

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SANJEEV NATH, M.D.**

I. PREAMBLE

Sanjeev Nath, M.D. (“Nath”) hereby 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 promote compliance with the statutes, regulations, program requirements and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”). This commitment to promote compliance applies to any entity that Nath owns or in which Nath has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and any such entity’s employees, agents, contractors and all third parties with whom Nath or such entity may choose to engage to act as billing or coding consultants for the purposes of claiming reimbursement from the Federal health care programs (“Covered Persons”). Contemporaneously with this IA, Nath is entering into a Settlement Agreement with the United States, and this IA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE IA

Except as otherwise provided, the period of compliance obligations assumed by Nath under this IA shall be three (3) years from the effective date of this IA. The effective date of this IA shall be the date on which the final signatory of this IA executes this IA (“Effective Date”).

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

III. INTEGRITY OBLIGATIONS

Nath shall establish a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

If Nath is not the Compliance Contact, then within thirty (30) days of execution of this IA, Nath shall designate a person to be the Compliance Contact for the 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 OIG regarding compliance with the IA obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this IA, Nath shall notify OIG, in writing, within fifteen (15) days of such a change.

B. Posting of Notice

Within the first thirty (30) days following the Effective Date of this IA, Nath shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include 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. An example of such a notice is attached as Attachment 2.

C. Written Policies and Procedures

Within ninety (90) days of the Effective Date of this IA, Nath shall develop, implement, and make available to all Covered Persons written policies that address the following:

1. Nath's commitment to operate his business in full compliance with all Federal health care program requirements;
2. A requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Nath's own Policies and Procedures as implemented pursuant to Section III.C (including the

requirements of this IA);

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

4. The requirement that Nath shall not hire as employees or engage as contractors any Ineligible Person. For the 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 falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Nath 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://oig.hhs.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, Nath shall conduct annual checks of all employees against each exclusion list;

5. Nath's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;

6. The proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;

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

8. The requirement that all claims submitted to the Federal health care programs be accurate, fully and adequately document the services performed, and reflect the level of service performed.

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

Within ninety (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 shall abide by Nath's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within fifteen (15) days after becoming a Covered Person or within ninety (90) days of the Effective Date of the IA, whichever is later.

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

D. Training and Certification

Within ninety (90) days following the Effective Date of this IA, and at least once each year thereafter, Nath and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least eight (8) hours of training from an individual or entity, other than Nath or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, *e.g.*, preparation or submission of claims to Federal health care programs for the types of services provided by Nath and may be received from a variety of sources (*i.e.*, CME classes, hospitals, associations, carriers).

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 thirty (30) days after becoming a Covered Person or within ninety (90) 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.

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

following topics:

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;
2. The written Policies and Procedures developed pursuant to Section III.C, above;
3. The legal sanctions for improper billing or other violations of the Federal health care program requirements; and
4. Examples of proper and improper billing practices.

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. Nath shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. Third Party Billing

Nath presently contracts with a third party billing company to submit claims to the Federal health care programs. Nath represents that he does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If Nath intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this IA, Nath shall notify OIG thirty (30) days prior to any such proposed involvement.

Within one hundred and twenty (120) days of the Effective Date of this IA, Nath shall obtain and include in the Implementation Report a certification from the third party billing company that (i) it is presently in compliance with all Federal health care program requirements as they relate to submission of claims to the Federal health care programs; (ii) it has a policy of not knowingly employing any person who has been excluded, debarred or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iii) it provides the required training in accordance with Section III.D of the IA for those employees involved in the preparation and submission of claims to Federal health care programs. If Nath contracts with a new third party billing company during the term of

this IA, Nath shall, within thirty (30) days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

E. Review Procedures.

1. *General Description.*

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

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

c. Retention of Records. The IRO and Nath shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Nath) 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 fifty (50) Paid Claims submitted by or on behalf of Nath.

The Paid Claims shall be reviewed based on the supporting documentation available from Nath (or under Nath'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, Nath should, as appropriate, further analyze any errors identified in the Discovery Sample. Nath recognizes that OIG or another 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.2.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' ("CMS") statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available from Nath (or under Nath's control) and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For the purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Nath may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of the Full Sample. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Nath 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 Nath's Discovery Sample identifies an Error Rate of 5% or greater, Nath'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 Nath 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, Nath shall repay within thirty (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. Nath shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

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 OIG has reason to believe that: (a) Nath's Claims Review fails to conform to the requirements of this IA; or (b) the IRO's findings or Claims Review results are inaccurate, 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"). Nath shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated before one year after Nath's final submission (as described in Section II) is received by OIG.

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

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

F. Reporting of Overpayments and Material Deficiencies

1. Overpayments

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

b. Reporting of Overpayments. If, at any time, Nath identifies or learns of any overpayments, Nath shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within thirty (30) days of identification of the overpayment and take remedial steps within sixty (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 thirty (30) days of identification of the overpayment, Nath shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within thirty (30) days of identification, Nath 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 shall be done in accordance with the payor’s

policies, and for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this IA. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor shall be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For the purposes of this IA, a “Material Deficiency” means anything that involves:

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

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

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

- (i) If the Material Deficiency results in an overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.F.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (A) the payor’s name, address, and contact person to whom the overpayment was sent; and
 - (B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded.

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

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

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

G. Notification of Government Investigations or Legal Proceedings

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

IV. NEW BUSINESS UNITS, LOCATIONS OR RELATIONSHIPS

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

Prior to Nath's entering into an employment or contractual relationship with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Nath shall notify that party of this IA. This notification will include a copy of the IA, the remaining reporting period(s) of the IA, and a summary of Nath's obligations under the IA. In addition, Nath shall notify OIG of such relationship as described in Section XI.D of this IA.

V. REPORTS

A. Implementation Report

Within one hundred and twenty (120) days after the Effective Date of this IA, Nath shall submit a written report to 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 Nath's Compliance Contact, if different from the Compliance Contact listed in this IA;
2. A copy of the notice Nath posted in his office as described in Section III.B and a description of where and when the notice has been posted;
3. A copy of the written policies and procedures required by Section III.C of this IA;
4. A certification signed by Nath attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;
5. A copy of all training materials used for the training required by Section III.D, a description of the training, including a summary of the topics covered, the length of the session(s) and a schedule of when the training session(s) were held;
6. A certification signed by Nath attesting that all employees have completed the initial training required by Section III.D and have executed the required certifications;
7. A copy of the certification from the third party billing company required by Section III.E of the IA;
8. The name and qualifications of the IRO(s) engaged by Nath, a summary/description of all engagements between Nath and the IRO(s), including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;
9. A certification from the IRO(s) regarding its professional independence

and/or objectivity from Nath;

10. A list of all of Nath's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the name and address of the Medicare contractor to which Nath currently submits claims; and
11. A certification from Nath 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.

B. Annual Reports

Nath shall submit to OIG Annual Reports with respect to the status of and findings regarding Nath's compliance activities for each of the three (3) one-year periods beginning on the Effective Date of this IA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by OIG no later than sixty (60) days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. If revisions were made to the written policies and procedures developed pursuant to Section III.C of this IA, a copy of any such revised policies and procedures;
2. A certification by Nath that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;
3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with Section III.D of this IA;
4. A certification signed by Nath that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D of this IA ;

5. A complete copy of all reports prepared pursuant to the IRO's Billing Engagement, including the Claims Review Report and Process Review Report, along with a copy of the IRO's engagement letter;
6. Nath's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO;
7. A summary/description of all engagements between Nath and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
8. A certification from the IRO(s) regarding its professional independence and/or objectivity from Nath;
9. A summary of Material Deficiencies (as defined in Section III.F) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
10. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
11. A certification, signed by Nath, that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and
12. A certification, signed by Nath, that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this IA, 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
 Office of Inspector General
 U.S. Department of Health and Human Services
 Cohen Building, Room 5527
 330 Independence Avenue, SW
 Washington, DC 20201
 Telephone 202-619-2078
 Facsimile 202-205-0604

Dr. Nath: Sanjeev Nath, M.D.
 56 E. 66th Street
 New York, NY 10021
 Telephone 212-861-0800
 Facsimile 212-628-4065

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 the purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Nath's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Nath's locations for the purpose of verifying and evaluating: (a) Nath's compliance with the terms of this IA; and (b) Nath's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Nath to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for the purposes of this provision, OIG or its duly authorized representative(s) may interview any of Nath's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Nath shall assist

OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Nath's employees may elect to be interviewed with or without a representative of Nath present.

VIII. DOCUMENT AND RECORD RETENTION

Nath shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this IA, for six (6) years (or longer if otherwise required by law).

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Nath fails to:
 - a. have in place a Compliance Contact as required in Section III.A;
 - b. post the notice required in Section III.B;

- c. implement and make available the Policies and Procedures required in Section III.C;
- d. require that Covered Persons attend the training required by Section III.D of the IA within the time frames required in that Section;
- e. retain an IRO within the timeframe required in Section III.E.1, or to submit the IRO's annual Claims Review Report and Process Review Report as required in Section III.E and Appendix A; or
- f. meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of \$750 (which shall begin to accrue on the date the failure to comply began) for each day Nath employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Nath's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Nath can demonstrate that he did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.5) as to the status of the person).

3. A Stipulated Penalty of \$750 for each day Nath fails to grant access to the information or documentation as required in Section VII of this IA. (This Stipulated Penalty shall begin to accrue on the date Nath fails to grant access.)

4. A Stipulated Penalty of \$750 for each day Nath fails to comply fully and adequately with any obligation of this IA. In its notice to Nath, OIG shall state the specific grounds for its determination that Nath has failed to comply fully and adequately with the IA obligation(s) at issue and steps Nath shall take to comply with the IA. (This Stipulated Penalty shall begin to accrue ten (10) days after the date Nath receives notice from OIG of the failure to comply). A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under paragraphs 1-3 of this Section.

B. Timely Written Requests for Extensions

Nath may, in advance of the due date, submit a timely written request for an

extension of time to perform any act or file any notification or report required by this IA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one (1) day after Nath fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three (3) business days after Nath receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

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

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

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

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

D. Exclusion for Material Breach of this IA

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

- a. a failure by Nath to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.F;
- b. a repeated or flagrant violation of the obligations under this IA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to retain and use an Independent Review Organization in accordance with Section III.E.

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

3. *Opportunity to Cure.* Nath shall have thirty (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. Nath is in compliance with the obligations of the IA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Nath has begun to take action to cure the material breach; (ii) Nath is pursuing such action with due diligence; and (iii) Nath has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Nath fails to satisfy the requirements of Section X.D.3, OIG may exclude Nath from participation in the Federal health care programs. OIG shall notify Nath in writing of its determination to exclude Nath (this letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect thirty (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, Nath wishes to apply for reinstatement, Nath shall submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Nath of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this IA, Nath 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, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (“DAB”), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within ten (10) days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within twenty-five (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 Nath was in full and timely compliance with the obligations of this IA for which OIG demands payment; and (b) the period of noncompliance. Nath shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this IA and orders Nath to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision unless Nath requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds OIG’s determination, the Stipulated Penalties shall become due and payable twenty (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 Nath was in material breach of this IA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that:
 - (i) Nath had begun to take action to cure the material breach within that period;
 - (ii) Nath has pursued and is pursuing such action with due diligence; and
 - (iii) Nath provided to OIG within that period a reasonable timetable for curing the material breach and Nath has followed the timetable.

For the purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Nath, only after a DAB decision in favor of OIG. Nath's election of his contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Nath upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Nath may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect twenty (20) days after the DAB decision. Nath shall waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Nath, Nath shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or the 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.

XI. EFFECTIVE AND BINDING IA


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

- A. This IA shall be binding on the successors, assigns and transferees of Nath;
- B. This IA shall become final and binding on the date the final signature is obtained on the IA;
- C. Any modifications to this IA shall be made with the prior written consent of the parties to this IA;
- D. If Nath enters into an employment or contractual relationship with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Nath shall notify OIG within thirty (30) days of the date of the establishment of such relationship. Upon receipt of Nath's notification, OIG may request information regarding the party's compliance program. OIG may agree to modify the IA based on its evaluation of Nath's new business relationship, his role in such relationship, and the party's compliance program;
- E. OIG may agree to a suspension of Nath's obligations under this IA in the event of Nath's cessation of participation in Federal health care programs. If Nath withdraws from participation in Federal health care programs and is relieved from his IA obligations by OIG, Nath shall notify OIG thirty (30) days in advance of Nath's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the IA shall be reactivated or modified.
- F. The undersigned Nath 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 this IA.


IN WITNESS WHEREOF, the parties hereto affix their signatures:

SANJEEV NATH, M.D.

Dec 6 02
Date


Sanjeev Nath, M.D.

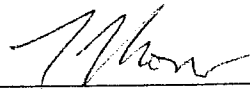
11/26/02
Date


Kenneth J. Kaplan, Esq.
Counsel for Dr. Nath

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

Date

12/4/02



LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human
Services

appraising Items included in the Claims Review, any Paid Claim for which Nath cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Nath for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

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

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

1. Claims Review Methodology.

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

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

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

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

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

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

2. Statistical Sampling Documentation.

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. Claims Review Findings.

a. Narrative Results.

- i. A description of Nath’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 Nath (“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 Nath.
- 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.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

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

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

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

PROVIDER/PHYSICIAN/SUPPLIER NAME _____
 ADDRESS _____
 PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
 CONTACT PERSON: _____ PHONE # _____
 AMOUNT OF CHECK \$ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:

Patient Name _____ HIC # _____
 Medicare Claim Number _____ Claim Amount Refunded \$ _____
 Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reason per claim)

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

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

For Institutional Facilities Only:

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

For OIG Reporting Requirements:

Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

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

NOTICE

[Practitioner] is committed to complying with all Federal health care program requirements in the operation of its businesses.

Anyone who has information or concerns about a possible violation of **[Practitioner's]** policies and procedures or any Federal health care program requirements should contact the Compliance Contact at (____) ____ - ____ or via email at _____. Reporting may also be made anonymously by sending correspondence to:

*[Bob Jones
Physician Organization ABC
244 Circle Dr.
New Town, ST 10000
Fax: (123) 456-7788]*