INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RAPHAEL FARRA, M.D.

I. PREAMBLE

Raphael Farra, M.D. (Dr. Farra) hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(Federal health care program requirements) by Dr. Farra. This commitment to promote compliance also applies to any entity that Dr. Farra owns or in which he has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Farra's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Farra is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of compliance obligations assumed by Dr. Farra under this Agreement shall be five years from the effective date of this Agreement (Effective Date), unless otherwise specified. The Effective Date shall be the date on which the final signatory of this Agreement executes this Agreement. Each one-year period beginning with the one-year period following the Effective Date shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:

a. Dr. Farra and any co-owners, officers, directors, and employees of Dr. Farra;

b. all contractors and agents that provide patient care items or services or that perform billing or coding functions on behalf of Dr. Farra;

c. all other individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports, or other request for reimbursement for such items or services on behalf of Dr. Farra.

III. INTEGRITY OBLIGATIONS

Dr. Farra shall establish or maintain a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days after the Effective Date, Dr. Farra shall designate a person to be responsible for compliance activities (Compliance Contact). The Compliance Contact shall: (1) develop and implement policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; and (2) shall respond to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, Dr. Farra shall notify the OIG, in writing, within 15 days after such a change.

B. Posting of Notice

Within 30 days after the Effective Date, Dr. Farra 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 also include the following information: (i) a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously; (ii) Dr. Farra's commitment to maintain the confidentiality of the report; and (iii) notification that reporting a suspected violation will not result in retribution or retaliation by Dr. Farra. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date, Dr. Farra shall develop, implement, and make available to all Covered Persons written policies (Policies and Procedures) that address the following:

1. Dr. Farra's commitment to full compliance with all Federal health care program requirements, including his commitment to prepare and submit accurate claims consistent with such requirements;

2. Dr. Farra's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Dr. Farra's own Policies and Procedures as implemented pursuant to this section III.C (including the requirements of this Agreement);

3. The requirement that all of Dr. Farra's Covered Persons shall be expected to report to Dr. Farra or the Compliance Contact suspected violations of any Federal health care program requirements or Dr. Farra's own Policies and Procedures;

4. The commitment of Dr. Farra 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;

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

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

Within 90 days after the Effective Date and annually thereafter, each Covered

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

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

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

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, Dr. Farra 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 four hours of training from an individual or entity, other than Dr. Farra 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 Dr. Farra 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 30 days after becoming a Covered Person or within 90 days after the Effective Date, 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. the submission of accurate claims 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 claims; and

4. Examples of proper and improper claims submission 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 the training was received. Dr. Farra shall retain the certifications, along with all training course materials. The training course materials shall be provided in the Annual Report. The certifications shall be made available to OIG, upon request.

To the extent that Covered Persons have received training that satisfies the requirements set forth above in this section III.D within 180 days prior to the Effective Date of this Agreement, the OIG shall credit that training for purposes of satisfying the training obligations for the first year of this Agreement.

E. Annual Review Procedures

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days after the Effective Date, Dr. Farra shall retain an individual or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Dr. Farra in assessing and evaluating his billing and coding practices pursuant to this Agreement and the Settlement Agreement. Each IRO retained by Dr. Farra shall have expertise in the billing, coding, reporting and other requirements applicable to physicians treating nursing home patients and in the general requirements of the Federal health care programs from which Dr. Farra seeks reimbursement. Each IRO shall assess, along with Dr. Farra, whether it can perform the IRO review in a professionally independent and/or objective fashion, taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze Dr. Farra'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 Reporting Periods. For the first three Reporting Periods, the IRO(s) shall perform all components of each annual Claims Review. However, after the IRO performs Claims Review for the third Reporting Period, Dr. Farra, at his option, may request the OIG to permit that the Claims Review be conducted internally for the remainder of the term of the Agreement. The OIG retains sole discretion over whether to permit the Claims Review to be conducted internally by Dr. Farra after the third Reporting Period. In making its decision, the OIG will consider, among other factors, the results of the Claims Reviews during the first three Reporting Periods and Dr. Farra's audit capabilities to perform the Claims Reviews internally. If the OIG denies Dr. Farra's request to shift the audit responsibilities, Dr. Farra agrees to engage the IRO to perform the remaining Claims Reviews in accordance with this Agreement.

c. Retention of Records. The IRO and Dr. Farra shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports (those exchanged between IRO and Dr. Farra) 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 Agreement, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of Dr. Farra (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at Dr. Farra's office or under Dr. Farra'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, Dr. Farra should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Farra recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority, may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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 shall be designed to (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform 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 Dr. Farra's office or under Dr. Farra'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, Dr. Farra may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of his Full Sample. OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. Farra 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. Stratification of Sample. The universe of Paid Claims, from which the Discovery Sample, and if necessary, the Full Sample are to be selected shall be stratified. The first strata shall contain Paid Claims for services Dr. Farra provided in nursing facilities and the second strata shall contain Paid Claims for services Dr. Farra

provided in his office. For each Reporting Period, the IRO shall determine the proportion of claims that were reimbursed in each strata. Based on the IRO's calculated proportions, the IRO shall then select for review the number of Paid Claims from each strata that represent, proportionally, services that Dr. Farra provided in nursing facilities and in his office.

d. Systems Review. If Dr. Farra's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Farra's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

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

3. *Claims (and System) Review Report(s).* The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report), and a report based upon the Systems Review (System Review Report) if one is necessary. Information to be included in the Claims Review Report is detailed in Appendix A and information to be included in the System Review Report is detailed above in section III.E.2.d.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Farra's Claims Review fails to conform to the requirements of this Agreement; 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 Agreement and/or the findings or Claims Review results are inaccurate (Validation Review). Dr. Farra shall 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 within one year after Dr. Farra's final submission (as described in section II) is received

by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Farra 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, Dr. Farra 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 proposed Validation Review. Dr. Farra 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 Dr. Farra 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/Objectivity Certification.* The IRO shall include in its report(s) to Dr. Farra a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the review conducted, with regard to the Claims and/or Systems Review and that it has concluded that it is, in fact, independent and/or objective.

F. Ineligible Persons.

1. *Definition.* For purposes of this Agreement, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (b) 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.

2. *Screening Requirements.* Dr. Farra shall ensure that all owners, officers, directors, employees, contractors, and agents of Dr. Farra are not Ineligible Persons. To ensure that such individuals are not Ineligible Persons, Dr. Farra shall screen such persons prior to engaging their services by: (a) requiring such persons to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists shall hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) Dr. Farra to refrain from billing Federal health care programs for services

of the Ineligible Person.

3. *Review and Removal Requirement.* Within 90 days after the Effective Date, Dr. Farra shall review the list of persons identified in Section III.F.2. against the Exclusion Lists. Thereafter, Dr. Farra shall review the list of such persons against the Exclusion Lists annually. In addition, Dr. Farra shall require such persons to disclose immediately any debarment, exclusion, suspension, or other event that makes such individual an Ineligible Person.

If Dr. Farra has actual notice that such person has become an Ineligible Person, he shall remove such person from responsibility for, or involvement with, his business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation 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 at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Dr. Farra has actual notice that a person identified in Section III.F.2. is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, involvement, or contract term, Dr. Farra shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

G. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Dr. Farra has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, Dr. Farra identifies or learns of any Overpayments, Dr. Farra shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to

by the payor) to correct the problem, including preventing the underlying problem and the Overpayments from recurring. Also, within 30 days after identification of the Overpayment, Dr. Farra shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Dr. Farra shall notify the payor of his efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this Agreement, a "Material Deficiency" means anything that involves:

(i) a substantial Overpayment; or

(ii) a matter that a reasonable person would consider a 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 Dr. Farra determines, by any means, that there is a Material Deficiency, Dr. Farra shall notify OIG, in writing, within 30 days after determining that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an Overpayment, the

report to the OIG shall be made at the same time as the notification to the payor required in section III.G.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) on which the Overpayment was repaid/refunded;

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

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

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

H. Notification of Government Investigations or Legal Proceedings

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

I. New Business Units, Locations, or Relationships

In the event that, after the Effective Date, Dr. Farra changes locations or sells, closes, purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Farra shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of the change of location, sale, closure, purchase or establishment. This notification shall

include the location of the new business unit or location(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 or supplier number. All Covered Persons at such locations shall be subject to the applicable requirements in this Agreement (e.g., completing certifications and undergoing training).

Prior to Dr. Farra 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, Dr. Farra shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Dr. Farra's obligations under the Agreement. In addition, Dr. Farra shall notify the OIG of such relationship as described in Section X.4.

IV. REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Dr. Farra shall submit a written report (Implementation Report) to OIG summarizing the status of his implementation of the requirements of this Agreement. This Implementation Report shall include:

1. The name, address and phone number of Dr. Farra's Compliance Contact;

2. A copy of the notice Dr. Farra posted in his office as described in Section III.B and a description of where and when the notice was posted;

3. A copy of the Policies and Procedures required by section III.C;

4. A certification signed by Dr. Farra 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 Dr. Farra attesting that all Covered Persons have

completed the initial training required by Section III.D and have executed the required certifications;

7. The name and qualifications of the IRO retained by Dr. Farra, a summary/description of all engagements between Dr. Farra and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual Claims Review;

8. A certification from the IRO regarding its professional independence/objectivity from Dr. Farra;

9. A summary of personnel actions (other than hiring) taken pursuant to Section III.F;

10. A list of all Dr. Farra'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 Dr. Farra currently submits claims; and

11. A certification from Dr. Farra 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

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

Each Annual Report shall include:

1. If revisions were made to the Policies and Procedures developed pursuant to section III.C, a copy of any Policies and Procedures that

were revised;

2. A certification by Dr. Farra 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;

4. A certification signed by Dr. Farra certifying that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in section III.D;

5. A complete copy of all reports prepared pursuant to the IRO's (or any internal) Claims Review including the Claims Review Report and any System Review Report, along with a copy of the IRO's engagement letter;

6. Dr. Farra's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO (or as a result of the internal audit, if permitted);

7. A summary/description of all engagements between Dr. Farra 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 regarding its professional independence/objectivity from Dr. Farra;

9. A summary of Material Deficiencies (as defined in III.G) 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.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such

investigation or legal proceeding;

11. A certification signed by Dr. Farra certifying that all prospective employees and contractors are being screened against the Exclusion Lists (as defined in section III.F); and

12. A certification signed by Dr. Farra certifying 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.

V. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under the terms of this Agreement 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
Ph: (202) 619-2078
Fax: (202) 205-0604

Dr. Farra:
Paulette Farra
503 Riverway Place
Bedford, New Hampshire 03110
Ph: (603) 623-3013
Fax: (603) 627-0620

with a copy to:
Christine G. Solt, Esquire
Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109-2804

phone: (617) 248-4084
fax: (619) 248-4000

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

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

VII. DOCUMENT AND RECORD RETENTION

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

VIII. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Dr. Farra prior to any release by OIG of information submitted by Dr. Farra pursuant to his obligations under this Agreement and identified upon submission by Dr. Farra as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With

respect to such releases, Dr. Farra shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. Farra shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

Dr. Farra is expected to fully and timely comply with all of his Agreement obligations throughout the term of this Agreement.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Farra 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 Agreement 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 (or, if permitted, the internal audit) annual Claims Review Report and any Systems Review Report as required in section III.E and Appendix A; or

   f. submit the Implementation or Annual Report(s) to the OIG as required in section IV.

2. A Stipulated Penalty of $750 (which shall begin to accrue on the date the

failure to comply began) for each day Dr. Farra employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Dr. Farra'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 Dr. Farra can demonstrate that he did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).

3. A Stipulated Penalty of $750 for each day Dr. Farra fails to grant access to the information or documentation as required in section VI of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Dr. Farra fails to grant access.)

4. A Stipulated Penalty of $5,000 for each false certification submitted by, or on behalf of, Dr. Farra as part of his Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG) or otherwise required by this Agreement.

5. A Stipulated Penalty of $750 for each day Dr. Farra fails to comply fully and adequately with any obligation of this Agreement. In its Demand Letter pursuant to Section IX.C.1 to Dr. Farra, OIG shall state the specific grounds for its determination that Dr. Farra has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps he must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after receipt of the Demand Letter.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under subsections 1-4 of this section.

B. Timely Written Requests for Extensions

Dr. Farra may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this Agreement. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Dr. Farra fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Dr. Farra receives OIG's written denial of such

request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

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

2. *Response to Demand Letter.* Within 10 days after receipt of the Demand Letter, Dr. Farra 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 IX.E. In the event Dr. Farra elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until he cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under section IX.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 V.

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

D. Exclusion for Material Breach of this Agreement

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

a. a failure by Dr. Farra to report a Material Deficiency, take

corrective action and make the appropriate refunds, as required in section III.G;

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section IX.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 Agreement by Dr. Farra constitutes an independent basis for Dr. Farra's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Farra has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Dr. Farra of: (a) Dr. Farra'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.* Dr. Farra shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Dr. Farra is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Farra fails to satisfy the requirements of section IX.D.3, OIG may exclude Dr. Farra from

participation in the Federal health care programs. OIG will notify Dr. Farra in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Dr. Farra wishes to apply for reinstatement, he must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Dr. Farra of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Dr. Farra shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Dr. Farra was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Dr. Farra shall have the burden of proving his full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Dr. Farra to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Farra requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

a. whether Dr. Farra was in material breach of this Agreement;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

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

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

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

X. EFFECTIVE AND BINDING AGREEMENT

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

1. This Agreement shall be binding on the successors, assigns and transferees of Dr. Farra;

2. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;

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

4. If Dr. Farra 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, Dr. Farra shall notify the OIG within 30 days after the date of the establishment of such relationship. Upon receipt of Dr. Farra's notification, the OIG may request information regarding the other party's compliance program, if any. The OIG may agree to modify the Agreement based on its evaluation of Dr. Farra's new business relationship, his role in such relationship, and the party's compliance program;

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

6. The undersigned Dr. Farra signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

RAPHAEL FARRA, M.D.

Raphael Farra — 12/2/03

Raphael Farra, M.D. Date
503 Riverway Place
Bedford, New Hampshire 03110

Christine G. Solt — 11/26/03

Christine G. Solt Date
Counsel for Dr. Farra
Choate, Hall & Stewart
Exchange Place
53 State Street
Boston, MA 02109-2804

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

Larry J. Goldberg — 12/31/03

Larry J. Goldberg 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

A. Claims Review.

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

a. Overpayment: The amount of money Dr. Farra 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 Dr. Farra and for which Dr. Farra has received reimbursement from the Medicare program.

d. Population: All Items for which Dr. Farra has submitted a code or line item and for which Dr. Farra has received reimbursement from the Medicare 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.

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 Dr. Farra cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Dr. Farra 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 Dr. Farra'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 Dr. Farra (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 Dr. Farra.

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), and 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: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

Claim Review Results

Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

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/SUPPLIERNAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____CHECK NUMBER#_____
CONTACT PERSON:_____PHONE #_____ AMOUNT OF CHECK $_____ CHECK DATE_____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name_____HIC #_____
Medicare Claim Number_____Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

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

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

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

For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? _____ Yes _____ No

Reason Codes:

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