COPY

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NILIMA V. SHUKLA, M.D.

I. PREAMBLE

Nilima V. Shukla, M.D., doing business as a sole proprietorship in private medical practice (hereafter referred to as "Shukla"), hereby agrees to enter into this Integrity Agreement with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of the federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Shukla, Shukla's employees and agents, any entity in which Shukla is an owner or has a control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)), and all third parties with whom Shukla may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the federal health care programs. Contemporaneous with this Integrity Agreement, Shukla is entering into a Settlement Agreement with the United States. This Integrity Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE INTEGRITY AGREEMENT

Except as otherwise provided in this Integrity Agreement, the period of compliance obligations assumed by Shukla under this Integrity Agreement shall be four (4) years from the date of execution of this Integrity Agreement. The effective date of this Integrity Agreement shall be the date on which the final signatory executes this Integrity Agreement (the "effective date").

III. INTEGRITY OBLIGATIONS

Within sixty (60) days of the date of the effective date of this Integrity Agreement, Shukla agrees to implement an Integrity Program (the "Program"), which shall include the following provisions under the following time frames:

A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Integrity Agreement, Shukla shall designate a person to be the contact person for purposes of the obligations herein. At all times during the term of this Integrity Agreement, there shall be a contact person who shall have operational responsibility for ensuring compliance with the integrity obligations in this Integrity Agreement. If a new contact person is designated during the term of this Integrity Agreement, Shukla shall notify the OIG, in writing, within ten (10) days of such a change.

B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this Integrity Agreement, Shukla shall post in a prominent place accessible to all patients and employees a notice detailing her commitment to comply with applicable statutes, regulations and directives applicable to the federal health care programs in the conduct of her medical practice and in seeking reimbursement from the federal health care programs for services and items furnished to patients of the federal health care programs. This notice shall identify a means (i.e., telephone number, address, etc.) through which matters of concern can be reported anonymously.

C. WRITTEN POLICIES AND PROCEDURES

Shukla agrees to develop and implement written policies and procedures within forty-five (45) days of the effective date of this Integrity Agreement, which written policies and procedures shall address the following:

a. Shukla's commitment to adhere to honest and accurate billing practices; and

b. The proper submission of claims to the federal health care programs, including verification that all claims meet applicable reimbursement standards;

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

d. A mechanism for employees and agents to make inquiries regarding

compliance with medical practice standards and federal health care program reimbursement standards without risk of retaliation or other adverse effect;

e. Shukla's commitment not to hire or engage as contractors any Ineligible Person. For purposes of this Integrity Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

D. TRAINING AND CERTIFICATION

Within sixty (60) days of the effective date of this Integrity Agreement, Shukla, Shukla's employees and anyone else engaged by Shukla to prepare or submit claims for reimbursement to the federal health care programs shall be trained in the proper reimbursement standards, program policies, and verification and compliance procedures to ensure the propriety and accuracy of claims for services and items furnished to federal health care programs patients. The training shall be designed to ensure that Shukla and all of her employees and agents are aware of all applicable federal health care program statutes, regulations and guidelines and the consequences (i.e., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the federal health care programs, etc.) both to the individual and Shukla that may ensue from any violation of such requirements.

Shukla agrees to arrange for each new employee to participate in such training no later than fifteen (15) days after the person begins to work for Shukla. Until the person has received the requisite training, such new employee shall work under the direct supervision of an employee who has received the required training.

This training program shall provide for no less than six (6) hours of training annually for each person.

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

1. Shukla's obligations under this Integrity Agreement;

2. The written policies and procedures developed pursuant to subsection C, above;

3. All applicable federal health care program statutes, rules, regulations, and guidelines related to reimbursement, and the legal sanctions for improper billing or other violations of these standards.

Shukla and each employee and agent shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the policies and procedures developed in accordance with paragraph III. C. of this Integrity Agreement and all applicable Federal health care program statutes, regulations and program requirements addressed in the training. These certifications will be maintained by Shukla and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

E. INDEPENDENT CLAIMS REVIEWS

On at least an annual basis and for the duration of this Integrity Agreement, Shukla agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "independent reviewer") to undertake a Claims Review of a statistically valid sample of the claims submitted by Shukla and her agents and/or employees to the federal health care programs. This review shall be undertaken in accordance with the requirements of Appendix A to the Integrity Agreement, which is attached hereto and incorporated herein by this reference. The purpose of this review is to determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the federal health care programs are medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. At the conclusion of each review, the independent reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as presenting the review findings and the reviewer's

conclusions and recommendations. A copy of this report shall be included in Shukla's Annual Reports to OIG.

F. REPORTING

1. *Reporting of Overpayments.* If, at any time, Shukla determines that she has received an overpayment from a Federal health care program, Shukla shall notify the payor (e.g., Medicare carrier or fiscal intermediary) within 30 days of discovering the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring.

2. *Reporting of Material Deficiencies.* If, at any time, Shukla determines that there is a material deficiency and the material deficiency results in an overpayment, Shukla shall notify the appropriate payor (e.g., Medicare carrier or fiscal intermediary) within 30 days of discovering the material deficiency and shall take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including steps to prevent the deficiency from reoccurring. The notice to the payor should state that the repayment is being made in accordance with the terms of this CIA and should include:

a. a description of the complete circumstances surrounding the overpayment;
b. the methodology by which the overpayment was determined;
c. the amount of the overpayment;
d. any claim specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and
e. the provider identification number under which the repayment is being made.

If Shukla determines that there is a material deficiency, Shukla shall notify the OIG within 30 days of discovering the material deficiency. Shukla's notification to the OIG shall include the following information. However, if the material deficiency does not involve an overpayment, the requirements of (a) and (b) below shall not apply:

a. all of the information provided to the payor in returning the

overpayment;
b. the name and the address of the payor where the overpayment was sent;
c. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
d. Shukla's actions to correct such material deficiency; and
e. any further steps Shukla plans to take to address such material deficiency and prevent it from reoccurring.

For purposes of this Integrity Agreement, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the federal heath care programs' statutes, regulations or program directives, including carrier and intermediary instruction.

For purposes of this Integrity Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment relating to the federal health care programs; (ii) conduct that impairs the financial integrity of the federal health care programs and that clearly violates the Federal health care program statutes, regulations or written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for federal health care program patients. A material deficiency may be the result of an isolated event or a series of occurrences.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Integrity Agreement, Shukla agrees to report to OIG any reliable evidence of actions or omissions by Shukla and/or her employees and agents (acting within the scope of employment or agency) that Shukla believes may constitute a probable violation of any state or federal criminal, civil or administrative statute, regulation, or rule governing a federal health care program. Shukla must make the required disclosure no later than thirty (30) calendar days after becoming aware of the existence of the probable violation.

Any disclosures made pursuant to this paragraph shall contain a certification by Shukla that the matter at issue has been fully investigated and that appropriate corrective actions have been taken to ensure compliance with all state and federal civil, criminal, and administrative statutes, regulations and rules governing all federal health care programs. Subject to the release provisions of the Settlement Agreement into which this Integrity Agreement is incorporated by reference, nothing in this paragraph shall be deemed to waive OIG's right to enforce any and all statutes and regulations related to any

federal health care program.

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Integrity Agreement, OIG or its duly authorized representative(s) may examine Shukla's books, records, and other documents and supporting materials in her possession or under her control for the purpose of verifying and evaluating: (i) Shukla's compliance with the terms of this Integrity Agreement; and (ii) Shukla's compliance with the requirements of the federal health care programs. OIG, HCFA, or the appropriate federal health care program contractor may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Shukla's compliance with the statutory and regulatory requirements of the federal health care programs.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within ninety (90) days of the effective date of this Integrity Agreement, Shukla shall provide the OIG with a written report demonstrating that she has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

1. A copy of the notice Shukla posted in her office as described in Section III.B.

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

3. A certification signed by Shukla attesting that all employees have completed the initial training required by Section III.D., as well as a summary of what the training included. The training materials will be made available to OIG upon request.

4. A certification from Shukla stating that she has reviewed the Implementation Report, she has made a reasonable inquiry regarding its content and believes that, upon her inquiry, the information is accurate and

truthful.

B. ANNUAL REPORTS

Shukla agrees to make annual written reports (each one of which is referred to throughout this Integrity Agreement as the "Annual Report") to OIG describing the measures she has taken to implement and maintain the Program and ensure compliance with the terms of this Integrity Agreement. In accordance with the provisions above, the Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented pursuant to section III.D. of this Integrity Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Integrity Agreement.

2. A copy of the audits and reviews conducted pursuant to section III.E. of this Integrity Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; copies of any disclosure notice documents made by Shukla pursuant to this section; and any corrective actions taken.

3. A certification signed by Shukla certifying that she has reviewed the Annual Report, she has made a reasonable inquiry regarding its content and believes that, upon her inquiry, the information is accurate and truthful.

The Annual Reports shall be due within forty-five (45) days of the end of the one-year period covered by the Annual Report. The first one-year period shall commence on the effective date of this Integrity Agreement.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with section IX below, all notifications and reports required under the terms of this Integrity Agreement shall be submitted to the entities listed below:

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

All correspondence to Shukla shall be sent to:

Contact Person _____
Address _____
City, State, Zip _____
Telephone _____
Fax _____

VIII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Shukla shall be expected throughout the duration of this Integrity Agreement with respect to all of the obligations herein agreed to by Shukla. In the event of Shukla's failure to comply with any of the obligations in this Integrity Agreement, the Integrity Agreement may be deemed in breach and the parties shall proceed in the appropriate manner as described below.

A. REMEDIES FOR MATERIAL BREACH OF THIS INTEGRITY AGREEMENT

If Shukla engages in conduct that OIG considers to be a material breach (as defined below) of this Integrity Agreement, OIG may decide to exclude Shukla from participation in the federal health care programs. Upon making its determination, OIG shall notify Shukla of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Shukla shall have thirty-five (35) days from the date of the letter to:

(1) cure the alleged material breach; or

(2) demonstrate to the OIG's satisfaction that the alleged material breach

cannot be cured within the thirty-five (35) day period, but that Shukla has begun to take action to cure the material breach and that Shukla will pursue such action with due diligence. Shukla shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and Shukla), Shukla fails to act in accordance with provisions (1) or (2) above, OIG may initiate steps to exclude Shukla from participation in the federal health care programs. OIG will notify Shukla in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter").

B. DISPUTE RESOLUTION

Upon OIG's delivery to Shukla of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Integrity Agreement, the OIG may initiate steps to exclude Shukla from participation in the federal health care programs. Shukla shall be entitled to certain due process rights similar to those afforded under 42 U.S.C. § 1320a-7(f) and 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in Section III.F of this Integrity Agreement; (ii) repeated or flagrant violation of the obligations under this Integrity Agreement, including, but not limited to, the obligations addressed in Section VI.A, VI.B and IX of this Integrity Agreement; or (iii) a failure to retain and use an independent reviewer for the purposes described in Section III.E of this Integrity Agreement.

IX. NEW ENTITIES OR LOCATIONS

In the event that Shukla purchases or establishes new business units after the effective date of this Integrity Agreement, Shukla shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment thereof. This notification shall include the location of the new operation(s), phone number, fax number, federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor

specific) that issued each provider number. All employees and agents at such locations shall be subject to the requirements in this Integrity Agreement that apply to new employees and agents (e.g., completing certifications and undergoing training).

X. EFFECTIVE AND BINDING INTEGRITY AGREEMENT

Consistent with the provisions in the Settlement Agreement into which this Integrity Agreement is incorporated, Shukla and OIG agree as follows:

1. this Integrity Agreement shall be binding on the successors, assigns and transferees of Shukla's Professional Corporation, who employ, contract with, or otherwise retain Shukla for the purpose of rendering services for which reimbursement is sought from the federal health care programs, and any person or entity that otherwise employs or contracts with Shukla for the purpose of rendering services for which reimbursement is sought from the federal health care programs;

2. this Integrity Agreement shall become final and binding only upon signing by each respective party hereto; and

3. any modifications to this Integrity Agreement shall be made with the prior written consent of the parties to this Integrity Agreement.

XI. POTENTIAL GROUNDS FOR MODIFYING THE CIA

In the event that Shukla (a) becomes an employee of an entity over which she has no ownership or control interest as defined in 42 U.S.C. §1320a-3(a)(3), her compensation is set in advance and is not based in any way on her billing, she has no involvement in the billing for her services, she no longer practices medicine in a private medical practice and is not employed or self-employed in any other health care related occupational activity outside the scope of her employment as an employee of the above-described entity, or (b) ceases to practice medicine altogether and does not engage in any other health care related occupational activity involving Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)), then, upon Shukla's notice of same to the OIG, Shukla and the OIG may modify this Integrity Agreement upon mutual written consent. The resulting modified Integrity Agreement shall be for a period that is at least equal to the remaining term under this Integrity Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR: NILIMA V. SHUKLA, M.D.

Nilima V Shukla MD — 6/7/00

Nilima V. Shukla, M.D. — Date

Craig Reutlinger — 6/7/00

Craig Reutlinger, Esquire — Date
Counsel for Nilima V. Shukla, M.D.

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

J Morris — 7/3/00

Lewis Morris, Esquire — Date
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

APPENDIX A to Integrity Agreement

A. Claims Review.

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

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

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

c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.F. of the Integrity Agreement, the amount of money Shukla has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this Integrity Agreement, Shukla shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by Shukla and for which Shukla has received reimbursement from any Federal health care program.

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

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

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

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

a. Confidence and Precision Requirements. The Claims Review Sample must contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items.* The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Shukla for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be

selected and reviewed. The estimated mean and standard deviation of the Population (based on the amount of Overpayments received by Shukla for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items*. The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by Shukla for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see section B, below).

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the

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

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

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

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

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

1. ***Claims Review Methodology***

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

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

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

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

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

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

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

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

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

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

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by Shukla ("Claim Submitted") differed from

what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

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

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in section B.3.b above.) The IRO may, in its report to Shukla, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

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

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

ATTACHMENT B

Nilima V. Shukla, M.D., agrees to secure her debt to the United States under this Agreement by granting the United States a first lien over the property described below, pursuant to the Uniform Commercial Code (UCC) filing attached to this Agreement as Attachment C:

> SEP/IRA Account No. 032977 of Nilima V. Shukla, M.D., held by MD Vest Investment Securities, 433 East Las Colinas Blvd., Irving, Texas 75039. The current balance of this account is approximately $162,658. Inquiries may also be directed to Dr. Shukla's financial consultant, Terry Parker Wallace, at 413 West Main Avenue, Gastonia, NC 28052, (704) 864-8767.

DATED: 6/7/00

Nilima V Shukla
NILIMA V. SHUKLA, M.D.

ATTACHMENT C

UCC filing granting the United States a first lien in property listed in Attachment B.

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AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND NILIMA SHUKLA. M.D.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Nilima Shukla, M.D. ("Dr. Shukla") entered into a Integrity Agreement ("IA") on July 3, 2000.

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

   Section III.E., Review Procedures of the IA is hereby superceded by the attached new section III.E., Review Procedures.

   Appendix A of Dr. Shukla's IA is hereby superceded by the attached new Appendix A.

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

3. The undersigned Dr. Shukla signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

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

ON BEHALF OF NILIMA SHUKLA, M.D.

Nilima Shukla
[*Name*]
[*Title*] NShukla MD

3/27/02
DATE

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

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

3/20/12
DATE

E. Review Procedures.

1. General Description

a. Retention of Independent Review Organization. On at least an annual basis and for the duration of this Integrity Agreement ("IA"), Shukla shall retain an independent and appropriately trained person or entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Shukla in assessing and evaluating her billing and coding practices and systems, and her compliance obligations pursuant to this IA and the Settlement Agreement. The IRO retained by Shukla shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this IA and in the statutes, regulations, requirements, and reimbursement policies and procedures of the Federal health care program(s) from which Shukla seeks reimbursement. The IRO shall assess, along with Shukla whether it can perform the review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO review shall address and analyze Shukla's billing and coding to determine that the claims submitted to the Federal health care programs are medically necessary and covered services under applicable program guidelines ("Claims Review").

b. Retention of Records. The IRO and Shukla shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Shukla) 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 A to this IA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Federal health care Paid Claims submitted by or on behalf of Shukla. The Paid Claims shall be reviewed based on the supporting documentation available at Shukla or under Shukla'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 A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, Shukla should, as appropriate, further analyze any errors identified in the Discovery Sample. Shukla recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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.a., the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Shukla or under Shukla'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, Shukla 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 statistically appropriate. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Shukla to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

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

Overpayments. The IRO shall provide to Shukla the IRO's 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.F.1, of the IA, Shukla agrees to 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. Shukla agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.

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

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Shukla's Claims Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the IA and/or the findings or Claims Review results are inaccurate ("Validation Review"). Shukla 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 Shukla's final Annual Report and any additional information requested by the OIG is received by the OIG.

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

5. *Independence Certification.* The IRO shall include in its report to Shukla a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

a. Overpayment: The amount of money Shukla 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 Shukla and for which Shukla has received reimbursement from any Federal health care program.

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

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

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

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which

Shukla cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Shukla for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

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

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

1. **Claims Review Methodology.**

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

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

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

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

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

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

2. **Statistical Sampling Documentation.**

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

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

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

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

3. **Claims Review Findings.**

a. Narrative Results.

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

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

b. Quantitative Results.

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

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

iv. Error Rate in the sample.

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

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

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