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

I. PREAMBLE

Contemporaneously with this CIA Biomet, Inc. ("Biomet") and Biomet Orthopedics, Inc. ("Biomet Orthopedics") entered into a Settlement Agreement with the United States and a Deferred Prosecution Agreement (DPA) with the United States Attorney's Office for the District of New Jersey. Biomet Orthopedics is a wholly owned subsidiary of Biomet engaged in the business of designing, manufacturing, marketing and selling joint reconstruction and replacement products. Biomet and Biomet Orthopedics 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 their 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). This CIA shall apply only to U.S. operations of Biomet that are subject to U.S. Federal health care program requirements.[1]

Biomet represented to the OIG that, prior to the effective date of this CIA, Biomet established a voluntary compliance program, which applies to Biomet Orthopedics and includes a corporate compliance officer, a corporate compliance committee, a Code of Business Conduct and Ethics 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. Biomet agrees to continue the operation of its compliance program in accordance with the terms set forth below for the term of this CIA.

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1 The CIA shall not apply to the following Biomet affiliated entities: Biomet Microfixation, Inc.; Biomet Biologics, Inc.; Biomet Sports Medicine, Inc.; EBI, L.P.; Biomet Manufacturing Corp.; and Biomet 3i, Inc.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Biomet and Biomet Orthopedics 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 a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Biomet's final annual report; or (2) any additional materials submitted by Biomet 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 Biomet Orthopedics that (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between Biomet or Biomet Orthopedics and any actual or potential source of health care business or referrals of health care business to Biomet Orthopedics or any actual or potential recipient of health care business or referrals from Biomet Orthopedics. 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 related to the provision of services to or for the benefit of Biomet Orthopedics, including but not limited to, training, education, consulting, research, clinical studies, focus groups, physician advisory boards, and product design agreements involving the development and/or transfer of intellectual property.

    b. "Non-Contractual Arrangements" shall mean all Arrangements that are not Contractual Arrangements, such as grants and charitable contributions.

2. "Covered Persons" includes:

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

b. all contractors, subcontractors, agents, and other persons who, on behalf of Biomet and Biomet Orthopedics, 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 Biomet and Biomet Orthopedics 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 Biomet Orthopedics' Arrangements.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee.

1. *Compliance Officer.* Biomet represented to the OIG that, prior to the Effective Date of this CIA, Biomet 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 by

Biomet and Biomet Orthopedics. Biomet 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 Biomet Compliance Officer shall be a member of senior management, shall make periodic (at least quarterly) reports regarding compliance matters directly to Biomet's Board of Directors and shall be authorized to report on compliance matters to Biomet's Board of Directors at any time. The Compliance Officer shall not be or be subordinate to Biomet's General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Biomet and Biomet Orthopedics, as well as for any reporting obligations imposed upon Biomet and Biomet Orthopedics under this CIA.

Biomet 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, Biomet shall appoint a Compliance Committee for Biomet and Biomet Orthopedics. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management of Biomet and Biomet Orthopedics 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 Biomet's risk areas and oversee monitoring of internal and external audits and investigations).

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

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

b. Biomet's and Biomet Orthopedics' requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements and with Biomet'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 Biomet or Biomet Orthopedics, suspected violations of any Federal health care program requirements or of Biomet's or Biomet Orthopedics' own Policies and Procedures;

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

To the extent not already accomplished, within 90 days after the Effective

Date, Biomet 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 Biomet's Code of Conduct. Biomet 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.

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, Biomet and Biomet Orthopedics shall implement written Policies and Procedures regarding the operation of Biomet's compliance program and Biomet's and Biomet Orthopedics' compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

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

c. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that may violate the Anti-Kickback Statute, and the applicability of the Anti-Kickback Statute to Arrangements as that term is defined in Section II.C.1; and

d. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute), including but not limited to the Arrangements Database, the internal review and approval process,

and the tracking of remuneration to and from sources of health care business or referrals.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures. Distribution may include publishing such Policies and Procedures on Biomet's intranet or other internal web sites available to all employees. If Biomet 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), Biomet 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, Biomet shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Biomet's:

a. CIA requirements; and

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

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

2. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least three hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

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

b. Biomet's and Biomet Orthopedics' 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 Biomet Orthopedics' Arrangements to know the applicable legal requirements and Biomet's and Biomet Orthopedics' policies and procedures;

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

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

New Arrangements Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Arrangements Covered Persons, or within 120 days after the Effective Date, whichever is later. A Biomet Orthopedics 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, Biomet 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.* Biomet 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 Biomet chooses to provide training pursuant to any such method, it 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. If Biomet chooses to provide the training required under the CIA through appropriate computer-based approaches, all applicable references to "hours" in this Section III.C. shall be "normative hours," meaning the number of hours usually required to complete the requirements of a training course through computer-based modules. (Normative hours may vary from the actual hours of training).

7. *Independent Distributors.* Where a Covered Person or an Arrangements Covered Person is an independent distributor, the General Training obligations under this CIA shall be met so long as the training is provided to a member of management of the independent distributor. Biomet Orthopedics shall request, and with respect to all new distributor agreements, require the independent distributor to take reasonable steps to apprise its employees and other personnel regarding the content of the training. In addition, Biomet Orthopedics 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 Biomet Orthopedics matters: (1) Biomet's or its own Code of Conduct; (2) copies of relevant Biomet policies and procedures relating to the work of the independent distributor; and (3) information about Biomet's Disclosure Program (including the hotline number);

c. provide either directly or through Biomet, 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 Biomet Orthopedics' Arrangements; and

d. certify to Biomet Orthopedics that all employees and subcontractors working on Biomet Orthopedics 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 Biomet's Code of Conduct or its own Code of Conduct and information about Biomet's Disclosure Program (including the hotline number); and (3) to the extent applicable, received Anti-Kickback training.

D. Compliance with the Anti-Kickback Statute.

1. *Arrangements Procedures*. Within 120 days after the Effective Date, Biomet and Biomet Orthopedics 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, Biomet Orthopedics shall comply with the following requirements (Arrangements Requirements):

a. Ensure that each Arrangement is set forth in writing and signed by Biomet Orthopedics 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 Biomet's Compliance Program, including the training related to the Anti-Kickback Statute. Additionally, Biomet Orthopedics shall provide each party to the Arrangement with a copy of its Code of Conduct and any applicable 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.* Biomet Orthopedics 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, Biomet Orthopedics 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 Biomet Orthopedics in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review).

The IRO shall assess, along with Biomet Orthopedics, 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 Biomet Orthopedics 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 Biomet Orthopedics shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Biomet Orthopedics) related to the reviews.

d. *Responsibilities and Liabilities.* Nothing in this Section III.E affects Biomet Orthopedics' 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 Biomet Orthopedics is complying with the Arrangements Procedures and Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA. The IRO shall randomly select a sample of 50 Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess whether Biomet Orthopedics has implemented the Arrangements Procedures and, for each selected Arrangement, the IRO shall assess whether Biomet Orthopedics 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 Biomet Orthopedics has met the requirements of Section III.D.2.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon each Arrangements Review performed (Arrangements Review Report). The Arrangements Review Report shall include the IRO's findings with respect to: (a) whether Biomet Orthopedics has generally implemented the Arrangements Procedures described in Section III.D.1; and (b) specific findings as to whether Biomet Orthopedics 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 Biomet Orthopedics' 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) Biomet Orthopedics' 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). Biomet Orthopedics 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 Biomet Orthopedics' final Annual Report must be initiated no later than one year after Biomet Orthopedics' final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Biomet 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, Biomet Orthopedics 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. Biomet Orthopedics 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 Biomet Orthopedics 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 Biomet Orthopedics a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the Arrangements Review and that it has concluded that it is, in fact, independent and objective.

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 Biomet Orthopedics that the suspension is rescinded. In the event that OIG provides notice to Biomet Orthopedics that suspension of the Section III.E requirements has been rescinded, within 90 days Biomet Orthopedics shall engage an IRO as set forth in Section III.E. Once Biomet Orthopedics engages an IRO, Biomet Orthopedics 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 Biomet Orthopedics and the IRO;

(d) the proposed start and completion dates of the Arrangements Review; and

(e) a certification from the IRO regarding its professional independence and objectivity with respect to Biomet Orthopedics.

Prior to rescinding the suspension of Section III.E requirements, OIG shall notify Biomet Orthopedics of its intent to do so and provide a written explanation of why OIG believes rescinding the suspension of Section III.E requirements is necessary. To resolve any concerns raised by the OIG, Biomet Orthopedics may request a meeting with the OIG. Biomet Orthopedics 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 Biomet Orthopedics prior to rescinding the suspension of Section III.E requirements. However, the final determination as to whether or nor to rescind the suspension of Section III.E requirements shall be made at the sole discretion of the OIG.

F. Disclosure Program.

Biomet represented to the OIG that, prior to the Effective Date of this CIA, it established a Disclosure Program, which applies to Biomet Orthopedics Biomet 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 Biomet's and Biomet Orthopedics' 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. Biomet 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.

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

G. Ineligible Persons.

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://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, and employees of Biomet and Biomet Orthopedics and all Covered Persons who perform functions related to the sale or marketing of items or services reimbursable by Federal health care programs.

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

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

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

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

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 Biomet or Biomet Orthopedics.

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

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

Orthopedics shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

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

iii. any further steps Biomet or Biomet Orthopedics' plans to take to address the Reportable Event and prevent it from recurring.

iv. if the Reportable Events involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities implicated.

IV. NEW BUSINESS UNITS

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Biomet and Biomet Orthopedics shall submit a joint written report to OIG summarizing the status of

their implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. a copy of the Code of Conduct required by Section III.B.1;

4. a copy of all Policies and Procedures required by Section III.B.2;

5. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

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

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions; and

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

7. a description of the Arrangements Database required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.e;

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

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

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

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

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

14. a description of Biomet's and Biomet Orthopedics' corporate structures, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

15. the certifications required by Section V.C.

B. Monitor Reports.

1. Biomet and Biomet Orthopedics shall submit to OIG any report or written recommendations produced by the Monitor pursuant to the DPA within 5 days of Biomet receiving any report or written recommendations from the Monitor.

2. Biomet and Biomet Orthopedics shall submit to OIG any report Biomet provides to the Monitor pursuant to the DPA at the same time Biomet provides such documentation to the Monitor.

3. Any written documentation Biomet or Biomet Orthopedics provides to the Monitor pursuant to the DPA shall be made available to the OIG upon request.

C. Annual Reports. Biomet and Biomet Orthopedics shall submit to OIG annually joint report with respect to the status of, and findings regarding, Biomet's and Biomet Orthopedics' compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee described in Section III.A;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., Monitor recommendation) and copies of any compliance-related Policies and Procedures;

3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);

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

a. a description of such training, including a summary of the topics covered, the length of sessions and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

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

5. a description of any changes to the Arrangements Database required by Section III.D.1.a;

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

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

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

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

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

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

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

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

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

15. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G; the actions taken by Biomet and Biomet Orthopedics in response to the screening and removal obligations set forth in Section III.G; and the actions taken to identify, quantify, and repay any overpayments to Federal health care programs relating to items or services furnished, ordered or prescribed by an Ineligible Person;

16. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

17. a description of all changes to the most recently provided list of Biomet's and Biomet Orthopedics' locations (including addresses) as required by Section V.A.15; the corresponding name(s) under which each location is doing business; the corresponding phone numbers and fax numbers; and each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s) (if applicable); and

18. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

D. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the applicable report, Biomet and Biomet Orthopedics are in compliance with all of the requirements of this CIA;

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

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

4. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful.

E. Designation of Information. Biomet and Biomet Orthopedics shall clearly identify any portions of their submissions that they believe are trade secrets, or

information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Biomet and Biomet Orthopedics 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

Biomet:

Jacqueline K. Huber
Vice President & Corporate Compliance Officer
Biomet, Inc.
56 E. Bell Drive
P.O. Box 587
Warsaw, Indiana 46581
Telephone: (574) 372-1573
Facsimile: (574) 372-1960

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Biomet's and Biomet Orthopedics' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Biomet's or Biomet Orthopedics' locations for the purpose of verifying and evaluating: (a) Biomet's and Biomet Orthopedics' compliance with the terms of this CIA; and (b) Biomet's and Biomet Orthopedics' compliance with the requirements of the Federal health care programs in which they participate. The documentation described above shall be made available by Biomet or Biomet Orthopedics 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 Biomet's or Biomet Orthopedics' 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. Biomet and Biomet Orthopedics shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Biomet's or Biomet Orthopedics' employees may elect to be interviewed with or without a representative of Biomet present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Biomet and Biomet Orthopedics prior to any release by OIG of information submitted by Biomet or Biomet Orthopedics pursuant to their obligations under this CIA and identified upon submission by Biomet or Biomet Orthopedics as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Biomet and Biomet Orthopedics shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Biomet and Biomet Orthopedics are 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, Biomet, Biomet Orthopedics 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 Biomet or Biomet Orthopedics fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer

b. a Compliance Committee;

c. a written Code of Conduct;

d. written Policies and Procedures;
e. the training of Covered Persons;

f. a Disclosure Program;

g. Ineligible Persons screening and removal requirements; and

h. Notification of Government investigations or legal proceedings.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Biomet Orthopedics fails to establish and implement the Arrangements Procedures and/or Arrangements Requirements described in Sections III.D.1 and III.D.2

3. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Biomet Orthopedics fails to engage

an IRO, as required in Section III.E and Appendix B.

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Biomet and Biomet Orthopedics fail to submit the Implementation Report, documentation required under Section V.B, or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

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

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

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

8. A Stipulated Penalty of $1,000 for each day Biomet or Biomet Orthopedics fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Biomet or Biomet Orthopedics, stating the specific grounds for its determination that Biomet or Biomet Orthopedics has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Biomet or Biomet Orthopedics shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Biomet receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions. Biomet and Biomet Orthopedics 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 Biomet or Biomet Orthopedics 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 Biomet or Biomet Orthopedics 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 Biomet or Biomet Orthopedics 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 Biomet or Biomet Orthopedics of: (a) Biomet's or Biomet Orthopedics' failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter"). Such Demand Letter shall specifically state the conduct that the OIG contends constitutes the basis for imposing the Stipulated Penalty.

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Biomet or Biomet Orthopedics 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 Biomet or Biomet Orthopedics elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Biomet or Biomet Orthopedics cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect

or otherwise set a standard for OIG's decision that Biomet or Biomet Orthopedics 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 Biomet or Biomet Orthopedics to report a Reportable Event, or take corrective action, as required in Section III.I;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or

d. a failure to engage and use an IRO in accordance with Section III.E.

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

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

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

Biomet, Biomet Orthopedics and OIG agree as follows:

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

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 Biomet's or Biomet Orthopedics' obligations under the CIA in the event of Biomet's or Biomet Orthopedics' cessation of the delivery, sale, marketing, or furnishing of items or services reimbursed by any Federal health care programs. If such cessation occurs and Biomet or Biomet Orthopedics is relieved of its CIA obligations by OIG, Biomet or Biomet Orthopedics

shall notify OIG at least 30 days in advance of the date on which Biomet or Biomet Orthopedics intends to begin delivering, selling, marketing, or furnishing items or services reimbursed by any Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned Biomet and Biomet Orthopedics signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

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

ON BEHALF OF BIOMET, INC. AND BIOMET ORTHOPEDICS, INC.

JEFFREY R. BINDER
President and Chief Executive Officer
Biomet, Inc. and Biomet Orthopedics, Inc.

9-27-07
DATE

JACQUELINE K. HUBER
Vice President & Corporate Compliance Officer
Biomet, Inc.

9-27-07
DATE

STEPHEN J. IMMELT
Hogan & Hartson, LLP
Counsel for Biomet, Inc. and Biomet Orthopedics, Inc.

DATE

ON BEHALF OF BIOMET, INC. AND BIOMET ORTHOPEDICS, INC.

_____ _____

JEFFREY R. BINDER DATE
President and Chief Executive Officer
Biomet, Inc. and Biomet Orthopedics, Inc.

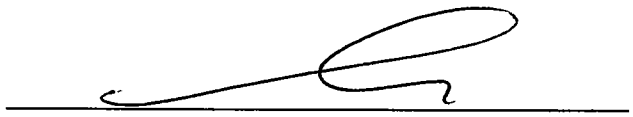
_____ _____

JACQUELINE K. HUBER DATE
Vice President & Corporate Compliance Officer
Biomet, Inc.

_____ 9/27/07

STEPHEN J. IMMELT DATE
Hogan & Hartson, LLP
Counsel for Biomet, Inc. and Biomet Orthopedics, Inc.

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



9/27/07

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

DATE

APPENDIX A

ARRANGEMENTS DATABASE

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

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

1. Each party involved in the Arrangement;

2. The type of Arrangement (e.g., physician employment contract, medical education and training, directorship, lease agreement, product development, consulting);

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

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

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

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

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

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

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

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

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

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

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

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

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement.

Biomet Orthopedics shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Biomet Orthopedics if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Biomet Orthopedics may continue to engage the IRO.

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

B. IRO Qualifications.

The IRO shall:

1. assign individuals qualified to conduct the Arrangements Review; and

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

C. IRO Responsibilities.

The IRO shall:

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

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

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

D. IRO Independence and Objectivity.

The IRO must perform the Arrangements Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Biomet Orthopedics.

E. IRO Removal/Termination.

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

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

Prior to requiring Biomet Orthopedics to engage a new IRO, OIG shall notify Biomet Orthopedics 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, Biomet Orthopedics may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Biomet Orthopedics shall provide any

additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Biomet Orthopedics prior to requiring Biomet Orthopedics to terminate the IRO. However, the final determination as to whether or not to require Biomet Orthopedics to engage a new IRO shall be made at the sole discretion of OIG.