INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
VIRGILIO F. FLORESCA, M.D.

I. PREAMBLE

Virgilio F. Floresca, M.D. ("Dr. Floresca") agrees to enter into this Integrity Agreement ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to ensure his compliance with the requirements of Medicare, TRICARE and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))("Federal health care program requirements"). Dr. Floresca's compliance with the terms and conditions in this Agreement shall constitute an element of his present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this Agreement, Dr. Floresca and his co-defendants, Anesthesia & Analgesia Associates, P.A., Bobby L. Escoe, D.O., Lawrence Harris, M.D., Charles R. Pitluck, D.O., Diane J. Zeglinksi, M.D., Stephen F. Danese, and Robert T. Caleb are entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

Except as otherwise provided, the period of compliance obligations assumed by Dr. Floresca under this Agreement shall be 3 years from the effective date of this Agreement. The effective date of this Agreement will be the date on which the final signatory executes this Agreement ("effective date").

Sections VI, VII, VIII, IX and X shall remain in effect for purposes of compliance with this Agreement until OIG has completed its review of the final Annual Report and any additional materials submitted by Dr. Floresca pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

A. Employment Status

Dr. Floresca and his co-defendants Dr. Bobby L. Escoe and Dr. Diane J. Zeglinski

are currently members of a medical group known as Bay Area Anesthesia, L.L.C. ("BAA") located in Florida. The physicians and staff within BAA document and code their own services. BAA contracts with an outside billing company to then create and submit claims to the appropriate payors. If, at any time during the term of this Agreement, Dr. Floresca's employment status with BAA changes, Dr. Floresca must notify the OIG in writing of any change in his employment status within 30 days of any such change. Dr. Floresca acknowledges that any such change in employment status may result in the renegotiation of the terms of this Agreement, including the possible expansion of his integrity obligations under this Agreement. Renegotiation will not affect the 3-year term of the Agreement.

Based upon the current employment circumstances of Dr. Floresca as represented to the OIG, Dr. Floresca agrees to adhere to the following integrity provisions:

B. Written Policies and Procedures

BAA, of which Dr. Floresca is a member, has developed and implemented written policies and procedures designed to assure that all claims submitted to Federal health care programs are accurately coded and appropriately documented.

At least annually (and more frequently if appropriate), Dr. Floresca shall review the BAA Billing Compliance Program, which includes the following policies and procedures:

1) Standards of Conduct;
3) Acquisition and Maintenance of Third Party Payor Publications;
4) Anesthesia End Time;
5) Anesthesia Start Time;
6) Document Retention Policy;
7) Education;
8) Evaluation of Billing Practices;
9) Handling Reports of Wrongdoing;
10) Medical Necessity;
11) Monitored Anesthesia Care;
12) Personally Performed Cases;
13) Professional Courtesies and Waiver of Copayments and Deductibles;
14) Quarterly Audits of Employee Documentation and Billing Activities;
15) Resolving Billing and Coding Issues;

Dr. Floresca shall execute a signed and dated written certification specifying the titles of the policies and procedures reviewed and include such certification with each Annual

Report that is submitted to the OIG. Copies of the applicable policies and procedures shall be provided to the OIG upon request.

C. Training

Dr. Floresca shall receive no less than 4 hours of training annually on the following topics:

1. The Federal health care program requirements related to the proper and accurate coding and billing of claims for services rendered or items provided to Medicare, TRICARE and all other Federal health care program beneficiaries;

2. The proper documentation of services and billing information in accordance with the Federal health care program requirements; and

3. The legal sanctions for violating the Federal health care program requirements, including federal and state laws related to health care fraud and abuse.

It is Dr. Floresca's responsibility to ensure that he receives such training from an individual or entity with expertise in the relevant subject areas, e.g., documentation and submission of claims to Federal health care programs for the types of services provided by Dr. Floresca. Dr. Floresca shall include with each Annual Report a written certification to the OIG verifying that he has participated in such training along with a schedule and topic outline of all applicable training sessions attended. Training sessions provided by BAA may satisfy the training requirements if the training covers the aforementioned training topics. Copies of the training materials shall be provided to the OIG upon request.

D. Annual Review Procedures

1. *Scope of Obligations*. The obligations of this Section III.D. were determined based upon Dr. Floresca's representation that he and Drs. Escoe and Zeglinski are currently employed with BAA. The obligations of this Section III.D. apply to all claims submitted to the Medicare and TRICARE programs for items and services provided by Dr. Floresca.

2. *Independent Review Organization*. Dr. Floresca shall arrange for a person or entity, such as a nurse reviewer, accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to perform a billing review to assess Dr. Floresca's billing and coding practices ("Claims Review") with respect to claims submitted to the Medicare and TRICARE programs for items and services

provided by Dr. Floresca. The IRO retained by Dr. Floresca shall have expertise in the Medicare and TRICARE program requirements of the particular section of the health care industry pertaining to this Agreement.

3. *Frequency of the Claims Review.* The Claims Review shall be performed annually and shall cover each of the 3 one-year periods following the effective date of this Agreement. The IRO shall perform all components of each annual Claims Review in accordance with the procedures detailed in Appendix 1, which is attached to and incorporated by reference into this Agreement.

4. *Retention of Records.* It is Dr. Floresca's responsibility to retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the Claims Review.

5. *Validation Review.* In the event the OIG has reason to believe that: (a) Dr. Floresca's Claims Review fails to conform to the requirements of this Agreement or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review complies with the requirements of the Agreement and/or the findings or Claims Review results are inaccurate. Dr. Floresca 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 the final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify Dr. Floresca of its intent to do so and provide an explanation for believing why such a review is necessary. In order to resolve any concerns raised by the OIG, Dr. Floresca may request a meeting with the OIG to discuss the results of any Claims Review findings; present any additional or relevant information to clarify the results or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. Dr. Floresca 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 Dr. Floresca 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.

E. Reporting of Overpayments and Material Deficiencies

1. *Overpayments*

a. Definition of Overpayments. For purposes of this Agreement, an "overpayment" shall mean the amount of money Dr. Floresca or

BAA on Dr. Floresca's behalf has received in excess of the amount due and payable under any Federal health care program requirements. Dr. Floresca or BAA 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, Dr. Floresca is notified of, identifies or learns of any overpayments related to items or services he furnished, Dr. Floresca or his designee shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments 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, Dr. Floresca or his designee 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, Dr. Floresca or his designee shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix 2 to this Agreement.

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 probable 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 Dr. Floresca determines that there is a Material Deficiency, Dr. Floresca 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 Dr. Floresca's or his designee's actions taken to correct the Material Deficiency; and

(iv) any further steps Dr. Floresca or his designee plan to take to address the Material Deficiency and prevent it from recurring.

F. Notification of Government Investigations or Legal Proceedings

Within 30 days of discovery, Dr. Floresca 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 Dr. Floresca has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Dr. Floresca 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. ANNUAL REPORTS

Dr. Floresca shall submit to OIG Annual Reports with respect to the status of and findings regarding his compliance with the terms of this Agreement for each of the 3 one-year periods following 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 no later than the anniversary date of the due date for the first Annual Report.

Each Annual Report shall include:

A. A signed and dated written certification from Dr. Floresca specifying the titles of the BAA policies and procedures reviewed during the Reporting Period;

B. A certification signed by Dr. Floresca verifying that he has participated in at least 4 hours of training as specified in section III.C.;

C. A training schedule and topic outline of all training sessions attended pursuant to section III.C.;

D. A complete copy of the IRO's Claims Review report, including a copy of the methodology used;

E. Dr. Floresca's response and corrective action plan(s) related to any issues raised by the IRO;

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

G. 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; and

H. A certification signed by Dr. Floresca 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.

V. 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 entities listed below:

ATTN: Civil Recoveries Branch - Compliance Unit
Office of Counsel to the 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

All correspondence to Dr. Floresca shall be sent to:

Vicki Myckowiak, Esq.
Myckowiak Associates
1724 Ford Building
Detroit, MI 48226
Ph: 313.963.1002
Fax: 303.962.3779

VI. 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 or request copies of Dr. Floresca's books, records, and other documents and supporting materials, and/or conduct on-site reviews of any of Dr. Floresca's employment locations for the purpose of verifying and evaluating: (i) Dr. Floresca's compliance with the terms of this Agreement; and (ii) Dr. Floresca's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Dr. Floresca to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. It is Dr. Floresca's responsibility to take reasonable steps to ensure that the OIG or its duly authorized representative(s) is given access to Dr. Floresca's records, even if such records are kept by his current employer. Furthermore, for purposes of this provision, if Dr. Floresca directly or indirectly employs or contracts with individuals to assist him in his practice, the OIG or its duly authorized representative(s) may interview any of Dr.

Floresca's employees, contractors or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Dr. Floresca agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Dr. Floresca's employees may elect to be interviewed with or without a representative of Dr. Floresca present.

VII. DOCUMENT AND RECORD RETENTION

Dr. Floresca shall ensure that all documents and records relating to his reimbursement from the Federal health care programs or to his compliance with this Agreement are maintained for inspection for 4 years (or longer if otherwise required).

VIII. 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 Dr. Floresca prior to any release by OIG of information submitted by Dr. Floresca pursuant to his obligations under this Agreement and identified upon submission by Dr. Floresca as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Dr. Floresca shall have the rights set forth at 45 C.F.R. § 5.65(d). Dr. Floresca shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Dr. Floresca 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 Dr. Floresca:

a. Fails to provide the written certification required in section III.B.;

b. Fails to attend the training or provide the written certification required by section III.C.;

c. Fails to annually submit the IRO's Claims Review Report as required in section III.D and Appendix 1; or

d. Fails to meet any of the deadlines for the submission of the Annual Reports to OIG.

2. A Stipulated Penalty of $750 for each day Dr. Floresca fails to grant access to the information or documentation as required in section VI of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Dr. Floresca fails to grant access.)

3. A Stipulated Penalty of $750 for each day Dr. Floresca fails to comply fully and adequately with any obligation of this Agreement. In its notice to Dr. Floresca, OIG shall state the specific grounds for its determination that Dr. Floresca has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Dr. Floresca must take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to Dr. Floresca 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 1or 2 of this section.

B. Timely Written Requests for Extensions

Dr. Floresca 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 1 day after Dr. Floresca 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 3 business days after Dr. Floresca 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 5 business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Dr. Floresca has failed to comply with any of the obligations described in section IX.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Dr. Floresca of: (a) Dr. Floresca's 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, Dr. Floresca 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 IX.E. In the event Dr. Floresca elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Dr. Floresca 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 IX.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 V.

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

D. Exclusion for Material Breach of this Agreement

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

a. a failure by Dr. Floresca 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 IX.A;

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

d. a failure to retain and use an IRO in accordance with section III.D.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Dr. Floresca constitutes an independent basis for Dr. Floresca's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Dr. Floresca has materially breached this Agreement and that exclusion should be imposed, OIG shall notify Dr. Floresca of: (a) Dr. Floresca's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Dr. Floresca shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. Dr. Floresca 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) Dr. Floresca has begun to take action to cure the material breach; (ii) Dr. Floresca is pursuing such action with due diligence; and (iii) Dr. Floresca has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If at the conclusion of the 30-day period, Dr. Floresca fails to satisfy the requirements of section IX.D.3, OIG may exclude Dr. Floresca from participation in the Federal health care programs. OIG will notify Dr. Floresca in writing of its determination to exclude Dr. Floresca (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section IX.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, Dr. Floresca wishes to apply for reinstatement, Dr. Floresca must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Dr. Floresca of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Dr. Floresca 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 Dr. Floresca was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Dr. Floresca shall have the burden of proving his 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 Dr. Floresca to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Dr. Floresca requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

a. whether Dr. Floresca was in material breach of this Agreement;

b. whether such breach was continuing on the date of the Exclusion

Letter; and

c. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) Dr. Floresca had begun to take action to cure the material breach within that period;

(ii) Dr. Floresca has pursued and is pursuing such action with due diligence; and

(iii) Dr. Floresca provided to OIG within that period a reasonable timetable for curing the material breach and Dr. Floresca has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Dr. Floresca, only after a DAB decision in favor of OIG. Dr. Floresca's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Dr. Floresca upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Dr. Floresca may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Dr. Floresca 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.

X. EFFECTIVE AND BINDING AGREEMENT

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

(1) This Agreement shall be binding on Dr. Floresca regardless of his employment situation (e.g., whether he remains employed with BAA, changes employers, opens his own practice);

(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) OIG may agree to a suspension of Dr. Floresca's obligations under this Agreement in the event of Dr. Floresca's cessation of participation in Federal health care programs. If Dr. Floresca withdraws from participation in Federal health care programs and is relieved from his Agreement obligations by the OIG, Dr. Floresca agrees to notify the OIG 30 days in advance of Dr. Floresca'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 CIA should be reactivated or modified;

(5) The undersigned signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

VIRGILIO F. FLORESCA, M.D.

Date

Dr. Virgilio F. Floresca

Date

Vicki Myckowiak, Esq.
Counsel for Dr. Floresca

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

10/17/07
Date

Lewis Morris
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:

VIRGILIO F. FLORESCA, M.D.

11/15/01
Date

Dr. Virgilio F. Floresca

11/15/01
Date

Vicki Myckowiak, Esq.
Counsel for Dr. Floresca

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

Date

Lewis Morris
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

APPENDIX 1

A. Claims Review

1. ***Claims Review.*** The IRO shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by Dr. Floresca, or on Dr. Floresca's behalf, to the Medicare and TRICARE programs.

2. ***Claims Review Report.*** The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be submitted to the OIG in the Annual Report.

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

   a. Claims Review Sample: A statistically valid, randomly selected, sample of Items selected for appraisal in the Claims Review.

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

   c. Overpayment: Consistent with the definition of Overpayment as articulated in section III.E.1.a of the Agreement, the amount of money Dr. Floresca or BAA has received in excess of the amount due and payable under the Medicare or TRICARE program requirements. For the purposes of the Claims Review and all reporting to the OIG under this CIA, Dr. Floresca shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

   d. Paid Claim: A code or line item submitted by Dr. Floresca or BAA, and for which Dr. Floresca or BAA have received reimbursement from the Medicare or TRICARE programs.

   e. Population: All Items for which Dr. Floresca or BAA have submitted a code or line item and for which Dr. Floresca or BAA have received reimbursement from the Medicare or TRICARE 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.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of Overpayments in the Population. The estimated mean and standard deviation of Overpayments in the Population are to be used to calculate the minimum number of Items that shall be included in the Claims Review Sample in order to achieve the required confidence and precision levels.

g. RAT-STATS: OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/oig/oas/ratstat.html".

B. Description of Claims Review

The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

1. ***Probe Sample.*** The IRO shall first review a Probe Sample which shall include at least 30 randomly selected Items. If the financial error rate (see section C.3.f.) is less than 5%, the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report. If the financial error rate is 5% or more, the IRO must conduct a full Claims Review Sample in accordance with the instructions that follow.

2. ***Confidence and Precision Requirements***. The Claims Review Sample should contain a sufficient number of Items (according to the RAT-STATS calculation) so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) should be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the

confidence interval would not be less than 75% of the midpoint of the confidence interval.

3. ***Use of a Probe Sample to Determine Claims Review Sample Size.*** To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of Overpayments in the Population must be estimated. Estimates for each unique Population shall be developed through the use of the Probe Sample results.

   Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of Overpayments in the Population shall be determined. This determination is based on the Overpayment amount received by Dr. Floresca or BAA for each Item in the sample. The "Difference Values Only" function located under the "Variable Appraisals" component of RAT-STATS shall be used to calculate the estimated mean and standard deviation of Overpayments in the Population. For purposes of estimating the mean and standard deviation of Overpayments in the Population, and entering this information into the "Variable Appraisals", "Difference Values Only" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment.

4. ***Calculation of Claims Review Sample Size and Selection of the Claims Review Sample.*** The estimates of the mean and the standard deviation of Overpayments in the Population obtained through the review of the Probe Sample shall be used to estimate the minimum size of the Claims Review Sample. In order to estimate the number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. Whereas the Claims Review Sample size is estimated from the results of the probe sample, there is a possibility that examining the number of Items identified by RAT-STATS may not achieve the 90% confidence and 25% precision levels. If the reviewer can demonstrate that the review was properly conducted, but the 90% confidence level and 25% precision interval could not be achieved, the reviewer will not be required to examine additional items. *

The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

5. ***Item Appraisal.*** For each Item appraised, only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IRO to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

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

7. ***Use of First Samples Drawn.*** For the purposes of all samples (Probe Sample and Claims Review Sample) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

C. **Claims Review Report.** The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

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

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in section A.3.b above, for purposes of this

Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Samples have 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. Sources 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, HCFA 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 Probe Sample and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

c. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

d. A copy of the RAT-STATS printout of the "Variable Appraisals", "Difference Values Only" function results for the Probe Sample, including a copy of the data file.

e. The Sampling Frame used in the Probe Sample and the Claims Review

Sample will be available to the OIG upon request.

3. ***Claims Review Results***

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

b. 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 Dr. Floresca or BAA.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. The IRO may, in its report to Dr. Floresca, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. The financial error rate. For purposes of reporting in the Claims Review Report to the OIG, underpayments shall not be offset or "netted out" when calculating the financial error rate.

e. The level of precision achieved by the Claims Review at a 90% confidence level.

f. 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.

4. ***Credentials.*** The names and credentials of the individuals who: (1) designed

the sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.