CORPORATE INTEGRITY AGREEMENT

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

AND

ANESTHESIA ASSOCIATES OF PINELLAS COUNTY, INC.

I. PREAMBLE

Anesthesia Associates of Pinellas County, Inc., (AAPC) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, AAPC is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM AND SCOPE OF THE CIA

- A. The period of the compliance obligations assumed by AAPC under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."
- B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) AAPC's final annual report; or (2) any additional materials submitted by AAPC pursuant to OIG's request, whichever is later.
 - C. The scope of this CIA shall be governed by the following definitions:
 - 1. "Covered Persons" includes:
 - a. all owners, officers, directors, and employees of AAPC; and

b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of AAPC.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all owners, officers, employees, contractors, subcontractors, and agents of AAPC, and other persons associated with AAPC, who provide patient care items or services or who perform billing or coding functions on behalf of AAPC.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. Compliance Officer. Within 90 days after the Effective Date, AAPC shall appoint an individual to serve as its Compliance Officer. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of AAPC, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Shareholders of AAPC, and shall be authorized to report on such matters to the Shareholders of AAPC at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by AAPC as well as for any reporting obligations created under this CIA.

AAPC shall report to OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any actions or changes that would affect the

Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. Compliance Committee. Within 90 days after the Effective Date, AAPC shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

AAPC shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

B. Written Standards.

- 1. Code of Conduct. Within 90 days after the Effective Date, AAPC shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. AAPC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:
 - a. AAPC's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements;
 - b. AAPC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with AAPC's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
 - c. the requirement that all of AAPC's Covered Persons shall be expected to report to the Compliance Officer or other appropriate

individual designated by AAPC suspected violations of any Federal health care program requirements or of AAPC's own Policies and Procedures;

- d. the possible consequences to both AAPC and Covered Persons of failure to comply with Federal health care program requirements and with AAPC's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and AAPC's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by AAPC's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

AAPC shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

- 2. Policies and Procedures. Within 90 days after the Effective Date, AAPC shall implement written Policies and Procedures regarding the operation of AAPC's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:
 - a. the subjects relating to the Code of Conduct identified in Section III.B.1; and
 - b. the proper documentation, coding, and billing of claims for anesthesia-related services, including, but not limited to, claims for medical direction services and medical supervision services, in

accordance with applicable Federal health care program requirements. Among other things, AAPC's third party billing company uses a concurrency module that generates a daily Concurrency Report that identifies all instances in which an anesthesiologist is reported to have performed, supervised, or medically directed five or more concurrent cases. AAPC shall review all services identified on the Concurrency Report and determine whether they are appropriately billed as medical direction services or as medical supervision services in accordance with applicable Federal health care program requirements; and

c. the documentation, coding, and billing of claims for anesthesiarelated services in a manner which accurately reflects the individual providing the services in accordance with applicable Federal health care program requirements.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education.

- 1. General Training. Within 90 days after the Effective Date, AAPC shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain AAPC's:
 - a. CIA requirements; and
 - b. AAPC's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

- 2. Specific Training. Within 90 days after the Effective Date, each Relevant Covered Person shall receive at least four hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:
 - a. the Federal health care program requirements regarding the accurate coding and submission of claims;
 - b. policies, procedures, and other requirements applicable to the documentation of medical records;
 - c. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
 - d. applicable reimbursement statutes, regulations, and program requirements and directives;
 - e. the legal sanctions for violations of the Federal health care program requirements; and
 - f. examples of proper and improper claims submission practices.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later. An AAPC employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least four hours of Specific Training annually.

3. *Certification*. Each individual who is required to attend training shall certify, in writing, or in electronic form, if applicable, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

To the extent that AAPC has provided training to Covered Persons that satisfies the requirements set forth in Sections III.C.1-2 within 120 days prior to the Effective Date, the OIG shall credit that training for purposes of satisfying AAPC's training obligations for the first year of this CIA.

- 4. *Qualifications of Trainer*. Persons providing the training shall be knowledgeable about the subject area.
- 5. Update of Training. AAPC shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the IRO Claims Review, and any other relevant information.
- 6. Computer-based Training. AAPC may provide the training required under this CIA through appropriate computer-based training approaches. If AAPC chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

- 1. General Description.
 - a. Engagement of Independent Review Organization. Within 90 days after the Effective Date, AAPC shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist AAPC in assessing and evaluating its billing and coding practices and certain other obligations pursuant to this Agreement and the Settlement Agreement.

Each IRO engaged by AAPC shall have expertise in the billing, coding, reporting, and other requirements pertaining to anesthesia services and in the general requirements of the Federal health care program(s) from which AAPC seeks reimbursement. Each IRO shall assess, along with AAPC, whether it can perform the IRO review in a professionally independent and/or objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist.

The IRO(s) review shall evaluate and analyze AAPC's coding, billing, and claims submission to the Federal health care programs and the reimbursement received (Claims Review), and shall analyze whether AAPC sought payment for certain unallowable costs (Unallowable Cost Review). The applicable requirements relating to the IRO are outlined in Appendix A to this Agreement, which is incorporated by reference.

- b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Claims Review.
- c. Frequency of Unallowable Cost Review. If applicable, the IRO shall perform the Unallowable Cost Review for the first Reporting Period.
- d. Retention of Records. The IRO and AAPC shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and AAPC) related to the reviews.
- 2. <u>Claims Review</u>. The Claims Review shall include two components. The first will be a Provider Number Discovery Sample and, if necessary, a Provider Number Full Sample. The second will be a Concurrency Review. The applicable definitions, procedures, and reporting requirements are outlined in Appendix B to this Agreement, which is incorporated by reference.

a. *Provider Number Discovery Sample*. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of AAPC (Provider Number Discovery Sample).

The Paid Claims shall be reviewed based on the supporting documentation available at AAPC's office or under AAPC's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed under the correct anesthesia provider (anesthesiologist and certified registered nurse anesthetist (CRNA)) numbers.

- i. If the Error Rate (as defined in Appendix B) for the Provider Number Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, AAPC should, as appropriate, further analyze any errors identified in the Provider Number Discovery Sample. AAPC recognizes that 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 Provider Number Discovery Sample or any other segment of the universe.)
- ii. If the Provider Number Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Provider Number Full Sample and a Systems Review, as described below.
- b. Provider Number 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 B. The Provider Number Full Sample shall be designed to: (i) 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 (ii) 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 AAPC's office or under AAPC's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed under the correct anesthesia provider (anesthesiologist and CRNA) numbers. For purposes of calculating the size of the Provider Number Full Sample, the Provider Number Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, AAPC may use the Items sampled as part of the Provider Number Discovery Sample, and the corresponding findings for those 50 Items, as part of its Provider Number Full Sample, if: (i) statistically appropriate and (ii) AAPC selects the Provider Number Full Sample Items using the seed number generated by the Provider Number Discovery Sample. OIG, in its sole discretion, may refer the findings of the Provider Number Full Sample (and any related workpapers) received from AAPC 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. Concurrency Review. AAPC's third party billing company uses and shall maintain as part of its electronic claims processing system a concurrency module that generates a daily Concurrency Report. The Concurrency Report identifies all instances in which an anesthesiologist is reported to have performed, supervised or medically directed five or more concurrent cases.
- i. AAPC shall maintain a Concurrency Compliance File containing each day's Concurrency Report, evidence of how Medicare and Medicaid cases appearing on the report were billed (e.g., as medically directed, medically supervised, or unbilled), and the documentation relied upon in determining that any of the reported concurrencies were "false", e.g., a copy of the anesthesia record showing a hand-off to another anesthesiologist or anesthesia start or stop times different from those entered into the electronic claims processing system.
- ii. The IRO shall review all Paid Claims for medical direction of those

cases appearing on the Concurrency Reports (the "Concurrency Population") to determine whether there was adequate, contemporaneous, documentary evidence to support that there were no more than four concurrent cases and that the Paid Claims were appropriately billed. The Paid Claims shall be reviewed based on the supporting documentation available at AAPC's office or under AAPC's control and applicable billing and coding regulations and guidance to determine whether the claim for medical direction was correctly coded, submitted, and reimbursed.

- d. Systems Review. If AAPC's Provider Number Discovery Sample or Concurrency Review identifies an Error Rate of 5% or greater, AAPC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Provider Number Discovery Sample and Provider Number Full Sample that resulted in an Overpayment, or for each claim in the Concurrency Review for which an error was identified, the IRO shall 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 and/or errors. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.
- e. Repayment of Identified Overpayments. In accordance with Section III.I.1 of this Agreement, AAPC shall repay within 30 days any Overpayment(s) identified in the Provider Number Discovery Sample or the Provider Number Full Sample (if applicable) and the Concurrency Review, regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. AAPC shall make available to OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor.
- 3. <u>Claims Review Report</u>. The IRO shall prepare a report based upon the Claims Review performed (Claims Review Report). Information to be included in the Claims Review Report is described in Appendix B.
- 4. <u>Unallowable Cost Review</u>. If applicable, the IRO shall conduct a review of AAPC's compliance with the unallowable cost provisions of the

Settlement Agreement. The IRO shall determine whether AAPC has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by AAPC or any affiliates. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

- 5. <u>Unallowable Cost Review Report</u>. If applicable, the IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether AAPC has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.
- 6. Validation Review. In the event OIG has reason to believe that:
 (a) any Claims Review, or Unallowable Cost Review (if applicable)
 (hereafter collectively "Review") fails to conform to the requirements of
 this Agreement; or (b) the IRO's findings or any Review results are
 inaccurate, OIG may, at its sole discretion, conduct its own review to
 determine whether the Review(s) complied with the requirements of the
 Agreement and/or the findings or any Review results are inaccurate
 (Validation Review). AAPC shall pay for the reasonable cost of any such
 review performed by OIG or any of its designated agents. Any Validation
 Review of Reports submitted as part of AAPC's final Annual Report must
 be initiated no later than one year after AAPC's final submission (as
 described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify AAPC of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, AAPC may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of any Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. AAPC agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Claims Review issues with AAPC 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 OIG.

7. <u>Independence/Objectivity Certification</u>. The IRO shall include in its report(s) to AAPC a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, with regard to any Review and that it has concluded that it is, in fact, independent and/or objective.

E. Third Party Billing

1. <u>Current Contract with Third Party Biller</u>. AAPC presently contracts with a third party billing company (Per Se, Inc.) to submit claims to the Federal health care programs. AAPC represents that it does not have an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company and is not employed by, and does not act as a consultant to, the third party billing company. If AAPC intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this CIA, AAPC shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, AAPC shall obtain (and provide to OIG in the Implementation Report) a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of

claims to Federal health care programs; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (iii) provides the required training in accordance with Section III.C of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If AAPC contracts with a new third party billing company during the term of this CIA, AAPC shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.E.1.

F. <u>Disclosure Program</u>.

Within 90 days after the Effective Date, AAPC shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with AAPC's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. AAPC shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, AAPC shall conduct an internal

review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG, upon request.

G. Ineligible Persons.

- 1. Definitions. For purposes of this CIA:
 - a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
 - b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov).

- c. "Screened Persons" include prospective and current owners, officers, directors, employees, contractors, and agents of AAPC.
- 2. Screening Requirements. AAPC shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.
- a. AAPC shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such persons to disclose whether they are an Ineligible Person.
- b. AAPC shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. AAPC shall implement a policy requiring all Screened Persons AAPC to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) AAPC to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

- 3. Removal Requirement. If AAPC has actual notice that a Screened Person has become an Ineligible Person, AAPC shall remove such person from responsibility for, or involvement with, AAPC's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.
- 4. Pending Charges and Proposed Exclusions. If AAPC has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, AAPC shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care

rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

1. Overpayments.

- a. <u>Definition of Overpayments</u>. For purposes of this CIA, an "Overpayment" shall mean the amount of money AAPC has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, AAPC identifies or learns of any Overpayment, AAPC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, AAPC shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, AAPC 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 payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information

contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

- a. <u>Definition of Reportable Event</u>. For purposes of this CIA, a "Reportable Event" 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: or

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

- b. Reporting of Reportable Events. If AAPC determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, AAPC shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:
 - i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (A) the payor's name, address, and contact person to whom the Overpayment was sent; and

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

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of AAPC's actions taken to correct the Reportable Event; and

iv. any further steps AAPC plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, AAPC changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, AAPC shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location shall be subject to all the requirements of this CIA.

V. <u>IMPLEMENTATION AND ANNUAL REPORTS</u>

- A. <u>Implementation Report</u>. Within 120 days after the Effective Date, AAPC shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:
 - 1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

- 2. the names and positions of the members of the Compliance Committee required by Section III.A;
- 3. a copy of AAPC's Code of Conduct required by Section III.B.1;
- 4. a copy of all Policies and Procedures required by Section III.B.2;
- 5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
- 6. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 7. a description of the Disclosure Program required by Section III.F;
- 8. the following information regarding the IRO(s): (a) identity, address and phone number; (b) a copy of the engagement letter; (c) a summary and description of any and all current and prior engagements and agreements between AAPC and the IRO; and (d) the proposed start and completion dates of any Review;
- 9. a certification from the IRO regarding its professional independence and/or objectivity with respect to AAPC;
- 10. a description of the process by which AAPC fulfills the requirements of Section III.G regarding Ineligible Persons;

- 11. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 12. a list of all of AAPC's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare provider number(s), provider identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which AAPC currently submits claims;
- 13. a description of AAPC's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
- 14. the certifications required by Sections III.E and V.C.
- B. <u>Annual Reports</u>. AAPC shall submit to OIG annually a report with respect to the status of, and findings regarding, AAPC's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

- 1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;
- 2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
- 3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions

(the documentation supporting this information shall be available to OIG, upon request);

- 4. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;
 - b. number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

- 5. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
- 6. AAPC's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
- 7. a summary/description of any and all current and prior engagements and agreements between AAPC and the IRO, if different from what was submitted as part of the Implementation Report;
- 8. a certification from the IRO regarding its professional independence and/or objectivity with respect to AAPC;
- 9. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events:
- 10. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely

reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report;

- 11. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 12. any changes to the process by which AAPC fulfills the requirements of Section III.G regarding Ineligible Persons;
- 13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by AAPC in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services relating to items or services furnished, ordered or prescribed by an Ineligible Person;
- 14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
- 15. a description of all changes to the most recently provided list of AAPC's locations (including addresses) as required by Section V.A.11; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare AAPC number(s), AAPC identification number(s), and/or supplier number(s); and the name and address of each Medicare contractor to which AAPC currently submits claims; and
- 16. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

- C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:
 - (1) to the best of his or her knowledge, except as otherwise described in the applicable report, AAPC is in compliance with all of the requirements of this CIA;
 - (2) he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and
 - (3) AAPC has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;
- D. <u>Designation of Information</u>. AAPC shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. AAPC shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch Office of Counsel to the Inspector General Office of Inspector General U.S. Department of Health and Human Services Cohen Building, Room 5527 330 Independence Avenue, S.W. Washington, DC 20201 Telephone: 202.619.2078 Facsimile: 202.205.0604

AAPC:

Administrator
Anesthesia Associates of Pinellas County, Inc.
300 Jeffords Street, Suite B
Clearwater, FL 22756
Telephone: 727.441.1524

727.443.4206

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

Facsimile:

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of AAPC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of AAPC's locations for the purpose of verifying and evaluating: (a) AAPC's compliance with the terms of this CIA; and (b) AAPC's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by AAPC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of AAPC'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. AAPC shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. AAPC's employees may elect to be interviewed with or without a representative of AAPC present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify AAPC prior to any release by OIG of information submitted by AAPC pursuant to its obligations under this CIA and identified upon submission by AAPC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, AAPC shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. Breach and Default Provisions

AAPC is expected to fully and timely comply with all of its CIA obligations.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, AAPC and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA 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 \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AAPC fails to establish and implement any of the following obligations as described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. the training of Covered Persons;
 - f. a Disclosure Program;
 - g. Ineligible Persons screening and removal requirements; and
 - h. Notification of Government investigations or legal proceedings.

- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AAPC fails to engage an IRO, as required in Section III.D and Appendix A.
- 3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AAPC fails to meet any deadlines for the submission of the Implementation Report or the Annual Reports to OIG as described in Section V.
- 4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day AAPC fails to submit the annual Claims Review Report and Unallowable Cost Review Report in accordance with the requirements of Section III.D and Appendix B.
- 5. A Stipulated Penalty of \$1,500 for each day AAPC fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date AAPC fails to grant access.)
- 6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of AAPC as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.
- 7. A Stipulated Penalty of \$1,000 for each day AAPC fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to AAPC, stating the specific grounds for its determination that AAPC has failed to comply fully and adequately with the CIA obligation(s) at issue and steps AAPC shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after AAPC receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.
- B. <u>Timely Written Requests for Extensions</u>. AAPC 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 CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after AAPC fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies

such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after AAPC receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that AAPC has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify AAPC of: (a) AAPC's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, AAPC shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event AAPC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until AAPC 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 CIA and shall be grounds for exclusion under Section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.
- 4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that AAPC has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

- a. a failure by AAPC to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage 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 CIA by AAPC constitutes an independent basis for AAPC's exclusion from participation in the Federal health care programs. Upon a determination by OIG that AAPC has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify AAPC of: (a) AAPC'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. AAPC 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. AAPC is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
 - b. the alleged material breach has been cured; or
 - c. the alleged material breach cannot be cured within the 30-day period, but that: (i) AAPC has begun to take action to cure the material breach; (ii) AAPC is pursuing such action with due diligence; and (iii) AAPC has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, AAPC fails to satisfy the requirements of Section X.D.3, OIG may exclude AAPC from participation in the Federal health care programs. OIG shall notify AAPC in writing of its

determination to exclude AAPC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of AAPC's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, AAPC may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

- 1. Review Rights. Upon OIG's delivery to AAPC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, AAPC 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 CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether AAPC was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. AAPC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders AAPC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless AAPC 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:
 - a. whether AAPC was in material breach of this CIA;
 - 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) AAPC had begun to take action to cure the material breach within that period; (ii) AAPC has pursued and is pursuing such action with due diligence; and (iii) AAPC provided to OIG within that period a reasonable timetable for curing the material breach and AAPC 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 AAPC, only after a DAB decision in favor of OIG. AAPC's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude AAPC 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 AAPC 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. AAPC shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of AAPC, AAPC shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this 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.

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This CIA shall be binding on the successors, assigns, and transferees of AAPC;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;
- D. OIG may agree to a suspension of AAPC's obligations under the CIA in the event of AAPC's cessation of participation in Federal health care programs. If AAPC withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, AAPC shall notify OIG at least 30 days in advance of AAPC's intent to reapply as a participating AAPC or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.
- E. The undersigned AAPC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF ANESTHESIA ASSOCIATES OF PINELLAS COUNTY, INC.

Scott Mantel, M.D.	DATE
Shareholder	
Anesthesia Associates of Pinellas County, Inc.	
Scott T. Kragie, Esq.	DATE
Squire, Sanders & Dempsey L.L.P.	
Counsel for Anesthesia Associates	
of Pinellas County, Inc.	

On Behalf of Anesthesia Associates of Pinellas County, Inc.

Scott Mantel, M.D.

Shareholder

Anesthesia Associates of Pinellas County, Inc.

Scott T. Kragie, Esq.

Squire, Sanders & Dempsey L.L.P. Counsel for Anesthesia Associates

of Pinellas County, Inc.

6/16/04 DATE

DATE 15,2004

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

LARRY J. GOLDBERG

Assistant Inspector General for Legal Affairs Office of Inspector General

U. S. Department of Health and Human Services

APPENDIX A INDEPENDENT REVIEW ORGANIZATION

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

A. <u>IRO Engagement</u>.

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

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

B. <u>IRO</u> Qualifications.

The IRO shall:

- 1. assign individuals to conduct the Claims Review and Unallowable Cost Review, if applicable engagement who have expertise in the billing, coding, reporting, and other requirements pertaining to anesthesia services and in the general requirements of the Federal health care program(s) from which AAPC seeks reimbursement;
- 2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;
- 3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification (e.g., CCA, CCS, CCS-P, CPC, RRA, etc.) and who have maintained this certification (e.g., completed applicable continuing education requirements); and
- 4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. <u>IRO Responsibilities</u>.

The IRO shall:

- 1. perform each Claim Review and Unallowable Cost Review in accordance with the specific requirements of the CIA;
- 2. follow all applicable Medicare and reimbursement guidelines in making assessments in the Claims Review;
- 3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);
 - 4. respond to all OIG inquires in a prompt, objective, and factual manner; and
- 5. prepare timely, clear, well-written reports that include all the information required by Appendix B.

D. <u>IRO Independence/Objectivity</u>.

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

E. <u>IRO Removal/Termination</u>.

- 1. Provider. If AAPC terminates its IRO during the course of the engagement, AAPC must submit a notice explaining its reasons to OIG no later than 30 days after termination. AAPC must engage a new IRO in accordance with Paragraph A of this Appendix.
- 2. OIG Removal of IRO. In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require AAPC to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring AAPC to engage a new IRO, OIG shall notify AAPC of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, AAPC may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. AAPC shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any

differences regarding the IRO with AAPC prior to requiring AAPC to terminate the IRO. However, the final determination as to whether or not to require AAPC to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B CLAIMS REVIEW

A. Claims Review.

- 1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:
 - a. Overpayment: The amount of money AAPC has received in excess of the amount due and payable under any Federal health care program requirements.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
 - c. <u>Paid Claim</u>: A code or line item submitted by AAPC and for which AAPC has received reimbursement from the Medicare program.
 - d. <u>Population</u>: The Concurrency Population is defined in Section III.D.2.c.ii of the CIA. For the first Reporting Period, the Population for purposes of the Provider Number Discovery (and Full) Sample(s) shall be defined as all Items for which a code or line item has been submitted by or on behalf of AAPC and for which AAPC has received reimbursement from Medicare (i.e., Paid Claim) during the 12-month period covered by the first Claims Review.

For the remaining Reporting Periods, the Provider Number Discovery (and Full) Sample(s) Population shall be defined as all Items for which AAPC has received reimbursement from Medicare (i.e., 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. <u>Error Rate</u>: 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 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. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which AAPC cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by AAPC for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- b. Replacement Sampling. Considering the Population shall consist only of Paid Claims and that Items with missing documentation cannot be replaced, there is no need to utilize alternate or replacement sampling units.
- c. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Provider Number Discovery Samples 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 (<u>i.e.</u>, 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. <u>Claims Review Report</u>. The following information shall be included in the Claims Review Report for the Concurrency Review and for <u>each Provider Number Discovery Sample</u> and Provider Number Full Sample (if applicable).
 - 1. Claims Review Methodology.
 - a. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review.
 - b. <u>Claims Review Population</u>. A description of the Populations subject to the Claims Review, including for the Provider Number Sample(s) and the Concurrency Review.
 - c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. <u>Sampling Frame</u>. A description of the sampling frame, which is the totality of Items from which the Provider Number Discovery Sample and, if any, Provider Number 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. <u>Source of Data</u>. A description of the specific 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 (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- f. <u>Review Protocol</u>. 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 Provider Number Discovery Sample and, if applicable, in the Provider Number 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 Provider Number Full Sample, if applicable.
 - d. A description or identification of the statistical sampling software package used to select the sample and determine the Provider Number Full Sample size, if applicable.
- 3. Claims Review Findings.
 - a. Narrative Results.
 - i. A description of AAPC'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 Provider Number

Discovery Sample, the results of the Provider Number Full Sample (if any), and the results of the Concurrency Review.

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by AAPC (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 AAPC.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: 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.

Attachment 1

Claim Review Results

Dollar Difference between Amt Reimbursed and Correct Allowed Amt						
Correct Allowed Amt Reimbursed (IRO determined)						
Correct Procedure Code (IRO determined)						
Allowed Amount Reimbursed						
Procedure Code Reimbursed						
Procedure Code Submitted						
Date of Service						
Bene HIC #						
Federal Health Care Program Billed						

AAPC Corporate Integrity Agreement:

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR
Date:
Contractor Deposit Control # Date of Deposit: Contractor Contact Name: Phone #
Contractor Contact Name: Phone #
Contractor Address.
Contractor Fax:
TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER
Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied
PROVIDER/PHYSICIAN/SUPPLIERNAMEADDRESS
PROVIDER/PHYSICIAN/SUPPLIER #CHECK NUMBER#
CONTACT PERSON: PHONE #
CONTACT PERSON: PHONE # AMOUNT OF CHECK \$ CHECK DATE
REFUND INFORMATION
For each Claim, provide the following:
Patient Name HIC #
Medicare Claim Number Claim Amount Refunded \$
Patient Name HIC # Medicare Claim Number Claim Amount Refunded \$
(Please list <u>all</u> claim numbers involved. Attach separate sheet, if necessary) Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling please indicate methodology and formula used to determine amount and reason for overpayment:
 For Institutional Facilities Only:
Cost Report Year(s)(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements: Do you have a Corporate Integrity Agreement with OIG? Yes No
Reason Codes:
Billing/Clerical Error O1 - Corrected Date of Service O2 - Duplicate O3 - Corrected CPT Code O4 - Not Our Patient(s) O5 - Modifier Added/Removed O6 - Billed in Error O7 - Corrected CPT Code O7 - Corrected CPT Code O8 - MSP Group Health Plan Insurance O9 - MSP No Fault Insurance O9

Appendix C AAPC Corporate Integrity Agreement

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Middle District of Florida, and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS)(collectively the "United States"); the State of Florida, acting through the Medicaid Fraud Control Unit (MFCU) of the Office of the Attorney General and on behalf of the Agency for Health Care Administration (AHCA), (collectively "the State of Florida"); Anesthesia Associates of Pinellas County, Inc. (AAPC); Clearwater Pain Management Associates, Inc. (CPM), and Morton Plant Mease Outpatient Anesthesiology, Inc. (MPMOA) (collectively "the Defendants"); and Ronald Lipton (hereafter referred to collectively as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

- A. AAPC, CPM, and MPMOA are incorporated, organized and existing under the laws of the State of Florida, and maintain their principal places of business in Pinellas County, Florida.
- B. Ronald Lipton (the "Relator") is a resident of Florida. On August 29, 2000, the Relator filed a qui tam action in the United States District Court for the Middle District of Florida captioned United States of America ex rel. Ronald Lipton v. Anesthesia Associates of Pinellas County, Inc.; Clearwater Pain Management Associates, Inc.; Morton Plant Mease Outpatient Anesthesiology, Inc., Stephen Barasch, Paul Borrelli, Winton Burns, J. Conway Dabney, Charles Kottmeier, Scott

Mantell, Andrew Rackstein, Alan Rudolph, Benjamin Sanchez, Saul Tuchman, William Vermazen, Civil Action No.8:00-cv-1806-T-17E (the "Civil Action"). On November 26, 2003, the Relator voluntarily dismissed all the individually named defendants in his <u>qui</u> tam complaint. The Relator worked as the practice administrator for the Defendant from March 1996 through December 1999.

- C. Investigators of the FBI, OIG-HHS, and the Office of the Attorney General MFCU conducted an investigation of the Defendants in the Middle District of Florida for certain conduct during the time period beginning in January 1996 and continuing through June 2002.
- D. The United States and the State of Florida contend that the Defendants submitted or caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg, and the Medicaid Program (Medicaid) Title XIX of the Social Security Act, 42 U.S.C. §§1396-1396v for certain anesthesia services.
- E. Under Medicare and Medicaid regulations, an anesthesiologist may bill for "medical direction" if he is directing no more than four concurrent anesthesia cases. If an anesthesiologist is overseeing more than four concurrent anesthesia services, he may only bill for "medical supervision." 42 C.F.R. § 415.110 and Medicaid Physicians Coverage and Limitations Handbook at 2-13.
- F. The United States, the State of Florida, and Relator contend from March 1996 through June 2002, the Defendants knowingly submitted claims for medical direction when the anesthesiologists were supervising more than four concurrent anesthesia services.
- G. Medicare Part B pays for anesthesia services furnished by certified registered nurse anesthetists (CRNAs) who are legally authorized to perform the services by the State in which the services are provided. 42 C.F.R. § 410.69. All Medicare providers, including CRNAs, must obtain a

Unique Practitioner Identification Number (UPIN) so that Medicare may verify the eligibility of individuals that provide services to Medicare beneficiaries. All Medicaid providers, including CRNAs, who practice in a group must obtain an individual treating provider number from Medicaid so that Medicaid may verify the eligibility of individuals that provide services to Medicaid recipients.

- H. The United States, the State of Florida, and Relator contend that from January 1995 through June 2002, the Defendants knowingly billed Medicare and Medicaid for services provided by certain CRNAs, while using the Medicare UPINs and Medicaid treating provider numbers of other CRNAs that had not actually provided the services.
- I. The United States and the State of Florida contend that they have certain civil claims against the Defendants, as specified below in Paragraph 3, for engaging in the conduct set forth in Paragraphs F and H (hereafter referred to as the "Covered Conduct").
- J. The United States also contends that it has certain administrative claims, as specified in Paragraph 4 below, against the Defendants for engaging in the Covered Conduct.
- K. This Agreement is neither an admission of liability by the Defendants nor a concession by the United States or the State of Florida that their claims are not well founded.
- L. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

1. The Defendants agree to pay the United States \$289,770 (the "Settlement Amount").

The United States agrees to pay \$49,261 of the Settlement Amount to the Relator (the "Relator's

- Share"). The Defendants agree to pay Relator \$7,950 for expenses and attorney's fees and costs. The foregoing payments shall be made as follows:
- a. The Defendants agree to pay the full Settlement Amount to the United

 States by electronic funds transfer pursuant to written instructions to be provided by the United States

 Attorney's Office for the Middle District of Florida. The Defendants agree to make this electronic

 funds transfer no later than the Effective Date of this Agreement.
- b. Contingent upon the United States receiving the Settlement Amount from the Defendants and as soon as feasible after receipt, the United States agrees to pay \$49,261 to the Relator by electronic funds transfer.
- 2. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of the Defendants in this Agreement and conditioned upon the Defendants' full payment of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release the Defendants, together with their current and former parent corporations, current or former owners, officers, directors, agents, and employees, from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, breach of contract, and fraud.
- 3. Subject to the exceptions in Paragraph 5 below, in consideration of the obligations of the Defendants in this Agreement and conditioned upon the Defendants' full payment of the Settlement Amount the State of Florida (on behalf of itself, its officers, agents, agencies and

departments) agrees to release the Defendants, together with their current and former parent corporations, current or former owners, officers, directors, agents, and employees, from any civil or administrative monetary claim the State of Florida has or may have under the Florida False Claims Act, Fla. Stats. §§ 68.081 et seq., or the common law theories of payment by mistake, unjust enrichment, breach of contract, and fraud, for the Covered Conduct.

- 4. In consideration of the obligations of the Defendants in this Agreement and the Corporate Integrity Agreement (CIA) incorporated by reference, conditioned upon the Defendants' full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from the Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against the Defendants under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities), for the Covered Conduct, except as reserved in Paragraph 5 below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude the Defendants from the Medicare, Medicaid, or other Federal health care program under 42 U.S.C. § 1320a-7(a)(mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct or practices, for which claims have been reserved in Paragraph 5 below.
- 5. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including the Defendants) are the following claims of the United States and the State of Florida:

- a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- d. Any liability to the United States or the State of Florida (or their agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon such obligations as are created by this Agreement;
- f. Any civil or administrative liability of individuals (including current or former directors, officers, employees, agents, or shareholders of the Defendants) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted, charged, or convicted, or who enter into a plea agreement related to the Covered Conduct;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services.
- 6. Conditioned upon receipt of the payment described in Paragraph 1(b), the Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release the United States and the State of Florida, their officers, agents, and employees, from any claims arising from or relating to 31 U.S.C. § 3730 or §§ 68.081-.089, Florida Statutes, in connection with this Civil Action, or arising from the filing of the Civil Action, including 31 U.S.C. §§ 3730(b), (c), (c)(5), (d), and

- (d)(1), and §§ 68.083, .084, .085, and .086, Florida Statutes, in connection with this Civil Action. The Relator agrees and confirms that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B) and § 68.084, Florida Statutes.
- 7. Conditioned upon receipt of the payment described in Paragraph 1, the Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, agrees to release the Defendants, together with their current and former parent corporations, current or former owners, officers, directors, agents, and employees, their officers, directors, agents, and employees, from any liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorney's fees and costs.
- 8. AAPC has entered into a CIA with OIG-HHS, attached at Exhibit A, which is incorporated into this Agreement by reference. AAPC will immediately upon execution of this Agreement implement its obligations under the CIA.
- 9. The Defendants waive and will not assert any defenses the Defendants may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. The Defendants agree that this Agreement is not punitive in purpose or effect. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

- 10. The Defendants fully and finally release the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which the Defendants have asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof. The Defendants fully and finally release the State of Florida, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which the Defendants have asserted, could have asserted, or may assert in the future against the State of Florida, its agencies, employees, servants, and agents, related to the Covered Conduct and the State of Florida's investigation and prosecution thereof. The Defendants fully and finally release the Relator, his heirs, successors, attorneys, agents, and assigns from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which the Defendants have asserted, could have asserted, or may assert in the future against the Relator, his heirs, successors, attorneys, agents, and assigns, related to the Covered Conduct.
- 11. The Settlement Amount will not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare or Medicaid carrier or intermediary, related to the Covered Conduct; and the Defendant shall not resubmit to any Medicare or Medicaid carrier or intermediary any previously denied claims related to the Covered Conduct, and shall not appeal any such denials of claims.
 - 12. The Defendants agree to the following:

- (a) <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulations (FAR) 48 C.F.R. § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of the Defendants, their present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):
 - (1) the matters covered by this Agreement,
- (2) the United States' audit(s) and civil investigation of the matters covered by this Agreement,
- (3) the Defendants' investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation in connection with the matters covered by this Agreement (including attorney's fees),
 - (4) the negotiation and performance of this Agreement,
- (5) the payment the Defendants make to the United States pursuant to this Agreement and any payments that the Defendants may make to Relator, including costs and attorneys fees, and
 - (6) the negotiation of, and obligations undertaken pursuant to the CIA to:
- (i) Retain an independent review organization to perform annual reviews as described in Section III of the CIA; and

- (ii) prepare and submit reports to the OIG-HHS. However, nothing in this Paragraph that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to Defendants.
- (b) Future Treatment of Unallowable Costs: These unallowable costs will be separately determined and accounted for by the Defendants, and the Defendants will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program, or seek payment for such unallowable costs through any cost report, cost statement, information statement, or payment request submitted by the Defendant or any of their subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- further agree that within 90 days of the Effective Date of this Agreement they will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by the Defendants or any of their subsidiaries or affiliates, and will request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. The Defendants agree that the United States, at a minimum, shall be entitled to recoup from the Defendants any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by the Defendants or any of their subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on the Defendants or any of their subsidiaries' cost reports, cost statements, or information reports.

- (d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine or re-examine the Defendants' books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph.
- 13. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraphs 2, 3, 4, 6, 7, 10 and 14.
- 14. The Defendants waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- 15. The Defendants warrant that they have reviewed their financial situation and that they currently are solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to the Defendants, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous

exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which the Defendants were or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

- 16. Except as expressly provided to the contrary in this Agreement, each Party will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 17. The Defendants represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 18. Ronald Lipton represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 19. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the Middle District of Florida, except that disputes arising under the CIA shall be resolved exclusively under the dispute resolution provisions in the CIA.
- 20. This Agreement, and the CIA which is incorporated herein by reference, constitute the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only AAPC and OIG-HHS must agree in writing to modification of the CIA.
 - 21. Upon receipt of the payments described in Paragraph 1 above, the United States

shall promptly sign and file in the Civil Action a Notice of Intervention and the United States and Relator shall file a Joint Stipulation of Dismissal with prejudice of the Civil Action pursuant to the terms of the Agreement.

- 22. The individuals signing this Agreement on behalf of the Defendants represent and warrant that they are authorized by the Defendants to execute this Agreement. The individual signing this Agreement on behalf of the Relator represents and warrants that he is authorized by Relator to execute this Agreement. The United States and State of Florida signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.
- 23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.
- 24. This Agreement is binding on the Defendants' successors, transferees, heirs, and assigns.
- 25. All parties consent to the United States' and State of Florida's disclosure of this Agreement, and information about this Agreement, to the public.
- 26. This Agreement is effective on the date of signature of the last signatory to the Agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 6/15/04	BY:	ANDY J. MAO Trial Attorney Commercial Litigation Branch Civil Division United States Department of Justice
DATED: 6/01/04	BY:	LATOUR LAFFERTY Assistant United States Attorney United States Attorney's Office for the Middle District of Florida
DATED: 10 June 2004	BY:	LARRY J. GOLDBERG Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General United States Department of Health and Human

Services

THE STATE OF FLORIDA

CHARLES J. CRIST, JR.

Attorney General

DATED: ////

BY:

GEORGE LEMIEUX

Deputy Attorney General for the

State of Florida Tallahassee, Florida

On behalf of the Defendants AAPC and CPM

DATED: 6/15/04

BY:

Scott Mantell, M.D., Shareholder

Anesthesia Associates of Pinellas County, Inc. and Clearwater Pain Management Associates, Inc.

DATED: 6/15/04

BY:

Scott T. Kragie

Squire, Sanders & Dempsey L.L.P. 1201 Pennsylvania Avenue, N.W.

P.O. Box 407

Washington, D.C. 20044-0407

Counsel for AAPC and CPM

On behalf of Defendant MPMOA

DATED: 678-04

BY:

Paul Gubbini, M.D., President

Morton Plant Mease Outpatient Anesthesiology, Inc.

On behalf of the Relator

DATED: 06/18/04

BY:

RONALD LIPTON

DATED: 6/20/09

BY: MARK HERDMAN

Herdman & Sakellarides, P.A.

2595 Tampa Road

Suite J

Palm Harbor, Florida 34684

Counsel for the Relator