

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND

CARDIOLOGY CONSULTANTS, P.A., Kevin Boyle, M.D., Arthur W. Colbourn, M.D., Barry S. Denenberg, M.D., Andrew J. Doorey, M.D., Anthony B. Furey, D.O., Edward M. Goldenberg, M.D., Richard F. Gordon, M.D., Harjinder S. Grewal, M.D., Robin A. Horn, M.D., Ronald A. Lewis, M.D., Raymond E. Miller, M.D., Lawrence A. Narun, M.D., Ashish B. Parikh, M.D., Michael J. Pasquale, M.D., Paul C. Pennock, M.D., David Ramos, M.D., James M. Ritter, M.D., Michael E. Stillablower, M.D., Kenneth P. Sunnergren, M.D., Henry L. Weiner, M.D., and Mark R. Zolnick, M.D.

I. PREAMBLE

Cardiology Consultants, P.A. and its current partners, Kevin Boyle, M.D., Arthur W. Colbourn, M.D., Barry S. Denenberg, M.D., Andrew J. Doorey, M.D., Anthony B. Furey, D.O., Edward M. Goldenberg, M.D., Richard F. Gordon, M.D., Harjinder S. Grewal, M.D., Robin A. Horn, M.D., Ronald A. Lewis, M.D., Raymond E. Miller, M.D., Lawrence A. Narun, M.D., Ashish B. Parikh, M.D., Michael J. Pasquale, M.D., Paul C. Pennock, M.D., David Ramos, M.D., James M. Ritter, M.D., Michael E. Stillablower, M.D., Kenneth P. Sunnergren, M.D., Henry L. Weiner, M.D., and Mark R. Zolnick, M.D. (“Practitioners”) hereby enter into this Integrity Agreement (“Agreement”) with the Office of Inspector General of the United States Department of Health and Human Services (“OIG/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. Contemporaneously with this Agreement, Practitioners are entering into a Settlement Agreement with the OIG/HHS, and this Agreement is incorporated by reference into the Settlement Agreement.

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

“Covered Persons” includes:

- a. All officers, directors and employees of Cardiology Consultants, P.A.;

b. All contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Cardiology Consultants, P.A. and its Practitioners, but excluding vendors whose sole connection with Practitioners is selling medical supplies or equipment to it.

For the purposes of this Agreement, the terms “contractors” and “agents” do not include those individuals who perform less than 160 hours of service for Practitioners during Practitioner’s fiscal year.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Practitioners under this Agreement shall be three (3) years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement.

Sections VI, VII, VIII, and IX shall remain in effect until OIG/HHS has completed its review of the final annual certification and any additional materials submitted by Practitioners pursuant to OIG/HHS’s request.

III. INTEGRITY OBLIGATIONS

Prior to the execution of this CIA, Practitioners established a corporate compliance program (Compliance Program). The Compliance Program includes written policies and procedures, an education and training component, monitoring and auditing of operations and claims submission process, mechanisms for employees and agents to report incidents of noncompliance in an anonymous way, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the Compliance Program by a duly appointed Compliance Officer. Practitioners agree to continue the operation of the Compliance Program for the term of this CIA. Practitioners may modify the Compliance Program as appropriate, but at a minimum, Practitioners shall ensure that it complies with the integrity obligations enumerated below.

A. Compliance Officer

As part of its current Compliance Program, Practitioners have designated a Compliance Officer. Among other duties, the Compliance Officer is responsible for: (i) developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program

requirements; and (ii) responding to questions and concerns from Covered Persons and the OIG/HHS regarding compliance with the Agreement obligations. In the event a new Compliance Officer is appointed during the term of this Agreement, or the duties of the Compliance Officer materially change, Practitioners shall notify the OIG/HHS, 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.

C. Written Policies and Procedures

As part of its Compliance Program, Practitioners have developed certain written policies and procedures (Policies and Procedures) that address Practitioners' participation in the Federal health care programs. Practitioners shall maintain their current or comparable written policies as to the following areas for the term of this Agreement.

1. The proper procedures for the honest and accurate submission of claims in accordance with Federal health care program requirements;
2. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;
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 related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Practitioners shall check all prospective employees and contractors prior to engaging their services against the OIG/HHS List of Excluded Individuals/Entities (available through the Internet at <http://www.hhs.gov/oig>) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

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 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, and to the OIG.

Within 120 days of the effective date of the Agreement, to the extent not already distributed, and upon any material revisions, Practitioners shall make available the relevant portions of the Policies and Procedures to all Covered Persons whose functions relate to those Policies and Procedures. 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 120 days of the effective date of the Agreement, whichever is later.

D. Training and Certification

1. Compliance Training

As part of its current Compliance Program, general compliance training is required of Practitioners and employees. In addition, Practitioners also conduct ongoing targeted training of all Practitioners and employees who are involved in the submission of claims for reimbursement, negotiate contracts, purchase goods or services, or engage in marketing activities. Practitioners agree to maintain their current or a comparable general and targeted compliance training and education program for the term of this Agreement and ensure that all Covered Persons receive the training that would be provided to employees. The training shall be 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 120 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 targeted training sessions for Covered Persons involved in contracts, purchasing, and marketing, shall cover the following topics:

- i. The legal sanctions and consequences for improper contracting or financial arrangements.
- ii. Examples of violations of the Anti-Kickback Statute and Stark Law.
- iii. 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. *Non-Employed Monitoring Physicians*

Notwithstanding that non-employed monitoring physicians (Monitoring Physicians) are included in the definition of Covered Persons for all other provisions in this CIA, the training requirements specified in this Section D that otherwise apply to all Covered Persons shall be modified with respect to Monitoring Physicians in the following manner.

Within 30 days after becoming a Monitoring Physician or within 120 days of the effective date of this Agreement, whichever is later, Practitioners shall ensure that each Monitoring Physician attends a compliance program orientation (Orientation) session that covers the following topics:

- i. a review of the applicable provisions of Practitioners' Compliance Program, including those provisions relating to Arrangements meeting the definition of Section III.E below;
- ii. the legal sanctions and consequences for improper contracting or financial arrangements;
- iii. examples of violations of the Anti-Kickback Statute and Stark Law.

Any individual Monitoring Physician that has satisfied this provision need not participate in any other of Practitioners' annual compliance training programs.

3. *Certifications*

Each Covered Person, other than a Monitoring Physician, shall annually certify in writing that he or she has received the required training. Each Monitoring Physician shall certify that he/she has attended an Orientation session that satisfies the requirements listed above. 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:

- i. (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 term “source” shall mean any physician, contractor, 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
- ii. is between any of Practitioners and a physician (or a physician’s immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Practitioners for 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 maintain written policies and maintain ongoing training to ensure contracts for the purchase of goods or services, entered into on behalf of Practitioners are not violative of the Anti-Kickback and Stark laws. Practitioners agree to maintain their current or comparable procedures 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. 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:

- i. The Arrangement shall be set forth in writing and signed by Practitioners and the contractor(s);
- ii. 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;
- iii. Practitioners shall certify and shall require the contractor(s) to 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; and
- iv. Practitioners shall require the contractor(s) to certify, at the time of signing the Arrangement, that the contractor(s) shall comply with Practitioners' Compliance Program related to the Anti-Kickback Statute and the Stark Law.

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.

3. *Fair Market Value*

As part of the Settlement Agreement entered into by Practitioners and the OIG on or about the date of this Agreement, Practitioners have agreed to ensure

that any payments made to physicians to monitor cardiac stress tests are consistent with fair market value and are commercially reasonable. Practitioners shall, as a part of this Agreement, satisfy the requirements of paragraph 11 of the Settlement Agreement.

F. Reporting of Overpayments and Material Deficiencies

As part of its existing Compliance Program, Practitioners have developed a written policy for identifying and repaying overpayments, and have implemented such policy. Practitioners agree to modify their current policies regarding the identification and reporting of overpayments in accordance with the provisions set out below, and to maintain such procedures for the term of this Agreement.

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, they shall notify the payor within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. 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 contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form.

2. *Material Deficiencies.*

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

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

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

b. Reporting of Material Deficiencies. If Practitioners determine, by any means, that there is a Material Deficiency, they shall notify OIG/HHS, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG/HHS shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG/HHS 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/HHS, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that they have committed a crime or have 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/HHS within 30 days of the resolution of the matter, and shall provide OIG/HHS with a description of the findings and/or results of the proceedings, if any.

IV. ANNUAL CERTIFICATIONS

In addition to the certifications required above, Practitioners shall submit to OIG/HHS annual certifications, in the form of affidavits, with respect to the status of and findings regarding Practitioners' compliance activities for each of the three years in one-year cycles beginning on the effective date of the Agreement. (The one-year period covered by each annual certification shall be referred to as "the Reporting Period"). The first annual certification shall be received by the OIG/HHS no later than one year and 60 days after the end of the first Reporting Period. Subsequent annual certifications shall be received by OIG/HHS no later than the anniversary date of the due date of the first annual certification.

Each affidavit shall include:

1. A certification by Practitioners that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C. (Monitoring Physicians shall only be required to make such certification in the first year of their Arrangement with Practitioners);

2. 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;

3. A certification signed by Practitioners certifying their full compliance with paragraph 11 of the Settlement Agreement, or, if Practitioners have not fully complied with paragraph 11 of the Settlement Agreement, a summary of all efforts made by Practitioners to comply with paragraph 11 of the Settlement Agreement;

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

5. 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;

6. A certification from Practitioners that: (1) they have met the requirements of Section III.E of this Agreement; and (2) they have maintained all written records relevant to such transactions, including the amounts, dates, and reasons for each such transaction; and (3) they have submitted an annual summary of all Arrangements in the form of Appendix A, which is complete and accurate;

7. A certification signed by Practitioners certifying that all prospective employees and contractors are being screened against the OIG/HHS 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 certification being submitted to OIG/HHS, they have made a reasonable inquiry regarding its content and believe that, upon such inquiry, the information is accurate and truthful.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications, certifications and reports required under the terms of this Agreement shall be submitted to the following:

If to the OIG/HHS: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General

U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax. 202.205.0604

If to Practitioners: Lawrence Narun, M.D.
Cardiology Consultants, P.A.
254 Chapman Road, Suite 100
Newark, DE 19702-5424
Ph. 302.366.7665
Fax. 302.366.0734

Unless otherwise specified, all notifications, certifications 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.

VI. OIG/HHS INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG/HHS may have by statute, regulation, or contract, OIG/HHS 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/HHS or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG/HHS 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/HHS. Practitioners agree to assist OIG/HHS or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG/HHS's request. Practitioners' employees may elect to be interviewed with or without a representative of Practitioners present.

VII. 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 (or longer if otherwise required).

VIII. DISCLOSURES

Consistent with OIG/HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG/HHS shall make a reasonable effort to notify Practitioners prior to any release by OIG/HHS of information submitted by Practitioners pursuant to their obligations under this Agreement and identified upon submission by their 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.

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Practitioners shall be 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/HHS 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:
 - a. Fail to have in place a Compliance Officer as required in section III.A;
 - b. Fail to post the notice required in section III.B;

- c. Fail to have in place and comply with the Policies and Procedures required in section III.C;
- d. Fail to meet any of the deadlines for the submission of the Annual Certifications to OIG/HHS;
- e. Or any applicable Covered Person fails to attend the training required by section III.D. of the Agreement within the time frames required in that section.

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 they 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 VI of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Practitioners fail to grant access.)

4. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Practitioners fail to comply fully and adequately with the provisions of paragraph 11 of the Settlement Agreement. The Stipulated Penalty described in this paragraph shall not apply for any time period during which Practitioners demonstrate that they had made all reasonable efforts to comply with paragraph 11 of the Settlement Agreement.

5. 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/HHS shall state the specific grounds for its determination that they have failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Practitioners must take to comply with the Agreement. (This

Stipulated Penalty shall begin to accrue 10 days after the date that OIG/HHS provides notice to Practitioners of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG/HHS has sought a Stipulated Penalty under paragraphs 1-4 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/HHS 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/HHS. Notwithstanding any other provision in this section, if OIG/HHS 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/HHS'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/HHS 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 IX.A and after determining that Stipulated Penalties are appropriate, OIG/HHS shall notify Practitioners of: (a) their failure to comply; and (b) OIG/HHS'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/HHS's satisfaction, notifying OIG/HHS of their corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG/HHS a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG/HHS's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section IX.E. In the event Practitioners elect to request an ALJ hearing and the ALJ determines Practitioners were compliant, no Stipulated Penalties shall be due for the period that Practitioners were in

compliance. In the event Practitioners elect to request an ALJ hearing and the ALJ determines Practitioners were not compliant for any period of time, Stipulated Penalties shall be due for that period of time and shall continue to accrue until Practitioners cure, to OIG/HHS'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 IX.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary, Department of Health and Human Services," and submitted to OIG/HHS at the address set forth in section V.

4. *Independence from Material Breach Determination.* Except as set forth in section IX.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG/HHS's decision that Practitioners have materially breached this Agreement, which decision shall be made at OIG/HHS's discretion and shall be governed by the provisions in section IX.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; or

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section IX.C.

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/HHS that Practitioners have materially breached this Agreement and that exclusion should be imposed, OIG/HHS shall

notify Practitioners of: (a) their material breach; and (b) OIG/HHS'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/HHS's satisfaction that:

- a. Practitioners are in compliance with the obligations of the Agreement cited by the OIG/HHS 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/HHS a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* OIG may exclude from participation in the Federal health care programs any or all Practitioners who have failed to satisfy the requirements of section IX. D.3 at the conclusion of the 30-day period. OIG/HHS will notify the affected Practitioners in writing of its determination to exclude them (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.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/HHS'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 were in full and timely compliance with the obligations of this Agreement for which OIG/HHS 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. If the ALJ agrees with OIG/HHS 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/HHS, 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/HHS within that period a reasonable timetable for curing the material breach and they have followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG/HHS, or, if the ALJ rules for Practitioners, only after a DAB decision in favor of OIG/HHS. Practitioners' election of their contractual right to appeal to the DAB shall not abrogate OIG/HHS's authority to exclude them upon the issuance of an ALJ's decision in favor of OIG/HHS. If the ALJ sustains the determination of OIG/HHS 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/HHS after an ALJ decision adverse to OIG/HHS, the exclusion shall take effect 20 days after the DAB decision. Practitioners agree to waive their right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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.

X. 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/HHS 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;

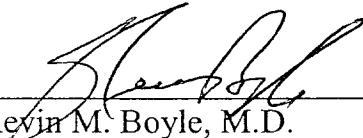
3. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;

4. The undersigned signatories for Practitioners represent and warrant that they are authorized to execute this Agreement. The undersigned OIG/HHS 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

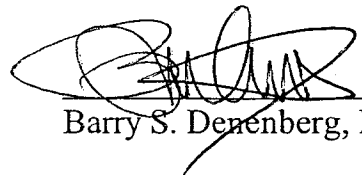
12/27/02
Date


Kevin M. Boyle, M.D.


12/30/02
Date


Arthur W. Colbourn, M.D.

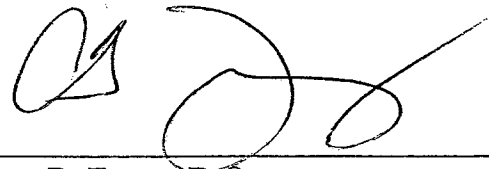
12/27/02
Date


Barry S. Denenberg, M.D.

12/27/02
Date


Andrew J. Doorey, M.D.

12/30/02
Date


Anthony B. Furey, D.O.

12/27/02
Date

Edward M. Goldenberg
Edward M. Goldenberg, M.D.

Date

Richard F. Gordon, M.D.

Attached

*see
Attached*

Date

Harjinder S. Grewal, M.D.

*

12/30/02
Date

Robin A. Horn, MD
Robin A. Horn, M.D.

12/30/02
Date

Ronald L. Lewis
Ronald L. Lewis, M.D.
D.O.

12/30/02
Date

Raymond E. Miller
Raymond E. Miller, M.D.

12/27/02
Date

Lawrence G. Narun
Lawrence G. Narun, M.D.

*

12-30-02
Date

Ashish B. Parikh
Ashish B. Parikh, M.D.

Date

Andrew J. Doorey, M.D.

Date

Anthony B. Furey, D.O.

Date

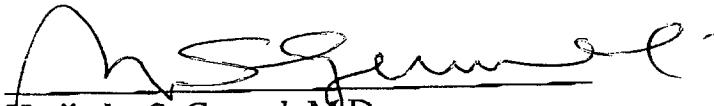
Edward M. Goldenberg, M.D.

Date

Richard F. Gordon, M.D.

Date

12/24/02



Harjinder S. Grewal, M.D.

Date

Robin A. Horn, M.D.

Date

Ronald L. Lewis, M.D.

Date

Edward M. Goldenberg, M.D.

Date

1/6/2003

Richard F. Gordon

Richard F. Gordon, M.D.

Date

Harjinder S. Grewal, M.D.

Date

Robin A. Horn, M.D.

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Ronald L. Lewis, M.D.

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Raymond E. Miller, M.D.

Date

Lawrence G. Narun, M.D.

Date

Ashish B. Parikh, M.D.

12/27/02
Date

Michael J. Pasquale
Michael J. Pasquale, M.D.

12/27/02
Date

Paul C. Pennock
Paul C. Pennock, M.D.

12/26/02
Date

David Ramos
David Ramos, M.D.

12/27/02
Date

James M. Ritter
James M. Ritter, M.D.

12/27/02
Date

Michael E. Stillabower
Michael E. Stillabower, M.D.

12/24/02
Date

Kenneth P. Sunnergren
Kenneth P. Sunnergren, M.D.

12/24/02
Date

Henry L. Weiner
Henry L. Weiner, M.D.

12/24/02
Date

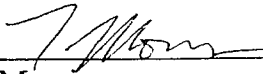
Mark R. Zolnick
Mark R. Zolnick, M.D.

12/27/02
Date

Michael E. Stillbornes, MD
Cardiology Consultants, P.A. *President*

The Office of the Inspector General

Date 4/8/03



Lewis Morris
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
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