

**CORPORATE INTEGRITY AGREEMENT**  
**BETWEEN THE**  
**OFFICE OF INSPECTOR GENERAL**  
**OF THE**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**AND**  
**SMITH & NEPHEW, INC.**

**I. PREAMBLE**

Smith & Nephew, Inc. (“Smith & Nephew”), a wholly owned subsidiary of Smith & Nephew plc, by its undersigned attorneys, pursuant to authority granted by the Board of Directors of Smith & Nephew, Inc. and Smith & Nephew plc, relative to the conduct of Smith & Nephew, Inc.’s unincorporated Orthopedic Reconstruction Global Business Unit (the “Company”), hereby enter into this 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, Smith & Nephew is entering into a Settlement Agreement and Deferred Prosecution Agreement (DPA) with the United States. This CIA shall apply only to U.S. operations of Smith & Nephew that are subject to U.S. Federal health care program requirements.

Smith & Nephew represented to the OIG that, prior to the effective date of this CIA, Smith & Nephew established voluntary compliance programs in its Global Business Units, which includes a Chief Compliance Officer, a Compliance Committee, a Code of Business Principles for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, an ineligible persons screening program, and internal audit and review procedures. Smith & Nephew agrees to continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Smith & Nephew under this CIA shall be five (5) 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 the “Reporting Period.”

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Smith & Nephew's final annual report; or (2) any additional materials submitted by Smith & Nephew 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 the Company that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between the Company and any actual or potential source of health care business or referrals of health care business to the Company or any actual or potential recipient of health care business or referrals from the Company. 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, or 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.
  - a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to the Company, including but not limited to, training, education, consulting, research, clinical studies, focus groups, physician advisory boards as well as intellectual property, grants, and charitable contributions.
  - b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.
2. "Covered Persons" includes:
  - a. all officers, directors and employees of Smith & Nephew, including but not limited to, all members of Smith & Nephew's respective management inclusive of senior vice presidents, vice presidents, directors, and managers;
  - b. all contractors, subcontractors, agents, and other persons who, on behalf of Smith & Nephew, perform functions related to the sale or

marketing of items or services reimbursable by Federal health care programs; and

c. all individuals that sell or market on behalf of Smith & Nephew items or services for which reimbursement may be made by the 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.

3. “Arrangements Covered Persons” includes Covered Persons involved in the development, approval, management, implementation, use, or review of any of the Company’s Arrangements.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Smith & Nephew shall maintain a compliance program that includes the following elements during the term of the CIA:

#### **A. Compliance Officer and Committee.**

1. *Compliance Officer.* Smith & Nephew represented to the OIG that, prior to the Effective Date of this CIA, Smith & Nephew’s Global Business Units each appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. Within 60 days of the Effective Date, Smith & Nephew will appoint a Chief Compliance Officer (“Compliance Officer”) for the term of the CIA and 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. The Compliance Officer shall be a member of senior management, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Chief Compliance Officer of Smith & Nephew plc, who is authorized to report on compliance matters to Smith & Nephew plc Board of Directors at any time. The Compliance

Officer shall not be or be subordinate to Smith & Nephew's General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Smith & Nephew as well as for any reporting obligations imposed upon Smith & Nephew under this CIA.

Smith & Nephew 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 120 days after the Effective Date, Smith & Nephew 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, human resources, legal, sales, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his or her responsibilities (e.g., assist in the analysis of Smith & Nephew's risk areas and oversee monitoring of internal and external audits and investigations).

Smith & Nephew 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.* Smith & Nephew represented to the OIG that, prior to the Effective Date of this CIA, Smith & Nephew is subject to a Code of Business Principles (the "Code of Conduct"). Smith & Nephew shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. To the extent not already addressed in the Code of Conduct, within 90 days of the Effective Date, the Code of Conduct shall be revised to include, at a minimum, the following elements:

a. Smith & Nephew's commitment to full compliance with all federal,

state and local laws and regulations (which includes Federal health care program requirements);

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

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

d. the possible consequences to Smith & Nephew and Covered Persons of failure to comply with all Federal health care program requirements and with Smith & Nephew's Policies and Procedures and the failure to report such non-compliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and Smith & Nephew's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, Smith & Nephew shall distribute the Code of Conduct (revised as necessary to include the elements set forth above) to each Covered Person and each Covered Person will certify, in writing or electronically, that he or she has received, read, understood and shall abide by Smith & Nephew's Code of Conduct. Smith & Nephew may distribute the Code of Conduct and the required certification to each Covered Person either electronically or in hard-copy form. 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 120 days after the Effective Date, whichever is later.

Smith & Nephew 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 or electronically, 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 120 days after the Effective Date, Smith & Nephew shall implement written Policies and Procedures regarding the operation of Smith & Nephew'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;
- 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 Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 120 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. Distribution may include publishing such Policies and Procedures on Smith & Nephew's intranet or other internal web sites available to all employees. If Smith & Nephew uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner, and it must adopt tracking procedures designed to track the distribution and reasonably ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Smith & Nephew 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 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, Smith & Nephew shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Smith & Nephew's:

- a. CIA requirements; and
- b. 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 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 three 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. Smith & Nephew's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

- c. the personal obligation of each individual involved in the development, approval, management, implementation, use, or review of Smith & Nephew's Arrangements to know the applicable legal requirements and Smith & Nephew'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 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Smith & Nephew 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 two hours of Arrangements Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training pursuant to this Section III.C shall, upon completion of the training, certify, in writing or in electronic form, 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 required by this Section III.C shall be knowledgeable about the subject area.

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

6. *Training Methods.* Smith & Nephew 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 Smith & Nephew chooses to provide training pursuant to any such method, they shall also make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

7. Independent Distributors. Where a Covered Person or Arrangements Covered Person is an independent distributor, the General Training obligations under this CIA shall be met so long as the training is provided to a member of management of the independent distributor. The Company shall request, and with respect to all new Arrangements, require the independent distributor to take reasonable steps to apprise its employees and other personnel regarding the content of the training. In addition, the Company shall require such entities to do the following:

- a. agree to abide by the Code of Conduct or adopt its own Code of Conduct addressing substantially all of the requirements of Section III.B.1;
- b. distribute the following materials to its employees and subcontractors working on the Company: (1) the Company's or its own Code of Conduct; (2) copies of relevant the Company policies and procedures relating to the work of the independent distributor; and (3) information about the Company's Disclosure Program (including the hotline number);
- c. provide either directly or through the Company, Anti-Kickback Training (as described in Section III.C.2) to its employees and subcontractors to the extent they are involved with the development, approval, management, implementation, use, or review of any of the Company's Arrangements;
- d. certify to the Company that all employees and subcontractors working on the Company matters have: (1) been screened to exclude Ineligible Persons in accordance with the requirements of Section III.G of the CIA; (2) received a copy of the Company's Code of Conduct or its own Code of Conduct, information about the Company's Disclosure Program (including the hotline number); and (3) to the extent applicable, received Anti-Kickback training.

#### D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 120 days after the Effective Date, the Company shall create 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, directives, and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a database of all existing and new or renewed Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, that shall contain the information specified in Appendix A (Arrangements Database);
- b. tracking remuneration to and from all parties to Arrangements;
- c. tracking service and activity logs to ensure that parties to an Arrangement are performing the services required under the applicable Arrangement;
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the Arrangement (if applicable);
- e. establishing and implementing a written review and prior approval process 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 existing and new or renewed Contractual Arrangements do not violate the Anti-Kickback Statute;
- f. establishing and implementing a written review and approval process for all Non-Contractual Arrangements, including but not limited to, an annual 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 Non-Contractual Arrangements do not violate the Anti-Kickback Statute;
- g. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide

a report on the results of such review to the Compliance Committee;  
and

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

2. *New or Renewed Arrangements.* With the exception of Non-Contractual Arrangements, prior to entering into new Arrangements or renewing existing Arrangements, in addition to complying with the Arrangements Procedures set forth above, the Company shall comply with the following requirements (Arrangements Requirements):

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

b. Include in the written agreement a requirement that all individuals who meet the definition of Covered Persons shall comply with Smith & Nephew's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, the Company shall provide each party to the Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures; and

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.* The Company shall retain and make available to OIG, upon request, the Arrangements Database 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. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, the Company 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 review to assist the Company in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review).

The IRO shall assess, along with the Company, whether it can perform the IRO 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 Arrangements Review shall not be deemed to create an attorney-client relationship between the Company and the IRO. The other applicable requirements relating to the IRO(s) are outlined in Appendix B to this CIA, which is incorporated by reference.

b. *Frequency of Arrangements Review.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

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

d. *Responsibilities and Liabilities.* Nothing in this Section III.E affects the Company’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.* The IRO shall perform a review to assess whether the Company is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 50 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether the Company has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether the Company has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (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 activity logs are properly completed and reviewed; (e) verifying (if applicable) that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored; (f) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when potential violations of the Anti-Kickback Statute are discovered; and (h) verifying that the Company has met the requirements of Section III.D.2.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (a) whether the Company has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether the Company has complied with the Arrangements Procedures and Arrangements Requirements with respect to each of the randomly selected Arrangements reviewed by the IRO. In addition, the Arrangements Review Report shall include observations, findings and recommendations, if any, on possible improvements to the Company's policies, procedures, and systems in place to ensure that all Arrangements do not violate the Anti-Kickback Statute.

4. *Validation Review.* In the event OIG has reason to believe that: (a) the Company's Arrangements Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Arrangements Review results are inaccurate, OIG may,

at its sole discretion, conduct its own review to determine whether the Arrangements Review complied with the requirements of the CIA and/or the findings or Arrangements Review results are inaccurate (Validation Review). The Company 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 the Company's final Annual Report must be initiated no later than one year after the Company's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify the Company 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, the Company 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 or to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. The Company 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 the Company 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.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to the Company 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 that it has concluded that it is, in fact, independent and objective.

6. *Suspension of Requirements of Section III.E.* Section III.E requirements will be suspended during the first 18 months of the CIA while the DPA is in effect, unless and until OIG provides notice to the Company that the suspension is lifted. In the event that OIG provides notice to the Company that Section III.E requirements are no longer suspended, within 90 days the Company shall engage an IRO as set forth in Section III.E. Once the Company engages an IRO, the Company shall provide the following information regarding the IRO:

- (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 the Company and the IRO; and
- (d) the proposed start and completion dates of the Arrangements Review;
- (e) a certification from the IRO regarding its professional independence and objectivity with respect to the Company;

Prior to lifting the suspension of Section III.E requirements, OIG shall notify the Company of its intent to do so and provide a written explanation of why OIG believes lifting the suspension of Section III.E requirements is reasonably necessary. To resolve any concerns raised by the OIG, the Company may request a meeting with the OIG. The Company 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 concerns raised by the OIG with the Company prior to lifting the suspension of Section III.E requirements. However, the final determination as to whether or not to lift the suspension of Section III.E requirements shall be made at the sole discretion of the OIG.

#### F. Disclosure Program.

Smith & Nephew represented to the OIG that, prior to the Effective Date of this CIA, it established a Disclosure Program. To the extent already not accomplished, within 120 days of the Effective Date Smith & Nephew shall maintain a Disclosure Program that includes a mechanism (e.g., 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 Smith & Nephew'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. To the extent no already accomplished, Smith & Nephew 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 include a reporting mechanism for anonymous communications for which appropriate confidentiality is 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, the Compliance Officer (or designee) shall conduct an internal review of the allegations set forth in that disclosure and ensure that proper follow-up is conducted.

Smith & Nephew's Compliance Officer (or designee) shall maintain a disclosure log, which includes 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"). 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 all 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, employees, contractors, and agents of Smith & Nephew.

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

a. Smith & Nephew 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 Screened Persons to disclose whether they are an Ineligible Person.

b. Smith & Nephew shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

3. *Removal Requirement.* If Smith & Nephew has actual notice that a Screened Person has become an Ineligible Person, Smith & Nephew shall remove such Screened Person from responsibility for, or involvement with, Smith & Nephew'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 Smith & Nephew 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, Smith & Nephew 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, Smith & Nephew shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Smith & Nephew, conducted or brought by a governmental entity or its agents involving an allegation that Smith & Nephew 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. Smith & Nephew 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

i. 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

ii. the filing of a bankruptcy petition by Smith & Nephew.

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

b. *Reporting of Reportable Events.* If Smith & Nephew determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Smith & Nephew 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 Smith & Nephew's actions taken to correct the Reportable Event; and
- iii. any further steps Smith & Nephew plans to take to address the Reportable Event and prevent it from recurring.
- iv. if the Reportable Events involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

#### **IV. NEW BUSINESS UNITS**

In the event that, after the Effective Date, Smith & Nephew sells, closes, purchases, or establishes a new business unit related to the delivery, sale, marketing, or furnishing of items or services that may be reimbursed by Federal health care programs, Smith & Nephew shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of sale, closure, purchase, or establishment. This notification shall include the address of the new business unit, phone number, fax number, any Medicare Provider number, provider identification number and/or supplier number (if applicable), and the corresponding contractor's name and address that has issued any such Medicare

number. Each new business unit shall be subject to all of the requirements under this CIA.

**V. IMPLEMENTATION AND ANNUAL REPORTS**

A. Implementation Report. Within 120 days after the Effective Date, Smith & Nephew 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; and
  - 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 Arrangements Database required by Section III.D.1.a;
8. a description of the internal review and approval process 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. a description of the process by which Smith & Nephew fulfills the requirements of Section III.G regarding Ineligible Persons;
12. 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;
13. a list of all of Smith & Nephew's locations (including locations and mailing addresses); the corresponding name(s) 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);
14. a description of Smith & Nephew's corporate structures, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
15. the certifications required by Section V.C.

**B. Monitor Reports.**

1. Smith & Nephew shall submit to OIG any report or written recommendations produced by the Monitor pursuant to the DPA within 10 days of Smith & Nephew receiving any report or written recommendations from the Monitor.

2. Smith & Nephew shall submit to OIG any report Smith & Nephew provides to the Monitor pursuant to the DPA at the same time Smith & Nephew provides such documentation to the Monitor.

3. Any written documentation Smith & Nephew provides to the Monitor pursuant to the DPA shall be made available to the OIG upon request.

C. Annual Reports. Smith & Nephew shall submit to OIG annually a report with respect to the status of, and findings regarding, Smith & Nephew'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. 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 Arrangements Database 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.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. Smith & Nephew'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 Smith & Nephew 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 Smith & Nephew;
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 Smith & Nephew 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 Smith & Nephew 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;

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 Smith & Nephew's locations (including addresses) as required by Section V.A.15; the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; and each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s) (if applicable); 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.

D. 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, Smith & Nephew is in compliance with all of the requirements of this CIA;

2. to the best of his or her knowledge, Smith & Nephew 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, Smith & Nephew 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.



E. Designation of Information. Smith & Nephew shall clearly identify any portions of their submissions that they believe 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. Smith & Nephew 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

Smith & Nephew:

Austin A. Byrd  
Vice President, Ethics, Compliance and Professional Affairs  
Orthopedic Reconstruction Global Business Unit  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, TN 38116  
Telephone: (901) 399-6752  
Facsimile: (901) 396-7824

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 Smith & Nephew's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Smith & Nephew's locations for the purpose of verifying and evaluating: (a) Smith & Nephew's compliance with the terms of this CIA; and (b) Smith & Nephew's compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Smith & Nephew 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 Smith & Nephew'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. Smith & Nephew shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Smith & Nephew's employees may elect to be interviewed with or without a representative of Smith & Nephew present. Smith & Nephew's employees shall have the right to be represented by counsel and any such employee may, at his or her option, be accompanied by counsel for Smith & Nephew and/or his or her personal counsel at any interview by the OIG. Notwithstanding such arrangement, the OIG recognizes that individuals have the right to refuse to submit to interviews, and Smith & Nephew shall not be obligated to require such individuals to submit to interviews. If any individual decides not to submit to an interview, such refusal shall not constitute a breach of this CIA. Smith & Nephew shall not discourage employees from submitting to interviews requested by the OIG.

## **VIII. DOCUMENT AND RECORD RETENTION**

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

## **X. BREACH AND DEFAULT PROVISIONS**

Smith & Nephew and the Company are expected to fully and timely comply with all of its CIA obligations. A breach of this CIA does not constitute a breach of the Settlement Agreement between Smith & Nephew and the Company and the United States executed contemporaneously herewith. Any breach of the terms of that agreement does not constitute a breach of this CIA, except to the extent that such a breach independently also constitutes a breach of this CIA. Section X of this CIA specifies all of the remedies available to the OIG if Smith & Nephew or the Company fails to satisfy its obligations under this CIA. The remedies available to the OIG under this Section X do not preempt or limit any action that any government entity may take against Smith & Nephew or the Company under appropriate authorities.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Smith & Nephew 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 Smith & Nephew 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 the Company 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 the Company 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 Smith & Nephew fail to submit the Implementation Report, documentation required under Section V.B, or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day the Company fails to submit the annual Arrangements Review Report in accordance with the requirements of Section III.E.

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

7. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Smith & Nephew as part of its Implementation Report, Annual Reports, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

8. A Stipulated Penalty of \$1,000 for each day Smith & Nephew or the Company fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Smith & Nephew, stating the specific grounds for its determination that Smith & Nephew has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Smith & Nephew shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Smith & Nephew 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 1-7 of this Section.

B. Timely Written Requests for Extensions. Smith & Nephew 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 Smith & Nephew 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 Smith & Nephew 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 Smith & Nephew 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 Smith & Nephew of: (a) Smith & Nephew'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"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Smith & Nephew 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 Smith & Nephew elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Smith & Nephew 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 Smith & Nephew 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 Smith & Nephew to report a Reportable Event, or 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.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Smith & Nephew constitutes an independent basis for Smith & Nephew's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Smith & Nephew has materially breached this CIA

and that exclusion is the appropriate remedy, OIG shall notify Smith & Nephew of: (a) Smith & Nephew'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.* Smith & Nephew 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. Smith & Nephew 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) Smith & Nephew has begun to take action to cure the material breach; (ii) Smith & Nephew is pursuing such action with due diligence; and (iii) Smith & Nephew has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Smith & Nephew fails to satisfy the requirements of Section X.D.3, OIG may exclude Smith & Nephew from participation in the Federal health care programs. OIG shall notify Smith & Nephew in writing of its determination to exclude Smith & Nephew (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 Smith & Nephew'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, Smith & Nephew 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 Smith & Nephew 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, Smith & Nephew 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 Smith & Nephew was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Smith & Nephew 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 Smith & Nephew to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Smith & Nephew 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 Smith & Nephew 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) Smith & Nephew has begun to take action to cure the material breach within that period; (ii) Smith & Nephew has pursued and is pursuing such action with due



diligence; and (iii) Smith & Nephew provided to OIG within that period a reasonable timetable for curing the material breach and Smith & Nephew 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 Smith & Nephew, only after a DAB decision in favor of OIG. Smith & Nephew's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Smith & Nephew 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 Smith & Nephew 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. Smith & Nephew 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 Smith & Nephew, Smith & Nephew 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**

Smith & Nephew and OIG agree as follows:

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

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. OIG may agree to a suspension of Smith & Nephew's obligations under the CIA in the event of Smith & Nephew's cessation of the delivery, sale, marketing, or

furnishing of items or services reimbursed by any Federal health care programs. If such cessation occurs and Smith & Nephew is relieved of its CIA obligations by OIG, Smith & Nephew shall notify OIG at least 30 days in advance of the date on which Smith & Nephew intends to begin delivering, selling, marketing, or furnishing items or services reimbursed by any Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Smith & Nephew 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.

**ON BEHALF OF SMITH & NEPHEW ORTHOPAEDICS, INC.**

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JOSEPH DEVIVO

President, Orthopaedic Reconstruction Global  
Business Unit (“Recon”)  
For Recon and Smith & Nephew, Inc.

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DATE

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AUSTIN B. BYRD, Esq.

Vice President, Ethics, Compliance  
and Professional Affairs  
Orthopaedic Reconstruction Global Business Unit  
Smith & Nephew, Inc.

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DATE

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DAVID A. VICINANZO, Esq.

MELISSA TEARNEY, Esq.

Nixon Peabody LLP

Counsel for Smith & Nephew Orthopaedics, Inc.

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DATE

**ON BEHALF OF SMITH & NEPHEW, INC.**

  
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Joseph DeVivo  
President, Orthopaedic Reconstruction Global  
Business Unit ("Recon")  
For Recon and Smith & Nephew, Inc.

9/27/07  
DATE

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Austin B. Byrd, Esq.  
Vice President, Ethics, Compliance  
and Professional Affairs  
Orthopaedic Reconstruction Global Business Unit  
Smith & Nephew, Inc.

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DATE

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David A. Vicinanza, Esq.  
Melissa Tearney, Esq.  
Nixon Peabody LLP  
Counsel for Smith & Nephew Orthopaedics, Inc.

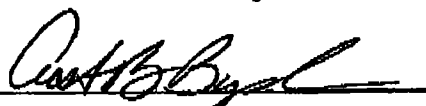
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Corporate Integrity Agreement between  
OIG-HHS and Smith & Nephew, Inc.

ON BEHALF OF SMITH & NEPHEW, INC.

\_\_\_\_\_  
Joseph DeVivo  
President, Orthopaedic Reconstruction Global  
Business Unit ("Recon")  
For Recon and Smith & Nephew, Inc.

\_\_\_\_\_  
DATE

  
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Austin B. Byrd, Esq.  
Vice President, Ethics, Compliance  
and Professional Affairs  
Orthopedic Reconstruction Global Business Unit  
Smith & Nephew, Inc.

\_\_\_\_\_  
9/27/07  
DATE

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David A. Vicinanza, Esq.  
Melissa Tearney, Esq.  
Nixon Peabody LLP  
Counsel for Smith & Nephew Orthopaedics, Inc.

\_\_\_\_\_  
DATE

Corporate Integrity Agreement between  
OIG-HHS and Smith & Nephew, Inc.

ON BEHALF OF SMITH & NEPHEW, INC.

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Joseph DeVivo  
President, Orthopaedic Reconstruction Global  
Business Unit ("Recon")  
For Recon and Smith & Nephew, Inc.

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DATE

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Austin B. Byrd, Esq.  
Vice President, Ethics, Compliance  
and Professional Affairs  
Orthopedic Reconstruction Global Business Unit  
Smith & Nephew, Inc.

\_\_\_\_\_  
DATE

*David A. Vicinanza DDP*  
*Melissa B. Tearney DDP*  
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David A. Vicinanza, Esq.  
Melissa Tearney, Esq.  
Nixon Peabody LLP  
Counsel for Smith & Nephew Orthopaedics, Inc.

*9/27/07*  
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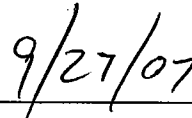
Corporate Integrity Agreement between  
OIG-HHS and Smith & Nephew, Inc.

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



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



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## APPENDIX A

### ARRANGEMENTS DATABASE

The Company shall create and maintain an Arrangements Database to track all new and existing Arrangements, including Contractual Arrangements and Non-Contractual Arrangements, in order to ensure that each Arrangement does not violate the Anti-Kickback Statute.

A. The Arrangements Database shall contain certain information to assist the Company 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, medical directorship, 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;
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 Arrangements Database shall contain certain information to assist the Company 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.

The Company 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 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 the Company if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Company may continue to engage the IRO.

If the Company 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, the Company shall submit the information identified in Section V.A.11 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 the Company if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, the Company may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals qualified to conduct the Arrangements Review; and
2. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each 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.3 of the CIA.

D. IRO Independence and Objectivity.

The IRO must perform the Arrangements 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 The Company.

E. IRO Removal/Termination.

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

Prior to requiring the Company to engage a new IRO, OIG shall notify the Company 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, the Company 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. The Company 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 the Company prior to requiring the Company to terminate the IRO. However, the final determination as to whether or not to require the Company to engage a new IRO shall be made at the sole discretion of OIG.