

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

I. PREAMBLE

DePuy Orthopaedics, Inc., (DePuy) hereby enter into this CIA with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by its officers, directors, employees, contractors, and agents with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, DePuy is entering into a Settlement Agreement and Deferred Prosecution Agreement (DPA) with the United States. This CIA shall apply only to U.S. operations of DePuy that are subject to U.S. Federal health care program requirements.

DePuy represented to the OIG that, prior to the effective date of this CIA, DePuy established a voluntary compliance program, which includes a corporate compliance officer, a corporate compliance committee, a Code of Business Conduct for all employees, written policies and procedures, educational and training initiatives, review and disciplinary procedures, a confidential disclosure program, an ineligible persons screening program, and internal audit and review procedures. DePuy agrees to continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by DePuy under this CIA shall be 5 years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as the "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) DePuy's final annual report; or (2) any additional materials submitted by DePuy pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction entered into by DePuy that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between DePuy and any actual or potential source of health care business or referrals of health care business to DePuy or any actual or potential recipient of health care business or referrals from DePuy. The term "source" shall include any physician, contractor, vendor, or agent; and the term "health care business or referrals" shall be read to include referring, recommending, or arranging for, ordering, leasing or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

a. "Contractual Arrangements" shall mean every Arrangement that is contractual in nature and shall include all Arrangements related to the provision of services to DePuy, including but not limited to, training, education, consulting, research, clinical studies, focus groups, physician advisory boards as well as intellectual property, grants, and charitable contributions.

b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements.

2. "Covered Persons" includes:

a. all officers, directors and employees of DePuy, including but not limited to, DePuy's CEO and President and all members of DePuy's respective management inclusive of senior vice presidents, vice presidents, directors, and managers;

b. all contractors, subcontractors, agents, and other persons who, on behalf of DePuy, perform functions related to the sale or marketing of items or services reimbursable by Federal health care programs; and

- c. all individuals that sell or market on behalf of DePuy items or services for which reimbursement may be made by the Federal health care programs.

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

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

III. CORPORATE INTEGRITY OBLIGATIONS

DePuy shall maintain a compliance program that includes the following elements during the term of the CIA:

A. Compliance Officer and Committee.

1. *Compliance Officer.* DePuy represented to the OIG that, prior to the Effective Date of this CIA, DePuy appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. DePuy shall maintain a Compliance Officer for the term of the CIA and the Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA. The DePuy Compliance Officer shall be a member of senior management, shall make periodic (at least quarterly) reports regarding compliance matters directly to DePuy’s Board of Directors and shall be authorized to report on compliance matters to DePuy’s Board of Directors at any time. The Compliance Officer shall not be or be subordinate to DePuy’s General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by DePuy as well as for any reporting obligations imposed upon DePuy under this CIA.

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

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

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

B. Written Standards.

1. *Code of Conduct.* DePuy represented to the OIG that, prior to the Effective Date of this CIA, DePuy developed a Code of Business Conduct ("the Code of Conduct"). DePuy shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. To the extent not already addressed in the Code of Conduct, within 90 days of the Effective Date, the Code of Conduct shall be revised to incorporate the AdvaMed Code of Ethics on Interactions With Healthcare Professionals (available at www.advamed.org), and shall include, at a minimum, the following elements:

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

- b. DePuy's requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with DePuy's own Policies and Procedures as implemented pursuant to this Section III.B (including the requirements of this CIA);
- c. the requirement that all Covered Persons shall be expected to report to their Compliance Officer, or other appropriate individuals designated by DePuy, suspected violations of any Federal health care program requirements or of DePuy's own Policies and Procedures;
- d. the possible consequences to DePuy and Covered Persons of failure to comply with all Federal health care program requirements and with DePuy's Policies and Procedures and the failure to report such non-compliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and DePuy's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 90 days after the Effective Date, DePuy shall distribute the Code of Conduct (revised as necessary to include the elements set forth above) to each Covered Person and each Covered Person will certify, in writing or electronically, that he or she has received, read, understood and shall abide by DePuy's Code of Conduct. DePuy may distribute the Code of Conduct and the required certification to each Covered Person either electronically or in hard-copy form. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* Within 90 days after the Effective Date, DePuy shall implement written Policies and Procedures regarding the operation of DePuy's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. the expectation that all Covered Persons shall comply with the Code of Conduct, the Policies and Procedures required under this Section, and this CIA;
- c. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.1; and
- d. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on DePuy's intranet or other internal web sites available to all employees. If DePuy uses such an electronic method of distribution, it must notify the individuals receiving the Policies and Procedures that the Policies and Procedures will be distributed in such a manner, and it must adopt tracking procedures designed to track the distribution and reasonably ensure that all appropriate individuals received the Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), DePuy 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 90 days after the Effective Date, DePuy shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain DePuy's:

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

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

2. *Arrangements Training.* Within 90 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;
- b. DePuy's policies, procedures, and other requirements relating to Arrangements, including but not limited to the Arrangements Database, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

- c. the personal obligation of each individual involved in the development, approval, management, implementation, use, or review of DePuy's Arrangements to know the applicable legal requirements and DePuy's policies and procedures;
- d. the legal sanctions under the Anti-Kickback Statute; and
- e. examples of violations of the Anti-Kickback Statute.

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 90 days after the Effective Date, whichever is later. A DePuy employee who has completed the Arrangements Training shall review a new Arrangements Covered Person's work until such time as the new Arrangements Covered Person completes his or her Arrangements Training.

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

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

4. *Qualifications of Trainer.* Persons providing the training required by this Section III.C shall be knowledgeable about the subject area.

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

6. *Training Methods.* DePuy may provide the training required under this CIA through videotape, DVD, appropriate computer-based training approaches, or other comparable methods not involving in-person training. If DePuy chooses to provide training pursuant to any such method, they shall also make available at reasonable times appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

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

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

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures.* Within 90 days after the Effective Date, DePuy shall create procedures reasonably designed to ensure that each existing and new or renewed Arrangement, including Contractual Arrangements and Non-Contractual Arrangements, does not violate the Anti-Kickback Statute (taking into account the regulations, directives, and guidance related to this statute) (Arrangements Procedures). These procedures shall include the following:

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

g. requiring the Compliance Officer to review the Arrangements Database, internal review and approval process, and other Arrangements Procedures on at least a quarterly basis and to provide a report on the results of such review to the Compliance Committee; and

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

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

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

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

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

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

E. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, DePuy shall engage an individual or entity (or entities), such as an auditing, law or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform a review to assist DePuy in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review).

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

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

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

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

2. *Arrangements Review.* The IRO shall perform a review to assess whether DePuy is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 75 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether DePuy has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether DePuy has complied with the Arrangements Procedures and Arrangements Requirements specifically with respect to that Arrangement. The IRO's assessment shall include, but is not limited to: (a) verifying that the Arrangement is listed in the Arrangements Database; (b) verifying that the Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented; (c) verifying that the remuneration related to the Arrangement is properly tracked; (d) verifying that the activity logs are properly completed and reviewed; (e) verifying (if applicable) that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored; (f) verifying that the Compliance Officer is reviewing the Arrangements Database, internal review and approval process, and other Arrangements Procedures on a quarterly basis and reporting the results of such review to the Compliance Committee; (g) verifying that effective responses are being implemented when potential violations of the Anti-Kickback Statute are discovered; and (h) verifying that DePuy has met the requirements of Section III.D.2.

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

4. *Validation Review.* In the event OIG has reason to believe that: (a) DePuy's Arrangements Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Arrangements Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Arrangements Review

complied with the requirements of the CIA and/or the findings or Arrangements Review results are inaccurate (Validation Review). DePuy shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of DePuy's final Annual Report must be initiated no later than one year after DePuy's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify DePuy 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, DePuy may request a meeting with OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. DePuy agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review issues with DePuy prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

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

- (a) identity, address, and phone number;
- (b) a copy of the engagement letter;
- (c) a summary and description of any and all current and prior engagements and agreements between DePuy and the IRO; and
- (d) the proposed start and completion dates of the Arrangements Review;

(e) a certification from the IRO regarding its professional independence and objectivity with respect to DePuy;

Prior to lifting the suspension of Section III.E requirements, OIG shall notify DePuy of its intent to do so and provide a written explanation of why OIG believes lifting the suspension of Section III.E requirements is necessary. To resolve any concerns raised by the OIG, DePuy may request a meeting with the OIG. DePuy agrees to provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any concerns raised by the OIG with DePuy prior to lifting the suspension of Section III.E requirements. However, the final determination as to whether or not to lift the suspension of Section III.E requirements shall be made at the sole discretion of the OIG.

F. Disclosure Program.

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

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

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

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

G. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).
- c. "Screened Persons" include all prospective and current owners (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, employees, contractors, and agents of DePuy.

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

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

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

c. DePuy shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) DePuy to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. DePuy understands that items or services furnished by excluded persons are not payable by Federal health care programs and that DePuy may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether DePuy meets the requirements of this section III.G.

3. *Removal Requirement.* If DePuy has actual notice that a Screened Person has become an Ineligible Person, DePuy shall remove such Screened Person from responsibility for, or involvement with, DePuy's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If DePuy has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her

employment or contract term, DePuy shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

1. *Reportable Events.*

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

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by DePuy.

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

b. *Reporting of Reportable Events.* If DePuy determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a

