

CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
SYNTHES, INC.

I. PREAMBLE

Synthes, Inc. hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Synthes, Inc. and its U.S. subsidiaries 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) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Hereafter, Synthes, Inc. and its U.S. subsidiaries shall be referred to collectively as "Synthes." Contemporaneously with this CIA, Synthes, Inc. is entering into a Settlement Agreement with the United States.

As referenced in the Settlement Agreement, Synthes, Inc. and a Synthes, Inc. subsidiary, Norian Corporation (Norian), agreed to plead guilty to certain criminal charges. The guilty plea by Norian will result in the mandatory exclusion of Norian under 42 U.S.C. § 1320a-7(a)(3). In addition to its agreement in this CIA to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements, Synthes also agrees to enter into a separate Divestiture Agreement with OIG relating to the exclusion of Norian.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Synthes under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date by which Synthes is obligated to pay the Settlement Amount as set forth in the Settlement Agreement between Synthes and the United States (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) Synthes' final Annual Report; or (2) any additional materials submitted by Synthes pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:

a. all owners of Synthes who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);

b. all officers and directors of Synthes;

c. (1) except as carved out below in this Section II.C.1, all employees of Synthes who are based in the United States, and (2) all employees of Synthes or of any foreign subsidiary of Synthes, Inc. who are based outside the United States and who have responsibilities for or perform Promotional and Product Services Related Functions, Clinical Investigation Related Functions, IDE-Exempted Investigation Related Functions or Reporting Related Functions (as defined, respectively, in Sections II.C.4-7 below)¹; and

d. all contractors, subcontractors, agents, and other representatives of Synthes who perform any Covered Functions on behalf of Synthes either in the United States or with U.S.-based health care practitioners (HCPs).

Notwithstanding the above, this term does not include: (a) 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; or (b) officers,

¹ The Promotional and Product Services Related Functions, Clinical Investigation Related Functions, IDE-Exempted Investigation Related Functions and Reporting Related Functions shall be referred to collectively as the "Covered Functions."

employees, contractors, subcontractors, agents, or other personnel engaged in manufacturing functions or involved with Synthes' veterinary products, so long as they do not (i) market, distribute, sell, or promote Government Reimbursed Products or (ii) have responsibilities for or perform any of the Covered Functions.

2. "Relevant Covered Persons" includes all Covered Persons who have responsibilities for or perform any of the Covered Functions.
3. "Government Reimbursed Products" refers to all human products of Synthes or any foreign subsidiary of Synthes, Inc. that are promoted or sold by Synthes or any foreign subsidiary of Synthes, Inc. in the United States and reimbursed by Federal health care programs.
4. "Promotional and Product Services Related Functions" include: (a) the promotion, marketing, advertising, and sale of Government Reimbursed Products; (b) the development or dissemination of materials or information about, or the provision of services, training, or consumer preference testing relating to Government Reimbursed Products; and (c) the activities of the Professional Relations Department.
5. "Clinical Investigation Related Functions" include: organizing, coordinating, administering, providing training for, monitoring, and FDA reporting related to clinical investigations, subject registries, and other research or studies involving the use of Government Reimbursed Products or Synthes products that Synthes expects or intends will become Government Reimbursed Products in one or more human subjects, as well as all relevant obligations under FDA's Investigational Device Exemption regulations, 21 C.F.R. Part 812, Protection of Human Subjects regulations, 45 C.F.R. Part 46 and 21 C.F.R. Part 50, Institutional Review Board regulations, 21 C.F.R. Part 56, and Financial Disclosure by Clinical Investigator regulations, 21 C.F.R. Part 54.
6. "IDE-Exempted Investigation Related Functions" include: organizing, coordinating, administering, providing training for, and monitoring consumer preference testing, market preference evaluations, testing of modifications, or testing of a combination of two or more devices in

commercial distribution, or other such testing in one or more human subjects involving Government Reimbursed Products or Synthes products that Synthes expects or intends will become Government Reimbursed Products that are exempted from IDE regulation, including, but not limited to those exempted under 21. C.F.R. § 812.2.

7. “Reporting Related Functions” include: identifying, tracking, gathering, and compiling information and preparing reports for the purpose of providing information to the FDA concerning Government Reimbursed Products or Synthes products that Synthes expects or intends will become Government Reimbursed Products. This includes reporting of adverse events (including reports required under 21 U.S.C. § 360i and the Medical Device Reporting (MDR) regulation at 21 C.F.R. § 803 and other reporting under FDA requirements, (including those required under 21 C.F.R. § 814.84)).
8. “Relevant Promotional and Product Services Covered Persons” includes all Covered Persons who have responsibilities for or perform Promotional and Product Services Related Functions.
9. “Relevant Clinical Investigation Covered Persons” includes all Covered Persons who have responsibilities for or perform Clinical Investigation Related Functions.
10. “IDE-Exempted Investigation Covered Persons” includes all Covered Persons who have responsibilities for or perform IDE-Exempted Investigation Related Functions.
11. “Relevant Reporting Covered Persons” includes all Covered Persons who have responsibilities for or perform Reporting Related Functions.
12. “Synthes Consultants” are employees of Synthes whose responsibilities include the provision of Promotional and Product Services Related Functions within assigned geographic territories within the United States, as well as those individuals who serve as Biomaterials Technical Specialists.

III. CORPORATE INTEGRITY OBLIGATIONS

Prior to the effective date, Synthes established a Compliance Program that includes the elements set forth below. Synthes shall maintain such a Compliance Program throughout the term of this CIA:

A. Compliance Responsibilities of Certain Synthes Employees and the Board of Directors.

1. *Chief Compliance Officer.* Prior to the Effective Date, Synthes appointed an individual to serve as its Chief Compliance Officer and Synthes shall maintain a Chief Compliance Officer for the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Chief Compliance Officer shall be a member of senior management and shall report to the Chief Executive Officer and to the Audit Committee of the Board. The Chief Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Synthes and shall be authorized to report on such matters to the Board of Directors at any time. The Chief Compliance Officer shall not be, or be subordinate to, the General Counsel or Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Synthes as well as for any reporting obligations created under this CIA. Any job responsibilities of the Chief Compliance Officer not related to compliance functions shall be limited and must not interfere with the Chief Compliance Officer's ability to perform the duties outlined in this CIA.

Synthes shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 5 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Synthes appointed a Compliance Committee, and Synthes shall maintain the Compliance Committee during the term of the CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and the members of senior management with responsibilities relevant to the requirements of this CIA, including the Chief Executive Officer, the Chief

Financial Officer, the Head of Global Operations, the Vice President of Global Human Resources, the Presidents of all of Synthes' business divisions, including Trauma, Spine, CMF, and Biomaterials, the General Counsel, the Vice President of Global Regulatory and Clinical Affairs (when such a position has been filled) and the Head of Internal Audit. The Chief Compliance Officer shall chair the Compliance Committee. The Committee and its individual members shall provide the support required for the Chief Compliance Officer to maintain an effective corporate compliance program for Synthes. This support shall include, but is not limited to: providing executive level guidance to the Chief Compliance Officer on matters related to corporate ethics and compliance; acting as a body to which to escalate, discuss, and resolve compliance issues; providing resources and support within their individual areas of responsibility for compliance initiative development, implementation and management; and monitoring and supporting the performance of Synthes' ethics and compliance-related initiatives, including reviewing and addressing monitoring results and risk areas and overseeing internal and external audits and evaluations.

Synthes 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.

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board shall, at a minimum, be responsible for the following:

a. Ensuring that the Audit Committee of the Board shall meet at least quarterly to review and oversee Synthes' Compliance Program, including but not limited to the performance of Synthes' Certifying Employees (as defined below in Section III.A.4) and Synthes' Chief Compliance Officer in the performance of their responsibilities to ensure compliance with the terms of this CIA.

b. The Board shall arrange for the performance of a review on the effectiveness of Synthes' Compliance Program (Compliance Program Review) by the Compliance Expert (described below) for each Reporting Period of the CIA. The Board shall review the Compliance Program Review Report (described below) of the Compliance Program Review as part of the review and assessment of Synthes'

Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by Synthes.

c. The Board shall retain an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert). The Compliance Expert shall create a work plan for the Compliance Program Review, oversee the performance of the Compliance Program Review, and prepare a written report about the Compliance Program Review and the results of the review. The written report (Compliance Program Review Report) shall include a description of the review and shall include recommendations with respect to the Compliance Program.

d. For each Reporting Period of the CIA, the Board shall adopt a resolution, signed by each individual member of the Board, summarizing its review and oversight of Synthes' compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors has made a reasonable inquiry into the operations of Synthes' Compliance Program, including the performance of the Certifying Employees and the Chief Compliance Officer in the performance of their responsibilities to ensure compliance with the terms of this CIA. In addition, the Board has retained a Compliance Expert with expertise in compliance with the Federal health care program and FDA requirements to support the Board's responsibilities. The Board also has arranged for the performance of, and reviewed the results of the Compliance Program Review, including the Compliance Program Review Report. Based on all of these steps, the Board has concluded that, to the best of its knowledge, Synthes has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Synthes.

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

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Synthes employees (“Certifying Employees”) are specifically expected to manage, monitor and oversee activities within their areas of authority, including implementation of this CIA, and shall annually certify that the applicable Synthes component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Synthes’ Chief Executive Officer, Chief Financial Officer, Head of Global Operations, Vice-President of Global Human Resources, the Presidents of all Synthes’ business divisions and regions, including Trauma, Spine, CMF, and Biomaterials, Senior Vice-President – Education, and the Vice-President of Global Regulatory and Clinical Affairs (when such position has been filled).

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Synthes is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

B. Written Standards.

1. *Code of Conduct.* To the extent not already accomplished, within 90 days after the Effective Date, Synthes shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Synthes shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

The Code of Conduct shall, at a minimum, set forth the following:

- a. Synthes' commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;
- b. Synthes' requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Synthes' own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Synthes' Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Synthes, suspected violations of any Federal health care program and FDA requirements or of Synthes' own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.E, and Synthes' 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 or electronically, that he or she has received, read, understood, and shall abide by Synthes' Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person (or 60 days if the Covered Person is based outside the United States) or within 120 days after the Effective Date (or 150 days if the Covered Person is based outside the United States), whichever is later.

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

understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct (or 60 days if the Covered Person is based outside the United States).

2. *Policies and Procedures.* To the extent not already completed, within 120 days after the Effective Date, Synthes shall implement written Policies and Procedures regarding the operation of the Compliance Program and Synthes' compliance with Federal health care program and FDA requirements (Policies and Procedures). At a minimum, the Policies and Procedures address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct the Covered Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. § 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions and Clinical Investigation Related Functions in compliance with all applicable FDA requirements including the requirements applicable to investigational devices under 21 C.F.R. § 812.7;
- d. appropriate ways to conduct IDE-Exempted Investigation Related Functions in compliance with all applicable FDA requirements including, but not limited to the requirements governing investigational device exemptions under 21 C.F.R. § 812.2 which bar the use of IDE-Exempted Investigations to gather safety or efficacy data or in cases where there is a risk of patient harm;
- e. the appropriate manner in which to conduct Reporting Related Functions in compliance with all applicable FDA requirements;

- f. the protection of human subjects, as required by 45 C.F.R. Part 46 and 21 C.F.R. Parts 50 and 56, and financial disclosure, as required by 21 C.F.R. Part 54;
- g. systems, processes, policies and procedures for ensuring that all devices Synthes introduces or causes to be introduced into interstate commerce within the United States are the subject of: (1) an FDA-approved pre-market approval application, under 21 U.S.C. § 360e(a)(2) and 21 C.F.R. Part 814; (2) a "510(k) clearance" by FDA for marketing because it is found to be substantially equivalent to an appropriate, legally marketed device, under 21 U.S.C. §§ 360c and 360(k) and 21 C.F.R. Part 807 -- Subpart E; (3) an investigational device exemption under 21 U.S.C. § 360j(g), for the investigational use of a device on humans; or (4) an exemption for certain devices as set forth in 21 U.S.C. § 360(l);
- h. the materials and information concerning Government Reimbursed Products, medical conditions, or medical indications that may be distributed by Synthes Consultants or other Synthes personnel, and the manner in which Synthes personnel respond to requests for information about non-FDA approved or cleared ("off-label") uses of Synthes' products;
- i. the materials and information concerning Government Reimbursed Products, medical conditions, or medical indications that Synthes may distribute through a medical services department (if and when such a department is established). In the event that Synthes elects to change its policies and provide written materials in response to requests for information about non-FDA approved or cleared ("off-label") uses of Synthes' products, the Policies and Procedures shall address the mechanisms through, and manner in which, Synthes will accept and respond to such requests (*e.g.*, through a medical services department), the form and content of information disseminated by Synthes in response to such requests, and the internal review process for the information disseminated. The Policies and

Procedures shall further require that Synthes develop a database to track such requests. This database shall be referred to as the "Inquiries Database."

The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about off-label uses of Synthes' products: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about an off-label indication for the product; 6) nature/form of the response from Synthes (including a record of the materials provided to the HCP or HCI in response to the request); 7) the name of the Synthes representative who called on or interacted with the HCP or HCI; and 8) the status and findings of any follow-up review conducted by Synthes in situations in which it appears that the Inquiry may have related to improper off-label promotion;

- j. if a physician determines that he or she will use a Synthes product for a non-FDA approved or cleared ("off-label") use, the technical assistance about the product that a Synthes employee in the United States may provide during the physician's use of the product in a surgical setting;
- k. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, market preference evaluations, training programs, speaker programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

- l. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Synthes' funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- m. funding of, or participation in, educational or training activities for HCPs or HCIs based in the United States. These Policies and Procedures shall be designed to ensure that Synthes' funding and/or sponsorship of such activities satisfies all applicable Federal health care program and FDA requirements;
- n. review of all promotional and other materials and information, including technique guides, containing claims or information about Government Reimbursed Products intended to be disseminated outside of Synthes within the United States by or on behalf of Synthes, by legal, regulatory, and other relevant personnel in a manner designed to ensure that legal, medical, and, regulatory concerns are properly addressed during Synthes' review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;
- o. sponsorship, funding of, and disclosures relating to research and development-related activities (including clinical trials, test markets, market research, and authorship of articles and other publications). These Policies and Procedures shall be designed to ensure that Synthes' funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- p. compensation (including salaries and bonuses) for Relevant Promotional and Product Services Covered Persons who are Synthes Consultants. These Policies and Procedures shall be designed to ensure that financial incentives do not

inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Synthes' products; and

- q. disciplinary policies and procedures for violations of Synthes' Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 30 days of their implementation, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Synthes 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 made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date for U.S.-based Covered Persons and 180 days after the Effective Date for Covered Persons based outside of the United States, Synthes shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Synthes':

- a. CIA requirements; and
- b. Synthes' Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

In addition, within 90 days after the Effective Date, Synthes shall notify all Covered Persons in writing or in electronic format of the fact that Synthes entered into a CIA and shall provide them with an explanation of Synthes' requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days (or 180 days if the Covered Person is based outside the United States) 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. *Specific Promotional and Product Services Training.* Within 120 days after the Effective Date for U.S.-based Covered Persons and 180 days after the Effective Date for Covered Persons based outside of the United States, each Relevant Promotional and Product Services Covered Person shall receive at least 4 hours of Specific Promotional and Product Services Training in addition to the General Training required above. This Specific Training shall include a discussion of:

- a. all applicable Federal health care program and FDA requirements and all Synthes Policies and Procedures relating to Promotional and Product Services Related Functions;
- b. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and with Synthes Policies and Procedures;
- c. the legal sanctions for violations of the Federal health care program and FDA requirements, the False Claims Act, and the Anti-kickback statute;
- d. examples of proper and improper practices related to Promotional and Product Services Related Functions; and
- e. the possible consequences to both Synthes and Relevant Covered Promotional and Product Services Persons of failure to comply with FDA and Federal health care program requirements and with Synthes' own Policies and Procedures and the failure to report such noncompliance.

New Relevant Promotional and Product Services Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming

Relevant Promotional and Product Services Covered Persons, or within 120 days (or 180 days if the Covered Person is based outside the United States) after the Effective Date, whichever is later. A Relevant Promotional and Product Services employee who is a Synthes Consultant shall not function independently in the field until after he or she has received training on the topics set forth above. A Relevant Promotional and Product Services Covered Person who is not a Synthes Consultant shall have his or her work reviewed by a Synthes employee who has completed the Specific Promotional and Product Services Training, to the extent that the work relates to Promotional and Product Services Functions, until such time as the person receives the training on the topics set forth above.

After receiving the initial Specific Promotional and Product Services Training described in this Section, each Relevant Promotional and Product Services Covered Person shall receive at least 3 hours of Specific Promotional and Product Services Training in each subsequent Reporting Period.

3. *Specific Clinical Investigation and Reporting Training.* Within 120 days after the Effective Date for U.S.-based Covered Persons and 180 days after the Effective Date for Covered Persons based outside of the United States, each Relevant Clinical Investigation Covered Person, IDE-Exempted Investigation Covered Person, and Relevant Reporting Covered Person shall receive at least 4 hours of Specific Clinical Investigation, IDE-Exempted Investigation, and Reporting Training in addition to the General Training required above. This Specific Clinical Investigation, IDE-Exempted Investigation, and Reporting Training shall include a discussion of:

- a. all applicable Federal health care program and FDA requirements and all Synthes' Policies and Procedures relating to the Covered Functions addressed in this Section III.C.3;
- b. the personal obligation of each individual involved in Covered Functions addressed in this Section III.C.3 to comply with all applicable Federal health care program and FDA requirements and with Synthes' Policies and Procedures, including the requirement to submit complete and accurate information to the FDA;
- c. the legal sanctions for violations of the Federal health care program and FDA requirements;

- d. examples of proper and improper practices related to each of the Covered Functions addressed in this Section III.C.3; and
- e. the possible consequences to both Synthes and Relevant Clinical Investigation Covered Persons, IDE-Exempted Testing Covered Persons, and Relevant Reporting Covered Persons of failure to comply with FDA and Federal health care program requirements and with Synthes' own Policies and Procedures and the failure to report such noncompliance.

New Relevant Clinical Investigation Covered Persons, new IDE-Exempted Investigation Covered Persons, and new Relevant Reporting Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Clinical Investigation Covered Persons, IDE-Exempted Investigation Covered Persons, or Relevant Reporting Covered Persons, or within 120 days (or 180 days if the Covered Person is based outside the United States) after the Effective Date, whichever is later. A Synthes employee who has completed the Specific Clinical Investigation, IDE-Exempted Investigation, and Reporting Training shall review (a) a new Relevant Clinical Investigation Covered Person's work, to the extent that the work relates to Clinical Investigation Related Functions, until such time as the new Relevant Clinical Investigation Covered Person completes his or her Specific Training, (b) a new IDE-Exempted Investigation Covered Person's work, to the extent to the work relates to IDE-Exempted Investigation Related Functions, until such time as the new Relevant IDE-Exempted Investigation Covered Person completes his or her Specific Training, and (c) a new Relevant Reporting Covered Person's work, to the extent that the work relates to Reporting Related Functions, until such time as the new Relevant Reporting Covered Person completes his or her Specific Training.

After receiving the initial Specific Clinical Investigation and Reporting Training described in this Section, each Relevant Clinical Investigation Covered Person, IDE-Exempted Investigation Covered Person, and Relevant Reporting Covered Person shall receive at least three hours of Specific Clinical Investigation and Reporting Training as described in this Section III.C.3 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 Chief 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 of the training, including applicable Federal health care program and FDA requirements.

5. *Update of Training.* Synthes shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* Synthes may provide the training required under this CIA through appropriate computer-based training approaches. If Synthes chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Synthes shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Synthes in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess Synthes' systems, processes, policies, procedures, and practices relating to the Covered Functions (collectively, "IRO Review").

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Generally speaking, each IRO engaged by Synthes shall have expertise in applicable Federal health care program and FDA

requirements as may be appropriate for the Review for which the IRO is retained. Each IRO shall assess, along with Synthes, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Review shall consist of two components – a Systems Review and a Transaction Review.

i. *Systems Review.* The Systems Review shall assess Synthes' systems, processes, policies, and procedures relating to Covered Functions. If there are no material changes in Synthes' systems, processes, policies, and procedures relating to any of the Covered Functions, the Systems Review shall be performed in the first and fourth Reporting Periods. If Synthes materially changes its systems, processes, policies, and procedures relating to any of the Covered Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

ii. *Transactions Review.* The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transactions Review.

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

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each IRO Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

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

Prior to initiating a Validation Review, OIG shall notify Synthes 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, Synthes may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Synthes agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Synthes 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.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Synthes 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 applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Prior to the Effective Date, Synthes established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Synthes' policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirements believed by the individual to be a potential violation of criminal, civil, or administrative law. Synthes shall maintain the Disclosure Program

described above during the term of this CIA and shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic emails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief 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, Synthes shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Chief 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.

F. 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>).

2. *Screening Requirements.* Synthes shall ensure that prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. Synthes shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Synthes shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

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

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

4. *Pending Charges and Proposed Exclusions.* If Synthes has actual notice that a Covered 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 Covered Person's employment or contract term, Synthes shall take all appropriate actions to ensure that the responsibilities of that Covered 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.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Synthes shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Synthes conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that Synthes 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. Synthes 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.

H. 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 and/or applicable to any FDA requirements for which penalties or exclusion may be authorized;

- ii. an adverse event that Synthes: (1) was required to report as an MDR and (2) failed to report to the FDA under 21 U.S.C. § 360i and 21 C.F.R. Part 803 within 30 days; or
- iii. the filing of a bankruptcy petition by Synthes.

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

b. *Reporting of Reportable Events.* If Synthes determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Synthes 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 and/or FDA authorities implicated;
- ii. a description of Synthes' actions taken to correct the Reportable Event; and
- iii. any further steps Synthes plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event 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 and/or FDA authorities implicated.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Synthes and the FDA that materially discusses Synthes' or a Covered Person's actual or potentially unlawful or improper promotion of Synthes' products (including any improper dissemination of information about off-label indications) or improper practices relating to Clinical Investigation Related Functions or IDE-Exempted Investigation Functions, Synthes shall provide a copy of the report, correspondence or communications to the OIG. Synthes shall also provide written notice to the OIG within 30 days after the resolution of any matter disclosed in accordance with the requirements set forth above, and it shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Internal Monitoring Program

To the extent not already accomplished, within 120 days after the Effective Date, Synthes shall establish an Internal Monitoring Program (IMP) to evaluate and monitor various aspects of Synthes' interactions with HCPs and HCIs, including interactions between Synthes Consultants and HCPs and HCIs. As set forth in more detail below, the IMP shall include two elements: i) Observations of Synthes personnel; and ii) Consultant Monitoring Activities.

1. *Observations.*

a. *U.S. Compliance Review Program.* Synthes' managers in the U.S. shall conduct direct field observations (Compliance Reviews) of their non-executive, directly reporting employees, to include sales management and Synthes Consultants, marketing personnel and management, product development personnel and management, and sales support personnel to assess whether those employees know, understand, and comply with the Policies and Procedures required by the CIA. Each Compliance Review shall consist of directly observing at least four hours of meetings between the reviewed employees and HCPs and other representatives of HCIs, and two Compliance Reviews shall be conducted per reviewed employee per year. At the completion of each Compliance Review, the reviewing manager shall prepare a report which includes:

- 1) the identity of the reviewed employee;
- 2) the identity of the manager/reviewer;

- 3) the date and duration of the Compliance Review;
- 4) an overall assessment of compliance with and understanding of the Policies and Procedures; and
- 5) the identification of any potential non-compliance with the Policies or Procedures, including any off-label promotional activity.

b. *Field Visit Program.* In addition to the Compliance Review Program, Synthes compliance personnel shall conduct direct field observations (Field Visits) of Synthes Consultants in the United States to assess whether the messages delivered and materials distributed to, and interactions with, HCPs and representatives of HCIs are consistent with Synthes' Policies and Procedures. These Field Visits shall be full day ride-alongs with Synthes Consultants, and each Field Visit shall consist of directly observing all meetings between a Synthes Consultant and HCPs and other representatives of HCIs during the workday. The Field Visits shall be scheduled throughout the year, randomly selected by Synthes compliance personnel, include each business division, and be conducted across the United States. At the completion of each Observation, Synthes compliance personnel or the designee shall prepare a report which includes:

- 1) the identity of the reviewed employee;
- 2) the identity of the Synthes compliance professional;
- 3) the date and duration of the Field Visit;
- 4) an overall assessment of compliance with and understanding of the Policies and Procedures; and
- 5) the identification of any potential non-compliance with the Policies or Procedures, including off-label promotional activity.

Synthes compliance personnel shall conduct at least 30 full-day Field Visits during each Reporting Period. The number of Field Visits conducted for each business division shall be proportional in number to the size of each division (*i.e.*, the number of Synthes Consultants in each division at the beginning of each Reporting Period), and shall be conducted across the United States.

c. *Reporting and Follow-up.* In the event that a compliance issue, including but not limited to potential off-label promotion or noncompliance with Synthes' compliance program or Policies and Procedures, is identified during any

Compliance Review or Field Visit (collectively “Observation”), Synthes shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Chief Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. The compliance department shall maintain records of any compliance issues identified during an Observation and any corrective action.

2. *Consultant Monitoring Activities.* To the extent that Synthes engages or reimburses an HCP to provide services or participate in training about Government Reimbursed Products (e.g., as a member of an advisory board, as an attendee at a product training session, as a trainer, or as a participant in data-gathering exercises (including market preference evaluations)), such HCPs shall be referred to for purposes of this subsection as “Consultants”. Synthes shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, expenses to be reimbursed, and compliance obligations for the Consultants. Consultants shall be paid and expenses reimbursed according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Synthes.

Prior to the retention of Consultants, Synthes shall ensure that a business rationale form has been completed to justify the retention of or payment to the Consultant. The business rationale form shall include an identification of the business need for the information to be provided by the Consultant and provide specific details about the consulting arrangement (including, for example, information about the numbers and qualifications of the HCPs to be engaged, the agenda for any proposed advisory board meeting, and a description of the proposed work to be done and type of work product to be generated by the Consultant).

To the extent not already accomplished, within 180 days after the Effective Date, Synthes shall establish a process to develop an annual Consultant budgeting plan that identifies the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Personnel from Synthes’ legal department shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan.

Within 180 days after the Effective Date, Synthes shall also establish a process to obtain legal review of all business rationale forms associated with the retention of any Consultant prior to the retention of the Consultant. The purpose of this legal review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements, and that Consultant arrangements are consistent with the applicable approved Consultant budgeting plan. Any deviations from the Consultant budgeting plans shall be documented in the business rationale form (or elsewhere, as appropriate) and shall be considered as part of the legal review. To the extent not already accomplished, within 120 days after the Effective Date, Synthes shall amend its policies to require the collection, assessment, and retention of work product generated by Consultants.

Within 120 days after the Effective Date, Synthes shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of the various types of consultant programs entered with HCPs. For the first Reporting Period, Synthes shall identify the 50 Consultants who received the largest amounts of compensation from Synthes during the year prior to the Reporting Period. Synthes shall audit all programs conducted by the selected Consultants during the Reporting Period. For the second and subsequent Reporting Periods, 90 days prior to the end of the applicable prior Reporting Period Synthes shall provide information to the OIG about the numbers of each type of consulting program, the numbers of Consultants retained for each type of program, and the aggregate amounts of funds expended for each type of consulting program during the Reporting Period. The OIG shall then select up to three types of programs to be audited and shall identify the number of each type of program to be audited by Synthes for each applicable Reporting Period. For the second and subsequent Reporting Periods, the Consultant Monitoring Program shall review Consultant programs both on a risk-based targeting approach and on a random sampling approach.

Personnel conducting the Consultant Program Audits shall review business rationale forms, consultant contracts, and materials relating to the program or work of the Consultant (including a verification that the work product resulting from any Consultant-related program or event or otherwise generated by the Consultant is consistent with the stated business need set forth on the business rationale form or elsewhere), in order to assess whether the programs and arrangements were conducted in a manner consistent with Synthes' Policies and Procedures. Results from the Consultant Program Audits shall

be compiled and reported to Synthes headquarters for review and remediation as appropriate. Potential violations of Synthes' Policies and Procedures shall be reported to the Compliance Department for appropriate follow-up activity.

3. *Reporting and Follow-up.* Personnel conducting the Observations and Consultant Program Audits shall have access to all relevant records and information of Synthes necessary to assess Synthes' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the Observations and Consultant Program Audits shall be compiled and reported to the Chief Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Department for appropriate follow-up activity.

In the event that a compliance issue, including but not limited to a potential off-label promotion or noncompliance with Synthes' legal requirements, compliance program requirements or Policies and Procedures, is identified through the IMP, Synthes shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.H above, as applicable.

Synthes shall include a summary of the IMP and its results as part of each Annual Report. As part of each Annual Report, Synthes also shall provide the OIG with copies of the Compliance Review Program or Field Visit Program reports for any instances in which it was determined that a Synthes employee engaged in improper conduct and a description of the action(s) that Synthes took as a result of such determinations. Synthes shall make the reports for all other IMP activities available to the OIG upon request.

K. Notice to Health Care Providers and Entities

Within 90 days after the Effective Date, Synthes shall send, by first class mail, postage prepaid and return receipt requested, a notice containing the language set forth below to the Chief Compliance Officer of each HCI that currently purchases Synthes products. Synthes shall request that the Chief Compliance Officer distribute the notice to all surgeons, purchasing staff, and other relevant personnel of such HCI. If the

HCI does not have a Chief Compliance Officer, Synthes shall send the notice to the Chief Medical Officer, Chief Executive Officer, or other officer or employee with equivalent responsibility. This notice shall be dated and shall be signed by Synthes' Chief Executive Officer. The body of the letter shall state the following:

As you may be aware, Synthes, Inc. recently entered into a global civil, criminal, and administrative settlement with the United States in connection with the promotion and use of certain of its products.

This letter provides you with additional information about the settlement, explains Synthes' commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Synthes engaged in unlawful conduct with regard to certain devices (calcium phosphate-based bone void fillers known as Norian XR and Norian SRS). To resolve these matters, a subsidiary of Synthes (Norian, Inc.) pled guilty to felony and misdemeanor criminal violations of the Federal Food, Drug & Cosmetic Act (FDCA). Synthes also pled guilty to misdemeanor criminal violations of the FDCA. Additionally, Synthes and Norian together agreed to pay more than \$22 million to the Federal Government. More information about this settlement may be found at the following: <http://us.synthes.com/compliance> and [Synthes shall also include a link to the USAO, and OCL websites in the letter.]

As part of the federal settlement, Synthes also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Synthes agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Synthes' representatives to Synthes' Compliance Department or the Food & Drug Administration (FDA).

Please call or email Synthes at 1-888-353-0503 or <https://www.incidentform.com/Synthes.jsp> if you have questions about the settlement referenced above or to report any instances in which you believe that a Synthes representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the

FDA's Center for Devices and Radiological Health, Office of Compliance at 301-796-5500. You should direct medical questions or concerns about the products to Synthes Customer Service Department at 1-800-273-9094.

We appreciate your time and attention. Synthes is dedicated to ensuring that you have access to the scientific and medical information you need to make well-informed decisions about whether Synthes products are right for your patients.

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, Synthes shall provide to the OIG a summary of the calls and messages received.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Synthes changes locations or closes a business unit or location related to any of the Covered Functions, Synthes shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Synthes purchases or establishes a new business unit or location related to any of the Covered Functions, Synthes shall notify OIG no later than the date that the purchase or establishment is publicly disclosed. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each such new business unit or location and all Covered Persons at each such new business unit or location shall be subject to the applicable requirements of this CIA. Synthes may consult with the OIG as to the plan and timeline for implementing CIA requirements applicable to such new business units or locations.

C. Sale of Unit or Location. In the event that, after the Effective Date, Synthes proposes to sell any or all of its business units or locations that are subject to this CIA,

Synthes shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the Effective Date, Synthes 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 Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Chief Compliance Officer may have, if any;

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the members of the Board of Directors referenced in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a copy of Synthes' Code of Conduct required by Section III.B.1;

6. 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);

7. a summary of all Policies and Procedures required by Section III.B.2 (a copy of such Policies and Procedures shall be made available to the OIG upon request);

8. 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;

9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Synthes and the IRO;

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

11. a description of the Disclosure Program required by Section III.E;

12. a description of the process by which Synthes fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

14. a certification by the Chief Compliance Officer that the notice required by Section III.K was mailed to each HCI, the number of HCIs that received a copy of the notice, a sample copy of the notice required by Section III.K, and a summary of the calls or messages received in response to the notice;

15. a list of all of Synthes' U.S. locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Synthes currently submits claims (if applicable);

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

17. a description of any transfers, divestitures, sales, and other business transactions involving Norian assets and operations which occurred within one year prior to the Effective Date or within 180 days after the Effective Date; and

18. the certifications required by Section V.C.

B. Annual Reports. Synthes shall submit to OIG annually a report with respect to the status of, and findings regarding, Synthes' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.2-4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a copy of the Board of Directors' resolution required by Section III.A.3;

3. 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 applicable requirements);

4. 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);

5. 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.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
7. Synthes' response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
8. a summary and description of any and all current and prior engagements and agreements between Synthes and the IRO, if different from what was submitted as part of the Implementation Report;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Synthes;
10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs or to Government Reimbursed Products;
11. any changes to the process by which Synthes fulfills the requirements of Section III.F regarding Ineligible Persons;
12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Synthes in response to the screening and removal obligations set forth in Section III.F;
13. a summary describing any ongoing investigation or legal proceeding

required to have been reported pursuant to Section III.G. 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;

14. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;

15. a summary describing any communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. all information required by Section III.J (relating to the Internal Monitoring Program);

17. a summary of the calls and messages received in response to the notice required by Section III.K and the disposition of those calls and messages;

18. a description of all changes to the most recently provided list of Synthes' U.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 Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Synthes currently submits claims (if applicable);

19. a description of any transfers, divestitures, sales, and other business transactions involving Norian assets and operations which occurred during the applicable Reporting Period; and

20. 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 following certifications shall be included in the Implementation Report and Annual Reports:

1. *Certifying Employees*: In each Annual Report, Synthes shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Chief Compliance Officer*: In each Implementation Report and Annual Report, Synthes shall include the following individual certification by the Chief Compliance Officer:

a. 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;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Synthes is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Synthes has complied with its obligations under the Settlement Agreement: 1) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; 2) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and 3) to identify and adjust any past charges or claims for unallowable costs; and

d. Synthes': 1) Policies and Procedures as referenced in Section III.B.2 above; 2) templates for standardized contracts and other similar documents related to any of the Covered Functions; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements.

In addition, Synthes' promotional materials and technique guides containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside of Synthes within the United States by or on behalf of Synthes has been reviewed by competent regulatory, legal or other relevant personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed by Synthes and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial

review of the documents listed above, only material changes to the documents must be reviewed by competent legal counsel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request.

D. Designation of Information. Synthes 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. Synthes 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

Synthes: Jeffrey B. Miller
Chief Compliance Officer
Synthes, Inc.
1302 Wrights Lane East
West Chester, PA 19380
Telephone: 610.719.5241
Facsimile: 610.719.5141

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. Upon request by OIG, Synthes may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

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 Synthes' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Synthes' locations for the purpose of verifying and evaluating: (a) Synthes' compliance with the terms of this CIA; and (b) Synthes' compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Synthes 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 Synthes' 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. Synthes shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Synthes' employees may elect to be interviewed with or without a representative of Synthes present.

VIII. DOCUMENT AND RECORD RETENTION

Synthes 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) 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 Synthes prior to any release by OIG of information submitted by Synthes pursuant to its obligations under this CIA and identified upon submission by Synthes as trade secrets, or information that is commercial or financial and

privileged or confidential, under the FOIA rules. With respect to such releases, Synthes shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Synthes 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, Synthes 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 Synthes fails to establish or implement any of the following obligations as described in Section III:

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. a resolution from the Board of Directors;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons and Relevant Covered Persons;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;
- j. reporting of Reportable Events;

k. notification of communications with FDA;

l. an Internal Monitoring Program; and

m. notification to HCIs as required by Section III.K.

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 Synthes fails to engage an IRO, as required in Section III.D and Appendices A-B.

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 Synthes 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.

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 Synthes fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A-B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Synthes 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 Synthes fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Synthes, stating the specific grounds for its determination that Synthes has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Synthes shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Synthes 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. Synthes 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 Synthes 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 Synthes 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 Synthes 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 Synthes of: (a) Synthes' 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, Synthes 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 Synthes elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Synthes 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

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 Synthes 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 Synthes to report a Reportable Event and take corrective action, as required in Section III.H;
- 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;
- d. a failure to engage and use an IRO in accordance with Section III.D; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Synthes constitutes an independent basis for Synthes' exclusion from participation in the Federal health care programs. Upon a determination by OIG that Synthes has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Synthes of: (a) Synthes' 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.* Synthes 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. Synthes 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) Synthes has begun to take action to cure the material breach; (ii) Synthes is pursuing such action with due diligence; and (iii) Synthes has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Synthes fails to satisfy the requirements of Section X.D.3, OIG may exclude Synthes from participation in the Federal health care programs. OIG shall notify Synthes in writing of its determination to exclude Synthes (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 Synthes' 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, Synthes 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 Synthes 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, Synthes 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 Synthes was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Synthes 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 Synthes to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Synthes 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 Synthes 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) Synthes had begun to take action to cure the material breach within that period; (ii) Synthes has pursued and is pursuing such action with due diligence; and (iii) Synthes provided to OIG within that period a reasonable timetable for curing the material breach and Synthes 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 Synthes, only after a DAB decision in favor of OIG. Synthes' election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Synthes 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 Synthes 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. Synthes 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 Synthes, Synthes 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

Synthes and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Synthes;
- 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. The undersigned Synthes 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; and
- E. 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 SYNTHES, INC.



Michel Orsinger
Chief Executive Officer
Synthes, Inc.

9/15/2010

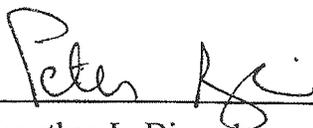
Date



Jeffrey B. Miller
Synthes Chief Compliance Officer
Synthes, Inc.

9/20/2010

Date

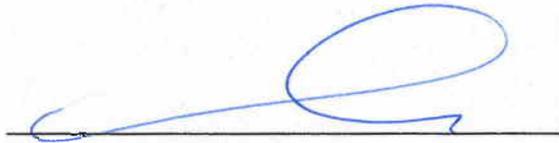


Jonathan L. Diesenhaus
Peter S. Spivack
Hogan Lovells US LLP
Counsel for Synthes, Inc.

9.22.10

Date

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



Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

9/23/10

Date

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

Synthes 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 the information set forth in Sections V.A.9 and 10 of the CIA, OIG will notify Synthes if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Synthes may continue to engage the IRO.

If Synthes 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, Synthes shall submit the information identified in Sections V.A.9 and 10 of the CIA 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 Synthes if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Synthes may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions, Clinical Investigation Related Functions, IDE-Exempted Investigation Related Functions, and Reporting Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Synthes products are reimbursed;

2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. 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 component of the IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must 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 engagements that may exist between the IRO and Synthes.

E. IRO Removal/Termination.

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

Prior to requiring Synthes to engage a new IRO, OIG shall notify Synthes 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, Synthes 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. Synthes

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

Appendix B **Synthes, Inc. CIA**

I. General Description

As specified more fully below, Synthes shall retain an Independent Review Organization (IRO) to perform reviews (IRO Reviews) to assist Synthes in assessing and evaluating its systems, processes, policies, procedures, and practices related to Synthes' Clinical Investigation Related Functions, IDE-Exempted Investigation Related Functions, Reporting Related Functions, and Promotional and Product Services Related Functions (collectively, "Covered Functions"). The IRO Review shall consist of two components - a systems review (Systems Review), and a transactions review (Transactions Review) as described more fully below. Synthes may engage, at its discretion, a single IRO to perform both components of the IRO Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Synthes' systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Synthes materially changes its systems, processes, policies, and procedures relating to any of the Covered Functions, the IRO shall perform a Systems Review for the materially changed Covered Function for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

II. Systems Review

A. Description of Reviewed Policies and Procedures

The Systems Review shall be a review of Synthes' systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain aspects of the Covered Functions. Where practical, Synthes personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Synthes pursuant to the preceding sentence.

Specifically, the IRO shall review certain of Synthes' systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures").

1. The IRO shall review Synthes' systems, policies, processes, and procedures applicable to Promotional and Product Services Related Functions:
 - a. Synthes' systems, policies, processes, and procedures applicable to the manner in which Synthes Consultants and other personnel handle and respond to request for information about any non-cleared or non-approved uses of the products;
 - b. the form and content of information and materials Synthes provides to physicians or other health care professionals (collectively "HCPs") or health care institutions (HCIs) regarding Synthes' products, including any technical assistance provided by a Synthes employee in the United States during a physician's use of the product in a surgical setting if the physician determines that he or she will use a Synthes product for a non-FDA approved or cleared ("off-label") use;
 - c. Synthes' systems, policies, processes, and procedures relating to Synthes' internal review of information and materials regarding Synthes' products that Synthes disseminates to HCPs or HCIs;
 - d. Synthes' systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, market preference evaluations, training programs, speaker programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
 - e. the processes and procedures by which Synthes' Compliance Department or other relevant departments monitor and identify situations in which it appears that improper promotion may have occurred; and
 - f. Synthes' systems, processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for situations potentially involving improper promotion.

2. The IRO shall review Synthes' systems, policies, processes, and procedures applicable to Clinical Investigation Related Functions:
 - a. Synthes' systems, policies, processes, and procedures for ensuring that Synthes does not introduce or cause to be introduced into interstate commerce devices prior to complying with one of the methods of FDA authorization: (1) an FDA-approved pre-market approval application, under 21 U.S.C. § 360e(a)(2) and 21 C.F.R. Part 814; (2) a "510(k) clearance" by FDA for marketing because it is found to be substantially equivalent to an appropriate, legally marketed device, under 21 U.S.C. §§ 360c and 360(k) and 21 C.F.R. Part 807 -- Subpart E; (3) an investigational device exemption under 21 U.S.C. § 360j(g), for the use of a device on humans on an experimental basis; or (4) an exemption for certain devices as set forth in 21 U.S.C. § 360(l);
 - b. Synthes' systems, processes, policies and procedures for ensuring that any devices approved under one of the methods of FDA authorization listed in section II.A.2.a are marketed and promoted for only uses authorized by the FDA;
 - c. Synthes' systems, processes, policies, and procedures to identify or evaluate when the use of a Synthes device is a clinical investigation;
 - d. Synthes' systems, processes, policies, and procedures to provide for the protection of human subjects, including obtaining informed consent, as provided in 21 C.F.R. Parts 50 and 56 and in 45 C.F.R. Part 45;
 - e. Synthes' systems, processes, policies, and procedures for clinical investigations site audits;
 - f. Synthes' processes, policies, and procedures regarding disclosure of financial interests of clinical investigators, as required by 21 C.F.R. Part 54, for studies using Synthes' products;
 - g. Synthes' systems, processes, policies, and procedures for complying with reporting obligations provided in 21 C.F.R. §

812.150 for devices with an approved investigational device exception.

- h. the processes and procedures by which Synthes' Compliance Department identifies situations in which it appears that non-compliance occurred with regard to the requirements for, or Synthes' policies and procedures relating to Clinical Investigations Related Functions; and
 - i. Synthes' processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for situations potentially involving non-compliant Clinical Investigations Related Functions.
3. The IRO shall review Synthes' systems, policies, processes, and procedures applicable to IDE-Exempted Investigation Related Functions:
- a. Synthes' systems, processes, policies, and procedures for complying with the requirement, under 21 C.F.R. § 812.2(c)(4) that IDE-Exempted Testing not be utilized to gather safety or efficacy data or when patient safety may be at risk;
 - b. Synthes' systems, processes, policies, and procedures for IDE-Exempted Testing (*i.e.*, market preference evaluations or consumer preference testing) site audits;
 - c. Synthes' processes, policies, and procedures regarding disclosure of financial interests of HCPs participating in IDE-Exempted Testing, such as, but not limited to market preference evaluations for Synthes' products;
 - d. Synthes' processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for situations where requirements related to the IDE-Exempted Investigation Related Functions are potentially violated.
4. The IRO shall review Synthes' systems, policies, processes, and procedures applicable to Reporting Related Functions:

- a. Synthes' processes, policies, and procedures for reporting adverse events, including processes to ensure compliance with MDR regulations at 21 C.F.R. Part 803;
- b. Synthes' processes, policies, and procedures relating to reporting obligations as provided in 21 C.F.R. § 814.84, including submission of summaries and bibliographies of information not submitted as part of a pre-market application, for devices with FDA premarket approval under 21 U.S.C. § 360e(a)(2);
- c. the processes and procedures by which Synthes' Compliance Department monitors and identifies situations in which it appears that Synthes has failed to comply with FDA Reporting Related requirements and/or Synthes' own Reporting Related policies and procedures; and
- d. Synthes' processes, policies, and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for failure to comply with Reporting Related requirements and/or Synthes' own Reporting Related policies and procedures.

B. Systems Review Report.

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of Synthes' systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-4 above, including a general description of Synthes' control and accountability systems (*e.g.*, documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-4 above are made known or disseminated within Synthes;

4. a detailed description of any system(s) used to track and respond to requests and inquiries regarding any non-cleared or non-approved uses of Synthes products;
5. findings and supporting rationale regarding any weaknesses in Synthes' systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
6. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Transactions Review

As described more fully below in Sections III.A-E, the Transactions Review shall be based upon a review of a sample of documents, including patient records and other documents relating to patients participating in Clinical Investigations, IDE-Exempted Investigations, or Clinical Registries involving Synthes' products. The IRO shall report on all aspects of the Transactions Review in the Transactions Review Reports.

A. Definitions.

1. Sampling Unit: A patient participating in a Clinical Investigation, IDE-Exempted Investigation, or Clinical Registry using a Synthes product conducted inside the United States.
2. Population: All patients participating in a Clinical Investigation, IDE-Exempted Investigation, or Clinical Registry using a Synthes product conducted inside the United States during the Reporting Period.
3. Error: Any sampled patient whose medical record and associated documents are missing documentation described in the methodology in Section III.C, below, or for whom there is an adverse finding for Inquiries as described in Sections III.C.3-7 below.

B. Sample: The IRO shall randomly select 40 patients from all patients participating in an IDE-Exempted Investigation, Clinical Investigation or Clinical Registry using a Synthes product conducted inside the United States during the reporting period. The IRO shall stratify the sample to ensure that the number of patients selected from each category of study is proportional to the number of studies undertaken of

that type in a given year. The IRO shall conduct the review based on supporting documentation in Synthes' possession and copies of supporting documentation and patient records obtained from the Clinical Investigation, IDE-Exempted Investigation, and Clinical Registry sites.

C. Methodology: For each Sampling Unit, the IRO shall review the documentation and evaluate or identify the following ("Inquiries"):

1. Identify the legal authority under which the Synthes may distribute, or cause the distribution of, the device used in the Clinical Investigation, IDE-Exempted Investigation, or Clinical Registry;
2. After evaluating the purpose of the study, whether the study was a Clinical Investigation, an IDE-Exempted Investigation, or a Clinical Registry;
3. Whether the patient was clinically eligible for inclusion in the Clinical Investigation, IDE-Exempted Investigation, or Clinical Registry;
4. If applicable, whether Institutional Review Board approval was obtained for the study;
5. Whether patient's informed consent was obtained;
6. If an adverse event occurred or any consumer complaints were received, whether it was appropriately reported within Synthes and whether appropriate follow-up occurred (*e.g.*, a complete autopsy was performed); and
7. If an adverse event occurred or any consumer complaints were received, whether it was appropriately reported to the FDA under the appropriate reporting requirements, including those at 21 C.F.R. Part 803 or 21 C.F.R. § 812.150.

D. Other Requirements.

1. Replacement Sampling. Replacement sampling is not permitted for Sampling Units with missing documentation.

2. Use of First Samples Drawn. Sampling Units selected in each first sample shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use).
- E. Transaction Review Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:
1. General Elements to Be Included in Report.
 - a. Review Objectives: A clear statement of the objective intended to be achieved by the review;
 - b. Population: A description of the Population;
 - c. Review Protocol: A detailed narrative description of the procedures performed and a description of the Sampling Unit and universe utilized in performing the procedures for each Sample Unit reviewed; and
 - d. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
 2. Statistical Sampling Documentation.
 - a. The number of Sampling Units in the sample;
 - b. The number of Sampling Units for which an Error was identified and an explanation of the Error;
 - c. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO, including the seed number; and
 - d. A description or identification of the statistical sampling software package used to select the sample.
 3. Results to be Included in Report. The following results shall be included in each Promotional and Product Services Review Report:

- a. A narrative explanation of the IRO's findings and supporting rationale (including reasons for Errors and patterns noted, etc.) based on the Inquiries conducted as part of the Transactions Review.
 - b. A narrative explanation of the IRO's findings and supporting rationale regarding any weaknesses in Synthes' systems, processes, policies, procedures, and practices relating to the Inquiries, if any;
 - c. recommendations for improvement in Synthes' systems, processes, policies, procedures, and practices relating to the Inquiries; and
 - d. a spreadsheet identifying by Sampling Unit the results of each Inquiry.
4. Credentials. The names and credentials of the individuals who:
(a) designed the statistical sampling procedure for the Transactions Review and (b) performed the Transactions Review.