# CORPORATE INTEGRITY AGREEMENT
## BETWEEN THE
## OFFICE OF INSPECTOR GENERAL
## OF THE
## DEPARTMENT OF HEALTH AND HUMAN SERVICES
## AND
## ADVANCED NEUROMODULATION SYSTEMS, INC.

## I. PREAMBLE

Advanced Neuromodulation Systems, Inc. (ANS) 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 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, ANS is entering into a Settlement Agreement with the OIG. This CIA shall apply only to U.S. operations of ANS that are subject to Federal health care program requirements.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by ANS under this CIA shall be 3 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, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) ANS's final annual report; or (2) any additional materials submitted by ANS pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Arrangements" shall mean every arrangement or transaction entered into by ANS that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) are between ANS and any actual or potential source of health care business or referrals to ANS or any actual or potential recipient of health care business or

referrals from ANS. The term "source" shall include any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

2. "Contractual Arrangements" shall mean every written Arrangement that is contractual in nature and involves physician consulting or other services and all related expenses (including conducting training or educational programs, speaking engagements, cadaver workshops, serving as a medical expert, or assisting with product development), licensing, royalties, pre-market clinical research/studies (including pre-market feasibility, pilot studies, and pivotal studies and all related agreements such as site and investigator agreements), and post-market clinical research/studies (including all related agreements such as site and investigator agreements).

3. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements (including plant tours, charitable contributions, scholarships, or educational programs sponsored by ANS). Notwithstanding the above, Non-Contractual Arrangements shall not include (a) demonstration samples or models such as non-functional samples or replicas of implantable devices, anatomical models, or other educational tools used to explain neuro stimulation; (b) ANS-branded promotional items that are less than $25 in value, including pens, notepads, and portfolios; and (c) sales of neuro stimulation products, including discounts provided as part of these sales.

4. "Covered Persons" includes:

    a. officers and employees of ANS; and

    b. all contractors, subcontractors, agents, and other persons who sell or market on behalf of ANS items or services for which reimbursement may be made by Federal health care programs.

    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.

5. "Arrangements Covered Persons" includes each Covered Person involved with the development, approval, management, implementation, use, or review of any of ANS's Arrangements, as such term is defined in Section II.C.1.

6. "ANS" shall mean the ANS subsidiary of St. Jude Medical, Inc. (SJM) and no other component or subsidiary of SJM.

## III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* ANS has appointed an individual to serve as its Compliance Officer and ANS shall maintain a Compliance Officer for the term of the CIA. 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 applicable Federal health care program requirements. The Compliance Officer shall report directly to the President of ANS, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Compliance Committee of ANS (which includes members of senior management), and shall be authorized to report on such matters to the Board of Directors of SJM 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 ANS as well as for any reporting obligations created under this CIA.

ANS 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.* To the extent ANS has not already done so, within 120 days after the Effective Date, ANS 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 Finance, Clinical Research and Regulatory Affairs, Human Resources, Marketing, Reimbursement and Sales). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his or 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).

ANS 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.* SJM has in place a Code of Conduct that applies to all of its subsidiary corporations. Within 120 days after the Effective Date, ANS shall distribute the written SJM Code of Conduct to all Covered Persons. In addition, within 120 days after the Effective Date, ANS shall prepare an Addendum to the SJM Code of Conduct and ANS shall distribute that Addendum to all Covered Persons. ANS shall make the promotion of, and adherence to, the SJM Code of Conduct and the Addendum an element in evaluating the performance of all employees. The SJM Code of Conduct or Addendum to the SJM Code of Conduct shall, at a minimum, set forth:

a. the commitment to full compliance with all applicable federal, state, and local laws and regulations (which includes applicable Federal health care program requirements);

b. the requirement that all Covered Persons shall be expected to comply with all applicable Federal health care program requirements and with ANS's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);

c. the requirement that all of ANS's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by ANS, suspected violations of any Federal health care program requirements or of ANS's own Policies and Procedures;

d. the possible consequences to both ANS and Covered Persons of failure to comply with Federal health care program requirements and with ANS'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.F, and ANS's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the SJM Code of Conduct and the Addendum to the Code of Conduct. New Covered Persons shall receive the SJM Code of Conduct and Addendum and shall complete the required certification within 60 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

The Code of Conduct, including the Addendum, shall be periodically reviewed to determine if revisions are appropriate and shall be revised as necessary based on such review. Any revised Code of Conduct, including the Addendum, shall be distributed within 60 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 60 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Within 120 days after the Effective Date, ANS shall implement written Policies and Procedures regarding the operation of ANS's compliance program and its compliance with applicable 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;

b. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures required under this Section, and this CIA;

c. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the

Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.1; and

d. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Tracked Arrangements Systems (described below), the internal review and approval process(es), and the tracking of Arrangements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons 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), ANS shall assess and update, as necessary, the Policies and Procedures. Within 60 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training*. Within 120 days after the Effective Date, ANS shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain ANS's:

a. CIA requirements; and

b. ANS's Compliance Program (including the SJM Code of Conduct, including the Addendum, and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 60 days after becoming a Covered Person or within 120 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 in each subsequent Reporting Period.

2. *Arrangements Training*. Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least two hours of Arrangements Training,

in addition to the General Training required above. The Arrangements Training shall include a discussion of:

a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;

b. ANS's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Tracked Arrangements Systems, the internal review and approval process(es), and the tracking of Arrangements as required by Section III.D of the CIA;

c. the personal obligation of each individual involved in the development, approval, management, or review of ANS's Arrangements to know the applicable legal requirements and the ANS's policies and procedures;

d. the legal sanctions under the Anti-Kickback Statute; and

e. examples of violations of the Anti-Kickback Statute.

New Arrangements Covered Persons shall receive this training within 60 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. An ANS employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least one hour of Arrangements Training in each subsequent Reporting Period.

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.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

5. *Update of Training.* At least annually, ANS shall review the training programs developed to satisfy the requirements of Section III.C of the CIA and, where appropriate, update the training to reflect changes in applicable Federal health care program requirements, any issues discovered during internal audits, the Arrangements Review, and any other relevant information.

6. *Training Methods.* ANS may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If ANS 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. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, ANS shall create systems, processes, and/or procedures reasonably designed to ensure that each existing and new or renewed Arrangement, including Contractual Arrangements and Non-Contractual Arrangements, does not violate the Anti-Kickback Statute (taking into account the regulations and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

a. creating and maintaining systems, processes, and/or procedures, as applicable, to track all existing and new or renewed Contractual Arrangements and Non-Contractual Arrangements, that shall contain the information specified in Appendix A (Tracked Arrangements Systems);

b. tracking remuneration to and from ANS to all other parties to Arrangements;

c. tracking time records or service invoices, where applicable, to ensure that parties to the Contractual Arrangement(s) are performing the services required under the applicable Contractual Arrangement(s) (if applicable);

d. establishing and implementing a written review and approval process(es) for all Contractual Arrangements, including but not limited to, a legal review by counsel with expertise in the Anti-Kickback Statute and appropriate documentation of all internal controls, the purpose of which is to ensure that all new and existing or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;

e. establishing and implementing written policies and procedures for all Arrangements to ensure that such Arrangements do not violate the Anti-Kickback Statute;

f. requiring the Compliance Officer to review the Tracked Arrangements Systems, internal review and approval process(es), and other Arrangements Procedures at least three times per reporting period and to provide a report on the results of such review to the Compliance Committee; and

g. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Section III.I (Reporting) when appropriate.

2. *New or Renewed Arrangements*. Before entering into new Contractual Arrangements or renewing existing Contractual Arrangements, in addition to complying with the Arrangements Procedures set forth above, ANS shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by ANS and the other parties to the Arrangement;

b. For such Arrangements in which the non-ANS party is a Covered Person, include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with ANS's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, ANS shall provide each Covered Person who is a party to the Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* ANS shall retain and make available to OIG, upon request, the information related to the Tracked Arrangements Systems and all supporting documentation of the Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements.

E. Review Procedures.

1. *General Description.*

a. *SJM Arrangements Review.* SJM shall conduct a review to assist ANS in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review).

b. *Engagement of Independent Review Organization for Verification Review.* Within 120 days after the Effective Date, ANS shall engage an individual or entity (or entities), such as an auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a verification of SJM's Arrangements Review (IRO Verification Review).

The IRO shall assess, along with SJM and ANS, whether it can perform the IRO Verification Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the IRO Verification Review shall not be deemed to create an attorney-client relationship between ANS and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix B to this Agreement, which is incorporated by reference.

c. *Frequency of Arrangements Review and IRO Verification Review.* The Arrangements Review and the IRO Verification Review shall be performed annually and shall cover each of the Reporting Periods.

d. *Retention of Records*. The IRO, SJM, and ANS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO, SJM and ANS) related to the Arrangements Review and IRO Verification Review.

e. *Responsibilities and Liabilities*. Nothing in this Section III.E affects ANS's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

2. *Arrangements Review*. SJM shall perform a review to assess whether ANS is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. SJM shall randomly select a sample of 40 Arrangements that were entered into or renewed during the Reporting Period. SJM shall assess whether ANS has implemented the Arrangements Procedures and, for each selected Arrangement, SJM shall assess whether ANS has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. SJM's assessment shall include, but is not limited to: (a) verifying that the Arrangement is tracked in the Tracked Arrangements Systems; (b) verifying that the Arrangement was subject to the internal review and approval process(es) (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the time records or service invoices are properly completed and reviewed (if applicable); (e) verifying that the Compliance Officer is reviewing the Tracked Arrangements Systems, internal review and approval process, and other Arrangements Procedures at least three times per reporting period and reporting the results of such review to the Compliance Committee; (f) verifying that effective responses are being implemented when violations of the Anti-Kickback Statute are discovered; and (g) verifying that the ANS has met the requirements of Section III.D.2.

3. *Arrangements Review Report*. SJM shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the SJM's findings with respect to: (a) whether ANS has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether ANS has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by SJM. In addition, the Arrangements Review Report shall include any

observations, findings and recommendations on possible improvements to ANS's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

4. *IRO Verification Review.* The IRO will verify the Arrangements Review by reviewing 25 percent of the Arrangements reviewed by SJM in its Arrangements Review. The IRO shall conduct the IRO Verification Review based on the information contained in the Arrangements Review Report and the documentation and other information SJM analyzed in connection with each Arrangement reviewed. The IRO shall prepare a report based upon its review (IRO Verification Review Report). The IRO Verification Report shall consist of its findings with respect to: (a) whether ANS has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) whether ANS has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by SJM. In addition, the IRO Verification Review Report shall include any observations, findings, or recommendations on improvements to how ANS complies with Section III.D of the CIA.

5. *Validation Review.* In the event OIG has reason to believe that: (a) ANS's Arrangements Review fails to conform to the requirements of this Agreement; or (b) the IRO's findings in connection with the IRO Verification Review are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the Agreement and/or the findings or Arrangements Review results are inaccurate (Validation Review). ANS 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 ANS's final Annual Report must be initiated no later than one year after ANS's final submission (as described in Section II) is received by OIG.

Before initiating a Validation Review, OIG shall notify ANS 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, ANS may request a meeting with OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. ANS 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 Arrangements Review issues with ANS before 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.

6. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to ANS a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Arrangements Review and that it has concluded that it is, in fact, independent and objective.

F. Disclosure Program.

To the extent ANS has not already done so, within 120 days after the Effective Date, ANS 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 ANS'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. ANS 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, ANS 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://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

c. "Screened Persons" include prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and employees of ANS. Screened Persons also includes all prospective and current contractors and agents of ANS who are Covered Persons.

2. *Screening Requirements.* ANS shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

a. ANS shall screen all Screened Persons against the Exclusion Lists before engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.

b. ANS shall screen all Screened Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

c. ANS shall implement a policy requiring all Screened Persons 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) ANS to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. ANS understands that items or services furnished by excluded persons are not payable by Federal health care programs and that ANS may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether ANS meets the requirements of this section III.G.

3. *Removal Requirement.* If ANS has actual notice that a Screened Person has become an Ineligible Person, ANS shall remove such Screened Person from responsibility for, or involvement with, ANS's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened 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 Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If ANS 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 the Screened Person's employment or contract term, ANS shall take all appropriate actions to ensure that the responsibilities of that Screened 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, ANS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to ANS conducted or brought by a governmental entity or its agents involving an allegation that ANS 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. ANS 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. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves a matter brought to the attention of senior management of ANS, that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

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

b. *Reporting of Reportable Events.* If ANS determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, ANS 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. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

ii. a description of ANS's actions taken to correct the Reportable Event; and

iii. any further steps ANS 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, ANS 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, ANS 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. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, ANS 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 the 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. the 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 Tracked Arrangements Systems required by Section III.D.1.a;

8. a description of the internal review and approval process(es) required by Section III.D.1.d; and the written policies and procedures required by Section III.D.1.e;

9. a description of the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

10. a description of the Disclosure Program required by Section III.F;

11. 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 ANS and the IRO; and (d) the proposed start and completion dates of the IRO Verification Review;

12. a certification from the IRO regarding its professional independence and objectivity with respect to ANS;

13. a description of the process by which ANS fulfills the requirements of Section III.G regarding Ineligible Persons;

14. 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;

15. a list of all of ANS's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; and, if applicable, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s);

16. a description of ANS's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

17. the certifications required by Section V.C.

B. Annual Reports. ANS shall submit to OIG annually a report with respect to the status of, and findings regarding, ANS's compliance activities for each of the three 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. the 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 description of any changes to the Tracked Arrangements Systems required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.d; and the written policies and procedures required by Section III.D.1.e;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a complete copy of all reports prepared pursuant to Section III.E, along with a copy of the IRO's engagement letter (if applicable);

9. ANS's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.E;

10. a summary and description of any and all current and prior engagements and agreements between ANS and the IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from the IRO regarding its professional independence and objectivity with respect to ANS;

12. 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;

13. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; (b) allege abuse or neglect of patients; or (c) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute.

14. any changes to the process by which ANS fulfills the requirements of Section III.G regarding Ineligible Persons;

15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by ANS 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;

16. 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;

17. a description of all changes to the most recently provided list of ANS's locations (including addresses) as required by Section V.A.15; 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

18. 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. Certifications. 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, ANS is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, ANS has implemented procedures reasonably designed to ensure that all Arrangements do not violate the Anti-Kickback Statute, including the Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, ANS has fulfilled the requirements for New and Renewed Arrangements under Section III.D.2 of the CIA; and

4. 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.

D. Designation of Information. ANS 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. ANS 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

ANS:

Jill Mason
Chief Compliance Officer
Advanced Neuromodulation Systems, Inc.
6901 Preston Rd.
Plano, TX 75024
Telephone: (972) 526-9680
Facsimile: (972) 526-9780

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

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 ANS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of ANS's locations for the purpose of verifying and evaluating: (a) ANS's compliance with the terms of this CIA; and (b) ANS's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by ANS 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 ANS'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.

ANS shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. ANS's employees may elect to be interviewed with or without a representative of ANS present.

## VIII. DOCUMENT AND RECORD RETENTION

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

## 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 ANS prior to any release by OIG of information submitted by ANS pursuant to its obligations under this CIA and identified upon submission by ANS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, ANS shall have the rights set forth at 45 C.F.R. § 5.65(d).

## X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, ANS 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 ANS 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 ANS fails to establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2.

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 ANS fails to engage an IRO, as required in Section III.E and Appendix B.

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 ANS fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission or the Arrangements Review Report in accordance with the requirements of Section III.E.

5. A Stipulated Penalty of $1,500 for each day ANS fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date ANS fails to grant access.)

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of ANS 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 ANS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to ANS, stating the specific grounds for its determination that ANS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps ANS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after ANS 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. Timely Written Requests for Extensions. ANS 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 ANS 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 ANS 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 ANS 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 ANS of: (a) ANS'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, ANS 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 ANS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ANS 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 ANS 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 ANS to report a Reportable Event, and take corrective action, 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 ANS constitutes an independent basis for ANS's exclusion from participation in the Federal health care programs. Upon a determination by OIG that ANS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify ANS of: (a) ANS'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.* ANS 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. ANS 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) ANS has begun to take action to cure the

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, ANS fails to satisfy the requirements of Section X.D.3, OIG may exclude ANS from participation in the Federal health care programs. OIG shall notify ANS in writing of its determination to exclude ANS (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 ANS'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, ANS 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 ANS 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, ANS 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 ANS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. ANS 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 ANS to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable 20 days after the ALJ issues such a decision unless ANS 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 ANS 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) ANS had begun to take action to cure the material breach within that period; (ii) ANS has pursued and is pursuing such action with due diligence; and (iii) ANS provided to OIG within that period a reasonable timetable for curing the material breach and ANS 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 ANS, only after a DAB decision in favor of OIG. ANS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude ANS 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 ANS 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. ANS 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 ANS, ANS 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, ANS and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of ANS;

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 ANS's obligations under the CIA in the event of ANS's cessation of participation in Federal health care programs. If ANS withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, ANS shall notify OIG at least 30 days in advance of ANS's intent to reapply as a participating provider 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 ANS 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.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

G. The Parties agree that in the event that SJM reorganizes and ANS ceases to be a separate corporate entity, SJM and OIG shall discuss appropriate modifications to the CIA so that the obligations under the CIA will apply only to the ANS division, functions, and/or products.

**ON BEHALF OF ADVANCED NEUROMODULATION SYSTEMS, INC.**

6.14.07

KIMBERLEY A. ELTING
Vice President and General Counsel
Advanced Neuromodulation Systems, Inc.

DATE

6-14-07

ERIC A. DUBELIER, ESQ.
Reed Smith, LLP
Counsel for Advanced Neuromodulation Systems, Inc.

DATE

Gina M. Cavalier /EAD

6-14-07

GINA M. CAVALIER, ESQ.
Reed Smith, LLP
Counsel for Advanced Neuromodulation Systems, Inc.

DATE

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

7/2/07

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

DATE

## APPENDIX A

## ARRANGEMENTS SYSTEMS, PROCESSES, AND/OR PROCEDURES

ANS shall create and maintain procedures, processes, and/or systems, as applicable, to track all existing and new or renewed Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, in order to ensure that each Arrangement does not violate the Anti-Kickback Statute.

A. The Tracked Arrangements Systems shall contain certain information to assist ANS in evaluating whether each Contractual Arrangement violates the Anti-Kickback Statute, including, but not limited to, the following:

1. Each party involved in the Arrangement;

2. The type of Arrangement (e.g., physician employment contract, consulting agreement, lease agreement);

3. The term of the Arrangement, including the effective and expiration dates and any automatic renewal provisions;

4. The amount of compensation to be paid pursuant to the Arrangement and the means by which compensation is paid (as applicable);

5. The methodology for determining the compensation under the Arrangements, including the methodology used to determine the fair market value of such compensation;

6. Whether the amount of compensation to be paid pursuant to the Arrangement is determined based on the volume or value of referrals between the parties;

7. Whether each party has fulfilled the requirements of Section III.D.2; and

8. Whether the Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

B. The Tracked Arrangements Systems shall contain certain information to assist ANS in evaluating whether each Non-Contractual Arrangement violates the Anti-Kickback Statute, including, but not limited to, the following:

1. The name of the entity or individual receiving the Non-Contractual remuneration;

2. The type of Non-Contractual remuneration (listing in the aggregate multiple distributions of the same type of Non-Contractual remuneration to each entity or individual);

3. The aggregate value of each type of Non-Contractual remuneration given to each entity or individual during the Reporting Period;

4. Whether the Non-Contractual remuneration given pursuant to the Non-Contractual Arrangement is determined based on the volume or value of referrals between the parties; and

5. Whether the Non-Contractual Arrangement satisfies the requirements of an Anti-Kickback Statute safe harbor.

## APPENDIX B
## INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

ANS 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 verification in a professionally independent and objective fashion, as set forth in Paragraph D. Within 60 days after OIG receives written notice of the identity of the selected IRO, OIG will notify ANS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ANS may continue to engage the IRO.

If ANS 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, ANS shall submit the information identified in Section V.A.11 to OIG within 60 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify ANS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ANS may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals qualified to conduct the IRO Verification Review; and

2. have sufficient staff and resources to conduct the IRO Verification Review required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform a verification review of 25 percent of the Arrangements reviewed in the Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquires in a prompt, objective, and factual manner; and

3. prepare timely, clear, well-written reports that include all the information required by Section III.E.4 of the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the IRO Verification Review in a professionally independent and 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 ANS.

E. IRO Removal/Termination.

1. *ANS.* If ANS terminates its IRO during the course of the engagement, ANS must submit a notice explaining its reasons to OIG no later than 30 days after termination. ANS 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 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 ANS to engage a new IRO in accordance with Paragraph A of this Appendix.

Before requiring ANS to engage a new IRO, OIG shall notify ANS 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, ANS 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. ANS 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 ANS before requiring ANS to terminate the IRO. However, the final determination as to whether or not to require ANS to engage a new IRO shall be made at the sole discretion of OIG.