

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
CANDITA CATUCCI, M.D.  
AND  
JUAN CARLOS ACOSTA**

**I. PREAMBLE**

Candita Catucci, M.D., (Catucci) and Juan Carlos Acosta (Acosta) hereby enter 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 Agreement applies to Catucci, Acosta, and any entity that Catucci or Acosta owns or in which Catucci or Acosta has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Catucci's and Acosta's and any such entity's Covered Persons as defined in Section II.C. Contemporaneously with this Agreement, Catucci and Acosta are entering into a Settlement Agreement with the OIG.

**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 Catucci and Acosta 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 from OIG's receipt of: (1) Catucci's and/or Acosta's final Annual Report; or (2) any additional materials submitted by Catucci and/or Acosta pursuant to OIG's request, whichever is later.

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

"Covered Persons" includes:

a. Catucci and Acosta;

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- b. all owners, partners, associates, and employees of Catucci and/or Acosta; and
- c. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Catucci and/or Acosta.

“Arrangements” shall mean every arrangement or transaction that:

- a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Catucci or Acosta and any actual or potential source of health care business or referrals to Catucci or any actual or potential recipient of health care business or referrals from Catucci. The term “source” shall mean any physician, contractor, vendor, or agent and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- b. is between Catucci or Acosta (or an immediate family member of Catucci or Acosta (as defined at 42 C.F.R. § 411.351)) and any health care provider to whom Catucci makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

### **III. INTEGRITY OBLIGATIONS**

Catucci and Acosta shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Contact**

Within 30 days after the Effective Date, Catucci and Acosta shall designate a person to be responsible for compliance activities (Compliance Contact). Catucci and Acosta shall maintain a Compliance Contact for the term of this Agreement. 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 Catucci and Acosta’s day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

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Catucci and Acosta 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 90 days after the Effective Date, Catucci and Acosta shall post in a prominent place accessible to all patients and Covered Persons a notice detailing their commitment to comply with all Federal health care program requirements in the conduct of their 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) Catucci and Acosta'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 Catucci and Acosta.

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, Catucci and Acosta shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Catucci and Acosta 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. Catucci and Acosta's commitment to full compliance with all Federal health care program requirements, including their commitment to prepare and submit accurate claims consistent with such requirements;
2. the expectation that all of Catucci and Acosta's Covered Persons shall be expected to comply with all Federal health care program requirements and with Catucci and Acosta's own written Policies and Procedures as

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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 Catucci and Acosta's own Policies and Procedures to the Compliance Contact or Catucci and/or Acosta, and Catucci and Acosta's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to such disclosures;

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

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

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

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

8. the commitment to comply with 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and all applicable regulations and to be aware of and to review other guidance documents related to these statutes;

9. the commitment to avoid business or financial arrangements or contracts that, directly or indirectly, induce the unlawful referral of Federal health care program beneficiaries, in violation of the Anti-Kickback Statute and/or the Stark Law; and

10. the requirements set forth in Section III.E (Compliance with the Anti-Kickback Statute and Stark Law), including but not limited to the Arrangements Database, the internal review and approval process, and the

tracking of remuneration to and from sources of health care business of referrals.

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 Catucci and Acosta'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), Catucci and Acosta 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 during each subsequent Reporting Period, Covered Persons shall receive at least two hours of training from an individual or entity, other than Catucci and Acosta 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.

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

1. the requirements of Catucci and Acosta's Agreement;
2. an overview of Catucci and Acosta's compliance program;
3. the written Policies and Procedures developed pursuant to Section III.C, above;
4. the legal sanctions for improper contracting or entering into unlawful financial arrangements;
5. examples of violations of the Anti-Kickback Statute and the Stark Law; and
6. a review of Catucci and Acosta's contracting Policies and Procedures related to "Arrangements," as defined in Section II.C above, as developed pursuant to Section III.C below, and the personal obligations of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Catucci and Acosta's Policies and Procedures.

Each Covered Person shall annually certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Contact shall retain the certifications, along with all training materials. Catucci and Acosta 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 Arrangements Review (See Section III.F.2 below), and any other relevant information.

If Catucci and Acosta choose, Catucci and Acosta may provide the training required under this Agreement through appropriate computer-based training approaches. If Catucci and Acosta choose to provide computer-based training, they 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. Compliance with the Anti-Kickback Statute and the Stark Law**

1. Arrangements Procedures. Within 90 days after the Effective Date, Catucci and Acosta shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to the Arrangement are performing the services required under the applicable Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Arrangements, including but not limited to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Arrangements do not violate the Anti-Kickback Statute and Stark Law;
- f. requiring the Compliance Contact to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis; and

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g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. New or Renewed Arrangements. Before entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, Catucci and Acosta shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Catucci and/or Acosta and the other parties to the Arrangement;

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Catucci and Acosta's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, Catucci and Acosta shall provide each party to the Arrangement with a copy of their written Policies and Procedures, including the Stark Law and Anti-Kickback Statute Policies and Procedures; and

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

3. Records Retention and Access. Catucci and Acosta shall retain and make available to OIG, upon request, the Arrangements Database and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

**F. Review Procedures**

1. General Description.

a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, Catucci and Acosta shall engage an

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individual or entity (or entities), such as an accounting, auditing, law or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a review to assist Catucci and Acosta in assessing their compliance with the obligations pursuant to Section III.E of this Agreement (Arrangements Review).

Each IRO shall assess, along with Catucci and Acosta, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between Catucci and/or Acosta and the IRO. The applicable requirements relating to the IRO are outlined in Appendix B to this Agreement, which is incorporated by reference.

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

c. Retention of Records. The IRO and Catucci and Acosta shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Catucci and Acosta) related to the Arrangements Review.

d. Responsibilities and Liabilities. Nothing in this Section III.F affects Catucci and/or Acosta's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

2. Arrangements Review. The IRO shall perform a review to assess whether Catucci and Acosta are complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.E.1 and III.E.2 of this Agreement. The IRO shall randomly select 25 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Catucci and Acosta have implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Catucci and Acosta have complied with the Arrangements

Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the service and activity logs are properly completed and reviewed (if applicable); (e) verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); (f) verifying that the Compliance Contact is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to Catucci and Acosta; (g) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute and Stark Law are discovered; and (h) verifying that Catucci and Acosta have met the requirements of Section III.E.2.

3. Arrangements Review Report. The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to (a) whether Catucci and Acosta have generally implemented the Arrangements Procedures described in Section III.E.1; and (b) specific findings as to whether Catucci and Acosta have complied with the Arrangements Procedures and Arrangements Requirements with respect to each of their Arrangements. In addition, the Arrangements Review Report shall include any observations, findings and recommendations on possible improvements to Catucci and Acosta's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute and Stark Law.

4. Validation Review. In the event OIG has reason to believe that: (a) Catucci and Acosta's Arrangements Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Arrangements Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the Agreement and/or the findings or Arrangements Review results are inaccurate ("Validation Review"). Catucci and Acosta 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 Catucci and Acosta's final submission (as described in Section II) is received by OIG.

Before initiating a Validation Review, OIG shall notify Catucci and Acosta 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, Catucci and Acosta may request a meeting with

OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional or relevant information to clarify the results of the Arrangements Review to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. Catucci and Acosta agree to provide any additional information requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Arrangement Review issues with Catucci and Acosta before conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

**G. 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://epls.arnet.gov>).

c. "Screened Persons" include prospective and current owners, officers, directors, employees, associates, contractors, and agents of Catucci, Acosta, or Catucci's medical practice.

2. Screening Requirements. Catucci and Acosta shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements:

- a. Catucci and Acosta shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require Screened Persons to disclose whether they are Ineligible Persons.
- b. Catucci and Acosta shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Catucci and Acosta shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

Nothing in this Section affects the responsibility or liability of Catucci and/or Acosta to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Catucci and/or Acosta have notice that a Screened Person has become an Ineligible Person, Catucci and Acosta shall remove such Screened Person from responsibility for, or involvement with, Catucci and Acosta's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services rendered, ordered, or prescribed by the Screened 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 Screened Person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If Catucci and/or Acosta have notice that a Screened Person is charged with a criminal offense that falls within the

ambit of 42 U.S.C. § 1320a-7(a), or a Screened Person is proposed for exclusion during the Screened Person's employment or contract term, Catucci and/or Acosta shall take all appropriate actions to ensure that the responsibilities of that Screened 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.

#### **H. Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Catucci and/or Acosta shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Catucci and/or Acosta conducted or brought by a governmental entity or its agents involving an allegation that Catucci and/or Acosta 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. Catucci and/or Acosta 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. Reporting**

##### **1. Overpayments**

a. Definition of Overpayments. For purposes of this Agreement, an "Overpayment" shall mean the amount of money Catucci 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, Catucci and/or Acosta identify or learn of any Overpayment, Catucci and/or Acosta 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, Catucci and/or Acosta 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, Catucci and/or Acosta shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when

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such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor's policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Appendix C 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. the filing of a bankruptcy petition by Catucci or Acosta.

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

b. Reporting of Reportable Event. If Catucci and/or Acosta determine (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Catucci and/or Acosta 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.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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(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 Catucci and/or Acosta's actions taken to correct the Reportable Event;

iv. any further steps Catucci and/or Acosta plan to take to address the Reportable Event and prevent it from recurring; and

v. if the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

#### IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Catucci, Acosta, or Catucci's medical practice change locations or sell, close, purchase, or establish a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Catucci and/or Acosta 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 Catucci and/or Acosta 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, Catucci and/or Acosta shall notify that party of this Agreement.

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This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Catucci and/or Acosta's obligations under the Agreement. In addition, Catucci and/or Acosta shall notify OIG of such relationship in their next Annual Report.

**V. REPORTS**

**A. Implementation Report**

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

1. 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. a copy of the notice Catucci and Acosta posted in their office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. 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. a description of the Arrangements Database required by Section III.E.1.a;
6. a description of the internal review and approval process required by Section III.E.1.e;
7. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;

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8. the following information regarding the IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between Catucci and Acosta and the IRO; and (d) the proposed start and completion dates of the Arrangements Review;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Catucci and Acosta;
10. a description of Catucci and Acosta's process to screen Screened Persons to determine if they are ineligible;
11. a summary of personnel actions (other than hiring) taken pursuant to Section III.G, the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G, and the actions taken in response to the obligations set forth in Section III.G;
12. a list of all Catucci and Acosta's business 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 Catucci or Catucci's medical practice currently submits claims;
13. if Catucci and/or Acosta 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, Catucci and/or Acosta shall inform OIG of the name, location, relationship, and their responsibilities with respect to Catucci and/or Acosta's employment or contract;
14. a certification by the Compliance Contact that:
  - a. the written Policies and Procedures required by Section III.C 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;

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

c. all Screened Persons 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, before entering into their relationship with Catucci and Acosta, as required by Section III.G; and

d. all Screened Persons were screened against the Exclusion Lists within 90 days after the Effective Date, as required by Section III.G and the date(s) of the screening.

15. a certification signed by Catucci and Acosta certifying (a) to the best of their knowledge, except as otherwise described in the Implementation Report, Catucci and Acosta are in compliance with all of the requirements of this Agreement; and (b) Catucci and Acosta have reviewed the Implementation Report and have made a reasonable inquiry regarding its content and believe that the information is accurate and truthful.

**B. Annual Reports**

Catucci and Acosta shall submit to OIG Annual Reports with respect to the status of, and findings regarding, their compliance activities for each of the three 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 Catucci and Acosta's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;

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4. 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. a description of any changes to the Arrangements Database required by Section III.E.1.a;
7. a description of any changes to the internal review and approval process required by Section III.E.1.e;
8. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.E.1;
9. a complete copy of all reports prepared pursuant to Section III.F, along with a copy of the IRO's engagement letter (if applicable);
10. Catucci and Acosta's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.F;
11. a summary and description of any and all current and prior engagements and agreements between Catucci and Acosta and the IRO, if different from what was submitted as part of the Implementation Report;
12. a certification from the IRO regarding its professional independence and objectivity with respect to Catucci and Acosta;
13. a description of Catucci and Acosta's process to screen Screened Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
14. a summary of personnel actions involving Ineligible Persons, other than hiring, taken pursuant to Section III.G; the name, titles, and responsibilities of any person who is determined to be an Ineligible Person

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under Section III.G; and Catucci and Acosta's actions taken in response to the obligations set forth in Section III.G;

15. 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;

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

17. 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;

18. a description of all changes to the most recently provided list of Catucci, Acosta, and Catucci's medical practice's business 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;

19. if Catucci and/or Acosta 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, Catucci and/or Acosta shall inform OIG of the name, location, relationship, and their responsibilities with respect to Catucci and/or Acosta's employment or contract;

20. 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.C, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C;

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

c. all Screened Persons that were hired, engaged or otherwise involved with Catucci and Acosta 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 Catucci and Acosta, as required by Section III.G; and

d. all Screened Persons were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.G and the date(s) they were screened;

21. a certification signed by Catucci and Acosta certifying that (a) to the best of their knowledge, except as otherwise described in the applicable Report, Catucci and Acosta are in compliance with all of the requirements of this Agreement and (b) Catucci and Acosta have reviewed the Annual Report and have 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**

Catucci and Acosta shall clearly identify any portions of their submission that they believe 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. Catucci and Acosta 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:

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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, D.C. 20201  
Telephone: (202) 619-2078  
Facsimile: (202) 205-0604

Catucci and Acosta:

**[Compliance Contact]**  
**[Address]**  
**[City, State Zip]**  
**[Telephone:]**  
**[Facsimile:]**

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 Catucci and/or Acosta's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Catucci and/or Acosta's locations for the purpose of verifying and evaluating: (a) Catucci and/or Acosta's compliance with the terms of this Agreement; and (b) Catucci and/or Acosta's compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Catucci and/or Acosta 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 Catucci and/or Acosta'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. Catucci and Acosta shall assist OIG or its duly authorized

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

**VIII. DOCUMENT AND RECORD RETENTION**

Catucci and/or Acosta 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 Catucci and Acosta prior to any release by OIG of  
information submitted by Catucci and Acosta pursuant to its obligations under this  
Agreement and identified upon submission by Catucci and Acosta as trade secrets, or  
information that is commercial or financial and privileged or confidential, under the  
FOIA rules. With respect to such releases, Catucci and Acosta shall have the rights set  
forth at 45 C.F.R. § 5.65(d).

**X. BREACH AND DEFAULT PROVISIONS**

Catucci and Acosta are expected to fully and timely comply with all of their  
Agreement obligations.

**A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Catucci and Acosta 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 Catucci and/or Acosta fail to:

- a. have a Compliance Contact in accordance with the requirements of  
Section III.A;

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- b. establish and/or post a notice in accordance with the requirements of Section III.B;
- c. 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. engage an IRO in accordance with the requirements of Section III.F and Appendix B;
- f. submit the IRO's annual Arrangements Review Report in accordance with the requirements of Section III.F;
- g. establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.E.1 and III.E.2;
- h. obtain and/or maintain the following documentation: Policies and Procedures certifications 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.G.2;
- i. screen Screened Persons in accordance with the requirements of Section III.G; or require Screened Persons to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.G; or
- j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.H.

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 Catucci and/or Acosta fail to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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3. A Stipulated Penalty of \$750 for each day Catucci and/or Acosta fail to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Catucci and/or Acosta fail to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Catucci and/or Acosta as part of their 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 Catucci and/or Acosta fail to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Catucci and/or Acosta stating the specific grounds for its determination that they have failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Catucci and/or Acosta shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Catucci and/or Acosta receive 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**

Catucci and Acosta 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 Catucci and/or Acosta fail 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 Catucci and/or Acosta receive 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 Catucci and/or Acosta have failed to comply with any of the obligations described in Section X.A and after determining that

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Stipulated Penalties are appropriate, OIG shall notify Catucci and/or Acosta of: (a) Catucci and/or Acosta'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, Catucci and/or Acosta 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 Catucci and/or Acosta elect to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Catucci and/or Acosta cure, 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 Catucci and/or Acosta have 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 Catucci and/or Acosta to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;

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

d. a failure to conduct an Arrangements Review in accordance with Section III.F.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Catucci and/or Acosta constitutes an independent basis for Catucci and/or Acosta's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Catucci and/or Acosta have materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Catucci and/or Acosta of: (a) Catucci and/or Acosta'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. Catucci and/or Acosta 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. Catucci and/or Acosta are 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) Catucci and/or Acosta have begun to take action to cure the material breach; (ii) Catucci and/or Acosta are pursuing such action with due diligence; and (iii) Catucci and/or Acosta have provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Catucci and/or Acosta fail to satisfy the requirements of Section X.D.3, OIG may exclude Catucci and/or Acosta from participation in the Federal health care programs. OIG shall notify Catucci and/or Acosta in writing of its determination to exclude Catucci and/or Acosta (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 Catucci and/or Acosta'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, Catucci and/or Acosta 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 Catucci and/or Acosta 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, Catucci and/or Acosta 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 Catucci and/or Acosta were in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Catucci and/or Acosta 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 Catucci and/or Acosta to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Catucci and/or Acosta 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 Catucci and/or Acosta were in material breach of this Agreement;

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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) Catucci and/or Acosta had begun to take action to cure the material breach within that period; (ii) Catucci and/or Acosta have pursued and are pursuing such action with due diligence; and (iii) Catucci and/or Acosta provided to OIG within that period a reasonable timetable for curing the material breach and Catucci and/or Acosta have 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 Catucci and/or Acosta, only after a DAB decision in favor of OIG. Catucci and/or Acosta's election of their contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Catucci and/or Acosta 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 Catucci and/or Acosta 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. Catucci and/or Acosta shall waive their 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 Catucci and/or Acosta, Catucci and/or Acosta 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, Catucci and Acosta and OIG agree as follows:

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

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B. The obligations set forth in this Agreement are binding on Catucci and Acosta in their individual capacities.

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

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

E. OIG may agree to a suspension of Catucci and/or Acosta's obligations under this Agreement in the event of Catucci and/or Acosta's cessation of participation in Federal health care programs. If Catucci and/or Acosta withdraws from participation in Federal health care programs and is relieved of their Agreement obligations by OIG, Catucci and/or Acosta shall notify OIG 30 days in advance of Catucci and/or Acosta'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.

F. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Catucci and Acosta'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.


G. The undersigned Catucci and Acosta 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.

H. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

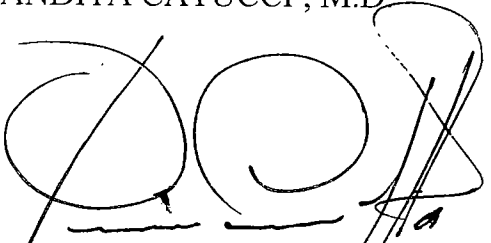
IN WITNESS WHEREOF, the parties hereto affix their signatures:

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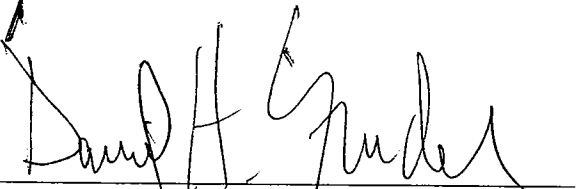
ON BEHALF OF CANDITA CATUCCI, M.D., AND JUAN CARLOS ACOSTA

  
CANDITA CATUCCI, M.D.

3-14-07  
Date

  
JUAN CARLOS ACOSTA

03/14/07.  
Date

  
DAVID H. GENDELMAN, ESQ.  
Counsel for Candita Catucci, M.D. and  
Juan Carlos Acosta

3-14-07  
Date

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



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GREGORY E. DEMSKE  
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

3/29/07

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Date

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## APPENDIX A

### ARRANGEMENTS DATABASE

Catucci and Acosta shall create and maintain an Arrangements Database to track all new and existing Arrangements in order to ensure that each Arrangement does not violate the Anti-Kickback Statute and Stark Law. The Arrangements Database shall contain certain information to assist Catucci and Acosta in evaluating whether each Arrangement violates the Anti-Kickback Statute and Stark Law, including but not limited to the following:

1. Each party involved in the Arrangement;
2. The type of Arrangement (e.g., physician employment contract, medical directorship, lease agreement);
3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;
4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid;
5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;
6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;
7. Whether each party has fulfilled the requirements of Section III.E.2; and
8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor and/or a Stark Law exception or safe harbor, as applicable.

**APPENDIX B  
INDEPENDENT REVIEW ORGANIZATION**

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.F of the Agreement.

A. IRO Engagement.

Catucci and Acosta shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and/or objective fashion, as set forth in Paragraph D. Within 30 days after the OIG receives written notice of the identity of the selected IRO, the OIG will notify Catucci and Acosta if the IRO is unacceptable. Absent notification from the OIG that the IRO is unacceptable, Catucci and Acosta may continue to engage the IRO.

If Catucci and Acosta engage a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Catucci and Acosta shall submit the information identified in Section V.A.8 of the Agreement to the OIG within 30 days of engagement of the IRO. Within 30 days after the OIG receives written notice of the identity of the selected IRO, the OIG will notify Catucci and Acosta if the IRO is unacceptable. Absent notification from the OIG that the IRO is unacceptable, Catucci and Acosta may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Arrangements Review who have expertise in the subject matter of the review the IRO is being engaged to perform and in the general requirements of the Federal health care program(s) from which HealthSouth seeks reimbursement; and

2. have sufficient staff and resources to conduct the review required by the Agreement on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the Agreement;

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2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by the Agreement.

D. IRO Independence/Objectivity.

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Catucci and/or Acosta.

E. IRO Removal/Termination.

1. *Catucci and Acosta.* If Catucci and Acosta terminate their IRO during the course of the engagement, Catucci and Acosta must submit a notice explaining their reasons to the OIG no later than 30 days after termination. Catucci and Acosta must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event the OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, the OIG may, at its sole discretion, require Catucci and Acosta to engage a new IRO in accordance with Paragraph A of this Appendix.

Before requiring Catucci and Acosta to engage a new IRO, the OIG shall notify Catucci and Acosta of its intent to do so and provide a written explanation of why the OIG believes such a step is necessary. To resolve any concerns raised by the OIG, Catucci and Acosta may request a meeting with the OIG to discuss any aspect of the IRO's qualifications, independence, or performance of its responsibilities and to present additional information regarding these matters. Catucci and Acosta shall provide any additional information as may be requested by the OIG under this Paragraph in an expedited manner. The OIG will attempt in good faith to resolve any differences regarding the IRO with Catucci and Acosta before requiring Catucci and Acosta to terminate the IRO. However, the final determination as to whether or not to require Catucci and Acosta to engage a new IRO shall be made at the sole discretion of the OIG

**APPENDIX C**  
**OVERPAYMENT REFUND**

**TO BE COMPLETED BY MEDICARE CONTRACTOR**

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

**TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER**

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

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

**REFUND INFORMATION**

**For each Claim, provide the following:**

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

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

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

**For Institutional Facilities Only:**

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

**For OIG Reporting Requirements:**

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

**Reason Codes:**

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

JCA  
C-C