INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CARDIAC SURGERY ASSOCIATES OF CNY, P.C.

I. PREAMBLE

Cardiac Surgery Associates of CNY, P.C., ("CSA") together with its principal shareholders Dr. Mehdi A. Marvasti, Dr. Joel M. Rosenberg, and Dr. Ahmad Nazem, formerly shareholders of St. Joseph's Cardiac Surgery Associates, P.C. ("SJCSA") (collectively, the principal shareholders and CSA are hereinafter the "Practice") hereby enter into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations, program requirements and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) ("Federal health care program requirements") by the Practice. This commitment to promote compliance applies to any entity that the Practice owns or in which the Practice has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and the Practice's and any such entity's officers, directors, managers, administrators, physicians, employees, agents, contractors, subsidiaries, affiliates, and any third parties with whom the Practice may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs ("Covered Persons"). Contemporaneously with this Agreement, SJCSA is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by the Practice under this Agreement shall be 5 years from the Effective Date of this Agreement. The Effective Date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement ("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 the Practice pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days of execution of this Agreement, the Practice shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, the Practice shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

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

C. Written Policies and Procedures

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

1. The Practice'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;

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 the Practice's Covered Persons shall be expected to report to the Practice or the Compliance Contact suspected violations of any Federal health care program requirements or the Practice's own Policies and Procedures. Any Covered Person who makes an inquiry regarding compliance with Federal health care program requirements shall be able to do so without risk of retaliation or other adverse effect.

5. The requirement that the Practice not hire, employ or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense subject to mandatory exclusion under 42 U.S.C. § 1320a-7(a) 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, the Practice shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs. Thereafter, and for the term of this Agreement, the Practice shall screen each of its employees and contractors by reviewing these lists semi-annually.

6. The commitment of the Practice to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements.

7. The specific requirements for providing "assistant-at-surgery" services and for billing those services to the Federal health care programs.

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

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

Copies of the written policies and procedures shall be included in the Implementation Report. Copies of any written policies and procedures that are subsequently revised shall be included in the Annual Report.

D. Training and Certification

Within 90 days following the Effective Date of this Agreement, the Practice and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 8 hours of training from an individual or entity, other than the Practice or another Covered Person. Each year thereafter for the duration of this Agreement, the Practice and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 4 hours of training from an individual or entity, other than the Practice or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by the Practice.

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

At a minimum, the annual and new employee training sessions shall cover the following topics:

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

2. The written Polices and Procedures developed pursuant to Section III.C., above;

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

4. The specific requirements for providing "assistant-at-surgery" services and for billing those services to the Federal health care programs.

5. Examples of proper and improper billing practices; and

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

E. Third Party Billing

The Practice 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, the Practice 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 the Practice 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, the Practice shall notify OIG 30 days prior to any such proposed involvement.

In the event the Practice 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 screening and not knowingly employing any person who has been excluded, debarred or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides the required training in accordance with Section III.D. of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs. If, the Practice contracts with a new third party billing company during the term of this Agreement, the Practice 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, the Practice 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 the Practice's billing and coding practices ("Billing Engagement"). The Independent Review Organization retained by the Practice 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. The IRO shall assess, along with the Practice, whether it can perform the IRO engagement in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

2. *Frequency of the Billing Engagement.* The Billing Engagement shall be performed at least 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 and prepare the required reports in accordance with the procedures detailed in Appendix A to this Agreement, which is incorporated by reference into this Agreement.

3. *Retention of Records.* The IRO and the Practice shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

4. *Independence Certification.* Within 120 days from the Effective Date of this Agreement, the IRO shall provide to the Practice a certification or sworn affadavit that it has evaluated its professional independence with regard to the Billing Engagement and that it has concluded that it is, in fact, independent. Such certification shall be included in the Practice's Implementation Report submission.

5. *Compliance Review.* Within 90 days of the Effective Date, the Practice shall retain a person or entity to serve as an IRO to conduct a review of the Practice'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, however, if different, must also certify that they are professionally independent. The Compliance Review shall consist of a review of the Practice'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 the Practice's compliance with the terms of this Agreement.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) the Practice's Billing Engagement or Compliance Review 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 reviews to determine whether the Billing Engagement or Compliance Review complies with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate. Prior to initiating such a review, OIG shall notify the Practice of the specific failure to conform or inaccuracy that prompted the additional review. The Practice 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 the Practice's final submission (as described in Section II) is received by the OIG.

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 the Practice has received in excess of the amount due and payable under any Federal health care program requirements. The Practice may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this Agreement.

b. Reporting of Overpayments. If, at any time, the Practice identifies or learns of any overpayments, the Practice shall notify the payor within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, the Practice shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, the Practice shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the 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 the Practice determines, by any means, that there is a Material Deficiency, the Practice 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 implicated;

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

(iv) any further steps the Practice 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, the Practice 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 the Practice 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. The Practice 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, the Practice changes locations, engages a new physician to serve as a shareholder, director, officer, employee or agent or if the Practice purchases or establishes a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs, the Practice 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 or supplier number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

In the event Dr. Mehdi A. Marvasti, Dr. Joel M. Rosenberg, or Dr. Ahmad Nazem discontinue their affiliation with Cardiac Surgery Associates of CNY, P.C. for any reason, the individual physicians shall remain subject to the requirements in this Agreement for

the term of this Agreement.

V. REPORTS

A. Implementation Report

Within 120 days after the Effective Date of this Agreement, the Practice shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. The name and phone number of the Practice's Compliance Contact;

2. A copy of the notice the Practice posted in their office as described in Section III.B and a description of where and when the notice has been posted;

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

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

5. A description of the training required by Section III.D., including a summary of the topics covered and a schedule of when the training session(s) were held;

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

7. If applicable, a copy of the certification from the third party billing company required by Section III.E of the Agreement;

8. The name and qualifications of the IRO(s) that the Practice has retained to conduct the Billing Engagement and Compliance Review and the proposed start and completion dates of the first annual review;

9. A certification from the IRO(s) regarding its professional independence from the Practice;

10. A list of all the Practice'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

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

B. Annual Reports

The Practice shall submit to OIG Annual Reports with respect to the status of and findings regarding the Practice's compliance activities for each of the 5 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 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

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

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

3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with Section III.D. of this Agreement;

4. A certification signed by the Practice's Compliance Contact certifying that he or she is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D. of this Agreement;

5. A complete copy of all reports prepared pursuant to the IRO's Compliance Review and Billing Engagement, including the Claims Review Report and Process Review Report, along with a copy of the IRO's engagement letter;

6. The Practice's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;

7. A summary/description of all engagements between the Practice and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting;

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

9. 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;

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

11. A certification signed by the Practice's Compliance Contact certifying that he or she has reviewed the Annual Report, 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 following:

If to the OIG:
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

If to the Practice:
Cardiac Surgery Associates of CNY, P.C.
Attn: Rose Ann Salvatore
101 Union Avenue, Suite 813
Syracuse, NY 13203
Ph. 315.423.7192
Fax 315.423.8013

cc to:
MedComp Alliance, LLC
Attn: Beth Sassano, President and Chief Compliance Officer
250 S. Clinton Street, 5th Floor
Syracuse, NY 13202
Ph. 315.471.3000
Fax 315.471.3420

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 the Practice's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of the Practice's locations for the purpose of verifying and evaluating; (a) the Practice's compliance with the terms of this Agreement; and (b) the

Practice's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by the Practice 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 the Practice'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. The Practice agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. The Practice's employees may elect to be interviewed with or without a representative of the Practice present.

VIII. DOCUMENT AND RECORD RETENTION

The Practice shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for 6 years (or longer if otherwise required).

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, the Practice 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 the Practice:

a. Fails to have in place a Compliance Contact as required in Section III.A;

b. Fails to post the notice required in Section III.B;

c. Fails to have in place the Policies and Procedures required in Section III.C;

d. Fails to ensure that each applicable Covered Person attend the training required by Section III.F. of the Agreement within the time frames required in that section;

e. Fails to retain an IRO within the time frame required in Section III.F.1, or annually submit the IRO's Claims Review Report and Process Review Report as required in Section III.F and Appendix A; or

f. Fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of $750 (which shall begin to accrue on the date the failure to comply began) for each day the Practice employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, the Practice'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 the Practice can demonstrate that the Practice did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.5) as to the status of the person).

3. A Stipulated Penalty of $750 for each day the Practice 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 the Practice fails to grant access.)

4. A Stipulated Penalty of $750 for each day the Practice fails to comply fully and adequately with any obligation of this Agreement. In its notice to the Practice, OIG shall state the specific grounds for its determination that the Practice has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Practice must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to the Practice of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-3 of this section. With respect to the Stipulated Penalty provision described in this Section X.A.4 only, the OIG shall not seek a Stipulated Penalty if the Practice demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, and that: (i) the Practice has begun to take action to cure the failure to comply, (ii) the Practice is pursuing such action with due diligence, and (iii) the Practice has provided to OIG a reasonable timetable for curing the failure to comply.

B. Timely Written Requests for Extensions

The Practice 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 the Practice 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 three business days after the Practice 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 the Practice 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 the Practice of: (a) the Practice's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, the Practice shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of its corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event the Practice elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the Practice cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that the Practice 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 the Practice to report a material deficiency, take corrective action and make the appropriate refunds, as required in Section III.G;

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

Section X.A;

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by the Practice constitutes an independent basis for the Practice's exclusion from participation in the Federal health care programs. Upon a determination by OIG that the Practice has materially breached this Agreement and that exclusion should be imposed, OIG shall notify the Practice of: (a) the Practice'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.* The Practice 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 Practice is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

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

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

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

(iii) The Practice provided to OIG within that period a reasonable timetable for curing the material breach and the Practice 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 Practice, only after a DAB decision in favor of OIG. The Practice's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude the Practice 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 Practice may request review of the ALJ decision by the DAB. If the DAB finds in favor of the Practice after an ALJ decision adverse to the Practice and the OIG has in the interim excluded the Practice from participation in Federal health care programs on the basis of the prior ALJ determination, the Practice 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. The Practice agrees to waive his/her right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

5. The undersigned the Practice signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatories represents that they are signing this Agreement in their official capacity and that they are authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

CARDIAC SURGERY ASSOCIATES OF CNY, P.C.

4/18/01
Date

MEHDI A. MARVASTI, M.D., Individually and as Authorized Representative of the Practice

4/18/01
Date

JOEL M. ROSENBERG, M.D., Individually and as Authorized Representative of the Practice

4/18/01
Date

AHMAD NAZEM, M.D., Individually and as Authorized Representative of the Practice

4/18/01
Date

STEPHEN H. COHEN, Esq.
Counsel for the Practice
Scolaro, Shulman, Cohen, Lawler
& Burstein, P.C.
90 Presidential Plaza
Syracuse, N.Y. 13202-2200

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

4/17/01
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 "Process Review." The IRO shall prepare a Claims Review Report and a Process Review Report to communicate the findings of the reviews.

1. ***Claims Review.*** The IRO shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by the Practice to the Medicare, Medicaid, TRICARE, and Federal Employees Health Benefits programs.

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 submitted to the OIG in the Annual Report.

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

4. ***Process Review Report.*** The IRO shall prepare a report based upon the Process Review ("Process Review Report"). The Process Review Report shall include the IRO's findings and supporting rationale regarding the strengths and weaknesses in the Practice'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, and a discussion of how the Practice can implement such recommendations. The Process 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. Paid Claim: A code or line item submitted by the Practice and for which the Practice has received reimbursement from the Medicare, Medicaid, TRICARE, and Federal Employees Health Benefits programs.

d. Population: All Items for which the Practice has submitted a code or line item and for which the Practice has received reimbursement from the Medicare, Medicaid, TRICARE, and Federal Employees Health Benefits 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. 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. 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, 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 Sample, any Paid Claim for which the Practice cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the Practice 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 the 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 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 Claims Review 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. 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. The number of Items appraised in the Claims Review Sample;

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

c. 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 the Practice ("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 the Practice;

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 the Practice, 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; and

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.

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.

OVERPAYMENT REFUND FORM

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 reason 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	MSP/Other Payer Involvement	Miscellaneous
01 - Corrected Date of Service	08 - MSP Group Health Plan Insurance	13 - Insufficient Documentation
02 - Duplicate	09 - MSP No Fault Insurance	14 - Patient Enrolled in an HMO
03 - Corrected CPT Code	10 - MSP Liability Insurance	15 - Services Not Rendered
04 - Not Our Patient(s)	11 - MSP, Workers Comp.(Including Black Lung	16 - Medical Necessity
05 - Modifier Added/Removed		17 - Other (Please Specify)
06 - Billed in Error	12 - Veterans Administration	_____
07 - Corrected CPT Code		