

(ii). Nothing in this CIA or any other communication or report made pursuant to this CIA, shall constitute a waiver by Palumbo of his attorney-client, attorney work-product, or other

applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Palumbo to avoid his obligations to comply with the provisions of this CIA.

2. *Validation Review.* In the event the OIG has reason to believe that: (a) Palumbo's Legal Review fails to conform to the requirements of this Integrity Agreement; or (b) the Legal Reviewer's findings are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Legal Review complies with the requirements of the Integrity Agreement and/or the Legal Reviewer's findings are inaccurate. Palumbo 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.

3. *Independence Certification.* Within 120 days from the effective date of this Integrity Agreement, the Legal Reviewer shall provide to Palumbo a certification or sworn affidavit that it has evaluated its professional independence with regard to the Legal Review and that it has concluded that it is, in fact, independent. Such certification shall be included in Palumbo's Implementation Report submission.

G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments.*

a. *Definition of Overpayments.* For purposes of this Integrity Agreement, an "Overpayment" shall mean the amount of money Palumbo has received in excess of the amount due and payable under any Federal health care program requirements. Palumbo may not subtract any underpayments for purposes of determining the amount of relevant Overpayments for purposes of reporting under this Integrity Agreement.

b. *Reporting of Overpayments.* If, at any time, Palumbo identifies or learns of any Overpayments, Palumbo shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the Overpayment and take remedial steps within 60 days of identification (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, Palumbo 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, Palumbo shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of

when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix A to this Integrity Agreement. Notwithstanding the above, notification and repayment of an Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

a. *Definition of Material Deficiency.* For purposes of this Integrity 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 Palumbo determines, by any means, that there is a Material Deficiency, Palumbo shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

- (i) If the Material Deficiency results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.F.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (A) the payor's name, address, and contact person to whom the Overpayment was sent; and
 - (B) the date of the check and identification number

(or electronic transaction number) on which the Overpayment was repaid/refunded;

- (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (iii) a description of Palumbo's actions taken to correct the Material Deficiency; and
- (iv) any further steps Palumbo 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, Palumbo shall notify OIG, in writing, of any ongoing investigation known to Palumbo or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Palumbo has committed a criminal act 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. Palumbo 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 Integrity Agreement, Palumbo changes locations or sells, closes, purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Palumbo shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, 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. Palumbo and all Covered Persons at such new business units or locations shall be subject to the applicable requirements in this Integrity Agreement (e.g., completing certifications and undergoing training).

V. REPORTS

A. Implementation Report

Within 120 days after the effective date of this Integrity Agreement, Palumbo shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Integrity Agreement. This report, known as the "Implementation Report," shall include:

2. The name, address and phone number of Palumbo's Compliance Contact;
2. A copy of the notice Palumbo posted in his office as described in Section III.B. and a description of where and when the notice has been posted;
3. A copy of the written policies and procedures required by Section III.C. of this Integrity Agreement;
4. A certification signed by Palumbo attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
5. A copy of all training materials used for the training required by Section III.D., a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held;
6. A certification signed by Palumbo attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;
7. The name and qualifications of the Legal Reviewer, a summary/description of all engagements between Palumbo and the Legal Reviewer, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
8. A certification from the Legal Reviewer regarding its professional independence from Palumbo;
9. A list of all Palumbo's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider

identification number(s) and the name and address of the Medicare contractor to which Palumbo currently submits claims; and

10. A certification from the Palumbo stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Palumbo shall submit to OIG Annual Reports with respect to the status of and findings regarding Palumbo's compliance activities for each of the 5 one-year periods beginning on the effective date of the Integrity 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. If revisions were made to the written policies and procedures developed pursuant to Section III.C. of this Integrity Agreement, a copy of any policies and procedures that were revised;
2. A certification by Palumbo 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 Integrity Agreement;
4. A certification signed by Palumbo certifying that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D. of this Integrity Agreement;
5. A complete copy of all reports prepared pursuant to the Legal Reviewer's Reviews, along with a copy of the Legal Reviewer's engagement letter;
6. Palumbo's response and corrective action plan(s) related to any issues raised or recommendations made by the Legal Reviewer;
7. A summary/description of all engagements between Palumbo and the Legal Reviewer, including, but not limited to, any outside financial audits,

compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

8. A certification from the Legal Reviewer regarding its professional independence from Palumbo;

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

10. 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;

11. A certification signed by Palumbo 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

12. A certification signed by Palumbo certifying that he has reviewed the Annual Report, he 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 Integrity Agreement, all notifications and reports required under the terms of this Integrity Agreement shall be submitted to the following:

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
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

Palumbo: Kevin J. Darken, Esq.
Trenam Kemker
Attorney for Dr. Remigio Palumbo
2700 Bank of America Plaza
101 East Kennedy Boulevard
P.O. Box 1102 (33601)
Tampa, Florida 33602
Telephone: (813) 223-7474
Facsimile: (813) 229-6553

Unless otherwise specified, all notifications and reports required by this Integrity 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 Palumbo's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Palumbo's locations for the purpose of verifying and evaluating: (1) Palumbo's compliance with the terms of this Integrity Agreement; and (2) Palumbo's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Palumbo 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 Palumbo'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. Palumbo agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Palumbo's employees may elect to be interviewed with or without a representative of Palumbo present.

VIII. DOCUMENT AND RECORD RETENTION

Palumbo shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Integrity Agreement, for four years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with the Freedom of Information Act (FOIA) procedures for HHS set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Palumbo prior to any release by OIG of information submitted by Palumbo pursuant to its obligations under this Integrity Agreement and identified upon submission by Palumbo as trade secrets, or information that is commercial or financial and privileged or confidential, under these FOIA rules. With respect to such releases, Palumbo shall have the rights set forth at 45 C.F.R. § 5.65(d). Palumbo 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 Palumbo is expected throughout the duration of this Integrity Agreement with respect to all of the obligations herein agreed to by Palumbo.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Palumbo and OIG hereby agree that failure to comply with certain obligations set forth in this Integrity 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 Palumbo fails to:
 - a. have in place a Compliance Contact as required in Section III.A.;
 - b. post the notice required in Section III.B.;
 - c. implement and make available the Policies and Procedures required in Section III.C.;
 - d. require that Covered Persons attend the training required by Section III.D. of the Integrity Agreement within the time frames required in that Section;
 - e. retain an Legal Reviewer within the time frame required in Section III.F.1, or to submit the Legal Reviewer's annual Review as required in Section

III.F.; or

f. meet any of the deadlines for the submission of the Implementation Report or 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 Palumbo employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Palumbo's business operations related to the Federal health care programs; or (b) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Palumbo can demonstrate that Palumbo did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.4) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day Palumbo fails to grant access to the information or documentation as required in Section VII. of this Integrity Agreement. (This Stipulated Penalty shall begin to accrue on the date Palumbo fails to grant access.)

4. A Stipulated Penalty of \$750 for each day Palumbo fails to comply fully and adequately with any obligation of this Integrity Agreement. In its notice to Palumbo, OIG shall state the specific grounds for its determination that Palumbo has failed to comply fully and adequately with the Integrity Agreement obligation(s) at issue and steps the Palumbo must take to comply with the Integrity Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Palumbo receives notice from the OIG 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 subsections 1-3 of this Section.

B. Timely Written Requests for Extensions

Palumbo 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 Integrity 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 Palumbo 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 Palumbo 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 Palumbo 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 Palumbo of: (a) Palumbo'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, Palumbo shall respond by either: (a) curing the breach to OIG's satisfaction 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 Palumbo elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Palumbo 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 Integrity 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 Palumbo has materially breached this Integrity 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 Integrity Agreement

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

- a. a failure by Palumbo 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 Integrity 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 a Legal Reviewer in accordance with Section III.F.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Integrity Agreement by Palumbo constitutes an independent basis for Palumbo's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Palumbo has materially breached this Integrity Agreement and that exclusion should be imposed, OIG shall notify Palumbo of: (a) Palumbo'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.* Palumbo 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. Palumbo is in compliance with the obligations of the Integrity 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) Palumbo has begun to take action to cure the material breach; (ii) Palumbo is pursuing such action with due diligence; and (iii) Palumbo has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Palumbo fails to satisfy the requirements of Section X.D.3, OIG may exclude Palumbo from

participation in the Federal health care programs. OIG will notify Palumbo in writing of its determination to exclude Palumbo (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, Palumbo wishes to apply for reinstatement, Palumbo 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 Palumbo of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Integrity Agreement, Palumbo 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 Integrity Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS administrative law judge (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 Integrity Agreement shall be: (a) whether Palumbo was in full and timely compliance with the obligations of this Integrity Agreement for which OIG demands payment; and (b) the period of noncompliance. Palumbo shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Integrity Agreement and orders Palumbo to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Palumbo 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 Integrity Agreement shall be:

- a. whether Palumbo was in material breach of this Integrity 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) Palumbo had begun to take action to cure the material breach within that period;
 - (ii) Palumbo has pursued and is pursuing such action with due diligence; and
 - (iii) Palumbo provided to OIG within that period a reasonable timetable for curing the material breach and Palumbo 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 Palumbo, only after a DAB decision in favor of OIG. Palumbo's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Palumbo 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 Palumbo 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. Palumbo agrees to waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Palumbo, Palumbo will be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Integrity Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Integrity Agreement.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- a. This Integrity Agreement shall be binding on the successors, assignees and transferees of Palumbo, including any reorganized corporation or debtor;
2. This Integrity Agreement shall become final and binding on the date the final signature is obtained on the Integrity Agreement;
3. Any modifications to this Integrity Agreement shall be made with the prior written consent of the parties to this Integrity Agreement;
4. The OIG will agree to a suspension of Palumbo's obligations under this Integrity Agreement upon receipt of credible evidence from Palumbo that he has ceased his participation in the Federal health care programs. If Palumbo's obligations under this Integrity Agreement are suspended by the OIG in accordance with this provision, the suspension shall remain in effect only so long as Palumbo does not participate in the Federal health care programs. If Palumbo once again participates in any respect in Federal health care programs, the suspension of the Integrity Agreement will be automatically lifted and Palumbo will be responsible for all obligations under the Integrity Agreement for the remainder of its five year term. The effective date of the lifting of the suspension shall be the date on which Palumbo again participates in Federal health care programs. In any event, Palumbo must provide the OIG with written notice within 10 days of his withdrawal or renewed participation in the Federal health care programs.

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR DR. REMIGIO PALUMBO

Remigio Palumbo

Remigio Palumbo, M.D.
2913 Whittington Avenue
Tampa, Florida 33614

5-30-02

Date

Ke. Dar

Kevin J. Darken, Esq.
Trenam Kemker
Attorney for Dr. Remigio Palumbo
2700 Bank of America Plaza
101 East Kennedy Boulevard
P.O. Box 1102 (33601)
Tampa, Florida 33602

6-4-02

Date

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

D. McCarty Thornton

D. McCarty Thornton
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW, Room 5527
Washington, DC 20201

6-12-02

Date

OVERPAYMENT REFUND FORM

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
 Contractor Deposit Control # _____
 Date of Deposit: _____
 Contractor Contact Name: _____
 Phone #: _____
 Contractor Address: _____
 Contractor Fax #: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____
 CHECK NUMBER# _____
 CONTACT PERSON: _____
 PHONE# _____
 AMOUNT OF CHECK \$ _____
 CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____
 HIC # _____
 Medicare Claim Number _____
 Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:

Cost Report Year(s) _____
 (If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:

Do you have an Integrity Agreement with OIG? Yes No

Reason Codes:

<u>Billing/Clerical Error</u>	<u>MSP/Other Payer Involvement</u>	<u>Miscellaneous</u>
01 - Corrected Date of Service	08 - MSP Group Health Plan Ins.	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp. (Including Black Lung)	16 - Medical Necessity
05 - Modifier Added/Removed	12 - Veterans Administration	17 - Other (Please Specify) _____
06 - Billed in Error		
07 - Corrected CPT Code		