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

I. PREAMBLE

Genesee Valley Cardiothoracic ("GVC") hereby enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by GVC and any entity which GVC owns or has a controling interest in (as defined in 42 U.S.C. § 1320a-3(a)(3)) and by all Covered Persons and Covered Contractors (as these terms are defined herein) 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)) (hereinafter collectively referred to as "Federal health care program requirements"). The individuals covered by this Agreement shall be defined as follows:

1. "Covered Persons": includes all a) officers; b) directors; c) managers; d) administrators; e) physicians; and f) employees of GVC with responsibility for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services; and

2. "Covered Contractors": includes all a) contractors; b) agents; and c) other third parties with responsibility for the provision, marketing or documentation of items or services reimbursable by Federal health care programs or are engaged to bill and/or submit claims for reimbursement to Federal health care programs.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by GVC under this Agreement shall be 3 years from the date of execution of this Agreement.

The Effective Date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement (the "Effective Date").

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by GVC pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

GVC hereby agrees to establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Prior to the Effective Date of this Agreement, GVC represents that it has designated a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. In the event a new Compliance Contact is appointed during the term of this Agreement, GVC shall notify the OIG, in writing, within 30 days of such a change.

B. Posting of Notice

Within the first 30 days following the Effective Date of this Agreement, GVC shall post in a prominent place accessible to all patients, Covered Persons and Covered Contractors a notice detailing GVC's 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 any questions or concerns can be addressed. A copy of this notice should be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date of this Agreement, GVC agrees to develop, implement, and make available to all Covered Persons and Covered Contractors written policies that address the following:

1. GVC's commitment to operate their business in full compliance with all Federal health care program requirements;

2. The proper procedures for the honest and accurate submission of claims in accordance with Federal health care program requirements, including but not limited to, the requirement that only properly documented services are billable to the Federal health care programs;

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

4. The requirement that all of GVC's Covered Persons and Covered Contractors shall be expected to report to GVC or the Compliance Contact suspected violations of any Federal health care program requirements or GVC's own Policies and Procedures. Any Covered Person or Covered Contractor who makes an inquiry regarding compliance with medical practice standards or Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

5. The requirement that GVC not hire, employ or engage Covered Persons or Covered Contractors who are Ineligible Persons. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, 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, GVC shall require all prospective Covered Persons and Covered Contractors to disclose whether they are Ineligible Persons and shall check all prospective Covered Persons and Covered Contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov). Thereafter, GVC shall review the lists annually.

6. The commitment of GVC to remain current with all applicable Federal health care program requirements by obtaining and reviewing applicable

program memoranda, newsletters, and any other correspondence from the Fiscal Intermediary or Carrier related to Federal health care program requirements.

At least annually (and more frequently if appropriate), GVC shall assess and update as necessary the Policies and Procedures. Within 30 days of the Effective Date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions are related to those Policies and Procedures.

Within 120 days of the Effective Date of the Agreement and annually thereafter, each Covered Person and Covered Contractor shall certify in writing that he or she has read, understood, and will abide by GVC's Policies and Procedures. New Covered Persons and Covered Contractors shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or Covered Contractor or shall make such certification within 120 days of the Effective Date of the Agreement, whichever is later.

D. Training and Certification

Within 90 days following the Effective Date of this Agreement and at least once each year thereafter, Covered Persons or Covered Contractor involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 2 hours of training from an individual or entity, other than another Covered Person.

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

At a minimum, all training sessions shall cover the following topics:

1. The requirements of this Agreement;

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

3. Applicable Federal health care program requirements related to proper documentation;

4. All other applicable Federal health care program requirements;

5. The legal sanctions for improper billings;

6. Examples of proper and improper billing practices.

Each Covered Person shall certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. GVC shall retain the certifications, along with the training course materials.

E. Third Party Billing

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

In the event GVC engages a third party billing company it shall, prior to such engagement, obtain a certification from the third party billing company that (i) it is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs; (ii) it has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides at

least 6 hours of training per year in billing and coding related to the Medicare and other Federal health care programs for those employees involved in the preparation and submission of claims to those programs. GVC shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

F. Annual Review Procedures

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

2. *Frequency of the Billing Engagement.* The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the Effective Date of this Agreement. The IRO shall perform all components of each annual Billing Engagement in accordance with the procedures detailed in Appendix A including the reporting obligations contained therein.

3. *Retention of Records.* The IRO and GVC shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the Billing Engagement for the time period specified in section VIII of this Agreement.

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

5. *Compliance Review.* Within 90 days of the Effective Date, GVC shall retain a person or entity to serve as an IRO to conduct a review of GVC's compliance activities ("Compliance Review") for the first one-year period beginning with the Effective Date of this Agreement. The IRO who conducts the Compliance Review may be different from the IRO which conducts the Billing Engagement. The Compliance Review shall consist of a review of GVC's compliance with the obligations set forth in this Agreement and the IRO who conducts the Compliance Review shall report as part of the first Annual Report its findings (including any supporting materials) regarding GVC's compliance with the terms of this Agreement.

G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money GVC has received in excess of the amount due and payable under any Federal health care program requirements. GVC may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, GVC identifies or learns of any overpayments, GVC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem by GVC and the overpayments due to such GVC problem from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

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

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

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

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

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

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

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

H. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, GVC shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that GVC has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. GVC shall also provide written notice to OIG within 30 days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this Agreement, GVC changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, GVC shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

V. REPORTS

A. Implementation Report

Within 135 days after the Effective Date of this Agreement, GVC shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. A copy of the notice GVC posted in their office as described in Section III.B;

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

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

4. A copy of all training materials required by Section III.D., and a schedule of when the training session(s) were held;

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

6. A copy of the certification from the third party billing company, if applicable, as required by section III.E. of the Agreement;

7. The name of the person(s) or entity(ies) GVC has retained to conduct the Billing Engagement and Compliance Review and the proposed start and completion dates of the first annual review;

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

9. A certification from the Compliance Contact stating that he or she has reviewed GVC's Implementation Report, has made a reasonable inquiry regarding the report's content and believes that, upon his or her inquiry, the information is accurate and truthful;

B. Annual Reports

GVC shall submit to OIG Annual Reports with respect to the status of and findings regarding GVC's compliance activities for each of the 3 one-year periods beginning on the Effective Date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than one year and 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

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

2. A certification by GVC that all Covered Persons have executed the annual Policies and Procedures certification required by section III.C.;

3. A copy of the training materials utilized in accordance with section III.D. of this Agreement if different from those submitted with the Implementation Report;

4. A certification signed by the Compliance Contact certifying that he or she is maintaining written certifications from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement;

5. A complete copy of all reports prepared pursuant to the IRO(s) Billing Engagement and Compliance Review;

6. GVC's response and corrective action plan(s) related to any issues raised by the IRO;

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

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

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

10. A certification signed by the Compliance Contact certifying that he or she has reviewed the Annual Report, he or she has made a reasonable inquiry regarding its content and believes that, upon his or her inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

ATTN: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Ph. 202.619.2078
Fax 202.205.0604

All correspondence to GVC shall be sent to:

Peter Knight, MD
Compliance Officer
1415 Portland Ave., Suite 240
Rochester, NY 14621
Ph. 716.544.6550
Fax 716.338.2997

Unless otherwise specified, all notifications and reports required by this Agreement may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of GVC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of GVC's locations for the purpose of verifying and evaluating: (a) GVC's compliance with the terms of this Agreement; and (b) GVC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by GVC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of GVC's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. GVC agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. GVC's employees may elect to be interviewed with or without counsel or a representative of GVC present.

VIII. DOCUMENT AND RECORD RETENTION

GVC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for 4 years (or longer if otherwise required by law).

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify GVC prior to any release by OIG of information submitted by GVC pursuant to its obligations under this Agreement and identified upon submission by GVC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GVC shall have the rights set forth at 45 C.F.R. § 5.65(d). GVC shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by GVC shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by GVC.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, GVC and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day GVC or the applicable Covered Persons fail to complete the training required by section III.D. of the Agreement.

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day GVC fails to submit the IRO's Claim's Review Report and System's Review Report, as required in section III.F and Appendix A.

3. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day GVC fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of $750 (which shall begin to accrue on the date the failure to comply began) for each day GVC employs or contracts with Covered Persons or Covered Contractors who are Ineligible Persons and that Ineligible Person: (i) has

responsibility for, or involvement with, GVC's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which GVC can demonstrate that it 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).

5. A Stipulated Penalty of $750 for each day GVC fails to grant access to the information or documentation as required in section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date GVC fails to grant access.)

6. A Stipulated Penalty of $750 for each day GVC fails to comply fully and adequately with any obligation of this Agreement not already covered in paragraphs 1-5. In its notice to GVC, OIG shall state the specific grounds for its determination that GVC has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the GVC must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to GVC of the failure to comply.)

B. Timely Written Requests for Extensions

GVC may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after GVC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after GVC receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that GVC has failed to comply with any of the obligations described in section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify GVC of: (a) GVC's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, GVC shall respond by either: (a) curing the breach to OIG's satisfaction, paying the applicable Stipulated Penalties and notifying OIG of his corrective actions; or (b) sending in writing to the 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 GVC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GVC cures, to OIG's satisfaction, the alleged breach in dispute and all accrued Stipulated Penalties shall become due and payable as specified in section X.E.2. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section X.D.

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

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

D. Exclusion for Material Breach of this Agreement

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

a. a failure by GVC to report a material deficiency, take corrective action and make the appropriate refunds, as required in section III.G;

b. repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in

section X.A; or

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by GVC constitutes an independent basis for GVC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that GVC has materially breached this Agreement and that exclusion should be imposed, OIG shall notify GVC of: (a) GVC's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* GVC 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. GVC is in full compliance with this Agreement;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, GVC fails to satisfy the requirements of section X.D.3, OIG may exclude GVC from participation in the Federal health care programs. OIG will notify GVC in writing of its determination to exclude GVC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, GVC wishes to apply for reinstatement, GVC 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 GVC 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, GVC shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for an ALJ 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 GVC was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. GVC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders GVC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GVC requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

a. whether GVC was in material breach of this Agreement;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured

within the 30 day period, but that:

(i) GVC had begun to take action to cure the material breach within that period;

(ii) GVC has pursued and is pursuing such action with due diligence; and

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

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the GVC, only after a DAB decision in favor of OIG. GVC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude GVC upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that GVC may request review of the ALJ decision by the DAB. If the DAB finds in favor of GVC after an ALJ decision adverse to GVC and the OIG has in the interim excluded GVC from participation in Federal health care programs on the basis of the prior ALJ determination, GVC shall be entitled to submit any and all claims for payment to the Federal health care programs that it would otherwise have submitted during the period of exclusion but for the OIG's exclusion. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

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

IX. EFFECTIVE AND BINDING AGREEMENT

GVC and the OIG agree as follows:

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

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 GVC signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

12-22-00
Date

RONALD KIRSHNER, MD
Authorized Representative of GVC

12/22/00
Date

PETER KNIGHT, MD
Authorized Representative of GVC

12/22/00
Date

DAVID CHEERAN, MD
Authorized Representative of GVC

1/30/01
Date

HENRY DePIPPO
Counsel for GVC
Nixon Peabody LLP
Clinton Square
P. O. Box 1051
Rochester, New York 14603-1051

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

12/7/00
Date

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A

A. Billing Engagement

The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The IRO shall prepare a Claims Review Report and a Systems Review Report to report the findings of the reviews. The Claims Review and Claims Review Report are discussed in detail in Appendix A to this Agreement, which is incorporated by reference.

1. ***Claims Review.*** The IRO shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by GVC to the Federal health care programs. The Claims Review shall be performed in accordance with the procedures set forth in Section B of this Appendix A.

2. ***Claims Review Report.*** The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Section C of this Appendix A. The Claims Review Report shall be submitted to the OIG in the Annual Report.

3. ***Systems Review.*** The IRO shall review GVC's billing and coding systems and/or operations (the "Systems Review"). This review shall examine the coding and claim submission process (e.g., reviewing the process, reviewing the systems edits).

4. ***Systems Review Report.*** The IRO shall prepare a report based upon the Systems Review ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding the strengths and weaknesses in GVC's coding systems and/or operations and claims submission process. This report shall also include any recommendations the IRO may have to improve any of these systems, operations, and processes. The Systems Review Report shall be submitted to the OIG in the Annual Report.

B. Claims Review

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

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

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

d. Paid Claim: A code or line item submitted by GVC and for which GVC has received reimbursement from the Federal health care programs.

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

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

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

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

a. Claims Review Sample Size Options.

Option 1: Review a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate.

To determine how many Items must be included in the Claims Review Sample, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by GVC for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment.

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

including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

If no Overpayments are found in this Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample. The results of the Probe Sample shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see Section C, below); or

Option 2: Review a minimum 100 Items Claims Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report (See Section C, below).

b. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

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

d. Use of First Samples Drawn. For the purposes of all samples (Probe Sample and Claims Review Sample) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

C. Claims Review Report.

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

1. ***Claims Review Methodology***

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

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

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

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

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

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

2. ***Statistical Sampling Documentation***

a. Documentation Required Under Option 1:

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

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

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

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

v. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample shall be available to the OIG upon request.

b. Documentation Required Under Option 2:

i. The number of Items appraised in the Claims Review Sample.

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

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

3. ***Claims Review Results***

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

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

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of

the Overpayments identified in Section C.3.b above.) The IRO may, in its report to GVC, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

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

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

Claim Review Results

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ Date of Deposit: _____
Contractor Contact Name:_____ Phone #_____
Contractor Address:_____
Contractor Fax:_____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____
AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reaso
n per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

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

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

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

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND GENESEE VALLEY CARDIOTHORACIC, P.C.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Genesee Valley Cardiothoracic, P.C. ("GVC") entered into an Integrity Agreement ("IA") on January 30, 2001.

A. Pursuant to section IX.3. of GVC's IA, modifications to the IA may be made with the prior written consent of both the OIG and GVC. Therefore, the OIG and GVC hereby agree that GVC's IA will be amended as follows:

Section III.F., Annual Review Procedures, of the IA is hereby superseded by the attached new section III.F., Review Procedures.

Appendix A of GVC's IA is hereby superseded by the attached new Appendix A.

B. The OIG and GVC agree that all other sections of GVC's IA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and GVC.

C. The undersigned GVC signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF GVC

David Cheeran, MD
Authorized Representative of GVC

6/4/02
DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

6/14/02
DATE

F. Annual Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the Effective Date of this IA, GVC shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist GVC in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this IA and the Settlement Agreement. Each IRO retained by GVC shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which GVC seeks reimbursement. Each IRO shall assess, along with GVC, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze GVC's billing and coding to the Federal health care programs ("Claims Review") and shall analyze GVC's compliance with the obligations assumed under this IA and the Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the IA beginning with the Effective Date of this IA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the Effective Date of this IA.

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

2. *Claims Review.*

a. Option 1: The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this IA, which is incorporated by reference.

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

A. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, GVC should, as appropriate, further analyze any errors identified in the Discovery Sample. GVC recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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

ii. Full Sample. If necessary, as determined by procedures set forth in Section III.F.2.a.i, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on

supporting documentation available at GVC or under GVC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, GVC may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from GVC to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

iii. Systems Review. If GVC's Discovery Sample identifies an Error Rate of 5% or greater, GVC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to GVC the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

b. Option 2: Review a minimum of 100 Items Claims Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report.

c. Repayment of Identified Overpayments. In accordance with section III.G.1 of the IA, GVC agrees to repay within 30 days any Overpayment(s) identified in the Claims Review Report, regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. GVC agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

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

4. *Compliance Review.* The IRO shall conduct a review of GVC's compliance activities. The Compliance Review shall consist of a review of GVC's compliance with the obligations set forth in each section of this IA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding GVC's compliance with the terms of each section of the IA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) GVC's Claims Review or Compliance Review fails to conform to the requirements of this IA; or (b) the IRO's audit findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). GVC agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after GVC's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify GVC of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, GVC may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. GVC agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with GVC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to GVC a certification or sworn affidavit that it has evaluated its professional independence with

regard to the Claims Review or Compliance Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

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

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

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

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

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

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

2. **Other Requirements.**

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

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

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

1. **Claims Review Methodology.**

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical

review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

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

b. Quantitative Results.

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

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

iv. Error Rate in the sample.

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

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

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

Attachment 1

Claim Review Results

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

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND GENESEE VALLEY CARDIOTHORACIC, P.C.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Genesee Valley Cardiothoracic, P.C. ("GVC") entered into an Integrity Agreement ("IA") on January 30, 2001.

A. Pursuant to section IX.3. of GVC's IA, modifications to the IA may be made with the prior written consent of both the OIG and GVC. Therefore, the OIG and GVC hereby agree that GVC's IA will be amended as follows:

Section III.F., Annual Review Procedures, of the IA is hereby superseded by the attached new section III.F., Review Procedures.

Appendix A of GVC's IA is hereby superseded by the attached new Appendix A.

B. The OIG and GVC agree that all other sections of GVC's IA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and GVC.

C. The undersigned GVC signatory represents and warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. This effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF GVC

David Cheeran, MD
Authorized Representative of GVC

6/4/02
DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

6/14/02
DATE

F. Annual Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the Effective Date of this IA, GVC shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist GVC in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this IA and the Settlement Agreement. Each IRO retained by GVC shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this IA and in the general requirements of the Federal health care program(s) from which GVC seeks reimbursement. Each IRO shall assess, along with GVC, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze GVC's billing and coding to the Federal health care programs ("Claims Review") and shall analyze GVC's compliance with the obligations assumed under this IA and the Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the IA beginning with the Effective Date of this IA. The IRO(s) shall perform all components of each annual Claims Review.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the Effective Date of this IA.

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

2. *Claims Review.*

a. Option 1: The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to this IA, which is incorporated by reference.

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

A. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, GVC should, as appropriate, further analyze any errors identified in the Discovery Sample. GVC recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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

ii. Full Sample. If necessary, as determined by procedures set forth in Section III.F.2.a.i, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on

supporting documentation available at GVC or under GVC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, GVC may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from GVC to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

iii. Systems Review. If GVC's Discovery Sample identifies an Error Rate of 5% or greater, GVC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to GVC the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

b. Option 2: Review a minimum of 100 Items Claims Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report.

c. Repayment of Identified Overpayments. In accordance with section III.G.1 of the IA, GVC agrees to repay within 30 days any Overpayment(s) identified in the Claims Review Report, regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. GVC agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

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

4. *Compliance Review.* The IRO shall conduct a review of GVC's compliance activities. The Compliance Review shall consist of a review of GVC's compliance with the obligations set forth in each section of this IA.

5. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding GVC's compliance with the terms of each section of the IA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) GVC's Claims Review or Compliance Review fails to conform to the requirements of this IA; or (b) the IRO's audit findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). GVC agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after GVC's final Annual Report and any additional information requested by the OIG is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify GVC of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, GVC may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the Validation Review. GVC agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any Claims Review or Compliance Review issues with GVC prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to GVC a certification or sworn affidavit that it has evaluated its professional independence with

regard to the Claims Review or Compliance Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

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

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

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

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

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

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

2. **Other Requirements.**

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

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

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

1. **Claims Review Methodology.**

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

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

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

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

e. Source of Data. A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical

review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

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

b. Quantitative Results.

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

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

iv. Error Rate in the sample.

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

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

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

Attachment 1

Claim Review Results

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