EXHIBIT A

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
NICKOLAS JOHN COLLUCCI, D.O., P.A.

I. PREAMBLE

Nickolas John Collucci, D.O., P.A. ("Practitioner" and/or "Collucci") hereby enters into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance with the statutes, regulations, program requirements and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements") by Collucci. This commitment to promote compliance applies to any entity that Collucci owns or in which Collucci has a control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), and Collucci's and any such entity's employees, agents, contractors and all third parties with whom Collucci or such entity may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs, and all other individuals responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services ("Covered Persons"). Contemporaneously with this Agreement, Collucci is entering into a Settlement Agreement with the OIG, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Collucci under this Agreement shall be five (5) years from the effective date of this Agreement. The effective date of this Agreement shall be the date on which the final signatory of this Agreement executes this Agreement.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by Practitioner pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

Collucci hereby agrees to establish and maintain a Compliance Program that, at minimum, includes the following elements:

A. Compliance Contact

Within 30 days of execution of this Agreement, Collucci shall designate a person to be the Compliance Contact for purposes of developing and implementing policies, procedures and practices designed to ensure compliance with the obligations herein and with Federal health care program requirements. In addition, the Compliance Contact is responsible for responding to questions and concerns from Covered Persons and the OIG regarding compliance with the Agreement obligations. The name and phone number of the Compliance Contact shall be included in the Implementation Report. In the event a new Compliance Contact is appointed during the term of this Agreement, Collucci shall notify the OIG, in writing, within 15 days of such a change.

B. Posting of Notice

Within the first 30 days following the effective date of this Agreement, Collucci shall post in a prominent place accessible to all patients and Covered Persons a notice detailing his commitment to comply with all Federal health care program requirements in the conduct of his business. This notice shall include a means (i.e., telephone number, address, etc.) by which instances of misconduct may be reported anonymously. A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days of the effective date of this Agreement, Collucci agrees to develop, implement, and make available to all Covered Persons written policies that address the following:

1. Collucci's commitment to operate his business in full compliance with all Federal health care program requirements.

2. The proper procedures for the honest and accurate submission of claims in accordance with Federal health care program requirements.

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

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

5. The requirement that Collucci not hire, employ or engage as an employee or contractor any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, Collucci shall check all prospective employees and contractors prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

6. The commitment of Collucci 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.

7. The commitment of Collucci and all Covered Persons that he or they will not offer or pay remuneration to induce the referral of Federal health care program patients or business.

8. The requirement that Collucci (and all Covered Persons) shall not offer, pay, solicit, or receive any remuneration to or from individual or entity who may be in a position to refer Federal health care program patients or business to Collucci (or receive such referrals from Collucci) unless the offer, payment, solicitation, or receipt is made

under a written arrangement that has been reviewed by an attorney with expertise in legal requirements relevant to such transactions, e.g., 42 U.S.C. §§ 1320a-7b(b) and 1395nn. Collucci shall maintain written records of all such transactions, including the amounts, dates, and reasons for each such transaction. Such records shall be available to the OIG upon request. Collucci shall certify in the Annual Report that he is in compliance with the requirements of this provision.

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

Within 90 days of the effective date of the Agreement and annually thereafter, each Covered Person shall certify in writing that he or she has read, understood, and will abide by Collucci's Policies and Procedures. New Covered Persons shall review the Policies and Procedures and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the Agreement, whichever is later.

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

D. Training and Certification

Within 90 days following the effective date of this Agreement and at least once each year thereafter, Collucci and Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive at least 8 training hours from an individual or entity, other than Collucci or another Covered Person. The training shall be conducted by individuals with expertise in the relevant subject areas, e.g., preparation or submission of claims to Federal health care programs for the types of services provided by Collucci.

New Covered Persons involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program shall receive the training described above within 30 days after becoming a Covered Person or within 90 days of the effective date of this Agreement,

whichever is later. The training for New Covered Persons may either be provided internally by a qualified Covered Persons who has completed the required annual training and is proficient with the training material or externally by a qualified individual or entity. Until they have received the requisite training, such New Covered Persons shall work under the direct supervision of a Covered Person who has received such training.

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

1. Federal health care program requirements related to the proper submission of accurate bills for services rendered and/or items provided to Federal health care program patients;

2. The written Policies and Procedures developed pursuant to Section III.C, above;

3. The legal sanctions for improper billing or other violations of the Federal health care program requirements;

4. Examples of proper and improper billing practices; and

5. The legal sanctions under the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), for the payment or receipt of remuneration to induce or in exchange for the referral of Federal health care program patients or business and the requirements of and legal sanctions under The Stark Law, 42 U.S.C. § 1395nn.

Each Covered Person shall annually certify in writing that he or she has received the required training. The certification shall specify the type of training received and the date received. Collucci shall retain the certifications, along with the training course materials. The training course materials shall be provided in the Annual Report.

E. <u>Reporting of Overpayments and Material Deficiencies</u>

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money Collucci has received in excess of the amount due and payable under any Federal

health care program requirements. Collucci may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this Agreement.

b. Reporting of Overpayments. If, at any time, Collucci identifies or learns of any overpayments, he shall notify the payor within 30 days of identification of the overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, Collucci shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, Collucci shall notify the payor of his efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form.

2. *Material Deficiencies.*

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

(i) a substantial overpayment; or

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

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

b. Reporting of Material Deficiencies. If Collucci determines, by any means, that there is a Material Deficiency, he shall notify OIG, in writing, within 30 days of making the determination that the

Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.E.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

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

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

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

F. <u>Notification of Government Investigations or Legal Proceedings</u>

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

IV. NEW BUSINESS UNITS OR LOCATIONS

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

V. REPORTS

A. Implementation Report

Within 120 days after the effective date of this Agreement, Collucci shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement. This report, known as the "Implementation Report," shall include:

1. The name and phone number of Collucci's Compliance Contact;

2. A copy of the notice Collucci posted in his office as described in Section III.B and a description of where and when the notice has been posted;

3. A copy of the written policies and procedures required by Section III.C of this Agreement;

4. A certification signed by Collucci attesting that the Policies and Procedures are being implemented and have been made available to all Covered Persons;

5. A description of the training required by Section III.D, including a summary of the topics covered and a schedule of when the training session(s) were held;

6. A certification signed by Collucci attesting that all employees have completed the initial training required by Section III.D and have executed the required certifications; and

7. A certification from Collucci stating that he has reviewed the Implementation Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

B. <u>Annual Reports</u>

Collucci shall submit to OIG Annual Reports with respect to the status of and findings regarding Collucci's compliance activities for each of the five years in one-year cycles beginning on the effective date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period"). The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

Each Annual Report shall include:

1. If revisions were made to the written policies and procedures developed pursuant to Section III.C of this Agreement, a copy of any policies and procedures that were revised;

2. A certification by Collucci that all Covered Persons have executed the annual Policies and Procedures certification required by Section III.C;

3. A schedule, topic outline and copies of the training materials for the training programs attended in accordance with Section III.D of this Agreement;

4. A certification signed by Collucci certifying that he is maintaining written certifications from all Covered Persons that they received training pursuant to the requirements set forth in Section III.D of this Agreement;

5. A summary of any Material Deficiencies (as defined in Section III.E) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

6. A summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.F. 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;

7. A certification from Collucci that: (1) he has not offered, paid, solicited, or received any remuneration to or from any health care provider who may be in a position to refer Federal health care program patients or business to Collucci (or receive such referrals from Collucci) unless the offer, payment, solicitation, or receipt was made under a written arrangement that was reviewed by an attorney with expertise in legal requirements relevant to such transactions, e.g., 42 U.S.C. §§ 1320a-7b(b) and 1395nn; and (2) he has maintained all written records relevant to such transactions, including the amounts, dates, and reasons for each such transaction.

8. A certification signed by Collucci certifying that all prospective employees and contractors are being screened against the HHS/OIG List of Excluded Individuals/Entities and the General Services Administration's List of Parties Excluded from Federal Programs; and

9. A certification signed by Collucci certifying that he has reviewed the Annual Report, he has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated subsequent to the execution of this Agreement, all notifications and reports required under the terms of this Agreement shall be submitted to the following:

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

If to Collucci: Ellis Faught, Jr., Esq.
Attorney At Law
206 Mason Street
Brandon, Florida 33511
Ph. 813.681.4246
Fax 813.684.5922

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

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Collucci shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Collucci.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

1. A Stipulated Penalty of $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Collucci:

   a. Fails to have in place a Compliance Contact as required in Section III.A;

   b. Fails to post the notice required in Section III.B;

   c. Fails to have in place and comply with the Policies and Procedures required in Section III.C;

d. Or each applicable Covered Person fails to attend the training required by Section III.D of this Agreement within the time frames required in that section; or

e. Fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

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

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

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

B. <u>Timely Written Requests for Extensions</u>

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

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, Collucci shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of his corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Collucci elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Collucci 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 Collucci 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 Collucci to report a material deficiency, take corrective action and make the appropriate refunds, as required in Section III.E;

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; or

d. failure to comply with the policy described in Section III.C.8.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Collucci constitutes an independent basis for Collucci's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Collucci has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Collucci of: (a) his 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.* Collucci 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. Collucci is in compliance with the obligations of the Agreement cited by the OIG as being the basis for the material breach;

b. the alleged material breach has been cured; or

c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Collucci has begun to take action to cure the material breach; (ii) Collucci is pursuing such action with due

diligence; and (iii) Collucci has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Collucci fails to satisfy the requirements of Section X.D.3, OIG may exclude Collucci from participation in the Federal health care programs. OIG will notify Collucci in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, Collucci wishes to apply for reinstatement, Collucci must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

1. *Review Rights.* Upon OIG's delivery to Collucci 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, Collucci 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Collucci was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Collucci shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Collucci to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless

Collucci 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 Collucci 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) Collucci had begun to take action to cure the material breach within that period;

(ii) Collucci has pursued and is pursuing such action with due diligence; and

(iii) Collucci provided to OIG within that period a reasonable timetable for curing the material breach and he 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 Collucci, only after a DAB decision in favor of OIG. Collucci's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude him 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 Collucci 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. Collucci agrees to waive his right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ

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, Collucci and the OIG agree as follows:

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

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

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

4. If Collucci does not own or have a control interest in an entity, as defined in 42 U.S.C. § 1320a-3(a)(3), that provides items or services to Federal health care program beneficiaries, and is a bona fide employee of another company, Collucci is only required to annually submit a notarized certification to the OIG stating: Collucci certifies that the only income he receives related to the treatment of Federal health care program beneficiaries is through a bona fide employee relationship;

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

6. The undersigned signatories for Collucci 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:

NICKOLAS JOHN COLLUCCI, D.O., P.A.

5/24/2001
Date

Nickolas John Collucci, D.O., P.A.

5-24-2001
Date

Ellis Faught, Jr., Esq.
206 Mason Street
Brandon, Florida 33511
Ph. 813.681.4246
Fax 813.684.5922

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

6-5-01
Date

D. McCarty Thornton
Chief Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health & Human Services
Room 5527, Cohen Bldg.
330 Independence Ave., S.W.
Washington, D.C. 20201