EXHIBIT B

INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ANGELO LUZZI, D.P.M.

I. PREAMBLE

Angelo Luzzi, D.P.M. ("Luzzi") hereby agrees to enter into this Integrity Agreement ("Agreement") with the Office of Inspector General of the United States Department of Health and Human Services ("OIG") to provide for the establishment of certain integrity measures to ensure compliance with the requirements of Medicare, Medicaid and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) by Luzzi, Luzzi's employees and agents, any entity in which Luzzi is an owner or has a control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)), and all third parties with whom Luzzi may choose to engage to act as billing or coding consultants for purposes of claiming reimbursement from the Federal health care programs. Luzzi's compliance with the terms and conditions of this Agreement shall constitute an element of Luzzi's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Luzzi is entering into a Settlement Agreement with the United States. This Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

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

III. INTEGRITY OBLIGATIONS

Within thirty (30) days of the date of the effective date of this Agreement, Luzzi agrees to implement an Integrity Program (the "Program"), which shall include the following provisions:

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A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Agreement, Luzzi shall designate a person to be the contact person for purposes of the obligations herein. At all times during the term of this Agreement, there shall be a contact person who shall have operational responsibility for ensuring compliance with the integrity obligations in this Agreement. If a new contact person is designated during the term of this Agreement, Luzzi shall notify the OIG, in writing, within ten (10) days of such a change.

B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this Agreement, Luzzi shall post in a prominent place accessible to all patients and employees a notice detailing his commitment to comply with applicable statutes, regulations and written directives applicable to the Medicare, Medicaid and other Federal health care programs in the conduct of his medical practice and in seeking reimbursement for services and items furnished to patients of the Federal health care programs. This notice shall identify a means (i.e., telephone number, address, etc.) through which matters of concern can be reported anonymously.

C. WRITTEN POLICIES AND PROCEDURES

Luzzi agrees to develop and implement written policies and procedures within sixty (60) days of the effective date of this Agreement, which written policies and procedures shall address the following:

a. Luzzi's commitment to adhere to honest and accurate billing practices; and

b. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;

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

d. A mechanism for employees and agents to make inquiries regarding compliance with medical practice standards and Federal health care program reimbursement standards without risk of retaliation or other

adverse effect;

e. Luzzi's commitment not to hire or engage as contractors any Ineligible Person. For purposes of this Agreement, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

D. TRAINING AND CERTIFICATION

Within ninety (90) days of the effective date of this Agreement, Luzzi, Luzzi's employees and anyone else engaged by Luzzi to prepare or submit claims for reimbursement to the Federal health care programs shall be trained in the proper reimbursement standards, program policies, and verification and compliance procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal health care programs patients. The training shall be designed to ensure that Luzzi and all of his employees and agents are aware of all applicable Federal health care program statutes, regulations and guidelines and the consequences (e.g., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal health care programs) both to the individual and Luzzi that may ensue from any violation of such requirements.

Luzzi agrees to arrange for each new employee to participate in such training no later than fifteen (15) days after the person begins to work for Luzzi. Until the person has received the requisite training, such new employee shall work under the direct supervision of an employee who has received the required training.

This training program shall provide for no less than four (4) hours of training annually for each person.

At a minimum, the training sessions shall cover the following topics:

1. Luzzi's obligations under this Agreement;

2. All applicable Federal health care program statutes, rules, regulations, and

guidelines related to reimbursement, and the legal sanctions for improper billing or other violations of these standards; and

3. The written policies and procedures developed pursuant to subsection C. above, including the proper billing standards and procedures for the submission of accurate claims to the Medicare, Medicaid and other Federal health care programs.

Luzzi and each employee and agent shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the policies and procedures and all applicable Federal health care program standards addressed in training. These certifications will be maintained by Luzzi and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be kept with the certifications.

E. INDEPENDENT REVIEWS

On at least an annual basis and for the duration of this Agreement, Luzzi agrees to contract with an independent third-party reviewer (e.g., a health care billing auditor or a consultant) (hereinafter the "independent reviewer") to undertake a review of a statistically valid sample of the claims submitted by Luzzi and his agents and/or employees to the Federal health care programs. The purpose of this review is determine whether the claims are in compliance with the appropriate billing requirements. This review will be conducted by an independent and appropriately trained person or entity with knowledge of Federal health care program statutes, regulations, requirements, and reimbursement policies and procedures. These reviews shall cover, at a minimum, the preceding one (1) year period and shall seek to determine that the claims submitted to the Federal health care programs are medically necessary and covered services under applicable program guidelines and that the claims are appropriately coded and billed. At the conclusion of each review, the independent reviewer shall prepare a report describing the review's parameters, methodologies and procedures, as well as presenting the review findings and the reviewer's conclusions and recommendations. A copy of this report shall be included in Luzzi's Annual Reports to OIG.

If any of these reviews uncovers claims processing and/or billing policies, procedures or practices that result in material deficiencies, Luzzi shall notify the

entity in charge of processing the claim for reimbursement (such as the Medicare carrier or other federal health care payor), within fifteen (15) days of discovering the deficiency and take remedial steps within thirty (30) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency from recurring.

Contemporaneous with Luzzi's notification to the payor as provided above, Luzzi shall notify OIG of: (1) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Luzzi's findings concerning the material deficiency; (4) Luzzi's actions to correct such material deficiency; and (5) any further steps Luzzi plans to take to address such material deficiency and prevent it and similar billing deficiencies from recurring.

For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment relating to the Federal health care programs; (ii) conduct that impairs the financial integrity of the Federal health care programs and that clearly violate the Federal health care program statutes, regulations or written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents; or (iii) serious quality of care implications for Federal health care program patients. A material deficiency may be the result of an isolated event or a series of occurrences.

If Luzzi learns of any overpayment (regardless of its size and regardless of whether it results from a material deficiency) received from a Federal health care program, Luzzi shall notify the appropriate payor, make appropriate refunds and take any steps necessary to prevent any recurrence.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

During the term of this Agreement, Luzzi agrees to report to OIG any reliable evidence of actions or omissions by Luzzi and/or his employees and agents (acting within the scope of employment or agency) that Luzzi believes may constitute a probable violation of any state or Federal criminal, civil or administrative statute, regulation, or rule governing a Federal health care program. Luzzi must make the required disclosure no later than forty-five (45) calendar days after becoming aware of the existence of the probable violation.

Any disclosures made pursuant to this paragraph shall contain a certification by

Luzzi that the matter at issue has been fully investigated and that appropriate corrective actions have been taken to ensure compliance with all state and Federal civil, criminal, and administrative statutes, regulations and rules governing all Federal health care programs. Nothing in this paragraph waives OIG's right to enforce any and all statutes and regulations governing any Federal health care program, subject to the release provisions of the Stipulation and Order of Settlement and Dismissal into which this Agreement is incorporated by reference.

V. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other right OIG may have by statute, regulation, contract or pursuant to this Agreement, OIG or its duly authorized representative(s) may examine Luzzi's books, records, and other documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) Luzzi's compliance with the terms of this Agreement; and (ii) Luzzi's compliance with the requirements of the Federal health care programs. OIG, HCFA, or the appropriate Federal health care program contractor may conduct unannounced on-site visits at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Luzzi's compliance with the statutory and regulatory requirements of the Federal health care programs.

VI. REPORTS

A. IMPLEMENTATION REPORT

Within one hundred twenty (120) days of the effective date of this Agreement, Luzzi shall provide the OIG with a written report demonstrating that he has complied with the Program's requirements. This report, known as the "Implementation Report," shall include:

1. A copy of the notice Luzzi posted in his office as described in Section III.B.

2. A certification signed by Luzzi attesting that all employees have completed the initial training required by Section III.D. as well as a summary of what the training included. The training materials will be made available to OIG upon request.

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

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

B. ANNUAL REPORTS

Luzzi agrees to make annual written reports (each one of which is referred to throughout this Agreement as the "Annual Report") to OIG describing the measures he has taken to implement and maintain the Program and ensure compliance with the terms of this Agreement. In accordance with the provisions above, the Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented pursuant to section III.D. of this Agreement, and a written certification from all appropriate personnel that they received training pursuant to the requirements set forth in section III.D. of this Agreement.

2. A copy of the audits and reviews conducted pursuant to section III.E. of this Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; copies of any disclosure notice documents made by Luzzi pursuant to this section; and any corrective actions taken.

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

The first Annual Report shall be submitted no later than one year and thirty (30) days after the effective date of this Agreement. Subsequent Annual Reports will be submitted on the anniversary date of the date of submission of the first Annual Report.

VII. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with section IX below, all notifications and reports required under the terms of this Agreement shall be submitted to the entities listed below:

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If to 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
Tel. 202.619.2078
Fax 202.205.0604

If to Luzzi: Angelo Luzzi, D.P.M.
2 Hidden Acres Drive
Voorhees, NJ 08043
Tel. 609.772.6311

VIII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Luzzi shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Luzzi. In the event of Luzzi's failure to comply with any of the obligations in this Agreement, the Agreement may be deemed in breach and the parties shall proceed in the appropriate manner as described below.

A. REMEDIES FOR MATERIAL BREACH OF THIS AGREEMENT

If Luzzi engages in conduct that OIG considers to be a material breach (as defined below) of this Agreement, OIG may determine to exclude Luzzi from participation in the Federal health care programs. Upon making its determination, OIG shall notify Luzzi of the alleged material breach by certified mail and of its intent to exclude as a result thereof (this notice shall be referred to hereinafter as the "Intent to Exclude Letter"). Luzzi shall have thirty-five (35) days from the date of the letter to:

(1) cure the alleged material breach; or

(2) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the thirty-five (35) day period, but that Luzzi has begun to take action to cure the material breach and that Luzzi will pursue such action with due diligence. Luzzi shall, at this time, submit a timetable for curing the material breach for the OIG's approval.

If at the conclusion of the thirty-five (35) day period (or other specific period as subsequently agreed by OIG and Luzzi), Luzzi fails to act in accordance with provisions 1 or 2 above, OIG may initiate steps to exclude Luzzi from participation in the Federal health care programs. OIG will notify Luzzi in writing of its determination to exclude him (this letter shall be referred to hereinafter as the "Exclusion Letter").

B. DISPUTE RESOLUTION

Upon OIG's delivery to Luzzi of its Exclusion Letter, and as an agreed upon contractual remedy for the resolution of disputes arising under the obligations in this Agreement, the OIG may initiate steps to exclude Luzzi from participation in the Federal health care programs. Luzzi shall be entitled to certain due process rights similar to those afforded under 42 U.S.C. § 1320a-7(f) and 42 C.F.R. § 1005. Specifically, the OIG's determination to seek exclusion shall be subject to review by a Department of Health and Human Services ("HHS") Administrative Law Judge ("ALJ") in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. The ALJ's decision, in turn, may be appealed to the HHS Departmental Appeals Board ("DAB") in a manner consistent with the provisions in 42 C.F.R. § 1005.21. OIG and Luzzi agree that the decision by the DAB, if any, shall constitute the final decision for purposes of the exclusion under this Agreement.

For purposes of this section, a "material breach" shall mean: (i) a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in section III.E of this Agreement; (ii) repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section VI.A, VI.B and IX. of this Agreement; or (iii) a failure to retain and use an independent reviewer for the purposes described in section III.E.

IX. NEW ENTITIES OR LOCATIONS

In the event that Luzzi purchases or establishes new business units after the effective date of this Agreement, Luzzi shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All employees at such locations shall be subject to the requirements in this Agreement that apply to new employees (e.g., completing certifications and undergoing training). Luzzi represents that to the extent legally

possible, he will sever all professional and financial relationships with Joseph Picciotti, D.P.M., and shall not enter into a new professional or financial relationship with Joseph Picciotti, D.P.M. during the term of this Agreement.

X. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Stipulation and Order of Settlement and Dismissal pursuant to which this Agreement is reached, and into which this Agreement is incorporated, Luzzi and OIG agree as follows:

1. this Agreement shall be binding on the successors, assigns and transferees of Luzzi who employ, contract with, or otherwise retain Luzzi for the purpose of rendering services for which reimbursement is sought from the Federal health care programs;

2. this Agreement shall become final and binding only upon signing by each respective party hereto; and

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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

FOR: ANGELO LUZZI, D.P.M.

Angelo Luzzi, D.P.M. — Date: 7-14-99

Counsel for Angelo Luzzi, D.P.M. — Date: 7/14/99

EXHIBIT B

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

Lewis Morris, Esquire
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

July 14, 1999
Date

AMENDMENT TO THE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ANGELO LUZZI, D.P.M.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Angelo Luzzi, D.P.M. ("Dr. Luzzi") entered into an Integrity Agreement ("IA") on July 15, 1999.

A. Pursuant to section X of Dr. Luzzi's IA, modifications to the IA may be made with the prior written consent of both the OIG and Dr. Luzzi. Therefore, the OIG and Dr. Luzzi hereby agree that Dr. Luzzi's IA will be amended as follows:

Section III.E., Independent Reviews of the IA is hereby superceded by the attached new section III.E., Review Procedures.

The attached Appendix A is hereby added to Dr. Luzzi's IA.

B. The OIG and Dr. Luzzi agree that all other sections of Dr. Luzzi's IA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Dr. Luzzi.

C. The undersigned Dr. Luzzi warrants that he is authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF DR. LUZZI

Angelo Luzzi, D.P.M.

6-20-02
DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

6/24/02
DATE

E. Review Procedures.

1. *General Description.*

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

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

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

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

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of Luzzi to Federal health care programs. The Paid Claims shall be reviewed based on the supporting documentation available at Luzzi or under Luzzi's control and applicable

billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.

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

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.E.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at Luzzi or under Luzzi's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, Luzzi may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from Luzzi to the appropriate Federal health care program payor, including the Medicare contractor (*e.g.*, carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

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

d. Repayment of Identified Overpayments and/or Material Deficiencies. If Luzzi learns of any overpayment (i.e., as a result of the Discovery Sample, Full Sample, or any other review undertaken to meet the terms of the Agreement) received from Federal health care program, Luzzi shall notify the entity in charge of processing the claim for reimbursement (such as the Medicare carrier or any other Federal health care program payor), within fifteen (15) days of discovering the deficiency and take remedial steps within thirty (30) days of discovering the deficiency (or such additional time as may be agreed to by the payor) to correct the problem, and prevent the deficiency form recurring.

Contemporaneous with Luzzi's notification to the payor as provided above, Luzzi shall notify OIG of: (I) all of the information provided to the payor in returning the overpayment; (2) the name and the address of the payor to which the overpayment was sent; (3) Luzzi's finding concerning the material deficiency; (4) Luzzi's actions to correct such material deficiency; and (5) any further steps Luzzi plans to take to address such material deficiency and prevent it and similar billing deficiencies from recurring.

Definition of Material Deficiency. For purposes of this Agreement, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment relating to the Federal health care programs; (ii) conduct that impairs the financial integrity of the Federal health care programs and that clearly violate the Federal health care program statutes, regulations or written directives issued by Centers for Medicare and Medicaid Services ("CMS") and/or its agents; or (iii) serious quality of care implications for Federal health care program patients. A material deficiency may be the results of an isolated event or a series of occurrences.

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

4. *Validation Review.* In the event the OIG has reason to believe that: (a) Luzzi's Claims Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complied with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate ("Validation Review"). Luzzi agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after Luzzi's final Annual Report and any additional information requested by the OIG is received by the OIG.

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

5. *Independence Certification.* The IRO shall include in its report(s) to Luzzi a certification or sworn affidavit that it has evaluated its professional independence with regard to the Claims Review and that it has concluded that it is, in fact, independent.

APPENDIX A

A. Claims Review.

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

a. Overpayment: The amount of money Luzzi has received in excess of the amount due and payable under any Federal health care program requirements.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Paid Claim: A code or line item submitted by Luzzi and for which Luzzi has received reimbursement from the Medicare program.

d. Population: All Items for which Luzzi has submitted a code or line item and for which Luzzi has received reimbursement from the Medicare and any other Federal health care program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Luzzi cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Luzzi for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

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

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

1. **Claims Review Methodology.**

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

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

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

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

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

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

2. **Statistical Sampling Documentation.**

a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.

b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. **Claims Review Findings.**

a. Narrative Results.

i. A description of Luzzi's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by Luzzi ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Luzzi.

iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

iv. Error Rate in the sample.

v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. **Systems Review.** Observations, findings and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

5. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.