

EXHIBIT A

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RICHARD WITLIN, M.D.**

I. PREAMBLE

Richard Witlin, M.D. ("Witlin") 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 Witlin, Witlin's employees and any entity which participates in the federal health care programs in which Witlin has an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)). Witlin's compliance with the terms and conditions of this Agreement shall constitute an element of Witlin's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Witlin 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 Witlin 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 ninety (90) days of the date of the effective date of this Agreement, Witlin agrees to implement an Integrity program (the "Program"), which shall include the following provisions:

A. COMPLIANCE CONTACT

Within fifteen (15) days of the effective date of this Agreement, Witlin 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, Witlin shall notify the OIG, in writing, within fifteen (15) days of such a change.

B. POSTING OF NOTICE

Within fifteen (15) days of the effective date of this agreement, Witlin 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

Witlin 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:

1. Witlin's commitment to adhere to honest and accurate billing practices;
2. The proper submission of claims to the Federal health care programs, including verification that all claims meet applicable reimbursement standards;
3. The proper documentation of services and billing information and the retention of such information in a readily retrievable form;
4. 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; and

5. Witlin'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, Witlin and Witlin's employees who are directly or indirectly involved in the preparation or submission of claims for reimbursement of the Federal health care programs ("Covered Employees") 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 program beneficiaries. The training shall be designed to ensure that Witlin and all Covered Employees 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 employee and to Witlin that may ensue from any violation of such requirements.

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

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

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

1. Witlin'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 III. 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.

Witlin and each Covered Employee 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 developed in accordance with paragraph III. C. of this Agreement and all applicable Federal health care program statutes, regulations and program requirements addressed in the training. These certifications will be maintained by Witlin 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. THIRD PARTY BILLING

Witlin presently employs a third party billing company to submit claims to the Federal health care programs. Witlin states that he does not have an ownership or control interest in the company and is not employed by, and does not act as a consultant to, the company. If Witlin intends to obtain an ownership or control interest in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, Witlin shall notify OIG thirty (30) days prior to any such proposed involvement.

Within thirty (30) days of the effective date of this Agreement, Witlin shall obtain and send to OIG a certification from his third party billing company that (i) it is presently in compliance with all applicable statutes, regulations and program requirements as they relate to submission of claims to the Federal health care programs, (ii) it is presently in compliance with all applicable statutes, regulations and program requirements as they relate to submission of claims to the Federal health care programs; (iii) it has a policy of not knowingly employing any person who has been excluded, debarred, suspended or declared ineligible to participate in Medicare or other Federal health care programs, and who has not yet been reinstated to participate in those programs; and (iv) it provides at least four (4) hours of training per year in billing and coding related to the Medicare and other Federal health care programs for those employees involved in the preparation and submission of claims to those programs. If Witlin contracts with a new third party billing company during the term of this Agreement, Witlin shall, within thirty (30)

days of entering into such contract, obtain and send to OIG the certification described in this paragraph.

F. **INDEPENDENT REVIEWS**

On at least an annual basis and for the duration of this Agreement, Witlin 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 to the Medicare and other Federal health care programs by Witlin or by any third party billing company on behalf of Witlin. The purpose of these reviews is to determine whether the claims are in compliance with the appropriate billing requirements. These reviews will be conducted by an independent reviewer which is an 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. The reviews shall also determine whether appropriate equipment was available and operational for those services requiring such equipment. 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 Witlin's Annual Reports to OIG.

G. **REPORTING**

1. *Reporting of Overpayments.* If, at any time, Witlin determines that it has received an overpayment from a Federal health care program, Witlin shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering 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.
2. *Reporting of Material Deficiencies.* If, at any time, Witlin determines that there is a material deficiency and the material deficiency results in an overpayment, Witlin shall notify the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the material deficiency and shall take remedial steps within 60 days (or such additional time as may be agreed to by the payor) to correct the problem, including steps to prevent the deficiency

from reoccurring. The notice to the payor should state that the repayment is being made in accordance with the terms of this CIA and should include:

- a. a description of the complete circumstances surrounding the overpayment;
- b. the methodology by which the overpayment was determined;
- c. the amount of the overpayment;
- d. any claim specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date); and
- e. the provider identification number under which the repayment is being made.

If Witlin determines that there is a material deficiency, Witlin shall notify the OIG within 30 days of discovering the material deficiency. Witlin's notification to the OIG shall include the following information; however, if the material deficiency does not involve an overpayment, the requirements of a. and b. below do not apply:

- a. all of the information provided to the payor in returning the overpayment;
- b. the name and the address of the payor where the overpayment was sent;
- c. a complete description of the material deficiency; including the relevant facts, persons involved, and legal and program authorities;
- d. Witlin's actions to correct such material deficiency; and
- e. any further steps Witlin plans to take to address such material deficiency and prevent it from reoccurring.

For purposes of this Agreement, an "overpayment" shall mean the amount of money the provider has received in excess of the amount due and payable under the federal health care programs' statutes, regulations or program directives, including carrier and intermediary instruction.

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.

IV. SELF-DISCLOSURE OF PROBABLE VIOLATIONS

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

Any disclosure made pursuant to this paragraph shall contain a certification by Witlin and 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 relating to Medicare and other Federal health care programs. Subject to the release provisions of the Settlement Agreement into which this Integrity Agreement is incorporated by reference, nothing in this paragraph shall be deemed to waive OIG's right to enforce any and all statutes and regulations related to any Federal health care program.

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 Witlin's books, records, and other documents and supporting materials in his possession or under his control for the purpose of verifying and evaluating: (i) within's compliance with the terms of this Agreement; and (ii) Within's compliance with the requirements of the Federal health care programs. OIG, or its duly authorized representative(s) may conduct unannounced on-site visits at his place of business at any time to review patient medical records and other related documentation for the purpose of verifying and evaluating Within's compliance with the statutory and regulatory requirements of the Federal health care programs.

VI. REPORTS

- A. Within one hundred twenty (120) days of the effective date of this Agreement, Witlin 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 Witlin posted in his office as described in Section III.B

2. A certification signed by Witlin attesting that all covered 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 II.C of this Agreement.
4. A certification from Witlin stating the 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

Witlin 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 Integrity Agreement and ensure compliance with the terms of this Agreement. 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 covered Employees that they received training pursuant to the requirements set forth in Section III.D. of this Agreement.
2. A copy of the annual review conducted pursuant to Section III.F. of this Agreement relating to the year covered by the Annual Report; a complete description of the findings made during the reviews; and any corrective actions taken.
3. A certification signed by Witlin 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 (1) 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. NOTIFICATION AND SUBMISSION OF REPORTS

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

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, D.C. 20201
Tel. (202) 619-2078
Fax (202) 205-0604

If to Witlin: Richard L. Friedman, Esq.
Giordano, Halleran & Ciesla, P.C.
125 Half Mile Road
P.O. Box 190
Middletown, NJ 07748
Tel. (732) 741-3900
Fax (732) 224-6599

VIII. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by Witlin shall be expected throughout the duration of this Agreement with respect to all of the obligations herein agreed to by Witlin. In the event of Witlin'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 Witlin engages in conduct that OIG considers to be a material breach (as defined below) of this Agreement, OIG may determine to exclude Witlin from participation in the Federal health care programs. Upon making its determination, OIG shall notify Witlin 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"). Witlin 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 Witlin has begun to take action to cure the material breach and that Witlin will pursue such action with due diligence. Witlin 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 Witlin), Witlin fails to act in accordance with provisions (1) or (2) above, OIG may initiate steps to exclude Witlin from participation in the Federal health care programs. OIG will notify Witlin 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 Witlin 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 Witlin from participation in the Federal health care programs. Witlin 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. §§ 1005.2-1005.21. 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. § 1005.21 OIG and Within agrees that the decision by the DAB, if any, shall constitute the final decision for purposes of the exclusion under this Agreement.

The review by an ALJ or the DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Witlin agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

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. G. of this Agreement; (ii) repeated or flagrant violation 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.F.

IX. NEW ENTITIES OR LOCATIONS

In the event that Witlin purchases or establishes new business units after the effective date of this Agreement, Witlin 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 Covered Employees at such locations shall be subject to the requirements in this Agreement that apply to new employee (e.g., completing certifications and undergoing training).

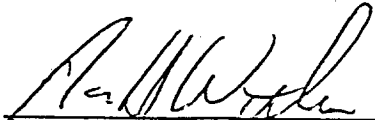
X. EFFECTIVE AND BINDING AGREEMENT

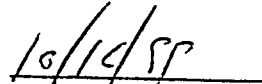
Consistent with the provisions in the Settlement Agreement to which this Integrity Agreement is incorporated by reference, Witlin and OIG agree as follows:

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

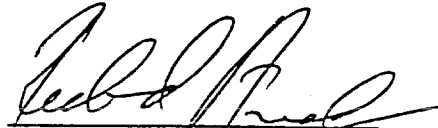
IN WITNESS WHEREOF, the parties hereto affix their signatures:

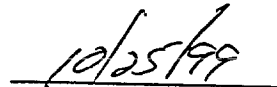
RICHARD WITLIN, M.D.


Richard Witlin, M.D.


Date

COUNSEL FOR RICHARD WITLIN, M.D.


Richard Friedman, Esq.
Giordano, Halleran & Ciesla
125 half Mile Road
Middletown, New Jersey 07748


Date

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

Lewis Morris, Esq.
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

IN WITNESS WHEREOF, the parties hereto affix their signatures:

RICHARD WITLIN, M.D.

Richard Witlin, M.D.


Date

COUNSEL FOR RICHARD WITLIN, M.D.

Richard Friedman, Esq.
Giordano, Halleran & Ciesla
125 half Mile Road
Middletown, New Jersey 07748

Date

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



Lewis Morris, Esq.
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

**AMENDMENT TO THE INSTITUTIONAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RICHARD S. WITLIN, M.D.**

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Richard S. Witlin, M.D. entered into an Corporate Integrity Agreement ("CIA") on November 15, 1999.

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

Section III.F., Independent Review, of the CIA is hereby superceded by the attached new section III.F., Review Procedures and Appendix A.

The attached Appendix A is hereby added to Dr. Witlin's CIA.

- B. The OIG and Dr. Witlin agree that all other sections of Dr. Witlin's CIA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and Dr. Witlin.
- C. The undersigned Dr. Witlin signatory represent and warrant 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.

F. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this Agreement, Witlin shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist Witlin or any third party billing company submitting claims on behalf of Witlin in assessing and evaluating its billing and coding practices and systems pursuant to this Agreement. Each IRO retained by Witlin shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to Witlin’s Agreement and in the general requirements of the Federal health care program(s) from which Witlin seeks reimbursement. Each IRO shall assess, along with Witlin, 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 Witlin’s and his third party billing company’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 Witlin 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 Witlin) related to the reviews.

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

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare and other Federal health care program Paid Claims

submitted by or on behalf of Witlin. The Paid Claims shall be reviewed based on the supporting documentation available at Witlin or under Witlin'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, Witlin should, as appropriate, further analyze any errors identified in the Discovery Sample. Witlin 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.F.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 Witlin or under Witlin'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, Witlin 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 Witlin 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 Witlin's Discovery Sample identifies an Error Rate of 5% or greater, Witlin'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 Witlin the IRO's observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

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) Witlin'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"). Witlin 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 Witlin'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 Witlin 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, Witlin 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. Witlin 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 Witlin 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 Witlin 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 Witlin 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 Witlin and for which Witlin has received reimbursement from the Medicare or other Federal health care programs.
- d. Population: All Items for which Witlin has submitted a code or line item and for which Witlin has received reimbursement from the Medicare and other Federal health care programs (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 Witlin cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Witlin 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 Witlin’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 Witlin (“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 Witlin.

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).

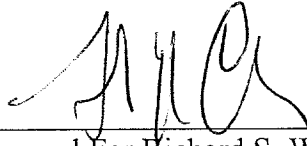
5. Credentials. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

ON BEHALF OF RICHARD S. WITLIN, M.D.



Richard S. Witlin, M.D.

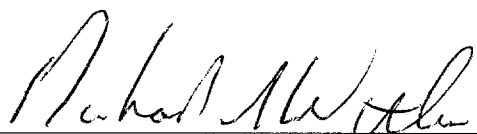
9/17/02
Date



Counsel For Richard S. Witlin, M.D.
Frank R. Ciesla, Esq.
Giordano, Halleran & Ciesla
125 Half Mile Road
Middletown, New Jersey 07748

9/30/02
Date

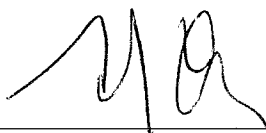
ON BEHALF OF RICHARD S. WITLIN, M.D.



Richard S. Witlin, M.D.

9/27/02

Date

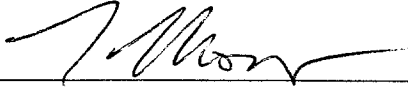


Counsel For Richard S. Witlin, M.D.
Frank R. Ciesla, Esq.
Giordano, Halleran & Ciesla
125 Half Mile Road
Middletown, New Jersey 07748

9/20/02

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

11/2/02
DATE