EXHIBIT A

INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND SHABBIR A. DHARAMSEY, M.D.

I. PREAMBLE

Shabbir A. Dharamsey, M.D. (Dharamsey) enters into this Integrity Agreement (IA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to ensure compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs as defined in 42 U.S.C. § 1320a-7b(f), as well as the obligations for health care practitioners established by 42 U.S.C. § 1320c-5 (hereinafter collectively Federal health care programs). Dharamsey's compliance with the terms and conditions in this IA shall constitute an element of Dharamsey's present responsibility with regard to participation in the Federal health care programs.

The requirements imposed upon Dharamsey by this IA apply to any entity that Dharamsey owns or in which Dharamsey has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity's officers and directors, employees, agents, contractors and all other individuals responsible for the provision of health care items, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services (Covered Persons). Contemporaneous with this Integrity Agreement, Dharamsey has entered into a Settlement Agreement with the OIG, and this IA is incorporated by specific reference into that Settlement Agreement.

II. TERM OF THE INTEGRITY AGREEMENT

The period of the obligations assumed by Dharamsey under this IA shall be three years from the Effective Date of this IA (unless otherwise specified). The Effective Date of this IA will be the date on which the final signatory executes this IA (Effective Date). Sections VII, VIII, IX, X, XI and XII of this IA shall expire no later than 120 days from the OIG's receipt of: (1) the final Consultant Report; or (2) any additional materials submitted by Dharamsey pursuant to the OIG's request, whichever is later.

III. INTEGRITY OBLIGATIONS

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

A. Compliance Contact

Within 30 days of execution of this IA, Dharamsey 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 terms and conditions of the IA. 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 IA, Dharamsey 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 IA, Dharamsey 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 medical practice. 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 60 days of the Effective Date of this IA, Dharamsey agrees to develop, implement, and make available to all Covered Persons, written policies that address the following:

- 1. Commitment to Compliance. Dharamsey's or a Covered Person's commitment to ensure that his practice of medicine fully complies with all Federal health care program requirements and the obligations imposed upon Dharamsey under this IA;
- 2. Medically Necessary Services. Dharamsey's or a Covered Person's full compliance with all Federal health care program requirements with respect to Dharamsey's or Covered Persons's provision and documentation of medically necessary health care items or services, or the submission of claims for payment for such items or

services;

- 3. Updating of Policies and Procedures. Dharamsey's agreement to update the policies and procedures at least semi-annually and more frequently, as appropriate. The policies and procedures will be provided to the OIG in the Implementation Report and will be made available to the OIG upon request;
- 4. Reporting Suspected Violations. The requirement that all Covered Persons shall be expected to report to Dharamsey or the Compliance Contact any suspected violations of Federal health care program requirements or Dharamsey's policies and procedures. Dharamsey's policies and procedures shall also state that any Covered Person who makes such an inquiry may do so without risk of retaliation or other adverse effect;
- 5. Ineligible Persons. The requirement that Dharamsey shall not hire as employees or engage as contractors any Ineligible Person. For purposes of this IA, an "Ineligible Person" shall be any 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 non-procurement programs; or (ii) has been convicted of a criminal offense that is within the meaning of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. To avoid hiring or contracting with any Ineligible Person, Dharamsey 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.oig.gov) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov). In addition to prospective checks, Dharamsey shall conduct semi-annual checks of all employees and contractors, whether Covered Persons or not, against each exclusion list;
- 6. Current Program Requirements. Dharamsey's commitment to remain current with applicable Federal health care program requirements and all relevant program memoranda, newsletters, and any other correspondence related to such requirements;
- 7. Accurate Claims. The proper protocols for the accurate preparation and submission of claims in accordance with Federal health care program requirements;
- 8. *Documentation*. The proper documentation of services and billing information and the retention of such information in a readily retrievable form; and

Copies of any revised or amended policies and procedures shall be included in the appropriate Consultant's Report as described in Section IV.B. of this IA. Within 30 days of the Effective Date of any such revisions, Dharamsey shall make available the relevant portions of any amended policies and procedures to the OIG and all individuals whose employment functions are related to those policies and procedures.

Within 90 days of the Effective Date of the IA and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Dharamsey'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 60 days of the Effective Date of the IA, whichever is later. Copies of all certifications shall be included in the appropriate Consultant's Report as described in Section IV.B. of this IA.

D. Internal Audits and Review Protocols

Dharamsey shall develop and implement, within 90 days of the Effective Date of this IA, a program for performing quarterly internal audits and reviews. The internal audits and reviews shall make findings as to:

- 1. Whether patients are receiving health care items and services that are medically necessary and proper and in accordance with professionally recognized standards of care for the geographic area in which Dharamsey resides;
- 2. Whether the policies and procedures mandated by this IA have been developed, implemented, and enforced;
 - 3. Whether training is performed in accordance with this IA;
 - 4. Whether identified problems are appropriately investigated; and
- 5. Whether Dharamsey's reporting obligations under this IA are fully complied with.

E. <u>Utilization Review Protocols</u>

Dharamsey shall develop, implement, and monitor utilization review protocols (<u>e.g.</u>, clinical indications) in conjunction with any hospital, or committee thereof, with which Dharamsey has admitting privileges (<u>e.g.</u>, Jefferson Regional Medical Center), to ensure that Dharamsey's or any Covered Person's arranging, ordering, or

provision of any health care item or service, for any individual, whether or not a Federal health care program patient or recipient, does not violate the statutory obligations for health care practitioners at 42 U.S.C. § 1320c-5(a). Such items or services include, but are not limited to, angiograms, arteriograms, echocardiograms, heart catheterizations, placement of pacemakers or stents, whether right, left, coronary, renal, lower, abdominal, carotid, sub-clavian, intracranial or otherwise in nature.

F. Second Opinion Protocols

Dharamsey shall develop and implement protocols under which Dharamsey or a Covered Person must obtain "second opinions" from a board-certified cardiologist (subject to approval by the OIG), prior to arranging, ordering, or providing any health care item or service within the scope of Section III.E., above.

G. Reporting of Adverse or Negative Outcomes or Complications

Dharamsey shall develop and implement protocols for the disclosure and reporting to the OIG of any adverse or negative outcome or complications arising from, or related to, the arranging, ordering or provision of any health care item or service within the scope of Section III.E., above, by Dharamsey or a Covered Person. For purposes of this IA, an "adverse or negative outcome or complication" shall mean that the person was exposed to, developed or suffered any health care related risk or problem as a result of, whether directly or indirectly, the arranging, ordering, or provision of a health care item or service by Dharamsey or a Covered Person.

H. Investigation of Suspected Violations

Dharamsey shall ensure that all internally (e.g., through reports to supervisors, complaints, audits, or monitoring) or externally (e.g., through CMS or the Consultant as defined in Section IV. of this IA) identified violations or failures to comply with Federal health care requirements are promptly and appropriately investigated and, if the investigation substantiates the issue, Dharamsey assesses the nature and scope of the problems, implements the appropriate response, and acts in accordance with the obligations imposed upon him by federal or state law, or under this IA.

I. Training and Certification

1. Training of Current Covered Persons. Within 90 days following the Effective Date of this IA and at least once each year thereafter for the term of the IA, Dharamsey 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 appropriate training from an individual or entity, other than Dharamsey or another Covered Person. The training shall be conducted by individuals with expertise in the applicable requirements for the provision, documentation, and billing for the provision of health care items and services within the scope of Section III.E. of this IA.

- 2. Training New Covered Persons. 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 120 days of the Effective Date of this IA, 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.
- 3. Training Topics. At a minimum, the annual and new employee training sessions shall cover the following topics: (a) the written policies and procedures developed pursuant to Section III.C., above; and (b) the relevant billing and documentation requirements for the health care items or services provided by Dharamsey (and if applicable, a Covered Person), within the scope of Section III.E., above.
- 4. Certification of Training. 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. Dharamsey shall retain the certifications, along with the training course materials, and include both in the appropriate Consultant's Report as described in Section IV.B. of this IA.
- 5. Continuing Medical Education. On an annual basis, Dharamsey (and Covered Persons, if applicable) shall obtain and certify completion of at least 20 hours of continuing medical education related to the provision of quality health care items or services within the scope of Section III.E., above, as well as medical ethics.

J. Reporting of Overpayments and Material Deficiencies

- 1. Overpayments.
 - a. Definition of Overpayments. For purposes of this IA, an "Overpayment" shall mean the amount of money Dharamsey has

received in excess of the amount due and payable under any Federal health care program requirement. Dharamsey may not subtract any underpayments for purposes of determining the amount of relevant Overpayments for purposes of reporting under this IA.

b. Reporting of Overpayments. If, at any time, Dharamsey identifies or learns of any Overpayments, Dharamsey shall notify the payor (e.g., Medicare Carrier) within 30 days of identification of the Overpayment and take remedial steps within 60 days of identification (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, Dharamsey 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, Dharamsey 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 payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, attached as Appendix A to this IA. Notwithstanding the above, notification and repayment of an 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. Material Deficiencies.

- a. Definition of Material Deficiencies. For purposes of this IA, a "Material Deficiency" means anything that involves:
 - (i). a substantial Overpayment;
 - (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 for which penalties or exclusion may be authorized; or
 - (iii). a violation of Dharamsey's obligation to provide items or services of a quality that meets professionally

recognized standards of health care where such violation has occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

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

- b. Reporting of Material Deficiencies. If Dharamsey determines, by any means, that there is a Material Deficiency, Dharamsey shall notify the 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 J.1., above, 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;
 - (B). the date of the check and identification number (or electronic transaction number) on which the Overpayment was repaid/refunded;
 - (C). a complete description of the Material
 Deficiency, including the relevant facts, persons
 involved, and legal and Federal health care
 program authorities implicated;
 - (D). a description of Dharamsey's actions taken to correct the Material Deficiency; and
 - (E). any further steps Dharamsey plans to take to address the Material Deficiency and prevent it from recurring.

K. Notification of Government Investigations or Legal Proceedings

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

IV. QUALITY CARE CONSULTANT AND REPORT

A. Quality Care Consultant

- 1. Retention of the Consultant. Within 60 days after the Effective Date of this IA, Dharamsey shall have retained an appropriately qualified Quality Care Consultant (Consultant) to monitor and review Dharamsey's obligations under this IA. The Consultant shall be a person or entity that has clinical experience in interventional cardiology, as well as familiarity with physician compliance and quality of care issues. Within 30 days after the Effective Date of this IA, Dharamsey shall provide the OIG with the names, addresses, telephone and facsimile numbers, and qualifications of at least three candidates for the Consultant. Once such persons have been identified by Dharamsey and approved as potential Consultants by the OIG, Dharamsey may select and hire any of the three pre-approved individuals.
- 2. Consultant's Fees. Dharamsey shall be responsible for the salary of the Consultant, as well as all fees and expenses incurred by the Consultant, including, but not limited to, travel costs; administrative personnel; office space and equipment; or the retention of additional personnel. The Consultant may be removed at the sole discretion of the OIG. If the Consultant resigns or is removed for any reason prior to the termination of the IA, Dharamsey shall hire another Consultant, after preapproval by the OIG, who will have the same functions, responsibilities, and authority.
- 3. Failure to Retain Consultant. Dharamsey's failure to retain the Consultant within 60 days after the Effective Date of the IA, pay an appropriately hired Consultant so that any required report is not timely submitted to the OIG, or interfere with the Consultant's obligations or ability to carry out its functions in accordance with this IA, shall constitute a breach of the IA and subject Dharamsey to one or more of the

remedies set forth in Section XI. of this IA. Should Dharamsey fail to retain the Consultant in the required 60 days, the Effective Date of this IA shall be delayed, extending the term of this IA until Dharamsey hires a Consultant in accordance with Section IV.A.1., above. Should such an event occur, once an appropriate Consultant has been approved by the OIG, the IA will resume in accordance with the original provisions and deadlines unless otherwise noted or agreed to in writing by the OIG.

- 4. General Responsibilities of Consultant. The Consultant shall monitor, evaluate, and make recommendations where appropriate based upon the results of Dharamsey's utilization review protocols, internal audit and reviews, and policies and procedures to ensure that Dharamsey and all Covered Persons are complying with Federal health care programs requirements and the obligations under this IA, until the term of the IA expires, or the parties agree otherwise in accordance with the provisions of this IA.
- 5. Access by Consultant. To carry out the obligations imposed upon the Consultant by this IA, the Consultant shall have access to all of Dharamsey's business units or locations, at any time and without prior notice, and all documents, including, but not limited to patient medical records or files; internal or external reports; reports or findings from medical review boards or committees, quality assurance committees, or peer review committees; clinical, billing, or claims data; financial statements; or any other information that the Consultant may deem relevant to fulfilling the duties required under this IA.
- 6. Confidentiality. The Consultant shall abide by all federal and state legal and ethical requirements to maintain the confidentiality of each patient's personal and clinical records, and to maintain as confidential and not disclose the records from Dharamsey, including, but not limited to, medical review committees, quality assurance committees or peer review committees. Nothing in the prior sentence, however, shall limit or affect the Consultant's obligation to provide information (including information from patient and resident clinical records), to the OIG, the Arkansas Foundation for Medical Care (AFMC), or if applicable, the Peer Review Organization from any other state in which Dharamsey may reside (hereinafter referred to as PRO) in accordance with the Consultant's obligations under this IA, or where appropriate or required, to other federal or state agencies.
- 7. Dharamsey's Obligations with Respect to Consultant. In addition to Dharamsey's obligations under Federal health care program requirements, other applicable federal or state law or regulation, and this IA, Dharamsey shall:
 - a. not impede the Consultant's access to Dharamsey's business

units or locations and shall provide all requested documentation within the time frame specified by the Consultant and to the extent practicable in the requested format, subject to any extensions or modifications requested by Dharamsey and granted by the Consultant;

- b. address any written recommendation made by the Consultant either by substantially implementing the recommendations or by explaining in writing why Dharamsey has elected not to do so;
- c. pay all Consultant's fees, bills, or costs within 30 days of receipt; and
- d. provide the Consultant (with a copy to the OIG) with a written report within 48 hours should any Level III "adverse or negative outcome or complication" occur that is related to the arranging, ordering, or provision of any health care item or service (Level III status shall be determined according to the approved protocols developed by Dharamsey pursuant to Section III.G. of this IA). Each such report shall contain the patient's full name, social security number, and date of birth, the date of the incident, and a brief description of the events surrounding the incident.
- 8. Ex Parte Communications. The Consultant may confer and correspond with Dharamsey or any other party on an <u>ex parte</u> basis at any time.
- 9. Disputes Regarding Implementation of Quality Provisions. If the Consultant or Dharamsey disagree with respect to the necessary protocols or procedures for monitoring, or the reporting of results or findings under the IA, the parties shall contact AFMC for assistance. Should AFMC be unable to resolve the matter, Dharamsey or the Consultant may contact the OIG at the address set forth in Section VII. of this IA for appropriate resolution and/or action consistent with the obligations of the parties under this IA, or the OIG's obligations under federal or state law or regulation.
- 10. Continued Quality of Care Concerns. After consulting with Dharamsey, if the Consultant has continued concerns with respect to recommendations or corrective action plans that are not being enforced, or the presence of repeated issues or problems that could impact Dharamsey's ability to render quality care to patients, then the Consultant shall report such concerns to the OIG. The OIG shall seek to resolve any such concerns with Dharamsey prior to seeking the imposition of any remedies pursuant to the

terms of this IA, or under federal or state law or regulation.

B. The Consultant's Report

- Date of this IA, and on a semi-annual basis (i.e., every 180 days) for each of the three reporting years thereafter, the Consultant shall prepare written findings compiled from the information described in Section IV.B.2., below (the Consultant's Report), and submit them to the OIG (with copies to the AFMC, or if applicable, PRO), for review and/or action by the OIG consistent with the requirements of this IA or federal or state law. Each Consultant's Report shall utilize at least four consecutive months of patient medical information and billing or claims data (with the exception of the first Consulting Report, which shall cover only three months). Should Dharamsey purchase or establish a new business unit or location as set forth in Section V. of this IA, the Consultant shall issue a separate Consultant's Report for each such new business unit or location.
- 2. Content of Consultant's Reports. The Consultant's Report shall address the following with respect to Dharamsey's (or if applicable, the Covered Person's) obligations under this IA:
 - a. a discussion, based upon the Consultant's randomly chosen sample of 5 patients whether the arranging, ordering, or provision of the health care item or service at issue violated any Federal health care program requirements, as well as a statement regarding:
 - (i). the circumstances under which Dharamsey satisfied or failed to meet any of his obligations set forth at 42 U.S.C. § 1320c-5(a), including all relevant patient information and the health care item or service in question;
 - (ii). if there was a violation, and whether the violation was either gross and flagrant, or represented a substantial violation in a substantial number of cases as those terms are defined by 42 C.F.R. § 1004.1;
 - (iii). if the violation resulted in an "adverse or negative outcome or complication," and if so, why;
 - (iv). Dharamsey's corrective action with respect to the

violation; and

- (v). proposed recommendations to avoid future violations, or to ensure continued compliance with Federal health care program requirements;
- b. Dharamsey's response to quality of care concerns or problems, whether identified externally or internally, including assessment of Dharamsey's ability to:
 - (i). identify problems;
 - (ii). determine the scope of the problem, including, but not limited to, whether it is isolated or systemic;
 - (iii). develop a corrective action plan to respond to the identified issue or problem;
 - (iv). implement and execute the corrective action plan;
 - (v). evaluate whether the initial concern, assessment, corrective action plan, or execution of that plan was timely and effective; and
 - (vi). provide or plan for the treatment of each patient's underlying illness or medical condition.
- c. conclusions regarding the overall pattern or practice of care as demonstrated by the utilization review protocols and internal audits and review required in Sections III.D. and III.E., above; and
- d. recommendations, if appropriate, for improving and refining the scope and quality of Dharamsey's internal audits and review program and utilization review protocols required by Sections III.D. and III.E., above, of this IA.
- 3. Additional Issues. Each Consultant's Report shall also include (if applicable):
 - a. a statement as to whether revisions were made to the written

policies and procedures developed pursuant to Section III.C. of this IA, and a copy of any policies and procedures that were revised;

- b. a summary of Material Deficiencies (as defined in Section III.J.2., above) identified since the submission of the previous Consultant Report and the status of any corrective and preventative action relating to all such Material Deficiencies; and
- c. Dharamsey's response and corrective action plan(s) related to any previous or prior issues raised or recommendations made by the Consultant Report.
- 4. OIG Review. Should the OIG have reason to believe that the Consultant's Report: (a) fails to conform to the requirements of this IA; or (b) contains findings that are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Consultant Report complies with the requirements of the IA and/or the Consultant's findings are accurate. Dharamsey 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 final submission (as described in Section II., above, of this IA) is received by the OIG.
- OIG Concerns. If at any time, with or without the input or assistance of AFMC or PRO, the OIG has concerns that the Consultant's recommendations are not being implemented, or that systemic or repeated problems with Dharamsey's provision of health care items or services to patients exists, the OIG shall provide notice to Dharamsey or the Compliance Contact of its conclusion. The OIG shall seek to resolve such concerns prior to invoking any remedy pursuant to the terms of this IA, but Dharamsey acknowledges and agrees that the OIG, AFMC, PRO, the Consultant, or any other federal or state agency cannot be prevented, or otherwise estopped from acting in accordance with their discretionary or nondiscretionary function by the findings or conclusions of the Consultant or the Consultant's Report. Should the Consultant or the Consultant's Report allege or indicate conduct or actions that could be unlawful or illegal, Dharamsey further agrees and acknowledges that the OIG may investigate all such conduct, and may pursue the responsible parties under its authority, or refer such individuals to the appropriate agency or office for action, including, but not limited, to the United States Department of Justice, United States Attorneys' Office, Medicaid Fraud Control Unit, CMS, AFMC, PRO, or other health care licensing or certification agency.

V. NEW BUSINESS UNITS OR LOCATIONS

Should Dharamsey move location, sell, close, purchase or establish a new business related to the furnishing of items or services that may be reimbursed by Federal health care programs after the Effective Date, Dharamsey shall notify the OIG of this fact as soon as possible, but no later than after 30 days of the date of the event. This notification shall include the name and location of the new operation(s), telephone facsimile numbers, Medicare provider or supplier number(s) (if any), and the corresponding contractor's name and address for each such provider or supplier number. Dharamsey and all Covered Persons at the new business units or locations shall be subject to the applicable requirements in this IA.

VI. IMPLEMENTATION REPORT

Within 90 days after the Effective Date of this IA, Dharamsey shall submit a written report to the OIG summarizing the status of his implementation of the requirements of this IA. This report, known as the "Implementation Report," shall include:

- 1. The name, address, and phone number of Dharamsey's Compliance Contact;
- 2. A copy of the notice Dharamsey posted in his office as described in Section III.B., above, 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 IA;
- 4. A certification signed by Dharamsey attesting that the policies and procedures are being implemented and have been made available to all Covered Persons;
- 5. A list of all Dharamsey's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone and facsimile numbers, each location's Medicare provider or supplier identification number(s) and the name and address of the Medicare contractor to which Dharamsey currently submits claims;
- 6. The name, address, telephone and facsimile numbers of the Consultant; and
 - 7. A certification from Dharamsey stating that he has reviewed the

Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VII. NOTIFICATION AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the Effective Date, all notifications and reports required under the terms of this IA shall be submitted to the following:

OIG: Administrative and Civil Remedies Branch

Office of Counsel to the Inspector General

U.S. Department of Health and Human Services 330 Independence Avenue, SW, Room 5527

Washington, DC 20201

Telephone: (202) 619-1306

Facsimile: (202) 205-0604

Dharamsey:

David Ivers, Esq.

Mitchell, Blackstock, Barnes, Wagoner and Ivers

1010 West Third Street

Little Rock, Arkansas 72201 Telephone: (501) 378-7870

Facsimile: (501) 375-1940

Copies of all Consultant Reports should be sent to AFMC at the following address:

Corporate Medical Director Office of Medical Director

Arkansas Foundation for Medical Care

410 West Capitol, Suite 250 Little Rock, Arkansas 72201 Telephone: (501) 375-5700

Facsimile: (501) 244-2101

If applicable, a copy of each Consultant Report should also be sent to the Medical Director for a PRO.

Unless otherwise specified, all notifications and reports required by this IA 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.

VIII. OIG Inspection, Audit, and Review Rights

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s), may examine or request original copies of Dharamsey's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dharamsey's business units or locations for the purpose of verifying and evaluating: (1) Dharamsey's compliance with the terms of this IA; and (2) Dharamsey's compliance with the requirements of the Federal health care programs in which he participates. The documents described above shall be made available by Dharamsey to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of Dharamsey'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 the OIG. Dharamsey agrees to assist the OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon the OIG's request. Dharamsey's employees may elect to be interviewed with or without a representative of Dharamsey present.

IX. DOCUMENT AND RECORD RETENTION

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

X. DISCLOSURES

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

Nothing in this IA or any other communication or report made pursuant to this IA, shall constitute a waiver by Dharamsey of attorney-client, attorney work-product, or other

applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by Dharamsey to avoid his obligations to comply with the provisions of this IA.

XI. Breach and Default Provisions

Full and timely compliance by Dharamsey is expected throughout the duration of this IA with respect to all of the obligations herein agreed to by Dharamsey.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy for breach and default under the IA, Dharamsey and the OIG agree and acknowledge that a failure to comply with certain obligations set forth in this IA, as determined by the OIG (with or without the recommendation of AFMC, PRO, or the Consultant), may lead to the imposition or assessment of monetary penalties (hereinafter referred to as Stipulated Penalties) as follows:

- 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 Dharamsey:
 - 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 implement and make available the policies and procedures required in Section III.C.;
 - d. fails to require that Covered Persons attend the training required by Section III.I. within the time frames required in that Section;
 - e. causes a delay in the Consultant's preparation or completion of any finding, statement, or provision required to be included in the Consulting Report by a refusal to assist the OIG, any designated agent of the OIG, or the Consultant in meeting or fulfilling their respective obligations under this IA;
 - f. interferes with the Consultant's obligations or ability to carry out its functions in accordance with this IA; or

- g. meet the deadline for the submission of the Implementation Report;
- 2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Dharamsey employs or contracts with an Ineligible Person and that person: (a) has responsibility for, or involvement with, Dharamsey's medical practice related to the Federal health care programs; or (b) 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 Dharamsey can demonstrate that Dharamsey 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 (which shall begin to accrue on the date Dharamsey fails to grant access) for each day Dharamsey fails to grant access to the information or documentation to any party or designated agent of the OIG as required in Section VIII. of this IA.
- 4. A Stipulated Penalty of \$5,000 for each instance in which the OIG has determined that Dharamsey or a Covered Person arranged, ordered, or provided a health care item or service that constituted a gross and flagrant violation (as defined in 42 C.F.R. § 1004.1) of the obligations for health care practitioners established by Federal health care program requirements. In the notice to Dharamsey, the OIG shall state the specific grounds for its determination that Dharamsey has failed to comply fully and adequately with the IA obligation(s) at issue.
- 5. A Stipulated Penalty of \$3,000 for each instance in which the OIG has determined that Dharamsey or a Covered Person arranged, ordered, or provided a health care item or service that constituted a substantial violation of the obligations for health care practitioners established by Federal health care program requirements in a substantial number of cases (as defined at 42 C.F.R. § 1004.1). In the notice to Dharamsey, the OIG shall state the specific grounds for its determination that Dharamsey has failed to comply fully and adequately with the IA obligation(s) at issue.
- 6. A Stipulated Penalty of \$750 (which shall begin to accrue 10 days after the date the OIG provides notice to Dharamsey of the failure to comply) for each day Dharamsey fails to fully and adequately comply with any obligation of this IA. In the notice to Dharamsey, the OIG shall state the specific grounds for its determination that

Dharamsey has failed to comply fully and adequately with the IA obligation(s) at issue. 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 subsections 1-5 of this Section.

B. <u>Timely Written Requests for Extensions</u>

Dharamsey may submit a timely written request for an extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this Section, if the 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 Dharamsey fails to meet the revised deadline set by the OIG. Notwithstanding any other provision in this Section, if the 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 Dharamsey receives the 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 the 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. <u>Payment of Stipulated Penalties</u>.

- 1. Demand Letter. Upon a determination by the OIG that Dharamsey has failed to comply with any of the obligations described in Section XI.A. and after determining that Stipulated Penalties are appropriate, the OIG shall notify Dharamsey of: (a) Dharamsey'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 the Demand Letter. Within 10 days of the receipt of the Demand Letter, Dharamsey shall respond by either: (a) curing the breach to the OIG's satisfaction and paying the applicable Stipulated Penalties; or (b) sending in writing to the OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section XI.E. In the event Dharamsey elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dharamsey cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this IA and shall be grounds for exclusion under Section XI.D.
 - 3. Form of Payment. Payment of the Stipulated Penalties shall be made

by certified or cashier's check, payable to Secretary, Department of Health and Human Services, and submitted to the OIG at the address in Section VII.

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

D. Exclusion for Material Breach of the Integrity Agreement

- 1. Definition of Material Breach. A material breach of this IA means:
 - a. a failure by Dharamsey to report a Material Deficiency, take corrective action, and make the appropriate refunds, as required in Section III.J., above;
 - b. a determination by the OIG that Dharamsey or a Covered Person arranged, ordered or provided a health care item or service that constituted a gross and flagrant violation (as defined in 42 C.F.R. § 1004.1) of the obligations for health care practitioners established by Federal health care program requirements;
 - c. A determination by the OIG that Dharamsey or a Covered Person arranged, ordered or provided a health care item or service that constituted a substantial violation of the obligations for health care practitioners established by Federal health care program requirements in a substantial number of cases (as defined at 42 C.F.R. § 1004.1);
 - d. flagrant or repeated violations of the obligations of the provisions of the IA;
 - e. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section XI.C.; or
 - f. a failure to hire and retain an approved Consultant in accordance with Section IV.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree

that a material breach of this IA by Dharamsey constitutes an independent basis for Dharamsey's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that Dharamsey has materially breached this IA and that an exclusion should be imposed, the OIG shall notify Dharamsey of:

- a. Dharamsey's material breach; and
- b. the OIG's intent to exercise its contractual right to impose a period of exclusion (this notification is hereinafter referred to as the Notice of Material Breach and Intent to Exclude).
- 3. Opportunity to Cure. Dharamsey 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. Dharamsey is in compliance with the obligations of the IA cited by the OIG as 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) Dharamsey has begun to take action to cure the material breach; (ii) Dharamsey is pursuing such action with due diligence; and (iii) Dharamsey has provided to the OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, Dharamsey fails to satisfy the requirements of Section XI.D.3., the OIG may exclude Dharamsey from participation in Federal health care programs. The OIG will notify Dharamsey in writing of its determination to exclude Dharamsey (this letter shall be referred to hereinafter as the Exclusion Letter) for the period of time stated in the Exclusion Letter. Subject to the Dispute Resolution provisions in Section XI.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, Dharamsey wishes to apply for reinstatement, Dharamsey must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

- 1. Review Rights. Upon the OIG's delivery to Dharamsey of its Demand Letter or Exclusion Letter and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, Dharamsey shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this IA. Specifically, the OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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 IA shall be: (a) whether Dharamsey was in full and timely compliance with the obligations of this IA for which the OIG demands payment; and (b) the period of noncompliance. Dharamsey shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this IA and orders Dharamsey to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dharamsey 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 the OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this IA shall be:
 - a. whether Dharamsey was in material breach of this IA;
 - b. whether such breach was continuing on the date of the Exclusion Letter; or
 - c. whether the alleged material breach could not have been

cured within the 30-day period, but that:

- (i). Dharamsey had begun to take action to cure the material breach within that period;
- (ii). Dharamsey has pursued and is pursuing such action with due diligence; and
- (iii). Dharamsey provided to the OIG within that period a reasonable timetable for curing the material breach and Dharamsey has followed the timetable.

For purposes of the exclusion described herein, exclusion shall take effect only after an ALJ decision favorable to the OIG, or, if the ALJ rules for Dharamsey, only after a DAB decision in favor of the OIG. Dharamsey's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Dharamsey upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Dharamsey may request review of the ALJ decision by the DAB. If the DAB finds in favor of the OIG after an ALJ decision adverse to the OIG, the exclusion shall take effect 20 days after the DAB decision. Dharamsey agrees to waive any further right to notice of the exclusion should the ALJ or DAB issue a decision upholding the exclusion. If the DAB finds in favor of Dharamsey, Dharamsey will 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 IA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this IA, and that neither party is entitled to seek or obtain judicial review.

XII. EFFECTIVE AND BINDING AGREEMENT

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

1. This IA shall be binding on the successors, assignees and transferees of Dharamsey, including any reorganized corporation or debtor;

- 2. This IA shall become final and binding on the Effective Date (i.e., the date the final signature is obtained on the IA);
- 3. Any modifications to this IA shall be made with the prior written consent of the parties to this IA;
- 4. Upon receipt of credible evidence from Dharamsey, the OIG will consider suspending Dharamsey's obligations under this IA in the event of a cessation of his participation in Federal health care programs. If Dharamsey's obligations under this IA are suspended by the OIG in accordance with this provision, the suspension shall remain in effect only so long as Dharamsey does not participate in Federal health care programs. If Dharamsey once again participates in any respect in Federal health care programs, the suspension of the obligations under the IA are automatically lifted and Dharamsey will be responsible for all obligations under the IA for any remaining time of the original three-year term. The Effective Date of the lifting of the suspension shall be the date in which Dharamsey again participates in Federal health care programs. In any event, within 10 days, Dharamsey must provide the OIG with written notice if he determines to either withdraw, or intends to again participate in the Federal health care programs.
- 5. The undersigned Dharamsey signatories represent and warrant that they are authorized to execute this IA. The undersigned OIG signatory represents that he is signing this IA in his official capacity and that he is authorized to execute its provisions. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR DR. SHABBIR DHARAMSEY

Shabbir A. Dharamsey, M.D.

1609 West 40th Avenue, Suite 312

Pine Bluff, Arkansas 71603

Date

David Ivers, Esq.

Date

12-11-02

Mitchell, Blackstock, Barnes, Wagoner, Ivers and Sneddon

1010 West Third Street

Little Rock, Arkansas 72201

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

Lewis Morris

Date

Chief Counsel to the Inspector General

Office of Counsel to the Inspector General

U.S. Department of Health and Human Services

330 Independence Avenue, SW, Room 5527

Washington, DC 20201

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05 - Modifier Added/Removed (Please Specify)	(Including Bla	٠,	17 - Other
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