INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VALLEY HEART CONSULTANTS, P.A., CARLOS D. MEGO, M.D., and SUBBARAO YARRA, M.D.

I. PREAMBLE

Valley Heart Consultants, P.A., Carlos D. Mego, M.D. ("Mego"), Subbarao Yarra, M.D. ("Yarra")(collectively, "Providers") hereby enter into this Integrity Agreement (IA) 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). This Integrity Agreement applies to both doctors Mego and Yarra as individual Providers and to Valley Heart Consultants, P.A., along with any Covered Persons of both the physicians and Valley Heart Consultants, P.A.. Contemporaneously with this IA, Valley Heart Consultants, P.A., Carlos D. Mego, M.D., and Subbarao Yarra, M.D., are entering into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE IA

A. This IA shall have a term of three years from the Effective Date. The Effective Date shall be the date on which the final signatory signs this IA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Provider's final Annual Report; or (2) any additional materials submitted by [Provider] pursuant to OIG's request, whichever is later.

C. The term "Covered Persons" includes:

1. Carlos D. Mego, MD, Subbarao Yarra, MD, and all employees and owners of Valley Heart Consultants, PA; and

2. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Providers (the employees of any third party billing company that submits claims to the Federal health care programs on behalf of the Providers shall not be considered Covered Persons, provided that the Providers and the third party billing company provide the certifications required by Section III.J).

III. INTEGRITY OBLIGATIONS

Providers shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer:

1. *Compliance Officer*. Within 90 days after the Effective Date, Providers shall appoint an individual to serve as their Compliance Officer and shall maintain a Compliance Officer for the term of the IA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this IA, Federal health care program requirements, and professionally recognized standards of care. The Compliance Officer shall also be responsible for monitoring the day-to-day compliance activities engaged in by the Providers and any reporting obligations created under this IA. The Compliance Officer shall ensure that the Providers are appropriately identifying and correcting quality of care problems. The Compliance Officer must have sufficient compliance and quality assurance experience to effectively oversee the implementation of the requirements of this IA. The Compliance Officer shall be either an owner or a member of senior management of Valley Heart Consultants, P.A., and if the latter shall report directly to the owners of Valley Heart Consultants, PA, shall make periodic (at least quarterly) reports regarding compliance matters directly to the owners of Valley Heart Consultants, PA, and shall be authorized to report on such matters to the owners of Valley Heart Consultants, PA, at any time. Copies of such quarterly reports and copies of the minutes of any meeting where such reports are presented to the owners of Valley Heart Consultants, PA, shall be included as an attachment to the Annual Report required by section V.C. Any noncompliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in this IA.

The Compliance Officer shall annually review and verify the credentials of all non-physician staff performing or assisting in the performance of single photon emission computed tomographic myocardial perfusion imaging (SPECT) tests, to assure that such staff comply with all state or federal licensing, certification, or registration requirements. The Compliance Officer shall notify the owners of Valley Heart Consultants, P.A., with regard to any staff person who does not have the proper, current licensure, certification, or registration as required by state and federal law. The Compliance Officer shall certify in the Annual Report required by section V.C of this IA that all such staff comply with all state and federal licensing, certification, or registration requirements, for the performance or assistance with the performance of SPECT testing.

The Providers shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

B. Posting of Notice

Within 90 days after the Effective Date, Providers shall post in a prominent place accessible to all patients and Covered Persons a notice that provides the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

C. Written Standards

1. Policies and Procedures. Within 90 days after the Effective Date, the Providers shall implement written Policies and Procedures regarding the performance of SPECT tests. At a minimum, the Policies and Procedures shall address:

    a. The appropriate credentialing of non-physician personnel or contractors who perform or assist in the performance of SPECT tests;

    b. A requirement that physicians review raw SPECT images on a computer monitor, rather than reviewing film or paper copies, as recommended by the American Society of Nuclear Cardiology;

    c. A requirement that physicians reviewing SPECT studies document in the medical record that they reviewed such studies on a computer monitor.

D. Training and Education

1. *Training*. Mego and Yarra shall complete a minimum of eight hours of training as set forth in this section within one year of the effective date of this Agreement. These training requirements may be satisfied only by the completion of courses, descriptions of which are provided to OIG prior to registration for the training course, for review and approval.

At a minimum, the required training sessions must include the following topics:

a. The medical necessity for and clinical indications for the performance of SPECT tests, 2-D echocardiograms, carotid Doppler studies, and CT angiography of the carotid arteries;

b. Correct documentation of the medical necessity for such tests;

c. Proper documentation in the medical record of the results of such tests;

d. Proper interpretation of the raw images of SPECT tests and proper documentation in the medical record of such interpretation.

The OIG may, in its discretion, require that the Providers and other Covered Persons complete additional hours of training regarding the topics identified above, or additional topics, in the second and third years of the IA. The OIG shall provide notice to the Providers of such additional required training at least 180 days prior to the required completion date for such training.

2. *Certification*. The Providers shall maintain written documentation (e.g., written or electronic certificates of completion from the training provider) that all Covered Persons required to receive training have in fact completed such training. The documentation shall specify the type of training (including the name and provider of the course, if it was provided by a Continuing Medical Education (CME) provider) received and the date received.

E. Review Procedures

1. *General Description*.

a. *Engagement of Independent Review Organization*. Within 60 days after the Effective Date, the Providers shall engage an individual or entity, such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The IRO must have the qualifications and must be able to meet the other requirements relating to the IRO outlined in Appendix A to this IA, which is incorporated by reference.

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

2. *Cardiac Test Procedures Review.* The IRO shall conduct a review of the medical necessity and appropriateness of SPECT tests, 2-D echocardiograms, carotid Doppler studies, and CT angiography of the carotid arteries performed by Mego and Yarra for each three-month period during the term of this IA (Cardiac Test Procedures Review) and shall prepare a Quarterly Cardiac Test Procedures Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Cardiac Test Procedures Review requirement shall begin 30 days after the Effective Date. Each Cardiac Test Procedures Report shall be submitted by the IRO to the OIG within 60 days of the end of the three-month period covered by the Quarterly Cardiac Test Procedures Review. The IRO shall randomly select and review a sample of 30 such procedures performed at Valley Heart Consultants, P.A. during the relevant quarter. The procedures shall be reviewed for the medical necessity of such tests (including the appropriate documentation of medical necessity), whether, in the case of SPECT tests, the physician's review of the raw images via computer monitor was documented in the record, the appropriateness of the reporting of the results of such tests, and the subsequent medical management of patients who had such tests. The procedures shall be reviewed based on the supporting documentation available at Valley Heart Consultants, P.A., or under Valley Heart Consultants' control, and applicable regulations and guidance to determine whether the procedure was medically necessary and appropriate, including but not limited to the established practice guidelines and generally accepted standards of medical practice described by the American Society of Nuclear Cardiology and the American College of Cardiology.

The IRO engaged by the Providers shall have expertise in the medical necessity and appropriateness of the cardiac test procedures and in the general requirements of the Federal health care program(s) from which the Providers seek reimbursement.

3. *Claims Review.* The IRO shall conduct a review of the Providers' coding, billing, and claims submission to the Federal health care programs and the reimbursement received for each three-month period during the term of this IA (Quarterly Claims Review) and shall prepare a Quarterly Claims Review Report, as outlined in Appendix B to this IA, which is incorporated by reference. The first three-month period for purposes of the Quarterly Claims Review requirement shall begin 30 days after the Effective Date. Each Quarterly Claims Review Report shall be submitted to OIG within 60 days following the end of the three-month period covered by the Quarterly Claims Review.

4. *Validation Review*. In the event OIG has reason to believe that: (a) the IRO's Cardiac Test Procedures Review or Claims Review fails to conform to the requirements of this IA; or (b) the IRO's Cardiac Test Procedures Review or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Cardiac Test Procedures Review or the Claims Review complied with the requirements of the IA and/or the findings of the Cardiac Test Procedures Review or the Claims Review are inaccurate (Validation Review). The Providers shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of the Providers' final Annual Report shall be initiated no later than one year after the Providers' final submission (as described above in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify the Providers of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, the Providers may request a meeting with OIG to: (a) discuss the results of any Cardiac Test Procedures Review or Claims Review, submissions or findings; (b) present any additional information to clarify the results of the Cardiac Test Procedures Review or Claims Review, or to correct the inaccuracy of the Cardiac Procedures Review or Claims Review; and/or (c) propose alternatives to the proposed Validation Review. The Providers agree to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any Cardiac Test Procedures Review or Claims Review issues with the Providers 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 OIG.

5. *Independence and Objectivity Certification.* Prior to performing the first Cardiac Test Procedures Review, and annually thereafter, the IRO shall provide to the Providers a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E and (b) concluded

that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this IA.

F. Ineligible Persons

1. *Definitions*. For purposes of this IA:

a. an "Ineligible Person" shall include an 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 nonprocurement programs; or

ii. has been convicted of (a) a criminal offense that is related to the delivery of an item or service under Medicare or any state health care program; (b) a criminal offense relating to neglect or abuse of patients; (c) a felony criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct in connection with the delivery of a health care item or service or with respect to a government funded health care program (other than Medicare or a state health care program); or (d) a felony criminal offense relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's System for Award Management (available through the Internet at http://www.sam.gov)

2. *Screening Requirements*. The Providers shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. The Providers shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Covered Persons to disclose whether they are Ineligible Persons.

b. The Providers shall screen all current Covered Persons against the Exclusion Lists within 30 days after the Effective Date and on a monthly basis thereafter.

c. The Providers shall require all Covered Persons to immediately disclose any debarment, exclusion, suspension, or other event that makes that Covered Person an Ineligible Person.

The Providers shall maintain documentation demonstrating that the Providers: (1) have checked the Exclusion Lists (e.g., print screens from search results) and determined that such individuals or entities are not Ineligible Persons; and (2) have required individuals and entities to disclose if they are an Ineligible Person (e.g., employment applications).

Nothing in this Section affects the Providers' responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. The Providers understand that items or services furnished by excluded persons are not payable by Federal health care programs and that the Providers may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether the Providers meet the requirements of Section III.F.

3. *Removal Requirement*. If the Providers have actual notice that a Covered Person has become an Ineligible Person, the Providers shall remove such Covered Person from responsibility for, or involvement with, the Providers' business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services rendered, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at

least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If the Providers have actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, the Providers shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

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

H. Repayment of Overpayments

1. *Definition of Overpayments*. For purposes of this IA, an "Overpayment" shall mean the amount of money the Providers have received in excess of the amount due and payable under any Federal health care program requirements.

2. *Reporting of Overpayments*. If, at any time, the Providers identify or learn of any Overpayment, the Providers shall repay the Overpayment to the appropriate payor (e.g., Medicare contractor) within 60 days after identification of the Overpayment and take steps to correct the problem and prevent the Overpayment from recurring within 90 days after identification (or such additional time as may be agreed to by the payor) to. If not yet quantified within 60 days after identification, the Providers shall notify the payor at that time of its efforts to quantify the Overpayment amount and provide a schedule of when such work is expected to be completed. The Providers should follow the payor's policies regarding the form of notification and the repayment process for any Overpayment refunds. Any questions regarding the repayment process should be directed to the payor.

I. Reportable Events

1. *Definition of Reportable Event*. For purposes of this IA, a "Reportable Event" means anything that involves:

a. a substantial Overpayment;

b. 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;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by any of the Providers.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events*. If the Providers determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Providers shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.G.1.a, the report to OIG shall be made within 30 days after making the determination that a substantial Overpayment exists, and shall include:

a. a description of the steps taken by the Providers to identify and quantify the Overpayment;

b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated; and

c. a description of the Providers' actions taken to correct the Reportable Event.

Within 60 days of identification of the Overpayment, the Providers shall send to OIG a copy of the notification and repayment to the payor required by Section III.H.2.

4. *Reportable Events under Section III.I.1.b and c.* For Reportable Events under Section III.I.1.b and III.I.1.c, the report to the OIG shall include

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

b. a description of the Providers' actions taken to correct the Reportable Event; and

c. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by the Providers to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.d.* If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

J. Third Party Billing

If, prior to the Effective Date or at any time during the term of this IA, the Providers contract with a third party billing company to submit claims to the Federal health care programs on behalf of any of the Providers, the Providers must certify to OIG that they do 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 are not employed by, and does not act as a consultant to, the third party billing company.

The Providers also shall obtain (as applicable) a certification from any third party billing company that the company: (i) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (ii) screens its prospective and current employees against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's System for Award Management; and (iii) provides training in the applicable requirements of the Federal

health care programs to those employees involved in the preparation and submission of claims to Federal health care programs.

If applicable, a copy of these certifications shall be included in the Providers' Implementation Report and each Annual Report required by Section V below.

IV. SUCCESSOR LIABILITY; CHANGES TO LOCATIONS OR BUSINESS; NEW EMPLOYMENT OR CONTRACTUAL ARRANGEMENT

A. Change or Closure of Location. In the event that, after the Effective Date, any of the Providers change locations or closes a location related to the furnishing of items or services that may be reimbursed by Federal health care programs, the Providers shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Location or Business. In the event that, after the Effective Date, any of the Providers purchase or establish a new location or business related to the furnishing of items or services that may be reimbursed by Federal health care programs, that Provider shall notify OIG at least 30 days prior to such purchase or the operation of the new location or business. This notification shall include the address of the new location or business, phone number, fax number, Medicare and state Medicaid program provider identification number and/or supplier number, and the name and address of each Medicare and state Medicaid program contractor to which the Provider currently submits claims. Each new location or business and all Covered Persons at each new location or business shall be subject to the applicable requirements of this IA, unless otherwise determined and agreed to in writing by OIG.

C. Sale of Location or Business. In the event that, after the Effective Date, any Provider proposes to sell any or all of the locations or businesses that are subject to this IA, the Provider shall notify OIG at least 30 days prior to the proposed sale. This notification shall include a description of the location or business to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. If Mego or Yarra propose to sell or otherwise transfer their interest in Valley Heart Consultants, PA, they shall notify OIG at least 30 days prior to the proposed sale or transfer of interest. This IA shall be binding on any purchaser of such location, business, or interest unless otherwise determined and agreed to in writing by OIG.

D. New Employment or Contractual Arrangement. At least 30 days prior to Mego or Yarra becoming an employee or contractor with another party related to the

furnishing of items or services that may be reimbursed by Federal health care programs, he shall notify OIG of his plan to become an employee or contractor and must provide OIG with the name, location, status (employee or contractor) and an explanation of his responsibilities with respect to such potential employer or contractor. In addition, prior to Mego or Yarra becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, he shall notify that party of this IA. This notification shall include a copy of the IA and a statement indicating the remaining term of the IA. The IA shall continue to apply to Mego or Yarra following the start of the new employment or contractual relationship, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION REPORT, IRO REPORTS AND ANNUAL REPORTS

A. Implementation Report. Within 90 days after the Effective Date, the Providers shall submit a written report to OIG summarizing the status of its implementation of the requirements of this IA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

2. a copy of the notice the Providers posted in all offices of Valley Heart Consultants, P.A., as required by Section III.A, a description of where the notice is posted, and the date the notice was posted;

3. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this IA; (d) a summary and description of any and all current and prior engagements and agreements between the Providers and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to the Providers;

4. a copy of the documentation demonstrating that the Providers have screened all Covered Persons against the Exclusion Lists, as required by section III.F, within 30 days of the Effective Date;

5. a copy of any certifications from the Providers and the third party billing company required by Section III.J (if applicable);

6. a list of all of the Providers' locations in which they do business (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 and state Medicaid program provider identification number(s), and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which the Providers currently submits claims; and

7. a certification by the Providers that: (a) they have reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Implementation Report, the Providers are in compliance with all of the requirements of this IA; and (c) they have reviewed the Implementation Report and have made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. IRO Reports. Within 60 days following the end of each three-month period during the term of this IA, Providers shall provide to OIG a copy of the Cardiac Test Procedures Review Report and the Claims Review Report prepared by the IRO for each Quarterly Cardiac Test Procedures Review and Quarterly Claims Review performed, along with Providers' response and corrective action plan related to any recommendations made by the IRO in the Quarterly Cardiac Test Procedures Review Report or the Quarterly Claims Review Report. Each Cardiac Test Procedures Review Report or Claims Review Report shall include the information specified in Appendix B to this IA.

C. Annual Reports. The Providers shall submit to OIG Annual Reports with respect to the status of, and findings regarding, the Providers' compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer described in Section III.A;

2. a description of any changes to the notice required by Section III.A, and the reason for such changes, along with a copy of the revised notice;

3. the following information regarding the eight hours of training required by Section III.B during the first reporting period (and any additional hours of

training required for the second and third reporting periods): a copy of the training program registration for Mego and Yarra, the name of the training course, the name of the entity that provided the training, the location, date and length of the training; and a training program brochure or other materials from the training program or training program sponsor that describe the content of the training program;

A copy of all training materials shall be made available to OIG upon request.

4. a certification from the IRO regarding its professional independence and objectivity with respect to the Providers;

5. a copy of the documentation demonstrating that the Providers screened all prospective and current Covered Persons against the Exclusion Lists, as required by section III.F;

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 summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

8. a report of the aggregate Overpayments that have been returned to the Federal health care programs during the Reporting Period. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

9. a copy of any certifications from the Providers and the third party billing company required by Section III.J (if applicable);

10. a description of all changes to the most recently provided list of the Providers' locations (including addresses) as required by Section V.A.6; and

11. a certification signed by the Providers that: (a) they have reviewed the IA in its entirety, understands the requirements described within, and maintains a copy for reference; (b) to the best of their knowledge, except as otherwise described in the Annual Report, the Providers are in compliance with all of the requirements of this IA; and (c) they has reviewed the Annual Report and has made a reasonable inquiry

regarding its content and believes that the information is accurate and truthful. The certification shall be signed by Mego and Yarra in their individual capacities and on behalf of Valley Heart Consultants, P.A., and shall be signed by all other owners of Valley Heart Consultants, P.A., on behalf of the entity.

The first Annual Report shall be received by 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.

D. Designation of Information. The Providers shall clearly identify any portions of its submissions that they believe are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. The Providers shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this IA shall be submitted to the following entities:

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

Provider:

Carlos D. Mego, M.D.
Subbarao Yarra, M.D.
Valley Heart Consultants, P.A.
1200 E. Savannah
Suite 7
McAllen, TX 78503

Unless otherwise specified, all notifications and reports required by this IA 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. Upon request by OIG, the Providers may be required to provide OIG with an electronic copy of each notification or report required by this IA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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

VIII. DOCUMENT AND RECORD RETENTION

The Providers shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this IA for four years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify the Providers prior to any release by OIG of information submitted by the Providers pursuant to its obligations under this IA and identified upon submission by the Providers as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, the Providers shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

The Providers are expected to fully and timely comply with all of their IA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the Providers and OIG hereby agree that failure to comply with certain obligations set forth in this IA (unless a timely written request for an extension has been submitted and approved in accordance with Section B below) 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 the Providers fail to:

   a. appoint and maintain a Compliance Officer in accordance with the requirements of Section III.A;

   b. establish and/or post a notice in accordance with the requirements of Section III.B;

   c. Establish Policies and Procedures in accordance with Section III.C;

d. complete the training required for the Providers and maintain training certifications, in accordance with the requirements of Section III.D;

e. engage and use an IRO in accordance with the requirements of Section III.E, Appendix A, and Appendix B;

f. screen Covered Persons in accordance with the requirements of Section III.F; or require Covered Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; and maintain documentation of screening and disclosure requirements in accordance with the requirements of Section III.F;

g. notify OIG of a government investigation or legal proceeding, in accordance with the requirements of Section III.G;

h. repay any Overpayments in accordance with Section III.H;

i. report a Reportable Event in accordance with Section III.I.; or

j. provide to OIG the certifications required by Section III.J relating to any third party biller engaged by the Providers during the term of the IA.

2. A Stipulated Penalty of $1,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the Providers fail to submit the Implementation Report, Quarterly Cardiac Procedures Review Report or Quarterly Claims Review Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of $1,000 for each day the Providers fail to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date the Providers fail to grant access.)

4. A Stipulated Penalty of $50,000 for each false certification submitted by or on behalf of the Providers as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by OIG), or as otherwise required by this IA.

5. A Stipulated Penalty of $1,000 for each day the Providers fail to comply fully and adequately with any obligation of this IA. OIG shall provide notice to the Providers stating the specific grounds for its determination that the Providers have failed to comply fully and adequately with the IA obligation(s) at issue and steps the Providers shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue 10 days after the date the Providers receive this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions. The Providers 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 IA. 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 the Providers 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 the Providers 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 the Providers 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 the Providers of: (a) the Providers' failure to comply; and (b) OIG's intent to exercise its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days of the receipt of the Demand Letter, the Providers shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send 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 the Providers elect to request an ALJ hearing, the Stipulated Penalties shall

continue to accrue until the Providers 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 IA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

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 the Providers have materially breached this IA, 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 IA.

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

a. a failure by the Providers to report a Reportable Event, 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 IA, 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 engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a material breach of this IA by the Providers constitutes an independent basis for the Providers' exclusion from participation in the Federal health care programs. Upon a determination by OIG that the Providers have materially breached this IA and that exclusion is the appropriate remedy, OIG shall notify the Providers of: (a) the Providers' material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion.

(This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Opportunity to Cure*. The Providers 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. The Providers are in compliance with the obligations of the IA cited by 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) the Providers have begun to take action to cure the material breach; (ii) the Providers are pursuing such action with due diligence; and (iii) the Providers have provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, the Providers fail to satisfy the requirements of Section X.D.3, OIG may exclude the Providers from participation in the Federal health care programs. OIG shall notify the Providers in writing of its determination to exclude the Providers. (This letter shall be referred to 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 Providers' receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, the Providers may apply for reinstatement, by submitting 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 the Providers of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, the Providers 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 IA. 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 after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after 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 IA shall be: (a) whether the Providers were in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. The Providers shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. 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 IA and orders the Providers to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless the Providers 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 IA shall be:

a. whether the Providers were in material breach of this IA;

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) the Providers had begun to take action to cure the material breach within that period; (ii) the Providers have pursued and are pursuing such action with due diligence; and (iii) the Providers provided to OIG within that period a reasonable timetable for curing the material breach and the Providers 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 the Providers, only after a DAB

decision in favor of OIG. The Providers' election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the Providers 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 the Providers 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. The Providers shall waive their 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 the Providers, the Providers shall be reinstated effective 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA.

XI. EFFECTIVE AND BINDING AGREEMENT

The Providers and OIG agree as follows:

A. This IA shall become final and binding on the date the final signature is obtained on the IA.

B. This IA constitutes the complete agreement between the parties and may not be amended except by prior written consent of the parties to this IA.

C. OIG may agree to a suspension of the Providers' obligations under this IA based on a certification by any of the Providers that they are no longer providing health care items or services that will be billed to any Federal health care programs and they do not have any ownership or control interest in any entity that bills any Federal health care program. If any of the Providers are relieved of their IA obligations, the Provider shall be required to notify OIG in writing at least 30 days in advance if the Provider plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, the OIG shall evaluate whether the IA will be reactivated or modified.

D. All requirements and remedies set forth in this IA are in addition to, and do not affect (1) the Providers' responsibility to follow all applicable Federal health care

program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable program requirements.

E. The undersigned Provider signatories represents and warrants that they are authorized to execute this IA. The undersigned OIG signatories represent that they are signing this IA in their official capacity and that they are authorized to execute this IA.

F. This IA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same IA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this IA.

ON BEHALF OF THEMSELVES AS INDIVIDUALS AND ON BEHALF OF VALLEY HEART CONSULTANTS, P.A.

/Carlos D. Mego, M.D./ 4/9/14

_____ _____

Carlos D. Mego, M.D. Date
[Address]

/Subbarao Yarra, M.D./ 4/9/14

_____ _____

Subbarao Yarra, M.D. Date
[Address]

_____ _____

Trey Martinez, Esq. Date

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

/Robert K. DeConti/ 4/22/14

ROBERT K. DECONTI DATE
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

/Geoffrey W. Hymans/ 4/11/2014

GEOFFREY W. HYMANS DATE
Senior Counsel
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the IA.

A. IRO Engagement

1. The Providers shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.3 of the IA or any additional information submitted by the Providers in response to a request by OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

2. If the Providers engage a new IRO during the term of the IA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, the Providers shall submit the information identified in Section V.A.3 of the IA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, or any additional information submitted by the Providers at the request of OIG, whichever is later, OIG will notify the Providers if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Providers may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, claims submission, and other Federal health care program requirements relating to claims for items and services submitted by Providers;

2. assign individuals to design and select the Claims Review

sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign individuals to conduct the Cardiac Test Procedures Review who have expertise in the proper conduct and interpretation of the specified procedures, expertise in determining the medical necessity for such procedures, expertise in the proper documentation of such medical necessity and in the proper documentation of the interpretation of the results of such procedures, and familiarity with the established practice guidelines and generally accepted standards of medical practice described by the American Society of Nuclear Cardiology and the American College of Cardiology. The IRO shall employ or contract with at least one board-certified nuclear cardiologist to perform such reviews; and

5. have sufficient staff and resources to conduct the reviews required by the IA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each Cardiac Test Procedures Review or Claims Review in accordance with the specific requirements of the IA;

2. follow all applicable Federal health care programs rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the IA.

D. IRO Independence and Objectivity

The IRO must perform the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *The Providers and the IRO*. If the Providers terminate the IRO or the IRO withdraws from the engagement during the term of the IA, the Providers must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. The Providers must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require the Providers to engage a new IRO in accordance with Paragraph A of this Appendix. The Providers must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring the Providers to engage a new IRO, OIG shall notify the Providers of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, the Providers may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any

differences regarding the IRO with the Providers prior to requiring the Providers to terminate the IRO. However, the final determination as to whether or not to require the Providers to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

CLAIMS AND CARDIAC TEST PROCEDURES REVIEWS

A. Claims Review.

The IRO shall conduct a review of the coding, billing, and claims submission to the Federal health care programs by or on behalf of the Providers, and the reimbursement received for cardiology items and services provided by the Providers, for each three-month period during the term of this IA (Quarterly Claims Review) and prepare a report for each Quarterly Claims Review performed.

1. *Definitions*. For the purposes of this Appendix B, the following definitions shall be used:

a. Overpayment: The amount of money the Providers received for cardiology items and services provided by the Providers in excess of the amount due and payable under any Federal health care program requirements, as determined by the IRO in connection with the claims reviews performed under this Appendix B, and which shall include any extrapolated Overpayments determined in accordance with Section A.3 of this Appendix B.

b. Paid Claim: A claim submitted by or on behalf of the Providers for cardiology items and services provided by the Providers for which the Providers have received reimbursement from the Medicare, Medicaid, or any Federal health care program.

c. Population: The Population shall be defined as all Paid Claims during the six-month period covered by the Quarterly Claims Review.

d. 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.

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

2. *Quarterly Claims Sample.* Within 15 days following the end of each three-month period during the term of this IA, the IRO shall randomly select a sample of 30 Paid Claims submitted by or on behalf of the Providers during the preceding three-month period (Quarterly Claims Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp. The Providers shall provide the IRO with a list of all the Providers' Paid Claims for the three-month period covered by the Quarterly Claims Sample. The IRO should number each Paid Claim in the Population sequentially prior to generating the random numbers used to select the Quarterly Claims Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the 30 Paid Claims in the Population that will be subject to review by the IRO. The randomly selected 30 Paid Claims will be reviewed by the IRO based on the supporting documentation available the Providers' offices or under the Providers' control and applicable billing and coding regulations and guidance to determine whether each claim was correctly coded, submitted, and reimbursed. The IRO shall prepare a written report of its findings from the Quarterly Claims Sample, as described in Section C below (Quarterly Claims Review Report). The Quarterly Claims Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Claims Review.

3. *Additional Steps if Error Rate is 5% or Greater*. If the Error Rate (as defined above) for any Quarterly Claims Review performed is 5% or greater, the IRO will estimate the actual Overpayment in the Population for that three-month period by identifying the point estimate. To identify the point estimate, the IRO shall extrapolate the Error Rate as determined in the Quarterly Claims Sample to the Population for the applicable Quarterly Claims Review. The Providers shall be required to repay the point estimate of the extrapolated Overpayment in accordance with Section E, below. OIG, in its sole discretion, may refer the findings of the Quarterly Claims Sample (and any related workpapers) to the appropriate Federal health care program payor for appropriate follow-up by that payor. The Quarterly Claims Review Report prepared by the IRO shall indicate the extrapolated Overpayment amount and the methodology used by the IRO to determine the extrapolated Overpayment amount.

B. Claims Review Report. The IRO shall prepare a Claims Review Report for each Quarterly Claims Review performed (Quarterly Claims Review Report). The

following information shall be included in each Quarterly Claims Review Report.

1. *Claims Review Methodology*.

   a. Claims Review Population. A description of the Population subject to the Quarterly Claims Review.

   b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Quarterly Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare contractor manual or bulletins (including issue and date), other policies, regulations, or directives).

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

   d. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of each Quarterly Claims Sample and the Providers shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Quarterly Claims Sample. If the IRO accepts any supplemental documentation or materials from the Providers after the IRO has completed its initial review of the Quarterly Claims Sample (Supplemental Materials), the IRO shall identify in the Quarterly Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Quarterly Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Statistical Sampling Documentation.* A copy of the printout of the random numbers generated by the "Random Numbers" function of RAT-STATS

used by the IRO to select the Quarterly Claims Sample.

3. *Claims Review Findings*.

a. Narrative Results.

i. For the first Quarterly Claims Review Report only, a description of the Providers' billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing. Subsequent Quarterly Claims Review Reports should describe any significant changes to the Providers' billing and coding system or, if no significant changes were made, state that the billing and coding systems remain the same as described in the prior Quarterly Claims Review Report.

ii. A narrative explanation of the results of the Quarterly Claims Sample, including reasons for errors, patterns noted, etc.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by the Providers (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 the Providers.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Quarterly Claims Sample results that includes the following information for each Paid Claim: 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.

c. Recommendations. The IRO's report shall include any recommendations for improvements to the Providers' billing and coding system based on the findings of the Quarterly Claims Review.

d. Credentials. The names and credentials of the individuals who: (1) designed the review methodology utilized for the Quarterly Claims Review and (2) performed the Quarterly Claims Review.

C. Other Requirements. The following requirements apply to any Quarterly Claims Review performed pursuant to this Appendix B.

1. *Paid Claims without Supporting Documentation*. Any Paid Claim for which the Providers cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the Providers for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

2. *Use of First Samples Drawn*. For the purposes of all samples discussed in this Appendix, the Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the sample).

D. Repayment of Identified Overpayments. The Providers shall repay within 60 days any Overpayment(s) identified in each Quarterly Claims Sample (including any extrapolated amounts identified in accordance with Section A.3 of this Appendix), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. The Providers shall make available to OIG all documentation that

reflects the refund of the Overpayment(s) to the payor.

E. Cardiac Test Procedures Review.

The IRO shall conduct a review of cardiac test procedures (SPECT tests, 2-D echocardiograms, carotid Doppler studies, and CT angiography of the carotid arteries) performed by Mego and Yarra for each three-month period during the term of this IA (Quarterly Cardiac Test Procedures Review). In conducting the Quarterly Cardiac Test Procedures Reviews, the IRO shall employ or contract with a physician board-certified in nuclear cardiology. The IRO shall prepare a report for each Quarterly Cardiac Test Review performed. The first review shall take place three months following the effective date of this agreement.

Definitions. For the purposes of the Cardiac Test Procedures Review, the following definitions shall be used:

a. Cardiac Test Procedure. Cardiac test procedures (including SPECT tests, 2-D echocardiograms, carotid Doppler studies, and CT angiography of the carotid arteries) performed by Mego and Yarra.

b. Population. For each Reporting Period, the Population shall be defined as all Cardiac Test Procedures performed by Mego and Yarra for which Mego, Yarra or Valley Heart Consultants has received reimbursement from Medicare, Medicaid, or other Federal health care programs during the three-month period covered by the Quarterly Cardiac Test Review.

F. *Quarterly Cardiac Test Procedures Sample*. Within 15 days following the end of each three-month period during the term of this IA, the IRO shall randomly select a sample of 30 Cardiac Test Procedures performed by Mego or Yarra during the preceding three-month period (Quarterly Cardiac Test Procedures Sample). The sample must be selected through the use of OIG's Office of Audit Services' Statistical Sampling Software, also known as RAT-STATS, which is currently available at https://oig.hhs.gov/compliance/rat-stats/index.asp. The Providers shall provide the IRO with a list of all of Mego and Yarra's Paid Claims for the three-month period covered by the Quarterly Cardiac Test Procedures Sample. The IRO should number each Cardiac Test Procedure in the Population sequentially prior to generating the random numbers used to select the Quarterly Cardiac Test Procedures Sample. The IRO should generate 30 random numbers using RAT-STATS and then use the random numbers to identify the

30 Cardiac Test Procedures in the Population that will be subject to review by the IRO. The randomly selected 30 Cardiac Test Procedures will be reviewed by the IRO based on the supporting documentation available at the Providers' offices or under the Providers' control and applicable billing and coding regulations and guidance to determine whether each procedure was medically necessary or appropriate, whether the medical records contained proper documentation of such medical necessity and proper documentation of the interpretation of the results of such procedures, and whether the medical records indicated if the raw SPECT images were viewed on a computer monitor. Review of medical necessity and documentation shall be based on established practice guidelines and generally accepted standards of medical practice as described by the American Society of Nuclear Cardiology and the American College of Cardiology. The IRO shall prepare a written report of its findings from the Quarterly Cardiac Test Procedures Sample, as described in Section G below (Quarterly Cardiac Test Procedures Review Report). The Quarterly Cardiac Test Procedures Review Report shall be submitted to the OIG within 60 days following the end of the three-month period covered by each Quarterly Cardiac Test Procedures Review.

G. Cardiac Test Procedures Review Report. The following information shall be included in the Cardiac Test Procedures Review for each Sample.

1. *Cardiac Test Procedures Review Methodology*.

   a. Cardiac Test Procedures Review Population. A description of the Population subject to the Test Review.

   b. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Cardiac Test Procedures Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

   c. Review Protocol. A narrative description of how the Cardiac Test Procedures Review was conducted and what was evaluated.

2. *Statistical Sampling Documentation.*

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

3. *Cardiac Test Procedures Review Findings*.

a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Cardiac Test Procedures Review, including the results of the Sample and recommendations for improvements to the Providers' performance of Cardiac Test Procedures based on the findings of the Cardiac Test Procedures Review.

b. Total number of instances in which the IRO determined (1) that the Cardiac Test Procedure was not medically necessary or appropriate based on established practice guidelines and generally accepted standards of medical practice as described by the American College of Nuclear Cardiology and the American College of Cardiology, (2) that the medical necessity for the test or interpretation of test was inappropriately documented in the medical record, or (3) that the medical record did not indicate whether the raw SPECT images were viewed on a computer monitor.

c. A spreadsheet of the Cardiac Test Procedures Review results that includes the following information for each Cardiac Test Procedure appraised: type of Cardiac Test Procedure performed, whether the Procedure was medically necessary and appropriate, whether such medical necessity was documented in the medical record, whether the test results were correctly interpreted and whether that interpretation was recorded in the medical record, whether the medical record indicated that the physician viewed the raw SPECT images on a computer monitor, beneficiary name, beneficiary health insurance claim number, date of service, procedure code submitted, Federal health care program billed, and amount reimbursed.

5. *Credentials*. The names and credential of the individuals who performed the Cardiac Test Procedures Review.