

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
FAMILY HEALTH GROUP, Cesar Vargas, M.D., Ricardo Cardona, M.D.,
and Ricardo Ruiz, M.D.**

I. PREAMBLE

Ricardo Cardona, M.D., Ricardo Ruiz, M.D., Cesar Vargas, M.D., and Family Health Group (collectively, "Practitioners") hereby enter 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 Practitioners.

Practitioners represent that, prior to the execution of this Agreement, Practitioners have taken steps to obtain additional training regarding the requirements of the Federal health care programs in which they participate, and OIG agrees that Practitioners may apply such training received within the six months immediately preceding the effective date of this agreement to the training time requirements of this Agreement, in accordance with the terms set forth below.

II. TERM OF THE AGREEMENT

A. Except as otherwise provided, the period of compliance obligations assumed by Practitioners under this Agreement shall be three 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.

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

III. INTEGRITY OBLIGATIONS

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

1. “Covered Entity” or “Covered Entities” include any entity that Practitioners own or in which they have a controlling interest, as defined in 42 U.S.C. § 1320a-3(a)(3);
2. “Covered Persons” includes:
 - a. Practitioners;
 - b. Practitioners’ and any Covered Entity’s employees, agents, and contractors;
 - c. All third parties with whom Practitioners or any Covered Entity engages to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs;
 - d. All individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs on behalf of Practitioners or any Covered Entity; and
 - e. All individuals responsible for the preparation of claims, reports, or other requests for reimbursement for such items or services on behalf of Practitioners or any Covered Entity.

Practitioners hereby agree to establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

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

C. Written Policies and Procedures

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

1. Practitioners' commitment to operate their business in full compliance with all Federal health care program requirements;
2. Practitioners' requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Practitioners' own Policies and Procedures as implemented pursuant to section III.C (including the requirements of this Agreement);
3. The requirement that all of Practitioners' Covered Persons shall be expected to report to Practitioners or the Compliance Contact suspected violations of any Federal health care program requirements or Practitioners' 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 Practitioners 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 that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Practitioners 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>). In addition to prospective checks, Practitioners shall conduct annual checks of all employees against each exclusion list.

5. The commitment of Practitioners 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;

8. The requirement that Practitioners and all Covered Persons ensure that their business relationships with one another comply with all Federal health care program requirements relating to 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), the regulations and other guidance documents related to these statutes. Practitioners will also ensure that

there are policies and procedures requiring compliance with the provisions of Section III.E below.

At least annually (and more frequently if appropriate), Practitioners 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 Practitioners' 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

1. Compliance Training

As part of a Compliance Program, general compliance training is required of Practitioners and employees. The training shall be at least 2 training hours and conducted by an individual or entity, other than Practitioners or a Covered Person, with expertise in the relevant subject areas, e.g., contracting requirements under the federal Anti-Kickback Statute and the Stark law.

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 90 days of the effective date of this Agreement, whichever is later. The training for New Covered Persons may either be provided internally by Covered Persons who have completed the required annual training or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

At a minimum, the annual and new employee training sessions for

Covered Persons shall cover the following topics:

- a. The legal sanctions and consequences for improper contracting or financial arrangements.
 - b. Examples of violations of the Anti-Kickback Statute and Stark Law.
 - c. A review of provider's contracting Policies and Procedures related to Arrangements, as defined in Section III.E below, and the personal obligation of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Provider's Policies and Procedures.
2. *Certifications*

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. Practitioners shall retain the certifications, along with the training course materials.

E. Contractual Compliance with the Anti-Kickback Statute and the Stark Law.

1. *Scope*

This Section shall apply to every arrangement or transaction that:

- a. (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between any of Practitioners and any actual or potential source of health care business or referrals to Practitioners or any actual or potential recipient of health care business or referrals from Practitioners. The terms "source" and "recipient" shall include any physician, contractor, health care provider or supplier, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- b. is between any of Practitioners and a provider or supplier of

designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

The arrangements and transactions described above, and the written versions thereof, are collectively referred to as “Arrangements.” The party(ies) to an Arrangement other than Practitioners shall be referred to herein as a “contractor.”

2. *Anti-Kickback/Stark Compliance*

As part of its Compliance Plan, Practitioners shall maintain written policies and maintain ongoing training to ensure that contracts for the purchase of items or services entered into on behalf of Practitioners are not violative of the Anti-Kickback statute and Stark law for the term of this Agreement. Additionally, Practitioners shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or the Stark Law or the terms of this Agreement. Provider shall summarize all Arrangements in the form of Appendix A. Provider shall update the summary with each Annual Certification.

Prior to entering into new Arrangements or renewing existing Arrangements, Provider shall ensure that all Arrangements are in compliance with the Anti-Kickback Statute and Stark Law, and the regulations, directives, and guidance related to these statutes, and comply with the following requirements:

- a. The Arrangement shall be set forth in writing and signed by Practitioners and the contractor(s);
- b. The Arrangement shall include a covenant that contractors shall comply with the Policies and Procedures in Practitioners’ Compliance Program related to the Anti-Kickback Statute and the Stark Law. Additionally, Practitioners shall provide each contractor with a copy of its Code of Conduct and Stark and Anti-Kickback Policies and Procedures;
- c. Practitioners shall certify at the time of signing the Arrangement and upon any material amendment to the terms of the Arrangement, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program.

Practitioners shall retain and make available to OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of duties under the Arrangements. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by Practitioners of their attorney-client, attorney work product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Practitioners to avoid their obligations to comply with the provisions of this CIA.

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 Practitioners have received in excess of the amount due and payable under any Federal health care program requirements. Practitioners 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, Practitioners identify or learn of any overpayments, Practitioners shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, Practitioners 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, Practitioners shall notify the payor of their efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor’s policies, and for Medicare contractors, must include the information contained on an Overpayment Refund Form.

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

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

b. *Reporting of Material Deficiencies.* If Practitioners determine, by any means, that there is a Material Deficiency, Practitioners 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 Practitioners' actions taken to correct the Material Deficiency; and

(iv) any further steps Practitioners plan 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, Practitioners shall notify OIG, in writing, of any ongoing investigation known to Practitioners or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that Practitioners have 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. Practitioners shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, of the effective date of this Agreement, Practitioners change locations or sell, close, purchase or establish a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, Practitioners shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. 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, Practitioners 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, address and phone number of Practitioners’ Compliance Contact;
2. A copy of the notice Practitioners posted in their 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 Practitioners 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 Practitioners attesting that all employees have completed the initial training required by Section III.D. and have executed the required certifications;

7. A list of all Practitioners' 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 Practitioners currently submit claims; and

8. A certification from the Practitioners stating that they have reviewed the Implementation Report, they have made a reasonable inquiry regarding their content and believes that, upon such inquiry, the information is accurate and truthful.

B. Annual Reports

Practitioners shall submit to OIG Annual Reports with respect to the status of and findings regarding Practitioners' compliance activities for each of the three 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 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 Practitioners 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 Practitioners certifying that they are 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 summary of 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;

6. 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;

7. A certification signed by Practitioners 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

8. A certification signed by Practitioners certifying that they have reviewed the Annual Report, they have 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:

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
 Ph. 202.619.2078
 Fax 202.205.0604

Practitioners: Helaine Gregory
 Lausell & Carlo, P.S.C.
 American Airlines Building-PH
 1509 Lopez Landron Street
 San Juan, P.R. 00911
 Ph 787.721.6010
 Fax 787.721.3972

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

VIII. DOCUMENT AND RECORD RETENTION

Practitioners 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 years.

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 Practitioners prior to any release by OIG of information submitted by Practitioners pursuant to their obligations under this Agreement and identified upon submission by Practitioners as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With

respect to such releases, Practitioners shall have the rights set forth at 45 C.F.R. § 5.65(d). Practitioners 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 Practitioners is expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Practitioners.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Practitioners 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 Practitioners fail 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. 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 Practitioners employ or contract with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Practitioners’ 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 Practitioners can demonstrate that Practitioners 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 Practitioners fail 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 Practitioners fail to grant access.)

4. A Stipulated Penalty of \$750 for each day Practitioners fail to comply fully and adequately with any obligation of this Agreement. In its notice to Practitioners, OIG shall state the specific grounds for its determination that Practitioners have failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Practitioners must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Practitioners receive notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section.

B. Timely Written Requests for Extensions

Practitioners 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 Practitioners fail to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Practitioners receive 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 Practitioners have failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Practitioners of: (a) Practitioners' 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, Practitioners shall respond by either: (a) curing the breach to OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.E. In the event Practitioners elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Practitioners cure, 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 Practitioners have 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 Practitioners 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 Practitioners constitutes an independent basis for Practitioners' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Practitioners have materially breached this Agreement and that exclusion should be imposed, OIG shall notify Practitioners of: (a) Practitioners' 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.* Practitioners 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. Practitioners are 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) Practitioners have begun to take action to cure the material breach; (ii) Practitioners are pursuing such action with due diligence; and (iii) Practitioners have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Practitioners fail to satisfy the requirements of section X.D.3, OIG may exclude Practitioners from participation in the Federal health care programs. OIG will notify Practitioners in writing of its determination to exclude Practitioners (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, Practitioners wish to apply for reinstatement, Practitioners 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 Practitioners 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, Practitioners shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Practitioners was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Practitioners shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Practitioners to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Practitioners request 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 Practitioners were 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) Practitioners had begun to take action to cure the material breach within that period;
 - (ii) Practitioners have pursued and are pursuing such action with due diligence; and
 - (iii) Practitioners provided to OIG within that period a reasonable timetable for curing the material breach and Practitioners have 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 Practitioners, only after a DAB decision in favor of OIG. Practitioners' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Practitioners 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 Practitioners 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. Practitioners agree to waive their rights 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 Providers, Providers will be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or

regulations. Consequently, the parties to this 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, Practitioners and the OIG agree as follows:

1. This Agreement shall be binding on the successors, assigns and transferees of Practitioners;
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 Practitioner 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:

Respondents

Date



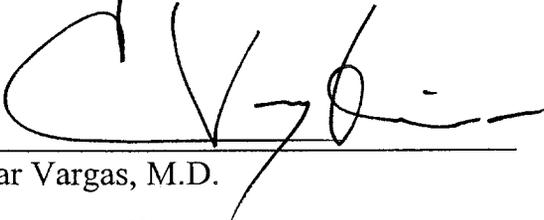
Ricardo Cardona, M.D.

Date



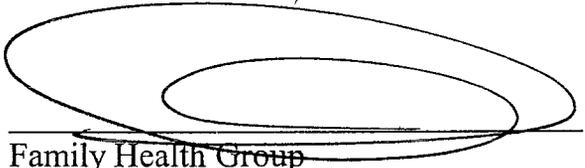
Ricardo Ruiz, M.D.

Date



Cesar Vargas, M.D.

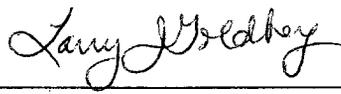
Date



Family Health Group

The Office of the Inspector General

4/22/03
Date



Larry J. Goldberg
Assistant Inspector General for Legal Affairs
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