

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
PRADEEP SRIVASTAVA, MD, AND PRADEEP SRIVASTAVA, PC**

I. PREAMBLE

Pradeep Srivastava, MD, and Pradeep Srivastava, PC (collectively, “Srivastava”) 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, all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), and the Federal Employees Health Benefits Program (FEHBP) (collectively, “Federal health care program requirements”). This Agreement applies to any entity that Srivastava owns or in which Srivastava has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Srivastava’s and any such entity’s Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Srivastava 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

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Srivastava under this Agreement shall be five years from the Effective Date of this Agreement. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

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

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

1. “Covered Persons” includes:

a. all owners, officers, directors, associates, and employees of Srivastava; and

b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Srivastava.

2. "Relevant Covered Persons" includes 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.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days after the Effective Date, Srivastava shall designate an employee other than himself to be responsible for compliance activities (Compliance Contact). Srivastava shall maintain a Compliance Contact for the term of this Agreement. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Srivastava's day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Srivastava shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

Within the 90 days after the Effective Date, Srivastava shall post in a prominent

place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which billing concerns and other issues may be reported anonymously; (ii) Srivastava's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by Srivastava.

This notice shall also include the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

A copy of this notice shall be included in the Implementation Report.

C. Independent Coding Officer

1. Within 60 days after the effective date of this CIA, Srivastava shall retain an appropriately qualified Independent Coding Officer (ICO), appointed by the OIG after consultation with Srivastava. The ICO shall have expertise in the rules governing submissions of claims to Federal health care programs and FEHBP for cardiology items and services. (The ICO may retain additional personnel, including but not limited to consultants, if needed to help meet the ICO's obligations under this CIA.) The ICO may be removed solely at the discretion of the OIG. If the ICO resigns or is removed by the OIG for any reason prior to the termination of the CIA, Srivastava shall retain another ICO appointed by the OIG, with the same functions and authorities.
2. Srivastava shall be responsible for all costs reasonably incurred by the ICO in carrying out the responsibilities specified in this CIA, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. Failure to pay the ICO within 30 calendar days of submission of his or her invoices for services previously rendered shall constitute a breach of the CIA and shall subject Srivastava to one or more of the remedies set forth in Section X *infra*.
3. The ICO shall have the sole authority and responsibility to develop policies, procedures, and guidelines for submission of claims to Federal health care programs and FEHBP for Srivastava's services and to determine which

claims for reimbursement for items and services furnished by Srivastava will be submitted to Federal health care programs and FEHBP. Srivastava shall bill Federal health care programs and FEHBP for items and services solely in accordance with the ICO's policies, procedures, and guidelines. Srivastava shall not participate in the ICO's development of these policies, procedures, and guidelines; his sole role will be to implement the policies, procedures, and guidelines developed by the ICO.

4. The ICO shall also be responsible for monitoring the day-to-day activities engaged in by Srivastava to implement the ICO's policies, procedures, and guidelines. As part of that monitoring, the ICO shall at least twice per year (and more frequently as he or she sees fit) conduct audits of Srivastava's compliance with the coding policies, procedures, and guidelines. Within 30 days after completion of each such audit, the ICO shall submit to Srivastava and the OIG a written report of his or her findings and recommendations. In the event an ICO audit detects that a claim submitted to a Federal health care program was at variance with the ICO's coding policies and procedures, the ICO shall investigate the discrepancy and require withdrawal of the claim or refund of payment as appropriate. Srivastava shall comply with the ICO's findings and implement the ICO's recommendations. The ICO shall keep documentation of his or her investigations for submission as part of the Annual Report. The ICO may confer and correspond with the OIG on an *ex parte* basis.
5. To facilitate performance of the ICO's responsibilities, Srivastava shall give the ICO:
 - a. immediate access to Srivastava's facilities, at any time and without prior notice, to assess compliance with this CIA;
 - b. prompt access to any of Srivastava's documents and data requested by the ICO to perform the duties required under this CIA; and
 - c. prompt access to Srivastava's staff for interviews outside the presence of supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals.

D. Written Policies and Procedures

Within 60 days after the Effective Date, Srivastava shall develop, implement,

and distribute written Policies and Procedures to all Covered Persons. In addition, Srivastava shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Srivastava's commitment to full compliance with all Federal health care program and FEHBP requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Srivastava's Covered Persons shall be expected to comply with all Federal health care program and FEHBP requirements and with Srivastava's own written Policies and Procedures as implemented pursuant to this Section III.D (including the requirements of this Agreement);
3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program or FEHBP requirements, or of Srivastava's own Policies and Procedures, to the Compliance Contact and Srivastava's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;
4. the possible consequences to both Srivastava and Covered Persons of failure to comply with all Federal health care program and FEHBP requirements or with Srivastava's written Policies and Procedures and the failure to report such noncompliance;
5. Srivastava's commitment to remain current with all Federal health care program and FEHBP requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program and FEHBP requirements;
6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program and FEHBP requirements;
7. the proper documentation of services and billing information;
8. the impropriety of billing CPT 93526 for a combined right and left heart catheterization when the physician has not performed a complete

right heart catheterization and has not advanced the catheter into the pulmonary artery for the purpose of taking certain heart pressures and measurements;

9. the impropriety of billing CPT code 36200 (introduction of catheter, aorta) in addition to billing for CPT codes 93526 (combined left and right heart catheterization), 93510 (left heart catheterization), 93501(right heart catheterization), or 93503 (insertion and placement of flow directed catheterization [Swan-Ganz catheter] for monitoring purposes);
10. the impropriety of billing CPT codes 37202 (transcatheter therapy, infusion other than for thrombolysis) in addition to billing for a cardiac catheterization, angioplasty, stent placement, or 93503 (Insertion and placement of flow directed catheterization [Swan-Ganz catheter] for monitoring purposes);
11. the impropriety of billing CPT code 75896 (transcatheter therapy, infusion, any method, radiological supervision and interpretation) in addition to billing for a cardiac catheterization, angioplasty, stent placement, or insertion of a catheter for monitoring purposes;
12. the impropriety of billing separate CPT codes for the five subparts of the percutaneous transluminal coronary angioplasty (PTCA) procedure instead of billing the component CPT Code 92982 (PTCA);
13. the impropriety of billing separate CPT codes for the seven components of the pacemaker implantation procedure instead of billing the applicable component CPT codes 33200, 22306, 33207, 33208, or 33210;
14. the impropriety of billing for angioplasty (CPT Code 92982) in addition to billing for a stent (CPT Code 92980) of the same vessel;
15. the impropriety of billing the CPT codes applicable to consultations when one is not the physician performing the consultation;
16. the impropriety of billing CPT codes applicable to consultations when there was no documented request for a consultation;

17. the impropriety of billing CPT codes applicable to consultations when the consulting physician has not submitted a written report of his or her findings to the referring physician;
18. the impropriety of billing CPT codes applicable to consultations when the billing physician is actually the patient's treating physician; and
19. the requirement to provide supporting medical documentation when submitting a bill for a procedure using a modifier, including but not limited to the following: modifier 79 (unrelated procedure or service by the same physician during the post-operative period); modifier 25 (significant, separately identifiable E&M service by the same physician on the same day of a procedure or other service); modifier 51 (used to describe multiple procedures performed on the same day or at the same session); modifier 59 (indicates that a procedure or service was distinct or independent from other services performed on the same day).

Within 60 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Srivastava's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually, and more frequently if appropriate, Srivastava shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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 next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Certification

1. General Training. Within 60 days after the Effective Date, Srivastava shall

provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall cover the following topics:

- a. the requirements of Srivastava's Agreement;
- b. an overview of Srivastava's compliance program; and
- c. the written Policies and Procedures developed pursuant to Section III.D, above.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training, described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within 60 days after the Effective Date, each Relevant Covered Person shall receive at least two hours of Specific Training in addition to the General Training required above. The Specific Training shall be provided by an individual or entity other than Srivastava or another Covered Person, and may be received from a variety of sources (e.g., CME classes, hospitals, associations, Medicare contractors).

This specific training shall include a discussion of:

- a. the accurate coding and submission of claims for services rendered and/or items provided to services and/or the preparation or submission of claims for reimbursement from any Federal health care program and FEHBP beneficiaries;
- b. policies, procedures, and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;
- e. the legal sanctions for the submission of improper claims or violations

of the Federal health care program and FEHBP requirements; and

f. examples of proper and improper claim submission practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming a Relevant Covered Person, or within 90 days after the Effective Date, whichever is later. A Srivastava employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program or FEHBP, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training, each Relevant Covered Person shall receive at least one hour of Specific Training in each subsequent Reporting Period. The Compliance Contact shall annually review the training, and where appropriate, update the training to reflect changes in Federal health care program and FEHBP requirements, any issues discovered during Claims Reviews and any other relevant information.

3. Certification. Each individual who is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Contact shall retain the certifications along with all training materials. The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

4. Qualifications of Trainer(s). Persons providing the training shall have expertise in the subject area. Persons providing Specific Training shall have particular expertise in the reimbursement statutes, regulations, and program requirements and directives applicable to billing Federal health care programs and FEHBP for cardiology items and services.

5. Update of Training. Srivastava shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program and FEHBP requirements, any issues discovered during the Claims Review, any ICO audit or review, or recommendation, and any other relevant information.

6. Computer Based Training. Srivastava may provide the training required under this Agreement through appropriate computer-based training approaches. If Srivastava chooses to provide computer-based training, he shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Review Procedures

1. General Description.

a. *Engagement of Independent Review Organization*. Within 60 days after the Effective Date, Srivastava shall engage an entity (or entities), (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Srivastava in assessing and evaluating his billing and coding practices, the medical necessity and appropriateness of interventional cardiac procedures, and certain other obligations pursuant to this Agreement and the Settlement Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

Each IRO shall assess, along with Srivastava, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement; taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze Srivastava’s coding, billing, and claims submission to the Federal health care programs and FEHBP and the reimbursement received (“Claims Review”). If Srivastava or an entity in which Srivastava has an ownership or control interest (as defined in 42 U.S.C. §1320a-3(a)(3)) submits cost reports, Srivastava shall engage an IRO to analyze whether Srivastava sought payment for certain unallowable costs (“Unallowable Cost Review”). The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

b. *Frequency of IRO Reviews*. The IRO Reviews shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual IRO Review.

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

2. Claims Review. 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 B to this Agreement, which is incorporated by reference.

a. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Medicare and 50 FEHBP Paid Claims submitted by or on behalf of Srivastava (Discovery Sample).

The Paid Claims shall be reviewed based on the supporting documentation available at Srivastava's office or under Srivastava's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

i. If the Error Rate (as defined in Appendix B) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Srivastava should, as appropriate, further analyze any errors identified in the Discovery Sample. Srivastava recognizes that 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 or any other segment of the universe.)

ii. 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.

b. *Full Sample.* If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to: (i) 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 (ii) conform to 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 Srivastava's office or under Srivastava'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, Srivastava 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, if: (i) statistically appropriate and (ii) Srivastava selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Srivastava to the appropriate Federal health care program and FEHBP payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. *Systems Review.* If Srivastava's Discovery Sample identifies an Error Rate of 5% or greater, Srivastava'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 shall 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 its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. *Repayment of Identified Overpayments.* In accordance with Section III.H.1, Srivastava shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Srivastava shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

e. *Claims Review Report.* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Attachment 1 to

Appendix B.

3. Cardiac Procedures Review. The IRO shall randomly select and review a sample of 50 interventional cardiac procedures performed by Srivastava. The IRO shall review the interventional cardiac procedures for appropriateness of case selection, quality of procedure, execution, proper response to intra-procedural problems, accurate assessment of procedure outcome, and appropriateness of procedure management. The procedures shall be reviewed based on the supporting documentation available from Srivastava or under Srivastava's control and applicable regulations and guidance to determine whether the procedure was medically necessary and appropriate, including but not limited to the established practice guidelines and generally accepted standards practice described by the American College of Cardiology. The Cardiac Procedures Review shall be performed annually and shall cover each of the Reporting Periods. The IRO engaged by Srivastava shall have expertise in the medical necessity and appropriateness of interventional cardiac procedures and in the general requirements of the Federal health care programs and FEHBP from which Srivastava seeks reimbursement. The IRO shall prepare a report based upon the Cardiac Procedures Review performed (Cardiac Procedures Review Report). Information to be included in the Cardiac Procedures Review Report is described in Appendix B.

4. Validation Review. In the event OIG has reason to believe that:
(a) Srivastava's Claims Review or Cardiac Procedures Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims Review or Cardiac Procedures Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Cardiac Procedures Review complied with the requirements of the Agreement and/or the findings or Claims Review or Cardiac Procedures Review results are inaccurate ("Validation Review"). Srivastava shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after Srivastava's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Srivastava of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Srivastava may request a meeting with OIG to: (a) discuss the results of any Claims Review or Cardiac Procedures Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Claims Review or Cardiac

Procedures Review to correct the inaccuracy of the Claims Review; and/or (c) propose alternatives to the proposed Validation Review. Srivastava agrees to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or Cardiac Procedures Review issues with Srivastava prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

6. Independence/Objectivity Certification. The IRO shall include in its report(s) to Srivastava a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Claims Review and Cardiac Procedures Review and that it has concluded that it is, in fact, independent and objective.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

- a. An “Ineligible Person” shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and (ii) the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>)
- c. “Screened Persons” include prospective and current owners, officers, directors, associates, employees, contractors, and agents of Srivastava.

2. Screening Requirements. Srivastava shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Srivastava shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Screened Persons to disclose whether they are Ineligible Persons.
- b. Srivastava shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Srivastava shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

Nothing in this Section affects the responsibility or liability of Srivastava to refrain from billing Federal health care programs and FEHBP for services of the Ineligible Person.

3. Removal Requirement. If Srivastava has notice that a Screened Person has become an Ineligible Person, Srivastava shall remove such Screened Person from responsibility for, or involvement with, Srivastava's business operations related to the Federal health care programs and FEHBP and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services rendered, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Srivastava has notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or a Screened Person is proposed for exclusion during his, her or its employment, involvement or contract term, Srivastava shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any

Federal health care program or FEHBP.

G. Notification of Government Investigation or Legal Proceedings

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

H. Reporting

1. Overpayments

a. *Definition of Overpayments.* For purposes of this Agreement, an “Overpayment” shall mean the amount of money Srivastava has received in excess of the amount due and payable under any Federal health care program and FEHBP requirements.

b. *Reporting of Overpayments.* If, at any time, Srivastava identifies or learns of any Overpayment, Srivastava shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Srivastava shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Srivastava shall notify the payor at that time 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 payor shall be done in accordance with the payor’s policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix C to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is

reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this Agreement, a “Reportable Event” means anything that involves:

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

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

b. *Reporting of Reportable Event.* If Srivastava determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Srivastava shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.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) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care

program and FEHBP authorities implicated;

iii. a description of Srivastava's actions taken to correct the Reportable Event; and

iv. any further steps Srivastava plans to take to address the Reportable Event and prevent it from recurring.

I. Third Party Billing

1. Current Contract with Third Party Biller. If Srivastava presently contracts with a third party billing company to submit claims to the Federal health care programs and FEHBP, Srivastava represents that he does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If Srivastava 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, Srivastava shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, Srivastava shall obtain (and provide to OIG in the Implementation Report) a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program and FEHBP requirements as they relate to the submission of claims to Federal health care programs and FEHBP; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs or FEHBP to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs and FEHBP; (iii) 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 and FEHBP.

If Srivastava contracts with a new third party billing company during the term of this Agreement, Srivastava shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.1.

2. Future Contract with Third Party Biller. If, at any time during the term of this Agreement, Srivastava contracts with a third party billing company to submit

claims to the Federal health care programs and FEHBP, at least 30 days prior to executing the contract, Srivastava shall submit a certification indicating whether he has an ownership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether he is employed by or acts as a consultant to the third party billing company.

Within 30 days after Srivastava contracts with the third party billing company, Srivastava shall obtain a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program and FEHBP requirements as they relate to the submission of claims to Federal health care programs and FEHBP; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs or FEHBP to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs and FEHBP; and (iii) provides the required training in accordance with Section III.D for those employees involved in the preparation and submission of claims to Federal health care programs and FEHBP.

If Srivastava contracts with a new third party billing company during the term of this Agreement, Srivastava shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.I.2.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Srivastava changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs and FEHBP, Srivastava shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to Srivastava becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs and FEHBP, Srivastava shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the

Agreement, and a summary of Srivastava's obligations under the Agreement. In addition, Srivastava shall notify OIG of such relationship in his next Annual Report.

V. REPORTS

A. Implementation Report

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

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;
2. a copy of the notice Srivastava posted in his office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C and the date these Policies and Procedures were implemented and distributed;
4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. the name and qualifications of the IRO(s), a summary/description of all engagements between Srivastava and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Claims Review.
6. a copy of the IRO's engagement letter, including the length of the engagement;
7. a certification from the IRO regarding its professional independence and/or objectivity with respect to Srivastava;

8. a description of Srivastava's process to screen Screened Persons to determine if they are ineligible;
9. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;
10. a copy of the certification from the third party billing company required by Section III.I;
11. a list of all Srivastava'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 number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Srivastava currently submits claims;
12. if Srivastava became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs or FEHBP, Srivastava shall inform OIG of the name, location, relationship, and his responsibilities with respect Srivastava's employment or contract;
13. a certification by the Compliance Contact that:
 - a. the written Policies and Procedures required by Section III.C have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C;
 - b. all Covered Persons and Relevant Covered Persons have completed the applicable training required by Section III.D; and that all Covered Persons and Relevant Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D;
 - c. all Screened Persons that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to

disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Srivastava, as required by Section III.F; and

d. all Screened Persons of Srivastava were screened against the Exclusion Lists within 30 days after the Effective Date, as required by Section III.F and the date(s) of the screening.

14. a certification signed by Srivastava certifying (a) to the best of his knowledge, except as otherwise described in the Implementation Report, Srivastava is in compliance with all of the requirements of this Agreement and (b) Srivastava has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

B. Annual Reports

Srivastava shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Srivastava's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Srivastava's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;
4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);
5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;

6. a complete copy of all reports prepared pursuant to the IRO's Claims Review, required by Section III.E (and, if applicable for the first Annual Report, a copy of the certification described in Section III.E.4.b);
7. if applicable, a certification by Srivastava stating that he does not currently and has not submitted any cost reports to any Federal health care programs or FEHBP since this Agreement was executed;
8. Srivastava's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO, as a result of the Review(s) performed pursuant to Section III.E;
9. a summary/description of all engagements between Srivastava and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
10. a certification from the IRO regarding its professional independence and objectivity to Srivastava;
11. a description of Srivastava's process to screen Screened Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
12. a summary of personnel actions/other than hiring taken pursuant to Section III.F; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and Srivastava's actions taken in response to the obligations set forth in Section III.F;
13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
15. a report of the aggregate Overpayments that have been returned to the Federal health care programs and FEHBP. Overpayment amounts shall be

broken down into the following categories: Medicare, Medicaid, other Federal health care programs, and FEHBP;

16. a copy of the certification from the third party billing company required by Section III.I, if applicable;

17. a description of all changes to the most recently provided list of Srivastava's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;

18. if Srivastava became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs and FEHBP, Srivastava shall inform OIG of the name, location, relationship, and his responsibilities with respect Srivastava's employment or contract;

19. copies of any revisions to the policies, procedures and guidelines developed by the ICO pursuant to section III.C;

20. Srivastava's response/corrective action plan to any issues raised by the ICO;

21. a certification by the ICO that Srivastava did not participate in or interfere with the development of any revisions to the policies, procedures, and guidelines required by section III.C, and that Srivastava has cooperated fully with the ICO in implementing these policies, procedures, and guidelines.

22. a certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.C, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C;

b. all Covered Persons and Relevant Covered Persons have completed the applicable training required by Section III.D and that all Covered Persons and Relevant Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section

III.D;

c. all Screened Persons have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Srivastava, as required by Section III.F;

d. all Screened Persons were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F and the date(s) they were screened;

e. (include in certification if Settlement Agreement included an Unallowable Cost provision) Srivastava has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program and FEHBP payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

22. a certification signed by Srivastava certifying that (a) to the best of his knowledge, except as otherwise described in the applicable Report, Srivastava is in compliance with all of the requirements of this Agreement and (b) Srivastava has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Designation of Information

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG: Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-060

Srivastava: [Compliance Contact]
[Address]
[City, State Zip]
[Telephone:]
[Facsimile:]

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

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

VIII. DOCUMENT AND RECORD RETENTION

Srivastava shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and FEHBP, or to compliance with this Agreement, for six 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, OIG shall make a reasonable effort to notify Srivastava prior to any release by OIG of information submitted by Srivastava pursuant to its obligations under this Agreement and identified upon submission by Srivastava as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Srivastava shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Srivastava is expected to fully and timely comply with all of its Agreement obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Srivastava and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Srivastava fails to:

- a. have a Compliance Contact in accordance with the requirements of Section III.A;
- b. establish and/or post a notice in accordance with the requirements of

Section III.B;

- c. establish, implement, maintain, distribute, and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;
- d. establish and implement a training program in accordance with the requirements of Section III.D.
- e. obtain a certification from the third party biller, send the third party biller certification to OIG in accordance with the requirements of Section III.I, or notify OIG within 30 days prior to Srivastava obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;
- f. engage an IRO in accordance with the requirements of Section III.E.1.a and Appendix A;
- g. submit the IRO's annual Claims Review Report in accordance with the requirements of Section III.E and Appendix B;
- h. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2.
- i. screen Screened Persons in accordance with the requirements of Section III.F; or require Screened Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F;
- j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.G; or
- k. retain the ICO in accordance with Section III.C.

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 Srivastava fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the

requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Srivastava fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Srivastava fails to grant access.)
4. A Stipulated Penalty of \$15,000 for each false certification submitted by or on behalf of Srivastava as part of its Implementation Report, Annual Reports, additional documentation to a Report (as requested by OIG), or as otherwise required by this Agreement.
5. A Stipulated Penalty of \$750 for each day Srivastava fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Srivastava stating the specific grounds for its determination that Srivastava has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Srivastava shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Srivastava receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.
6. A Stipulated Penalty of \$2,500 (which shall begin to accrue ten (10) days after the date OIG provides notice to Srivastava of the failure to comply) for each day Srivastava fails to comply fully and adequately with any of his obligations with respect to the ICO, as set forth in section III.C. In its notice to Srivastava, the OIG shall state the specific grounds for its determination that Srivastava has failed to comply fully and adequately with the CIA obligation(s) at issue.

B. Timely Written Requests for Extensions

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

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Srivastava shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Srivastava elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Srivastava 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 Srivastava 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 Srivastava to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;
- 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;
- d. a failure to engage and use an IRO in accordance with Section III.E; or
- e. a failure to engage and use an ICO in accordance with Section III.C.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Srivastava constitutes an independent basis for Srivastava's exclusion from participation in the Federal health care programs and FEHBP. Upon a determination by OIG that Srivastava has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Srivastava of: (a) Srivastava'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. Srivastava 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. Srivastava is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Srivastava has begun to take action to cure the material breach; (ii) Srivastava is pursuing such action with due diligence; and (iii) Srivastava has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Srivastava fails to satisfy the requirements of Section X.D.3, OIG may exclude Srivastava from

participation in the Federal health care programs and FEHBP. OIG shall notify Srivastava in writing of its determination to exclude Srivastava (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 Srivastava's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Srivastava may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. Review Rights. Upon OIG's delivery to Srivastava 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, Srivastava 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 after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

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

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

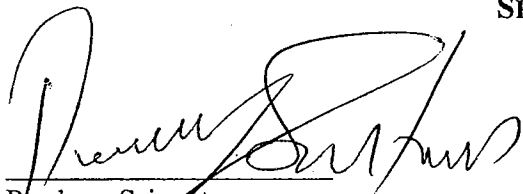
XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This Agreement shall be binding on the successors, assigns, and transferees of Srivastava;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. OIG may agree to a suspension of Srivastava's obligations under this Agreement in the event of Srivastava's cessation of participation in Federal health care programs and FEHBP. If Srivastava withdraws from participation in Federal health care programs and FEHBP and is relieved of his Agreement obligations by OIG, Srivastava shall notify OIG 30 days in advance of Srivastava's intent to reapply as a participating provider or supplier with any Federal health care program or FEHBP. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified.
- E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Srivastava's responsibility to follow all applicable Federal health care program and FEHBP requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.
- F. The undersigned Srivastava signatory[ies] represent[s] and warrant[s] that [he, she or 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:

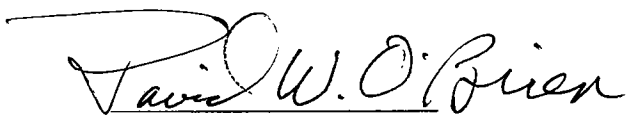
SRIVASTAVA



Pradeep Srivastava
9804 Bencross Drive
Potomac, Maryland 20854

7/24/07

Date

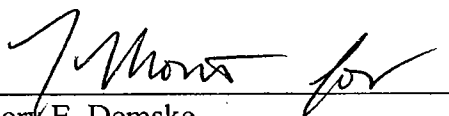


David O'Brien
Crowell & Moring
1001 Pennsylvania Ave. NW
Washington, DC 20004
Counsel for Srivastava

JULY 24, 2007

Date

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



Gregory E. Demske
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

7/24/07

Date

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Srivastava shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the reviews in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Srivastava if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Srivastava may continue to engage the IRO.

If Srivastava engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Srivastava shall submit the information identified in Section V.A.8 to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Srivastava if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Srivastava may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Claims Review engagement who have expertise in the billing, coding, reporting, and other requirements of billing for cardiology items and services and in the general requirements of the Federal health care program(s) and FEHBP from which Srivastava seeks reimbursement;

2. assign individuals to conduct the Cardiac Procedures Review engagement who have expertise in the medical necessity and appropriateness of interventional cardiac procedures, the established practice guidelines and generally accepted standards of medical practice described by the American College of Cardiology, and the general requirements of the Federal health care program(s) and FEHBP from which Srivastava seeks reimbursement;

3. assign individuals to design and select the Claims Review and Cardiac Procedures Review samples who are knowledgeable about the appropriate statistical sampling techniques;

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

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

C. IRO Responsibilities.

The IRO shall:

1. perform each Claim Review and Cardiac Procedures Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and FEHBP rules and reimbursement guidelines in making assessments in the Claims Review and Cardiac Procedures Review;

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

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

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

D. IRO Independence/Objectivity.

The IRO must perform the Claims Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Srivastava.

E. IRO Removal/Termination.

1. *Provider.* If Srivastava terminates the IRO during the course of the engagement, Srivastava must submit a notice explaining its reasons to OIG no later than 30 days after termination. Srivastava must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as

described in Paragraph C, OIG may, at its sole discretion, require Srivastava to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Srivastava to engage a new IRO, OIG shall notify Srivastava of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Srivastava may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Srivastava shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Srivastava prior to requiring Srivastava to terminate the IRO. However, the final determination as to whether or not to require Srivastava to engage a new IRO shall be made at the sole discretion of OIG.

**APPENDIX B
CLAIMS AND CARDIAC PROCEDURES REVIEWS**

A. Claims Review.

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

- a. Overpayment: The amount of money Srivastava 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 Srivastava and for which Srivastava has received reimbursement from the Medicare or FEHBP program.
- d. Population: For the first Reporting Period, the Population shall be defined as all Items for which a code or line item has been submitted by or on behalf of Srivastava and for which Srivastava has received reimbursement from Medicare or FEHBP (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Population shall be defined as all Items for which Srivastava has received reimbursement from Medicare or FEHBP (i.e., 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 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 Srivastava cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Srivastava for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.

c. 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 (*i.e.*, 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. Cardiac Procedures Review.

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

a. Interventional Cardiac Procedure: Any percutaneous coronary interventions, including but not limited to, percutaneous transluminal coronary angioplasties, balloon angioplasties, and implantation of intracoronary stenting, and any cardiac catheterization.

b. Population: For each Reporting Period, the Population shall be defined as all Interventional cardiac Procedures for which Srivastava has received reimbursement from Medicare or FEHBP. During the relevant 12-month Reporting Period.

2. *Other Requirements.*

a. Interventional Cardiac Procedures without Supporting Documentation. For the purpose of reviewing Interventional Cardiac Procedures, any Interventional Cardiac Procedure for which Srivastava cannot produce documentation sufficient to support the medical necessity or appropriateness of the Interventional Cardiac Procedure shall be

considered an error. Replacement sampling for Interventional Cardiac Procedures with missing documentation is not permitted.

- b. Replacement Sampling. Considering the Populations shall consist only of Interventional Cardiac Procedures and that Interventional Cardiac Procedures with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.
- c. Use of First Samples Drawn. For purposes of the Sample, the Interventional Cardiac Procedures selected in each first sample (or first sample for each strata, if applicable) shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one to be used.)

C. Claims Review and Cardiac Procedures Review Reports. The following information shall be included in the Claims Review and Cardiac Procedures Review Reports for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review and Cardiac Procedures Review Methodology.*

- a. Sampling Unit. A description of the Item as that term is utilized for the Claims Review and Cardiac Procedures Review.
- b. Claims Review and Cardiac Procedures Review Population. A description of the Population subject to the Claims Review and Cardiac Procedures Review.
- c. Claims Review and Cardiac Procedures Review Objective. A clear statement of the objective intended to be achieved by the Claims Review and Cardiac Procedures 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 specific documentation relied upon by the IRO when performing the Claims Review and Cardiac Procedures Review (*e.g.*, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and

issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).

f. Review Protocol. A narrative description of how the Claims Review and Cardiac Procedures Review were 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 select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

i. A description of Srivastava'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).

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Srivastava (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 Srivastava.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program or FEHBP 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. *Cardiac Procedures Review Findings.*

- a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Cardiac Procedures Review, including the results of the Sample.
- b. Total number of instances in which the IRO determined that the Interventional Cardiac Procedure was not medically necessary or appropriate, based on established practice guidelines and generally accepted standards of medical practice as described by the American College of Cardiology.
- c. A spreadsheet of the Cardiac Procedures Review results that includes the following information for each Interventional Cardiac Procedure performed, whether the Interventional Cardiac Procedure was medically necessary and appropriate, beneficiary name, beneficiary health insurance claims number, date of service, procedure code submitted, Federal health care program or FEHBP billed, and amount reimbursed.

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

6. *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 Cardiac Procedures Review; and (2) performed the Claims Review and Cardiac Procedures Review.

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/SUPPLIER NAME _____
 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:

- | | | |
|--------------------------------|---|---------------------------------|
| <u>Billing/Clerical Error</u> | <u>MSP/Other Payer Involvement</u> | <u>Miscellaneous</u> |
| 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 | 12 - Veterans Administration | 17 - Other (Please Specify) |
| 06 - Billed in Error | | |
| 07 - Corrected CPT Code | | |