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

I. PREAMBLE

Gerald Dorros, M.D. (Dr. Dorros) 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). This commitment to promote compliance applies to any entity that Dr. Dorros owns or in which Dr. Dorros has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Dr. Dorros's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Dr. Dorros is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Dr. Dorros under this Agreement shall be 5 years from the Effective Date of this Agreement. Each one-year period beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

C. The scope of this Agreement shall be governed by the following definition: "Covered Persons" includes: (1) Dr. Dorros; (2) all owners, officers, directors, and employees of Dr. Dorros; and (3) all contractors, agents, and other persons who provide patient care items or services for Dr. Dorros or who perform billing

or coding functions on behalf of Dr. Dorros.

III. INTEGRITY OBLIGATIONS

Dr. Dorros shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Contact

Dr. Dorros hereby certifies to OIG that he does not own or have a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), in any entity that submits claims to the Federal health care programs for reimbursement. So long as that representation is accurate, then Dr. Dorros shall not be required to perform the requirements set forth in Sections III.A, III.B, and III.C. Dr. Dorros shall notify OIG at least 30 days in advance if he intends to have ownership of or a control interest in any entity that submits claims to the Federal health care programs for reimbursement. If, during the term of this Agreement, Dr. Dorros owns or has a control interest in any entity that submits claims to the Federal health care programs for reimbursement, Dr. Dorros shall abide by the obligations required pursuant to Sections III.A, III.B, and III.C.

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

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

B. Posting of Notice

Within the 90 days after the Effective Date, Dr. Dorros shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business.

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

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

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

C. Written Policies and Procedures

Within 90 days after the Effective Date, Dr. Dorros shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition and if applicable, Dr. Dorros shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

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

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

3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program

requirements or of Dr. Dorros's own Policies and Procedures to the Compliance Contact or Dr. Dorros, as applicable, and Dr. Dorros's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

4. the possible consequences to both Dr. Dorros and Covered Persons of failure to comply with Federal health care program requirements or with Dr. Dorros's written Policies and Procedures and the failure to report such noncompliance;

5. Dr. Dorros'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; and

7. the proper documentation of services and billing information.

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

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

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Certification

Within 90 days after the Effective Date and at least once each year thereafter, Dr. Dorros and Covered Persons shall receive at least four hours of training from an individual or entity, other than Dr. Dorros or another Covered Person. Persons providing the training shall be knowledgeable about the subject area and may be received from a variety of sources (e.g., CME classes, hospitals, associations, carriers).

New Covered Persons 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 a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

At a minimum, the initial, annual, and, if applicable, new employee training sessions shall include the following topics:

1. the requirements of Dr. Dorros's Agreement;

2. an overview of the Dr. Dorros's compliance program;

3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;

4. applicable reimbursement statutes, regulations, and program requirements and directives;

5. if applicable, the written Policies and Procedures developed pursuant to Section III.C, above;

6. the policies, procedures, and other requirements applicable to the documentation of medical records;

7. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;

8. the legal sanctions for the submission, or causing the submission, of improper claims or violations of the Federal health care program requirements; and

9. examples of proper and improper coding and claim submission practices, including but not limited to, examples involving investigational procedures or procedures utilizing investigational devices.

Each Covered Person shall annually certify, in writing or in electronic format if the training is computerized, that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact or Dr. Dorros, as applicable, shall retain the certifications, along with all training materials. Dr. Dorros shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during the IRO Claims Review or other Review (as defined in Section III.E.6), if applicable, and any other relevant information.

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

The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

E. <u>Review Procedures</u>

Dr. Dorros hereby certifies to OIG that claims for services he performs are not submitted by him or any entity which he owns or has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), to the Federal health care programs for reimbursement. So long as that representation is accurate, then Dr. Dorros shall not be required to perform the requirements set forth in Section III.E. Dr. Dorros shall notify OIG at least 30 days in advance if he intends

to begin submitting claims to the Federal health care programs for reimbursement. If, during the term of this Agreement, Dr. Dorros begins submitting claims to the Federal health care programs for reimbursement, Dr. Dorros shall perform the review required pursuant to Sections III.E.

1. General Description.

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Dr. Dorros shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Dr. Dorros in assessing and evaluating his billing and coding practices and certain other obligations pursuant to this Agreement and the Settlement Agreement.

Each IRO engaged by Dr. Dorros shall have expertise in the billing, coding, reporting, and other requirements of investigational procedures or procedures utilizing investigational devices and in the general requirements of the Federal health care program(s) from which Dr. Dorros seeks reimbursement. Each IRO shall assess, along with Dr. Dorros, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement; taking into account any other business relationships or other engagements that may exist.

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

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

c. *Frequency of Unallowable Cost Review.* If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period. If not applicable, Dr. Dorros shall sign a certification, as required by Section III.E.4 below, stating that he does not currently and has not submitted a cost report since this Agreement was executed.

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

2. Claims Review. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

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

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

i. If the Error Rate (as defined in Appendix B) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, Dr. Dorros should, as appropriate, further analyze any errors identified in the Discovery Sample. Dr. Dorros recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

ii. If the Discovery Sample indicates that the Error Rate is 5%

or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. *Full Sample*. If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix B. The Full Sample shall be designed to: (i) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (ii) conform 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. Dorros's office or under Dr. Dorros'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. Dorros may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if: (i) statistically appropriate and (ii) Dr. Dorros selects the Full Sample Items using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from Dr. Dorros 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 Dr. Dorros's Discovery Sample identifies an Error Rate of 5% or greater, Dr. Dorros's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall perform a "walk through" of the system(s) and process(es) that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. *Repayment of Identified Overpayments*. In accordance with Section III.H.1 of this Agreement, Dr. Dorros 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. Dorros shall make available to OIG any and all documentation and the associated documentation that reflects the refund of the Overpayment(s) to the payor.

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

4. Unallowable Cost Review.

a. Unless Section III.E.4.b, below, applies, the IRO shall conduct a review of Dr. Dorros's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Dr. Dorros has complied with his obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and his obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Dorros or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

b. If Dr. Dorros executes and submits to the OIG in the first Annual Report a certification that neither Dr. Dorros nor any entity in which Dr. Dorros has any ownership or control interest has ever submitted any cost report or other submission to a Federal health care program seeking reimbursement based on costs, then no Unallowable Cost Review shall be required under this Agreement.

5. Unallowable Cost Review Report. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The

Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether Dr. Dorros has complied with his obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and his obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

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

Prior to initiating a Validation Review, OIG shall notify Dr. Dorros 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, Dr. Dorros may request a meeting with OIG to: (a) discuss the results of any Claims Review or other Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Claims Review or other Review to correct the inaccuracy of the Claims Review or other Review; and/or (c) propose alternatives to the proposed Validation Review. Dr. Dorros agrees to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review or other Review issues with Dr. Dorros 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.

7. Independence/Objectivity Certification. The IRO shall include in its report(s) to Dr. Dorros 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 or other Review and that it has concluded that it is, in fact, independent and/or objective.

F. Ineligible Persons

1. Definitions. For purposes of this Agreement:

a. An "Ineligible Person" shall include an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.arnet.gov)

2. Screening Requirements. Dr. Dorros shall ensure that all prospective and current owners, officers, directors, employees, contractors, and agents of Dr. Dorros are not Ineligible Persons. To ensure that such individuals and entities are not Ineligible Persons, Dr. Dorros shall require such individuals and entities to disclose immediately any debarment, exclusion, suspension, or other event that makes such individual or entity an Ineligible Person. Prior to engaging the services of such individuals and entities, Dr. Dorros shall screen such individuals and entities against the Exclusion Lists. In addition, Dr. Dorros shall:

a. Within 90 days after the Effective Date, review his list of individuals and entities identified in Section III.F.2 against the Exclusion Lists; and

b. Review his list of individuals and entities identified in Section III.F.2 against the Exclusion Lists annually.

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

Nothing in this Section affects the responsibility of (or liability for) Dr. Dorros to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Dr. Dorros has notice that any individual or entity in one of the positions identified in Section III.F.2 has become an Ineligible Person, Dr. Dorros shall remove such individual or entity from responsibility for, or involvement with, Dr. Dorros's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the individual or entity 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 individual or entity is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Dr. Dorros has notice that an individual identified in Section III.F.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), or an individual or entity identified in Section III.F.2 is proposed for exclusion during his, her or its employment, involvement or contract term, Dr. Dorros shall take all appropriate actions to ensure that the responsibilities of that individual or entity has 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. Notification of Government Investigation or Legal Proceedings

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

H. Reporting

1. Overpayments

a. *Definition of Overpayments*. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Dr. Dorros 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. Dorros identifies or learns of any Overpayment, Dr. Dorros shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Dr. Dorros 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. Dorros shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Attachment 1 to 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. Reportable Events.

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

i. a substantial Overpayment;

ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which

penalties or exclusion may be authorized; or

iii. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

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

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

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

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

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

I. Future Contract with Third Party Biller

If, at any time during the term of this Agreement, Dr. Dorros contracts with a third party billing company to submit claims to the Federal health care programs, at least 30 days prior to executing the contract, Dr. Dorros shall submit a certification indicating whether he has an ownership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether he is employed by or acts as a consultant to the third party billing company.

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

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

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Dr. Dorros 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. Dorros shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's

name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Prior to Dr. Dorros becoming an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Dr. Dorros 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. Dorros's obligations under the Agreement. In addition, Dr. Dorros shall notify OIG of such relationship in his next Annual Report.

V. REPORTS

A. Implementation Report

Within 120 days after the Effective Date, Dr. Dorros shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. if applicable, the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;

2. if applicable, a copy of the notice Dr. Dorros posted in her office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;

3. if applicable, a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;

4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;

5. if applicable, the name and qualifications of the IRO(s), a summary/description of all engagements between Dr. Dorros 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 and Unallowable Cost Review.

6. if applicable, a copy of the IRO's engagement letter, including the length of the engagement;

7. if applicable, a certification from the IRO regarding its professional independence and/or objectivity with respect to Dr. Dorros;

8. a description of Dr. Dorros's process to screen Covered Persons to determine if they are ineligible;

9. a summary of personnel actions (other than hiring) taken pursuant to Section III.F, the name, title and responsibilities of any person who is determined to be an Ineligible Person under Section III.F, and the actions taken in response to the obligations set forth in Section III.F;

10. a list of all Dr. Dorros's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Dr. Dorros currently submits claims;

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

12. a certification by the Compliance Contact or Dr. Dorros, as applicable, that:

> a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

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

c. all owners, officers, directors, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Dr. Dorros, as required by Section III.F of this Agreement; and

d. all current owners, officers, directors, employees, contractors, and agents of Dr. Dorros were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.F of this Agreement and the date(s) of the screening.

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

B. <u>Annual Reports</u>

Dr. Dorros shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Dr. Dorros's compliance activities for each of the 5 Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Dr. Dorros's Compliance Contact or Dr. Dorros's contact information, as applicable;

2. if applicable, any changes to the posted notice and the reason for such changes;

3. a copy of any new compliance-related Policies and Procedures;

4. if applicable, a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);

5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;

6. if applicable, a complete copy of all reports prepared pursuant to the IRO's Claims Review or other Review, required by Section III.E (and, if applicable for the first Annual Report, a copy of the certification described in section III.E.4.b);

7. if applicable, a certification by Dr. Dorros stating that he does not currently and has not submitted any cost reports to any Federal health care programs since this Agreement was executed;

8. if applicable, Dr. Dorros's response and corrective action plan(s) related to any issues raised or recommendations made by the IRO, as a result of the Review(s) performed pursuant to Section III.E;

9. if applicable, a summary/description of all engagements between Dr. Dorros and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;

10. if applicable, a certification from the IRO regarding its professional independence and/or objectivity to Dr. Dorros;

11. a description of Dr. Dorros's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);

12. a summary of personnel actions/other than hiring taken pursuant to Section III.F; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and Dr. Dorros's actions taken in response to the obligations set forth in Section III.F;

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

15. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;

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

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

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

19. A certification, where appropriate, by the Compliance Contact that certifies that:

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

b. all Covered Persons have completed the applicable training

required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, employees, contractors, and agents that were hired, engaged or otherwise involved with Dr. Dorros during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Dr. Dorros, as required by Section III.F of this Agreement;

d. all owners, officers, directors, employees, contractors, and agents (employed, engaged or otherwise involved with Dr. Dorros for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.F of this Agreement and the date(s) they were screened;

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

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

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

C. Designation of Information

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

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile:(202) 205-0604

Dr. Dorros:

David Stetler
Stetler & Duffy, Ltd.
11 S. LaSalle Street, Suite 1200
Chicago, IL 60603
Telephone: (312) 338-0200
Facsimile: (312) 338-0070

Unless otherwise specified, all notifications and Reports required by this Agreement shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Dr. Dorros's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Dr. Dorros's locations for the purpose of verifying and evaluating: (a) Dr. Dorros's compliance with the terms of this CIA; and (b) Dr. Dorros'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. Dorros 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. Dorros'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. Dorros shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dr. Dorros's employees may elect to be interviewed with or without a representative of Dr. Dorros present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

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

a. if applicable, have a Compliance Contact in accordance with the requirements of Section III.A;

b. if applicable, establish and/or post a notice in accordance with the requirements of Section III.B;

c. if applicable, establish, implement, maintain, distribute and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;

d. establish and implement a training program in accordance with the requirements of Section III.D.

e. if applicable, obtain a certification from the third party biller, send the third party biller certification to OIG in accordance with the requirements of Section III.I, or notify OIG within 30 days prior to Dr. Dorros obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;

f. if applicable, engage an IRO in accordance with the requirements of Section III.E.1.a and Appendix A;

g. if applicable, submit the IRO's annual Claims Review Report and

any other required Review in accordance with the requirements of Section III.E and Appendix B;

h. obtain and/or maintain the following documentation: Policies and Procedures certifications, if applicable, in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.F.2.

i. screen current or prospective owners, officers, directors, employees, contractors or agents in accordance with the requirements of Section III.F; or require owners, officers, directors, associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.F; or

j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.G.

2. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Dr. Dorros fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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

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

5. A Stipulated Penalty of $750 for each day Dr. Dorros fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Dr. Dorros stating the specific grounds for its determination that Dr. Dorros has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Dorros shall

take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Dr. Dorros receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

B. Timely Written Requests for Extensions

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

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Dr. Dorros shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Dr. Dorros elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Dorros cures, to OIG's satisfaction, the alleged

breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this Agreement

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

a. a failure by Dr. Dorros to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.H;

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

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;

d. a failure to engage and use an IRO in accordance with Section III.E; or

e. a failure to meet any obligation under this Agreement that has a significant impact on the quality of care rendered to any patients.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Dr. Dorros constitutes an

independent basis for Dr. Dorros's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Dorros has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Dr. Dorros of: (a) Dr. Dorros'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. Dorros 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. Dorros is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Dr. Dorros has begun to take action to cure the material breach; (ii) Dr. Dorros is pursuing such action with due diligence; and (iii) Dr. Dorros 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. Dorros fails to satisfy the requirements of Section X.D.3, OIG may exclude Dr. Dorros from participation in the Federal health care programs. OIG shall notify Dr. Dorros in writing of its determination to exclude Dr. Dorros (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Dr. Dorros's receipt 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. After the end of the period of exclusion, Dr. Dorros may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

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

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

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

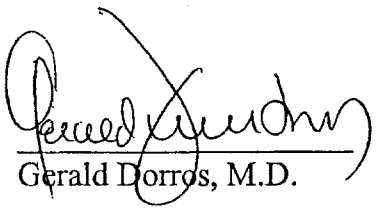
D. OIG may agree to a suspension of Dr. Dorros's obligations under this Agreement in the event of Dr. Dorros's cessation of participation in Federal health care programs. If Dr. Dorros withdraws from participation in Federal health care programs and is relieved of his Agreement obligations by OIG, Dr.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

E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Dr. Dorros's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements.

F. The undersigned Dr. Dorros 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:

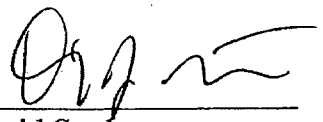
Dr. Dorros



Gerald Dorros, M.D.

24 February 05

Date

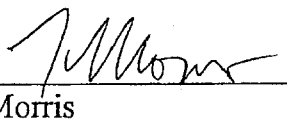


David Stetler
Counsel for Dr. Dorros

3/1/05

Date

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



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

3/8/05

Date