# INTEGRITY AGREEMENT
## BETWEEN THE
## OFFICE OF INSPECTOR GENERAL
## OF THE
## DEPARTMENT OF HEALTH AND HUMAN SERVICES
## AND
## LUIS FERNANDO ARANGO, M.D.



## I. PREAMBLE

Luis Fernando Arango, M.D., ("Dr. Arango") 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. Arango. This commitment to promote compliance applies to any entity that Dr. Arango owns or in which Dr. Arango has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Arango's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Arango 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

A. The period of compliance obligations assumed by Dr. Arango under this Agreement shall be six years from the effective date of this Agreement ("Effective Date") (unless otherwise specified). The Effective Date shall be the date on which the final signatory of this Agreement executes this Agreement. The one-year period beginning on the Effective Date shall be referred to as "the Reporting Period."

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

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all officers, directors, and employees;

b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Dr. Arango; and

c. 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;

2. "Relevant Covered Persons" includes all clinical, coding and billing personnel.

## III. INTEGRITY OBLIGATIONS

Dr. Arango shall establish a Compliance Program that, at minimum, includes the following elements:

### A. Compliance Contact

Within 30 days of the Effective Date, Dr. Arango shall designate a person to be responsible for compliance activities ("Compliance Contact"). The Compliance Contact shall (1) develop and implement policies, procedures, and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements; and (2) shall respond 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. Arango shall notify the OIG, in writing, within 15 days of such a change.

### B. Posting of Notice

Within the 30 days of the Effective Date, Dr. Arango 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 (e.g., telephone number or address) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in

the Implementation Report. An example of a notice is attached as Attachment 2.

### C. Written Policies and Procedures

Within 120 days of the Effective Date, Dr. Arango shall develop, implement, and make available to all Covered Persons written policies that address the following:

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

2. Dr. Arango's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Dr. Arango's own Policies and Procedures as implemented pursuant to Section III.C (including the requirements of this Agreement);

3. The requirement that all of Dr. Arango's Covered Persons shall be expected to report to Dr. Arango or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Arango'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 Dr. Arango shall 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, suspended, 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, suspended, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Dr. Arango 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://oig.hhs.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, Dr. Arango shall conduct annual checks of all employees against each exclusion list;

5. The commitment of Dr. Arango 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;

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 commitment of Dr. Arango and his staff to provide and bill for only the patient services that are medically necessary;

9. The importance of properly billing for medical services that are actually provided to patients.

Within 90 days of the Effective Date and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and shall abide by Dr. Arango's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days of the Effective Date, whichever is later.

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

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 of the Effective Date and at least once each year thereafter, Dr. Arango 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 eight hours of training from an individual or

entity, other than Dr. Arango 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. Arango and may be received from a variety of sources (i.e., CME classes, hospitals, associations, carriers).

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

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

4. Examples of proper and improper billing practices; and

5. The commitment of Dr. Arango and his staff to provide and bill only for patient services that are medically necessary;

6. The importance of properly billing for medical services that are actually provided to 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 the training was received. Dr. Arango shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

## E. Third Party Billing

Dr. Arango presently contracts with a third party billing company to submit claims to the Federal health care programs. Dr. Arango represents that he does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If Dr. Arango intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, Dr. Arango shall notify the OIG 30 days prior to any such proposed involvement.

Within 120 days of the Effective Date, Dr. Arango shall obtain and include in the Implementation Report a certification from the third party billing company that it (i) is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs; (ii) has a policy of not knowingly employing any person who has been excluded, debarred, or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs. If Dr. Arango contracts with a new third party billing company during the term of this Agreement, Dr. Arango shall, within 30 days of entering into such contract, obtain, and send to the OIG the certification described in this Paragraph.

## F. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the Effective Date, Dr. Arango shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Dr. Arango in assessing and evaluating its billing and coding practices and certain compliance obligations pursuant to this Agreement and the Settlement Agreement. Each IRO retained by Dr.

Arango shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this Agreement and in the general requirements of the Federal health care program(s) from which Dr. Arango seeks reimbursement. Each IRO shall assess, along with Dr. Arango, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Dr. Arango's billing and coding to the Federal health care programs ("Claims Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the Reporting Period. The IRO(s) shall perform all components of each annual Claims Review.

c. Retention of Records. The IRO and Dr. Arango shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Dr. Arango) related to the reviews.

2. *Claims Review.* The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this Agreement, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Dr. Arango. The Paid Claims shall be reviewed based on the supporting documentation available at Dr. Arango's office or under Dr. Arango's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Dr. Arango should, as appropriate,

further analyze any errors identified in the Discovery Sample. Dr. Arango recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.F.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Dr. Arango's office or under Dr. Arango's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Dr. Arango may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related work papers) received from Dr. Arango to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If Dr. Arango's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Arango's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es),

that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to Dr. Arango observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.G.1 of the Agreement, Dr. Arango shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Dr. Arango shall make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

3. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is described in Appendix A.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Arango's Claims Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). Dr. Arango shall pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Dr. Arango's final submission (as described in Section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Arango of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, Dr. Arango may request a meeting with the OIG to discuss the results of any Claims Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Dr. Arango agrees to provide any additional information as may be requested by the OIG under this Section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review with Dr. Arango prior to conducting a Validation Review. However, the final determination as to

whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to Dr. Arango a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and that it has concluded that it was, in fact, independent.

## G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

*a. Definition of Overpayments.* For purposes of this Agreement, an "Overpayment" shall mean the amount of money Dr. Arango has received in excess of the amount due and payable under any Federal health care program requirements.

*b. Reporting of Overpayments.* If, at any time, Dr. Arango identifies or learns of any Overpayment, Dr. Arango shall notify the payor (e.g., Medicare carrier) within 30 days of identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days of identification of the Overpayment, Dr. Arango shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days of identification, Dr. Arango 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 shall be done in accordance with the payor's policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor shall be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

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

(i) a substantial Overpayment;

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

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

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

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

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

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

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

(iii) a description of Dr. Arango's actions taken to correct the

Material Deficiency; and

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

## H. Notification of Government Investigations or Legal Proceedings

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

## IV. New Business Units, Locations or Relationships

In the event that Dr. Arango 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, Dr. Arango shall notify the 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. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

Prior to Dr. Arango entering into an employment or contractual relationship with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Arango shall notify that party of this Agreement. This notification will include a copy of the Agreement, the remaining reporting period of the Agreement, and a summary of Dr. Arango's obligations under the Agreement. In addition, Dr. Arango shall notify the OIG of such relationship as described in Section XI.4 of this Agreement.

## V. REPORTS

### A. Implementation Report

Within 120 days after the Effective Date, Dr. Arango shall submit a written report to the 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, address, and phone number of Dr. Arango's Compliance Contact;

2. A copy of the notice Dr. Arango posted in his office as described in Section III.B and a description of where and when the notice was posted;

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

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

7. A copy of the certification from the third party billing company required by Section III.E of the Agreement;

8. The name and qualifications of the IRO, a summary/description of all engagements between Dr. Arango and the IRO, 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;

9. A certification from the IRO regarding its professional independence from Dr. Arango;

10. A list of all Dr. Arango'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 Dr. Arango currently submits claims; and

11. A certification from Dr. Arango 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**

Dr. Arango shall submit to the OIG Annual Reports with respect to the status of and findings regarding Dr. Arango's compliance activities for each of the six Reporting Periods. 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 the 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. Arango 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. Arango 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. Arango's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;

7. A summary/description of all engagements between Dr. Arango and the IRO, 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 IRO regarding its professional independence from Dr. Arango;

9. A summary of Material Deficiencies (as defined in Section 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 Dr. Arango 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 Dr. Arango 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 in writing after the Effective Date, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

OIG:
Administrative and Civil Remedies Branch
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

Dr. Arango:
Luis Fernando Arango, M.D.
1901 South First Street
McAllen, Texas 78503
Telephone: 956.631.5395
Facsimile: 956.585.6058

Unless otherwise specified, all notifications and reports required by this Agreement shall 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 the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s) may examine or request copies of Dr. Arango's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Arango's locations for the purpose of verifying and evaluating: (a) Dr. Arango's compliance with the terms of this Agreement; and (b) Dr. Arango'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. Arango to the OIG or its duly authorized representative(s) at all reasonable times for

inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Dr. Arango'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 the OIG. Dr. Arango shall assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Dr. Arango's employees may elect to be interviewed with or without a representative of Dr. Arango present.

## VIII. DOCUMENT AND RECORD RETENTION

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

## IX. DISCLOSURE

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

Dr. Arango is expected to fully and timely comply with all of its Agreement obligations.

### A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Arango 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. Arango 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 Agreement within the time frames required in that Section;

e. retain an IRO within the timeframe required in Section III.F.1, or to submit the IRO's annual Claims Review Report and Process Review Report as required in Section III.E and Appendix A; 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 Dr. Arango employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Arango'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. Arango can demonstrate that Dr. Arango 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. Arango 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. Arango fails to grant access.)

4. A Stipulated Penalty of $750 for each day Dr. Arango fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Arango, the OIG shall state the specific grounds for its determination that Dr. Arango has failed to

comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Arango shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Arango receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection 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**

Dr. Arango 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 the 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. Arango fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Dr. Arango receives the 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 the 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. Arango has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, the OIG shall notify Dr. Arango of: (a) Dr. Arango's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Dr. Arango shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to the OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Dr. Arango elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Arango cures, to the 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 the 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 the OIG's decision that Dr. Arango has materially breached this Agreement, which decision shall be made at the 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. Arango to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.G;

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

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

d. a failure to retain and use an Independent Review Organization in accordance with Section III.F.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Dr. Arango constitutes an independent basis for Dr. Arango's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Dr. Arango has materially breached this Agreement and that exclusion shall be imposed, the OIG shall notify Dr. Arango of: (a) Dr. Arango's material breach; and (b) the 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. Arango shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to the OIG's satisfaction that:

a. Dr. Arango is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Arango has begun to take action to cure the material breach; (ii) Dr. Arango is pursuing such action with due diligence; and (iii) Dr. Arango has provided to the OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Arango fails to satisfy the requirements of Section X.D.3, the OIG may exclude Dr. Arango from participation in the Federal health care programs. The OIG shall notify Dr. Arango in writing of its determination to exclude Dr. Arango (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. Arango wishes to apply for reinstatement, Dr. Arango shall 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 the OIG's delivery to Dr. Arango 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. Arango 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, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and,

in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

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

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

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

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Dr. Arango, only after a DAB decision in favor of the OIG. Dr. Arango's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Dr. Arango upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Dr. Arango may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Dr. Arango shall waive his **[or her]** 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 Dr. Arango, Dr. Arango shall 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 Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

## XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

D. If Dr. Arango enters into an employment or contractual relationship with

another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Arango shall notify the OIG within 30 days of the date of the establishment of such relationship. Upon receipt of Dr. Arango's notification, the OIG may request information regarding the party's compliance program. The OIG may agree to modify the Agreement based on its evaluation of Dr. Arango's new business relationship, his role in such relationship, and the party's compliance program.

E. The OIG may agree to a suspension of Dr. Arango's obligations under this Agreement in the event of Dr. Arango's cessation of participation in Federal health care programs. If Dr. Arango withdraws from participation in Federal health care programs and is relieved from its Agreement obligations by the OIG, Dr. Arango shall notify the OIG 30 days in advance of Dr. Arango's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, the OIG shall evaluate whether the Agreement shall be reactivated or modified.

F. The undersigned Dr. Arango represent and warrant that he is 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:

Dr. Arango

Dr. Arango

4/29/03
Date

Jerry W. Stone
Counsel for Dr. Arango

4/29/03
Date

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

Larry J. Goldberg, 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

5/1/03
Date

# APPENDIX A

## A. Billing Engagement's Claims Review.

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

a. Overpayment: The amount of money Dr. Arango has received in excess of the amount due and payable under any Federal health care program requirements.

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

c. Paid Claim: A code or line item submitted by Dr. Arango and for which Dr. Arango has received reimbursement from the Medicare program.

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

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

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

2. **Other Requirements.**

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

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

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

1. **Claims Review Methodology.**

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the

IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

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

b. Quantitative Results.

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

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

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

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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

## Claim Review Results

| Federal Health Care Program Billed | Bene HIC # | Date of Service | Procedure Code Submitted | Procedure Code Reimbursed | Allowed Amount Reimbursed | Correct Procedure Code (IRO determined) | Correct Allowed Amt Reimbursed (IRO determined) | Dollar Difference between Amt Reimbursed and Correct Allowed Amt |
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# NOTICE

***Physician Organization ABC*** is committed to complying with all Federal health care program requirements in the operation of its business.

Anyone who has information or concerns about a possible violation of ***ABC's*** policies and procedures or any Federal health care program requirements should contact the Compliance officer at ***(123) 456-7890*** or via email at ***physicianorg@abc.net.*** Reporting may also be made anonymously by sending correspondence to:

*Steve Jones*
*Physician Organization ABC*
*244 Circle Dr.*
*New Town, ST 10000*
*Fax: (123) 456-7788*