

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
ORTHOFIX INTERNATIONAL, N.V.**

**I. PREAMBLE**

Orthofix International, N.V. (Orthofix N.V.) 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 Orthofix N.V. 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). Contemporaneously with this CIA, Orthofix N.V. and its wholly owned subsidiary, Orthofix, Inc. (OFX) are entering into a settlement agreement with the United States. Further, it is anticipated that in the near future Blackstone Medical Inc. d/b/a Orthofix Spinal Implants (OSI), a wholly owned subsidiary of Orthofix, N.V., will be entering into a separate settlement agreement with the United States. Hereafter, Orthofix N.V., along with its U.S. subsidiaries, will be referred to collectively as “Orthofix.”

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

A. The period of the compliance obligations assumed by Orthofix under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. 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, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Orthofix’s final annual report; or (2) any additional materials submitted by Orthofix pursuant to OIG’s request, whichever is later.

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

1. “Arrangements” shall mean every arrangement or transaction that:

- a. involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between Orthofix and any actual or potential source of health care business or referrals to Orthofix, or any actual or potential recipient of health care business or referrals from Orthofix. The term “source of health care business or referrals” shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program and the term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom Orthofix refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Orthofix purchases, leases or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or
- b. is between Orthofix and a physician (or a physician’s immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to Orthofix for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)).

2. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of Orthofix’s Arrangements.

3. “Arrangements Related Functions” includes developing, approving, managing, or reviewing any of Orthofix’s Arrangements.

4. “Covered Persons” includes:
  - a. all owners of Orthofix 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, directors, and employees of Orthofix;
  - c. all contractors, subcontractors, agents, independent distributors or sales personnel, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Orthofix, excluding vendors whose sole connection with Orthofix is selling or otherwise providing medical supplies or equipment to Orthofix and who do not bill the Federal health care programs for such medical supplies or equipment; and
  - d. all contractors, subcontractors, agents, independent distributors or sales personnel, and other persons who perform Arrangements Related Functions, Government Reimbursement Related Functions, or Promotional and Product Services Related Functions (as defined in Section II.C) on behalf of Orthofix.

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

5. “Focus Arrangements” means every Arrangement that:
  - a. is between OFX or OSI and any actual source of health care business or referrals to OFX or OSI and involves, directly or indirectly, the offer, payment, or provision of anything of

value, excluding Arrangements between OFX or OSI and independent distributors or sales personnel; or

- b. is between OFX or OSI and any physician (or a physician's immediate family member) (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to OFX or OSI for designated health services (as defined at 42 U.S.C. §1395nn(h))(6)).

Notwithstanding the foregoing provisions of Section II.C.5, any Arrangement that satisfies the requirements of 42 C.F.R. § 411.356 (ownership or investment interests), 42 C.F.R. § 411.357(g) (remuneration unrelated to the provision of designated health services); 42 C.F.R. § 411.357(i) (payments by a physician for items and services); 42 C.F.R. § 411.357(k) (non-monetary compensation); 42 C.F.R. § 411.357(m) (medical staff incidental benefits), 42 C.F.R. § 411.357(o) (compliance training), 42 C.F.R. § 411.357(q) (referral services), 42 C.F.R. § 411.357(s) (professional courtesy), 42 C.F.R. § 357(u) (community-wide health information systems), or any exception to the prohibitions of 42 U.S.C. § 1395nn enacted following the Effective Date that does not require a written agreement shall not be considered a Focus Arrangement for purposes of this CIA.

6. "Government Reimbursement Covered Persons" includes all Covered Persons whose job responsibilities relate to preparation or submission of claims for reimbursement from any Federal health care program.

7. "Government Reimbursed Products" refers to all products of Orthofix that are promoted or sold by Orthofix in the United States that are reimbursed by Federal health care programs.

8. "Government Reimbursement Related Functions" refers to the preparation or submission of claims for reimbursement from any Federal health care program.

9. "Promotional and Product Services Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.

10. “Promotional and Product Services Related Functions” includes: (a) the promotion, marketing, advertising, and sale of Government Reimbursed Products; (b) the development, preparation, or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products; and (c) post-marketing research, development, and publication related activities involving Government Reimbursed Products.

11. “Third Party Educational Activity” shall mean any third party continuing medical education (CME), disease awareness, or other scientific, educational, or professional program, meeting, or event governed by Federal health care program and/or FDA requirements, and supported by Orthofix, including but not limited to, sponsorship of symposia at medical conferences.

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

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

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

1. *Chief Compliance Officer.* Prior to the Effective Date, Orthofix appointed a Chief Compliance Officer. Orthofix 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 and FDA requirements. The Chief Compliance Officer shall be a member of senior management of Orthofix N.V., shall report directly to the Chief Executive Officer of Orthofix N.V., shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Orthofix N.V. (Audit Committee), and shall be authorized to report on such matters to the Audit Committee at any time. The Chief Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Orthofix as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Chief Compliance Officer shall be limited and must not interfere with the Chief Compliance Officer’s ability to perform the duties outlined in this CIA.

Orthofix shall report to OIG, in writing, any changes in the identity, reporting relationship, position description, or authority 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 five days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Orthofix established a Compliance Committee. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, legal, sales, marketing, human resources, regulatory operations, audit, and operations). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Orthofix's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

Orthofix 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. *Audit Committee Compliance Obligations.* The Audit Committee shall be responsible for the review and oversight of matters related to compliance with Federal health care program and FDA requirements and the obligations of this CIA.

The Audit Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Orthofix's Compliance Program, including but not limited to the performance and activities of the Chief Compliance Officer, Compliance Committee, and Compliance Office personnel; and
- b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Audit Committee summarizing its review and oversight of Orthofix's 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 Audit Committee has made a reasonable inquiry into the operations of Orthofix’s Compliance Program including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Audit Committee has concluded that, to the best of its knowledge, OFX and OSI have implemented an effective Compliance Program to meet Federal health care program requirements, and the obligations of the CIA.”

If the Audit Committee is unable to provide such a conclusion in the resolution, the Audit Committee 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 OFX and OSI.

Orthofix shall report to OIG, in writing, any changes in the composition of the Audit Committee, or any actions or changes that would affect the Audit Committee’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 Orthofix officers or employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Orthofix business unit, department, or functional area is compliant with applicable Federal health care program requirements, and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Presidents and Chief Financial Officers for the Orthofix Spine Global Business Unit and for the Orthofix Orthopedics Global Business Unit, the Chief Executive Officer of Orthofix N.V., and, to the extent that an OFX or OSI business unit, department, or functional area performs functions related to government reimbursement, promotion, marketing, sales, contracting, Arrangements, or compliance and is not covered by one of the above certifications, such other appropriate executives, vice-presidents, and directors, as would be necessary to ensure that there is a certifying officer or employee covering each such business unit, department, or functional area.

For each Reporting Period, each Certifying Employee except the Chief Executive Officer of Orthofix N.V. 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 [OFX or OSI, as applicable] is in compliance with all applicable Federal health care program and FCA requirements, and the obligations of the CIA.”

For each Reporting Period, the Chief Executive Officer of Orthofix N.V shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to OFX and OSI. My job responsibilities include oversight of OFX and OSI. I have made reasonable inquiry regarding OFX and OSI’s compliance with all applicable Federal health care program requirements, and the obligations of the CIA. To the best of my knowledge, except as otherwise described herein, OFX and OSI are in compliance with all applicable Federal health care program requirements, and the obligations of the CIA.”

If any Certifying Employee is unable to provide such a conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

**B. Written Standards**

1. *Code of Conduct.* Prior to the Effective Date, Orthofix developed, implemented, and distributed a written Code of Conduct to all Covered Persons. Orthofix shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Orthofix’s commitment to full compliance with all Federal health care program requirements, including its commitment

to prepare and submit accurate claims and to contract and enter into Arrangements consistent with such requirements;

- b. Orthofix's commitment to full compliance with all FDA requirements, including its commitment to comply with all requirements relating to Promotional and Product Services Related Functions and to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements.
- c. Orthofix's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Orthofix's own Policies and Procedures as implemented pursuant to Section III.B.2;
- d. the requirement that all of Orthofix's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Orthofix, suspected violations of any Federal health care program requirements or FDA requirements or of Orthofix's own Policies and Procedures; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Orthofix's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, Orthofix's Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Orthofix's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Orthofix shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any

revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* Prior to the Effective Date, Orthofix has implemented written Policies and Procedures regarding the operation of Orthofix's compliance program and Orthofix's obligation to comply with Federal health care program requirements. To the extent not already accomplished, within 120 days after the Effective Date, Orthofix shall implement written Policies and Procedures regarding the compliance program requirements outlined in this CIA and Orthofix's compliance with Federal health care program and FDA requirements. The Policies and Procedures shall also address:

- a. the Federal health care program requirements regarding the accurate submission of claims;
- b. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and 42 U.S.C. § 1395nn (Stark Law), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute or the Stark Law;
- c. the requirements set forth in Section III.D.2 and 3 (compliance with the Anti-Kickback Statute and Stark Law).
- d. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA and Federal health care program requirements;
- e. the materials and information that may be distributed by Orthofix sales representatives about Orthofix products and the manner in which Orthofix sales representatives respond to requests for information about Orthofix's products;
- f. the materials and information that may be distributed by Orthofix's clinical affairs or regulatory affairs departments in

response to requests for clinical information about Orthofix products and the mechanisms through, and manner in which, such clinical or regulatory affairs personnel receive and respond to requests for information about uses of the products; the form and content of the information disseminated by Orthofix in response to such requests; and the internal review process for the information disseminated;

- g. review of all promotional and other materials and information intended to be disseminated outside Orthofix by appropriate qualified personnel (such as legal, clinical, and/or regulatory personnel) in a manner designed to ensure that legal, regulatory, and/or clinical concerns are properly addressed during Orthofix's 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. The Policies and Procedures shall require review by appropriately qualified personnel of all promotional materials prior to the distribution or use of such materials;
- h. programs to educate sales representatives. These Policies and Procedures shall be designed to ensure that the programs are used in accordance with applicable Federal health care program and FDA requirements;
- i. consultant or other fee-for-service arrangements entered into with any health care professional (HCP) or health care institution (HCI) (including, but not limited to, speaker programs, speaker training 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 shall include requirements about

the content and circumstances of such arrangements and events;

- j. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Orthofix's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- k. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.11 above. These Policies and Procedures shall be designed to ensure that Orthofix's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that, with respect to Third Party Educational Activities that Orthofix agrees to fund after the Effective Date: (1) Orthofix disclose its financial support of the Third Party Educational Activity and any financial relationships with faculty, speakers, or organizers at such activity; (2) as a condition of funding, the third party shall agree to disclose Orthofix's financial support of the Third Party Educational Activity and any financial relationships that Orthofix might have with faculty, speakers, or organizers at such activity; (3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with Orthofix; (4) the Third Party Educational Activity have an educational focus; (5) the content, organization, and operation of the Third Party Educational Activity be independent of Orthofix control; (6) Orthofix support only Third Party Educational Activities that are non-promotional in tone/nature; and (7) Orthofix's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- l. sponsorship, funding of, and disclosures relating to research and development-related activities (including clinical trials, market research, or authorship of articles or other publications). These Policies and Procedures shall be designed to ensure that Orthofix's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- m. authorship of any articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all relationships between the author and Orthofix, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;
- n. compensation (including salaries and bonuses) for Promotional and Product Services Covered Persons. 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 Orthofix's products;
- o. the subjects relating to the Code of Conduct identified in Section III.B.1; and
- p. disciplinary policies and procedures for violations of Orthofix's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

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

C. Training and Education

1. *General Training.* Within 120 days after the Effective Date, Orthofix shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain:

- a. Orthofix's CIA requirements;
- b. Orthofix's Compliance Program, including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues; and
- c. the possible consequences to both Orthofix and Covered Persons of failure to comply with all FDA and Federal health care program requirements and with Orthofix's own Code of Conduct and Policies and Procedures and the failure to report such noncompliance.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Arrangements Covered Person and Government Reimbursement Covered Person shall receive at least three hours of Specific Training, as identified below, in addition to the General Training required above, as follows:

- a. Arrangements Training for Arrangements Covered Persons shall include a discussion of:

- i. Arrangements that potentially implicate the Anti-Kickback Statute or the Stark Law, as well as the regulations and other guidance documents related to these statutes;
  - ii. Orthofix's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Sections III.D.2 and III.D.3 of the CIA;
  - iii. examples of violations of the Anti-Kickback Statute and the Stark Law;
  - iv. the personal obligation of each individual involved in the development, approval, management, or review of Orthofix's Arrangements to know the applicable legal requirements and Orthofix's Policies and Procedures;
  - v. the legal sanctions under the Anti-Kickback Statute and the Stark Law; and
  - vi. the possible consequences to both Orthofix and Arrangements Covered Persons of failure to comply with all Federal health care program requirements and with Orthofix's own Code of Conduct and Policies and Procedures and the failure to report such noncompliance.
- b. Government Reimbursement Training for Government Reimbursement Covered Persons shall include a discussion of:
- i. the Federal health care program requirements regarding the accurate submission of claims;

- ii. examples of proper and improper claims submission practices;
- iii. policies, procedures, and other requirements applicable to the documentation of medical records;
- iv. applicable reimbursement statutes, regulations, and program requirements and directives;
- v. the personal obligation of each individual involved in the claims submission process to ensure that such claims are accurate;
- vi. the legal sanctions for violations of the Federal health care program requirements; and
- vii. the possible consequences to both Orthofix and Government Reimbursement Covered Persons of failure to comply with all Federal health care program requirements and with Orthofix's own Code of Conduct and Policies and Procedures and the failure to report such noncompliance.

Each new Arrangements Covered Person and Government Reimbursement Covered Person shall receive the appropriate training, as identified above, within 30 days after the beginning of their employment or becoming an Arrangements Covered Person or Government Reimbursement Covered Person or within 120 days after the Effective Date, whichever is later.

An Orthofix employee who has completed the Specific Training shall review a new Arrangements Covered Person's or Government Reimbursement Covered Person's work, to the extent that the work relates to an Arrangements Function or a Government Reimbursement Related Function, until such time as the Arrangements Covered Person or Government Reimbursement Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Arrangements Covered Person or Government Reimbursement Covered Person shall

receive at least two hours of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

3. *Board Member Training.* Within 120 days after the Effective Date, Orthofix shall provide at least two hours of training to each member of the Orthofix Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Orthofix Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

4. *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.

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

6. *Update of Training.* Orthofix shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, the Internal Monitoring Program, the Claims Review, or the Arrangements Review, and any other relevant information.

7. *Computer-based Training.* Orthofix may provide the training required under this CIA through appropriate computer-based training approaches. If Orthofix 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, Orthofix shall engage an individual (or individuals) or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in Section III.D. The applicable requirements relating to the IRO(s) are outlined below and in Appendix A to this CIA, which is incorporated by reference.
  - i. *Claims Review.* An IRO shall perform a review of OFX’s billing and claims submission to the Federal health care programs and the reimbursement received (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.
  - ii. *Arrangements Review.* An IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix C to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO(s) and Orthofix shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Orthofix) related to the reviews.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.D affects Orthofix’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.

- d. *Validation Review(s)*. In the event OIG has reason to believe that: (a) the Arrangements Review or Claims Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Arrangements Review or Claims Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review or Claims Review complied with the requirements of the CIA and/or the findings or Arrangements Review or Claims Review results are inaccurate (Validation Review(s)). Orthofix shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of IRO Reports submitted as part of Orthofix's final Annual Report shall be initiated no later than one year after Orthofix's final submission (as described in Section II.B) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Orthofix 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, Orthofix may request a meeting with OIG to: (a) discuss the results of any Arrangements Review or Claims Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or Claims Review or to correct the inaccuracy of the Arrangements Review or Claims Review; and/or (c) propose alternatives to the proposed Validation Review(s). Orthofix agrees to provide any additional information as may be requested by OIG under this Section III.D.1.d in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review or Claims Review issues with Orthofix 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.

- e. *Independence and Objectivity Certification*. The IRO(s) shall include in its (their) report(s) to Orthofix a certification or sworn affidavit that it has evaluated its professional

independence and objectivity and has concluded that it is, in fact, independent and objective.

2. *Compliance with the Anti-Kickback Statute and Stark Law; Focus Arrangements Procedures.*

Within 120 days after the Effective Date, Orthofix shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law or the regulations, directives, and guidance related to these statutes (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- d. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- e. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute and Stark Law, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and

documenting the fair market value of the remuneration specified in the Focus Arrangement;

- f. requiring the Chief Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- g. implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments pursuant to Sections III.H and III.I when appropriate.

3. *New or Renewed Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, Orthofix shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that each Focus Arrangement is set forth in writing and signed by Orthofix and the other parties to the Focus Arrangement;
- b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.2 of this CIA. Additionally, Orthofix shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and, for any Focus Arrangement that is new or renewed at any time after 120 days after the Effective Date, with a copy of its Stark Law and Anti-Kickback Statute Policies and Procedures;
- c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute and the Stark Law with respect to the performance of the Arrangement.

#### E. Disclosure Program

Prior to the Effective Date, Orthofix established a Disclosure Program. To the extent not already provided for in Orthofix's Disclosure Program, it shall include 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 Orthofix's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Orthofix shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a non-retribution, non-retaliation 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, Orthofix 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.

#### 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 scope 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.* Prior to the Effective Date, Orthofix established a process for ensuring that Covered Persons are not Ineligible Persons. To the extent not already accomplished in that process, Orthofix shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Orthofix shall screen all prospective 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. Orthofix shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

- c. Within 120 days after the Effective Date, Orthofix 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 Section III.F affects Orthofix's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Orthofix understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Orthofix may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Orthofix meets the requirements of Section III.F.

3. *Removal Requirement.* If Orthofix has actual notice that a Covered Person has become an Ineligible Person, Orthofix shall remove such Covered Person from responsibility for, or involvement with, Orthofix's 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 Orthofix has actual notice that a Covered Person is charged with a criminal offense that falls within the scope 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, Orthofix 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 any claims submitted to any Federal health care program.

#### G. Notification of Government Investigation or Legal Proceedings

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

1. *Definition of Overpayments.* For purposes of this CIA, an “Overpayment” shall mean the amount of money Orthofix has received in excess of the amount due and payable under any Federal health care program requirements.

##### 2. *Repayment of Overpayments.*

- a. If, at any time, Orthofix identifies any Overpayment, Orthofix shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 60 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. If not yet quantified, within 60 days after identification, Orthofix shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies.
- b. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

#### I. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- a. a substantial Overpayment;

- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program or FDA requirement for which penalties or exclusion may be authorized;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or
- d. the filing of a bankruptcy petition by Orthofix.

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

2. *Reporting of Reportable Events.* If Orthofix determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Orthofix shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to the OIG shall be made within 30 days of identification of the overpayment, even if not yet quantified. The report shall include:

- a. a description of the steps taken by Orthofix to identify and quantify the Overpayment;
- b. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program implicated;
- c. a description of Orthofix's actions taken to correct the Reportable Event; and
- d. any further steps Orthofix plans to take to address the Reportable Event and prevent it from recurring.

Orthofix shall also submit to OIG a copy of the notification and repayment to the payor required in Section III.H.2 simultaneous with the transmission of such notification and repayment to the payor.

4. *Reportable Events under Section III.I.1.b and c.* For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- b. a description of Orthofix's actions taken to correct the Reportable Event;
- c. any further steps Orthofix plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by Orthofix to identify and quantify the Overpayment.

5. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by Orthofix to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Sections III.H.2 and III.I.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

J. Internal Monitoring Program

1. *Observations.*

Within 120 days after the Effective Date, OFX and OSI shall establish an Internal Monitoring Program (IMP) to evaluate and monitor various aspects of OFX's and OSI's interactions with HCPs and HCIs, including interactions between OFX and OSI Promotional and Product Services Covered Persons; HCPs and HCIs; and HCP and HCI staff members.

a. *Compliance Review Program.* OFX and OSI managers shall conduct direct field observations (Compliance Reviews) of their directly reporting employees and contracted sales agents, including sales management and OFX and OSI Promotional and Product Services Covered Persons, marketing 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 a full day ride-along that includes direct observation of meetings between the reviewed employee and HCPs; other representatives of HCIs; and HCP and HCI staff members.

OFX and OSI shall conduct at least 50 Compliance Reviews annually (25 for OFX and 25 for OSI). The compliance reviews shall be scheduled throughout the year. Orthofix compliance personnel shall select the employees to be observed by utilizing a selection method that is randomized but provides for a distribution of Compliance Reviews across the United States in a manner proportionate to the size of each business division, across business divisions.

Orthofix compliance personnel shall accompany managers on at least 26 (13 from OFX and 13 from OSI) Compliance Reviews annually. Orthofix compliance personnel shall select the Compliance Reviews in which they will directly participate by utilizing a selection method that is randomized but provides for a distribution of Compliance Reviews across the United States in a manner proportionate to the size of each business division, across business divisions.

At the completion of each Compliance Review, the reviewing manager and the accompanying compliance personnel, if any, shall each 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;
- 5) the identification of any potential non-compliance with the Policies or Procedures; and
- 6) such other elements as Orthofix's Compliance Office may require.

b. *Reporting and Follow-up.* In the event that a compliance issue is identified during any Compliance Review, Orthofix 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.I above, if applicable. The Compliance Office shall maintain records of any compliance issues identified during a Compliance Review and any corrective action.

Orthofix shall include a summary of the IMP and its results as part of each Annual Report. Orthofix shall make the reports for all IMP activities available to the OIG upon request.

## 2. *Consultant Monitoring Activities.*

a. Prior to the Effective Date, Orthofix implemented a Needs Assessment program which requires, among other things, a written analysis be performed to justify the retention of or payment to any HCP, the identification of the business need for the consulting services to be provided, and specification of details about the consulting arrangement. To the extent not already implemented, within 120 days after the Effective Date, Orthofix shall establish a Consultant Monitoring Program (CMP) to evaluate and monitor various aspects of Orthofix's interactions with HCPs, as set forth in more detail below.

b. To the extent that Orthofix engages or compensates a 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, as a speaker, as a participant in data-gathering exercises, or being involved in tutorials, preceptorships, or research-related functions that relate to Government Reimbursed Products (in each case, including market preference evaluations, but excluding FDA-

registered clinical investigations)), such an HCP shall be referred to for purposes of this sub-section as a “Consultant.” Orthofix 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 Consultant. Consultants shall be paid and their expenses reimbursed according to a centrally managed, pre-set rate structure that is determined based on a fair market value analysis conducted by Orthofix.

c. Prior to the retention of a Consultant, Orthofix shall conduct a thorough written analysis (Needs Assessment) to justify the retention of or payment to the Consultant. The Needs Assessment shall include an identification of the business need for engagement or compensation of 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).

d. Within 180 days after the Effective Date, Orthofix 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 Orthofix’s legal department shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan.

e. To the extent not already accomplished, within 180 days after the Effective Date, Orthofix shall also establish a process to obtain compliance and legal review of all Needs Assessments associated with the retention of any Consultant prior to the retention of the Consultant. The purpose of this compliance and 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 Needs Assessments (or elsewhere, as appropriate) and shall be considered as part of the compliance and legal review. To the extent not already accomplished, within 120 days after the Effective Date, Orthofix shall amend its policies to require the collection, assessment, and retention of work product (if any) generated by Consultants.

f. Orthofix shall conduct audits (Consultant Program Audits) of the various types of consultant arrangements entered with HCPs. For the first Reporting Period, Orthofix shall identify the 25 Consultants who received the largest amounts of compensation from OFX and OSI during the six months prior to the end of the Reporting Period. Orthofix shall audit all activities provided by the selected Consultants during the six months prior to the end of the Reporting Period. For the second and subsequent Reporting Periods, 90 days prior to the end of the applicable prior Reporting Period Orthofix shall provide information to the OIG about the numbers of each type of consulting arrangement entered by OFX and OSI, the numbers of Consultants retained for each type of arrangement, and the aggregate amounts of funds expended for each type of consulting arrangement during the Reporting Period. The OIG shall then select up to three types of arrangements to be audited and shall identify the number of each type of program to be audited by Orthofix for each applicable Reporting Period. For the second and subsequent Reporting Periods, the Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a random sampling approach.

g. Personnel conducting the Consultant Program Audits shall review the Needs Assessment, consultant contracts, and materials relating to the arrangement 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 arrangements were conducted in a manner consistent with Orthofix's Policies and Procedures. Results from the Consultant Program Audits shall be compiled and reported to Orthofix headquarters for review and remediation as appropriate. Potential violations of Orthofix's Policies and Procedures shall be reported to the Compliance Office for appropriate follow-up activity.

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

In the event that a compliance issue is identified through the CMP, Orthofix 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.I above, as applicable.

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

#### **IV. CHANGES TO BUSINESS UNITS OR LOCATIONS**

##### **A. Change or Closure of Unit or Location**

In the event that, after the Effective Date, Orthofix changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Orthofix 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, Orthofix purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Orthofix shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s), and the name and address of each Medicare and state Medicaid program contractor to which Orthofix currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location

In the event that, after the Effective Date, Orthofix proposes to sell any or all of its business units or locations that are subject to this CIA, Orthofix shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. 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 150 days after the Effective Date, Orthofix 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;
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 Audit Committee 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 Orthofix's 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 made available to OIG upon request);

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

9. a description of (a) the Focus Arrangements Tracking System required by Section III.D.2.a, (b) the internal review and approval process required by Section III.D.2.e; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Sections III.D.2 and 3;

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

11. a description of the Internal Monitoring Program required by Section III.J;

12. the following information regarding each IRO: (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA, (d) a summary and description of any and all current and prior engagements and agreements between Orthofix and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to Orthofix;

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

14. 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;

15. a list of all of Orthofix's United States locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which Orthofix currently submits claims;

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

17. the certifications required by Section V.C.

B. Annual Reports

Orthofix shall submit to OIG annually a report with respect to the status of, and findings regarding, Orthofix's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, reporting relationship, or authority of the Chief Compliance Officer or any other noncompliance job responsibilities of the Chief Compliance Officer as well as any change in the membership of the Compliance Committee, the Audit Committee of the Board of Directors, or the group of Certifying Employees described in Section III.A;

2. the Board Audit Committee resolution required by Section III.A.3;

3. a summary of any changes or amendments to Orthofix's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

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 made available to OIG upon request);

5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);

6. the following information regarding each type of training required by Section III.C:

- a. a description of the initial and annual 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 complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

7. a description of (a) any changes to the Focus Arrangements Tracking System required by Section III.D.2.a; (b) any changes to the internal review and approval process required by Section III.D.2.e; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Sections III.D.2 and 3;

8. a complete copy of all reports prepared pursuant to Section III.D.1, along with a copy of each IRO's engagement letter;

9. Orthofix's response to the reports prepared pursuant to Section III.D.1, along with corrective action plan(s) related to any issues raised by the reports;

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

11. a certification from each IRO regarding its professional independence and objectivity with respect to Orthofix;
12. a summary and description of the Internal Monitoring Program's internal reviews pursuant to Section III.J, along with any corrective action plans undertaken related to any issues raised by the Internal Monitoring Program and/or the Consultant Monitoring Program;
13. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;
14. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare (if applicable), outpatient Medicare (Part B), Medicaid (report each applicable state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor or that are disclosed to CMS pursuant to the SRDP and Section III.I.6 do not need to be included in this aggregate Overpayment report;
15. a summary of the disclosures in the disclosure log required by Section III.E that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute or Stark Law (the complete disclosure log shall be made available to OIG upon request);
16. any changes to the process by which Orthofix fulfills the requirements of Section III.F regarding Ineligible Persons;
17. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Sections III.G-I. 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;
18. a description of all changes to the most recently provided list of Orthofix's United States locations (including addresses) as required by Sections IV and V.A.15; the corresponding name under which each location is doing business; the

corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each affected Medicare and state Medicaid program contractor to which Orthofix currently submits claims; and

19. the certifications required by Sections III.A and V.C.

The first Annual Report shall be received by OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Chief Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Orthofix is in compliance with all of the requirements of this CIA;
2. to the best of his or her knowledge, Orthofix has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute and Stark Law, including the Focus Arrangements Procedures required in Section III.D of the CIA;
3. to the best of his or her knowledge, Orthofix has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 and III.D.3 of the CIA;
4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful; and
5. to the best of his or her knowledge, Orthofix has complied with its obligations under the Settlement Agreements: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable

costs (as defined in the Settlement Agreement); and (c) if applicable, to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

Orthofix 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. Orthofix 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

Orthofix: Mark S. Boone  
Orthofix International, N.V.  
Senior Vice President & Chief Compliance Officer  
3451 Plano Parkway  
Lewisville, TX 75056  
Office: 214.937.2776  
Facsimile: 214.937.3014

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, Orthofix 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), 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 Orthofix's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Orthofix's locations for the purpose of verifying and evaluating: (a) Orthofix's compliance with the terms of this CIA; and (b) Orthofix's compliance with the requirements of the Federal health care programs and FDA requirements. The documentation described above shall be made available by Orthofix 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 Orthofix's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Orthofix shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Orthofix's employees may elect to be interviewed with or without a representative of Orthofix present.

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

Orthofix shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, and 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 Orthofix prior to any release by OIG of information submitted by Orthofix pursuant to its obligations under this CIA and identified upon submission by Orthofix as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Orthofix shall have the rights set forth at 45 C.F.R. § 5.65(d).

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

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

- a. a Chief Compliance Officer;
- b. a Compliance Committee;
- c. the Audit Committee compliance obligations;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. all training requirements pursuant to Section III.C;

- g. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.2 and III.D.3;
- h. a Disclosure Program pursuant to Section III.E;
- i. an Internal Monitoring Program and Consultant Monitoring pursuant to Section III.J;
- j. Ineligible Persons screening and removal requirements pursuant to Section III.F;
- k. notification of Government investigations or legal proceedings pursuant to Section III.G; and
- l. reporting of Reportable Events pursuant to Section III.I.

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

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 Orthofix fails to submit the Implementation Report or any 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 Orthofix fails to submit any Claims Review Report or annual Arrangements Review Report in accordance with the requirements of Section III.D.1, Appendix B, and Appendix C.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Orthofix 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 Orthofix fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Orthofix stating the specific grounds for its determination that Orthofix has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Orthofix shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Orthofix 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

Orthofix 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 Orthofix 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 Orthofix 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 Orthofix 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 Orthofix of: (a) Orthofix's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Orthofix 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 Orthofix elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Orthofix 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 Orthofix 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 Orthofix to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

- d. a failure to engage and use an IRO in accordance with Section III.D.1 and Appendices A-C.

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

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

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

Orthofix and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Orthofix;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;
- D. OIG may agree to a suspension of Orthofix's obligations under this CIA based on a certification by Orthofix that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If Orthofix is relieved of its CIA obligations, Orthofix will be required to notify OIG in writing at least 30 days in advance if Orthofix plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.
- E. The undersigned Orthofix signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represents that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.
- F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF ORTHOFIX INTERNATIONAL, N.V.**

/Robert S. Vaters/

---

5/31/2012

---

ROBERT S. VATERS  
President and Chief Executive Officer  
Orthofix International, N.V.

DATE

/Brien T. O'Connor/

---

5/31/2012

---

BRIEN T. O'CONNOR  
KIRSTEN V. MAYER  
MICHAEL B. LAMPERT  
Ropes & Gray LLP  
Prudential Tower, 800 Boylston Street  
Boston, MA 02199-3600

DATE

**ON BEHALF OF ORTHOFIX, INC.**

/R. Brian McCollum/

---

5/31/2012

---

R. BRIAN MCCOLLUM  
Senior Vice President and Chief Financial Officer  
Orthofix, Inc

DATE

/Brien T. O'Connor/

---

5/31/2012

---

BRIEN T. O'CONNOR  
KIRSTEN V. MAYER  
MICHAEL B. LAMPERT  
Ropes & Gray LLP  
Prudential Tower, 800 Boylston Street  
Boston, MA 02199-3600

DATE

**ON BEHALF OF BLACKSTONE MEDICAL INC.  
D/B/A ORTHOFIX SPINAL IMPLANTS**

/Jeffrey M. Schumm/

---

5/31/2012

---

JEFFREY M. SCHUMM  
General Counsel and Secretary  
Blackstone Medical Inc.

DATE

/Brien T. O'Connor/

---

5/31/2012

---

BRIEN T. O'CONNOR  
KIRSTEN V. MAYER  
MICHAEL B. LAMPERT  
Ropes & Gray LLP  
Prudential Tower, 800 Boylston Street  
Boston, MA 02199-3600

DATE

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

*/Gregory E. Demske/*

---

*6/6/2012*

---

GREGORY E. DEMSKE  
Chief Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

*/Andrea L. Treese Berlin/*

---

*6/5/2012*

---

ANDREA L. TREESE BERLIN  
Senior Counsel  
Office of Inspector General  
U. S. Department of Health and Human Services

DATE

*/Brian D. Bewley/*

---

*June 5, 2012*

---

BRIAN D. BEWLEY  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

DATE

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement.

1. Orthofix shall engage one or more IROs that possess the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO(s) 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 identified in Section V.A.12 of the CIA or any additional information submitted by Orthofix in response to a request by OIG, whichever is later, OIG will notify Orthofix if any IRO is unacceptable. Absent notification from OIG that any IRO is unacceptable, Orthofix may continue to engage the IRO.

2. If Orthofix 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, Orthofix shall submit the information identified in Section V.A.12 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Orthofix at the request of OIG, whichever is later, OIG will notify Orthofix if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Orthofix may continue to engage the IRO.

#### B. IRO Qualifications.

With regard to the Claims Review, the IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the billing, coding, reporting, and other requirements of device manufacturers and in the general requirements of the Federal health care program(s) from which Orthofix seeks reimbursement;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the billing and coding review portions of the Claims Review who have appropriate expertise; and

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

With regard to the Arrangements Review, the IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes; and

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

C. IRO Responsibilities.

With regard to the Claims Review, the IRO shall:

1. perform each Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, Medicaid, or other Federal health care program rules and reimbursement guidelines in making assessments in the Claims Review;

3. if in doubt of the application of a particular Medicare, Medicaid, or other Federal health care program policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary, carrier, or Durable Medical Equipment Medicare Administrative Contractor, as appropriate);

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

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

With regard to the Arrangements Review, the IRO shall:

1. perform each Arrangements Review in accordance with the specific requirements of the CIA;

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

3. prepare timely, clear, well-written reports that include all the information required by Appendix C to the CIA.

D. IRO Independence and Objectivity.

The IRO(s) must perform the reviews hereunder in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination.

1. *Provider and IRO.* If Orthofix terminates its IRO or if any IRO withdraws from the engagement during the term of the CIA, Orthofix must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. Orthofix must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe any IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Orthofix to engage a new IRO in accordance with Paragraph A of this Appendix. Orthofix must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring Orthofix to engage a new IRO, OIG shall notify Orthofix 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, Orthofix may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with Orthofix prior to requiring Orthofix to terminate the IRO. However, the final determination as to whether or not to require Orthofix to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Claims Review.

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

- a. Overpayment: The amount of money OFX has received in excess of the amount due and payable under any Federal health care program requirements.
- b. Paid Claim: A claim submitted by OFX, and for which OFX has received reimbursement from the Medicare, Medicaid, and/or other Federal health care program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review.
- d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Paid Claims in the sample.

2. *Discovery Sample*. The IRO shall randomly select and review a sample of 50 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at OFX's office or under their control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, OFX should, as appropriate, further analyze any errors identified in the Discovery Sample. OFX recognizes that OIG or another HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate; and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at OFX or under its control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from OFX to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or Durable Medical Equipment Medicare Administrative Contractor, as applicable), for appropriate follow-up by that payor.

4. *Systems Review.* If the Discovery Sample identifies an Error Rate of 5% or greater, Orthofix's IRO shall also conduct a Systems Review. The Systems Review shall consist of the following:

- a. a review of OFX's billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct inaccurate coding and billing);
- b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the

system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

5. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and OFX shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from OFX after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which OFX cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by OFX for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims 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 with the Discovery Sample or Full Sample).

6. *Repayment of Identified Overpayments.* Orthofix shall repay within 60 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. Orthofix shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Claims Review Methodology.*

- a. Claims Review Population. A description of the Population subject to the Claims Review.
- b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
- c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or bulletins (including issue and date), other policies, regulations, or directives).
- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation.*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A copy of the statistical software printout(s) estimating how many Paid Claims are to be included in the Full Sample, if applicable.

- c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Claims Review Findings.*

a. Narrative Results.

- i. A description of OFX's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO determined that the Paid Claims submitted by OFX (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Orthofix.
- iii. Total dollar amount of all Overpayments in the sample.
- iv. Total dollar amount of Paid Claims included in the sample and the net Overpayment associated with the sample.
- v. Error Rate in the sample.
- vi. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health

insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

- c. Recommendations. The IRO's report shall include any recommendations for improvements to OFX's billing and coding system based on the findings of the Claims Review.

4. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed (if applicable) that shall include the IRO's observations, findings, and recommendations regarding:

- a. the strengths and weaknesses in OFX's billing systems and processes;
- b. the strengths and weaknesses in OFX's coding systems and processes; and
- c. possible improvements to OFX's billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments.

5. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.

## APPENDIX C

### ARRANGEMENTS REVIEW

The Arrangements Review shall consist of two components: a systems review and a transactions review. The IRO shall perform all components of each Arrangements Review. If there are no material changes to OFX's or OSI's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If Orthofix materially changes the Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements 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. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of OFX's and OSI's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. OFX's and OSI's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;
2. OFX's and OSI's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;
3. OFX's and OSI's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
4. OFX's and OSI's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

5. OFX's and OSI's systems, policies, processes, and procedures for initiating Focus Arrangements, including those policies that identify the individuals with authority to initiate a Focus Arrangement and that specify the business need or business rationale required to initiate a Focus Arrangement;

6. OFX's and OSI's systems, policies, processes, and procedures for the internal review and approval of all Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by OFX or OSI, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute and Stark Law;

7. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Orthofix's internal review and approval process, and other Arrangements systems, process, policies, and procedures;

8. OFX's and OSI's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute and Stark Law are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate; and

9. OFX's and OSI's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Sections III.D.2 and 3 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The Arrangements Systems Review Report shall include the following information:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of OFX's and OSI's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in OFX's or OSI's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve OFX's and OSI's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

The IRO may prepare a single report with respect to both OFX and OSI, and may review OFX and OSI jointly.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 75 randomly selected Focus Arrangements that were entered into or renewed by OFX or OSI during the Reporting Period.

The 75 Focus Arrangements shall be divided into two strata. The first stratum shall consist of 40 Arrangements between OFX or OSI and physicians. The second stratum shall consist of 35 Arrangements between OFX or OSI and any other source of federal health care program referrals.

The IRO shall assess whether Orthofix has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.2 and 3 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in Orthofix's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (i.e., the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date, etc.)
2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;
3. verifying that the remuneration related to the Focus Arrangement is properly tracked;
4. verifying that the service and activity logs are properly completed and reviewed (if applicable);

5. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

6. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 and 3 of the CIA.

D. Arrangements Transaction Review Report. The IRO shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.
  - a. 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 the sample reviewed.
  - b. Sources of Data. A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.
  - c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transaction Review and Orthofix shall furnish such documentation and materials to the IRO, prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from Orthofix after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transaction Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transaction Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

2. *Review Findings.* The IRO's findings shall state whether Orthofix has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to Orthofix's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Focus Arrangements Procedures and Focus Arrangements Requirements.

3. *Report.* The IRO may prepare a single report with respect to both OFX and OSI, and may review OFX and OSI jointly.