INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
JOSE A. VIVO, M.D.

I. PREAMBLE

Jose A. Vivo, M.D. ("Dr. Vivo") 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. Vivo. This commitment to promote compliance applies to any entity that Dr. Vivo owns or has a control interest in as defined in 42 U.S.C. § 1320a-3(a)(3), Dr. Vivo's and any such entity's employees, agents, contractors and all third parties with whom Dr. Vivo 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, and all other individuals responsible for the preparation of claims, reports or other requests for reimbursement on behalf of Dr. Vivo ("Covered Persons"). Contemporaneously with this Agreement, Dr. Vivo is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

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

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. Vivo

pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

Dr. Vivo 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. Vivo 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. 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 Agreement, Dr. Vivo 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. Vivo shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct can be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

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

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

2. The proper procedures for the honest and accurate submission of

claims in accordance with Federal health care program requirements;

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

4. The requirement that all of Dr. Vivo's Covered Persons shall be expected to report to Dr. Vivo or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Vivo'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. Vivo 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. Vivo 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. Vivo 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.

7. The assignment of appropriate CPT codes, including, but not limited to, the proper use of CPT code 76805 when billing for outpatient treatment of Federal health care program patients.

At least annually (and more frequently if appropriate), Dr. Vivo 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. Vivo'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 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 Agreement and at least once each year thereafter, Dr. Vivo 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 at least six (6) hours of training from an individual or entity, other than Dr. Vivo or another Covered Person. 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. Vivo.

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

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

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

2. The written Polices 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;

4. Examples of proper and improper billing practices; and

5. The assignment of appropriate CPT codes, including, but not limited to, the proper use of CPT code 76805 when billing for outpatient treatment of Federal health care program patients.

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

E. <u>Annual Review Procedures</u>

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

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

Billing Engagement 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. Vivo shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

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

F. 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. Vivo has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Vivo 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. Vivo identifies or learns of any overpayments, Dr. Vivo shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the

Overpayment Refund Form, provided as Appendix B to this Agreement.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

(ii) a matter that a reasonable person would consider a potential violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If Dr. Vivo determines that there is a Material Deficiency, Dr. Vivo shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

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

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

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

(ii) a complete description of the Material Deficiency,

including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

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

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

G. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, Dr. Vivo 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. Vivo 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. Vivo 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, after the effective date of this Agreement, Dr. Vivo 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. Vivo 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. Implementation Report

Within 120 days after the effective date of this Agreement, Dr. Vivo shall submit a written report to OIG summarizing the status of its implementation of the

requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. The name and phone number of Dr. Vivo's Compliance Contact;

2. A copy of the notice Dr. Vivo 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 Agreement;

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

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

6. A certification signed by Dr. Vivo attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;

7. The name of the IRO Dr. Vivo has retained to conduct the billing engagement and the proposed start and completion dates of the first annual review;

8. A list of all Dr. Vivo's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the contractor's name and address that issued each provider identification number; and

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

B. Annual Reports

Dr. Vivo shall submit to OIG Annual Reports with respect to the status of and findings regarding Dr. Vivo's compliance activities for each of the five one-year periods beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than one year and 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

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

2. A certification by Dr. Vivo 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. Vivo 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 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. Vivo's response and corrective action plan(s) related to any issues raised by the IRO;

7. A summary of any Material Deficiencies (as defined in III.F.)

identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

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

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

10. A certification signed by Dr. Vivo 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 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
Telephone: 202.619.2078
Facsimile: 202.205.0604

If to Dr. Vivo:	**[Contact Person]**	PEGGY VIVO
	Address	8940 W. KENDALL DR, SUITE-901-E
	City, State Zip	MIAMI, FL 33176
	Ph.	305- 271-~~5574~~ 5533
	Fax	305 - 271-4874

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

VIII DOCUMENT AND RECORD RETENTION

Dr. Vivo shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six (6) 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. Vivo prior to any release by OIG of information submitted by Dr. Vivo pursuant to its obligations under this Agreement and identified upon submission by Dr. Vivo as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Vivo shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. Vivo 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. Vivo shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Dr. Vivo.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Vivo 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. Vivo:

   a. 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;

   b. Fails to annually submit the IRO's Claims Review Report and Process Review Report as required in section III.E and Appendix A; or

   c. Fails to 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 Dr. Vivo employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Vivo'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. Vivo can demonstrate that Dr. Vivo 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. Vivo 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. Vivo fails to grant access.)

4. A Stipulated Penalty of $750 for each day Dr. Vivo fails to comply fully and adequately with any obligation of this Agreement not already covered in paragraphs 1-3. In its notice to Dr. Vivo, OIG shall state the specific grounds for its determination that Dr. Vivo has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Vivo 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. Vivo of the failure to comply.)

B. Timely Written Requests for Extensions

Dr. Vivo 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. Vivo fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after Dr. Vivo 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. Vivo 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. Vivo of: (a) Dr. Vivo'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. Vivo shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his 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. Vivo elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Vivo 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. Vivo 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. Vivo to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.F;

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

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

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Vivo has begun to take action to cure the material breach; (ii) Dr. Vivo is pursuing such action with due diligence; and (iii) Dr. Vivo 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. Vivo fails to satisfy the requirements of section X.D.3, OIG may exclude Dr. Vivo from participation in the Federal health care programs. OIG will notify Dr. Vivo in writing of its determination to exclude Dr. Vivo (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. Vivo wishes to apply for reinstatement, Dr. Vivo 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. Vivo 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. Vivo shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Dr. Vivo was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Dr. Vivo 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. Vivo to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Vivo 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. Vivo 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. Vivo had begun to take action to cure the material breach within that period;

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

(iii) Dr. Vivo provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Vivo 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. Vivo, only after a DAB decision in favor of OIG. Dr. Vivo's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Vivo 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. Vivo may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

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

IX. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

4. The undersigned Dr. Vivo 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:

JOSE A. VIVO, M.D.

7/26/00
Date

Dr. Vivo

7/25/00
Date

Counsel for Dr. Vivo

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

8/1/00
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

C. Billing Engagement

The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Process Review." The IRO shall prepare a Claims Review Report and a Process Review Report to report the findings of the reviews.

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

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. Vivo'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).

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. Vivo's coding systems and/or operations and claims submission process. This report shall also include any recommendations the IRO may have to improve any of these systems, operations, and processes. The Process Review Report shall be submitted to the OIG in the Annual Report.

B. Claims Review

1. ***Definitions.*** For the purposes of the Claims Review, the following definitions shall be used:

a. Claims Review Sample: A statistically valid, randomly selected, sample

of items selected for appraisal in the Claims Review.

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

c. Overpayment: For purposes of this Agreement, an Overpayment shall mean the amount of money Dr. Vivo has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this Agreement, Dr. Vivo shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by Dr. Vivo and for which Dr. Vivo has received reimbursement from the Medicare and Medicaid programs.

e. Population: All Items for which Dr. Vivo has submitted a code or line item and for which Dr. Vivo has received reimbursement from the Medicare and Medicaid 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.

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

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

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Claims Review Sample Size

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

To determine how many Items must be included in the Claims Review Sample, the mean and standard deviation of overpayments in the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, a text file containing the overpayment value of each Item examined shall be created. For purposes of these estimates, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. The "Difference Values Only" of the Variable Appraisals function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of overpayments in the Population.

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

If no Overpayments are found in this Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample. The results of the Probe Sample shall be reported in lieu of the Claims

Review when preparing and submitting the Claims Review Report (see section B, below).

b. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), 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 and/or the Probe Sample, any Paid Claim for which Dr. Vivo cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Vivo 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 all samples (Probe Sample and Claims Review Sample) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

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

1. ***Claims Review Methodology***

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

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

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

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

e. Sources of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. ***Statistical Sampling Documentation Required***

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

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

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

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

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

3. ***Claims Review Results***

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

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

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

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

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

OVERPAYMENT REFUND

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/SUPPLIERNAME_____
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 reaso
n 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 a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____