

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

**I. PREAMBLE**

Life Spine, Inc. (“Life Spine”) hereby enters into this Corporate Integrity Agreement (“CIA”) with the Office of Inspector General (“OIG”) of the United States Department of Health and Human Services (“HHS”) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (“FDA requirements”). Life Spine represents that it has an established corporate compliance program (“Compliance Program”) which preceded the execution of this CIA. The Compliance Program includes a Compliance Officer, Compliance Committee, written policies and procedures, education and training programs, and a disclosure program. Life Spine will continue to operate its Compliance Program throughout the term of this CIA.

Effective November 6, 2019, Life Spine entered into a Stipulation and Order of Settlement and Dismissal (“Stipulation”) with the United States. In consideration of the obligations of Life Spine in the Stipulation and in this CIA, OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs against Life Spine under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct as defined in their respective Stipulations, except that the OIG expressly reserves all rights to comply with any statutory obligations to exclude Life Spine from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion).

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

A. Term of the CIA. The period of the compliance obligations assumed by Life Spine under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each

one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Expiration. Sections VII, X, and XI shall expire no later than 90 days after OIG’s receipt of: (1) Life Spine’s final annual report; or (2) any additional materials submitted by Life Spine pursuant to OIG’s request, whichever is later.

C. Scope of the CIA. The scope of this CIA is governed by the following definitions:

1. For purposes of this CIA, the term “Covered Persons” includes: (a) all owners of Life Spine who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of Life Spine; (b) all officers, directors and employees of Life Spine; and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Life Spine.

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 during a Reporting Period, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during a Reporting Period.

2. “Government Reimbursed Products” refers to all Life Spine products that are: (a) marketed or sold by Life Spine in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

3. The term “Covered Functions” includes: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to Life Spine’s review and approval processes for promotional materials and any applicable review committee(s); (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to Life Spine’s review and approval process for any non-promotional materials and any applicable review committees ; (d) contracting with health care providers (“HCPs”) for consulting services (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating to Government Reimbursed Products), or other fee-for-service arrangements relating to Government Reimbursed Products; (e) contracting with HCPs or health care

institutions (“HCIs”) for the purchase or licensing of intellectual property (including patents, patent applications, and the payment of royalties); and (f) reviewing and/or approving requests for grants or charitable contributions.

4. The term “Sponsorships” shall mean support for a program, event, or organization in return for the advertisement, or promotion of Life Spine products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

5. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Life Spine, including but not limited to, continuing medical education (“CME”), disease awareness, or symposia at medical conferences.

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

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

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Life Spine shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Life Spine; shall report directly to the Chief Executive Officer of Life Spine; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Life Spine. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of Life Spine (“Board”) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer’s reports to the Board shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Life Spine as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Life Spine shall report to OIG, in writing, any changes in the identity 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 five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Life Spine 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 sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Life Spine's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Life Spine shall report to OIG, in writing, 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 business days after such a change.

3. *Board Compliance Obligations.* The Life Spine Board shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

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

- a. meeting at least quarterly to review and oversee Life Spine's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;

- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Life Spine's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.
- d. for the first and fourth Reporting Period of the CIA, the Board shall retain an individual or entity with expertise in compliance with Federal health care program and FDA requirements ("Compliance Expert") to perform a review of the effectiveness of Life Spine's Compliance Program ("Compliance Program Review"). The Compliance Expert shall prepare a written report about the Compliance Program Review. The written report ("Compliance Program Review Report") shall include a description of the Compliance Program Review and any recommendations with respect to Life Spine's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Life Spine's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the first and fourth Annual Reports submitted by Life Spine. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

"The Board has made a reasonable inquiry into the operations of Life Spine, Inc.'s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Life Spine, Inc. has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

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

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Life Spine employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Life Spine business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: the Chief Executive Officer; the Chief Operating Officer; the Chief Financial Officer; and the Senior Vice President of Sales and Marketing. For each Reporting Period, each Certifying Employee shall sign a certification that states:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Life Spine, Inc.'s policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Life Spine, Inc. is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States."

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Life Spine shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (*e.g.*, reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, *etc.* prior to the Certifying Employee making the required certification).

B. Written Standards

1. *Policies and Procedures.* Within 120 days after the Effective Date, Life Spine shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Life Spine's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Life Spine shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. To the extent that Life Spine does not currently engage in any of the activities addressed below, Life Spine must develop and implement the applicable policies and procedures prior to engaging in such activity.

At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Covered Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;
- b. the development, implementation, and compliant use of promotional materials used by sales representatives (including any contract sales force) and other Life Spine representatives who promote and sell Government Reimbursed Products;
- c. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- d. agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and the payment of royalties);

- e. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
- f. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCPs' participation in education, research, training, or other Life Spine-sponsored programs or activities;
- g. sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs and HCIs;
- h. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.4 and II.C.5 above;
- i. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers;
- j. disciplinary policies and procedures for violations of Life Spine's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), Life Spine shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, Life Spine shall develop a written plan ("Training Plan") that outlines the steps Life Spine will take to ensure that: (a) all Covered Persons receive at least annual training regarding Life Spine's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Life Spine Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons required to attend each training session, length of the

training session(s), schedule for training, and format of the training. Life Spine shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1, within 120 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

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

3. *Training Records.* Life Spine shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

D. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Life Spine shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Life Spine to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Life Spine shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Life Spine shall engage an entity

(or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Retention of Records.* The IRO and Life Spine shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Life Spine) related to the reviews.
- c. *Access to Records and Personnel.* Life Spine shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *Systems and Transaction Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of two components: the Systems Reviews and Transactions Reviews.

- a. *Systems Review.* The Systems Reviews shall assess Life Spine’s systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Life Spine’s relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Life Spine materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.
- b. *Transactions Review.* The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO review performed (“IRO Review Report”). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Life Spine a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO’s certification shall include a summary of current and prior engagements between Life Spine and IRO.

F. Disclosure Program

Within 120 days after the Effective Date, Life Spine shall establish a Disclosure Program that includes a mechanism (*e.g.*, a 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 Life Spine’s policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Life Spine shall appropriately publicize the existence of the Disclosure Program and 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 shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by Life Spine. 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, Life Spine shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements, in the disclosure log within two business days of receipt of the disclosure. The disclosure log

shall include a summary of each disclosure received (whether anonymous or not), the individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

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 from participation in the Federal health care programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (“LEIE”) (available through the Internet at <http://www.oig.hhs.gov>).

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

- a. Life Spine shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Life Spine shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.
- c. Life Spine shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Life Spine’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Life Spine understands that items or services furnished,

ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Life Spine may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Life Spine meets the requirements of Section III.G.

3. *Removal Requirement.* If Life Spine has actual notice that a Covered Person has become an Ineligible Person, Life Spine shall remove such Covered Person from responsibility for, or involvement with, Life Spine's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If Life Spine has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Life Spine shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

#### H. Notification of Government Investigation or Legal Proceeding

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

#### I. Reportable Events

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

- a. 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;

- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Life Spine.

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

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

3. *Reportable Events under Sections III.I.1.a and III.I.1.b.* For Reportable Events under Sections III.I.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
- c. the Federal health care programs affected by the Reportable Event, if any;
- d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- e. a description of Life Spine's actions taken to correct the Reportable Event and prevent it from recurring.

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

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Life Spine completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

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

J. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between Life Spine and the FDA that materially discusses Life Spine's or a Covered Person's actual or potential unlawful or improper promotion of Life Spine's products (including any improper dissemination of information about off-label indications), Life Spine shall provide a copy of the report, correspondence, or communication to OIG. Life Spine shall also provide written notice to OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts

Within 120 days after the Effective Date, Life Spine shall establish a comprehensive Field Force Monitoring Program ("FFMP") to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations

(“Observations”) of sales personnel and (2) the monitoring and review of other records relating to sales personnel’s interactions with HCPs and HCIs (“Records Reviews”).

1. *Observations.* As a component of the FFMP, Monitoring Personnel shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Life Spine’s Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs regarding Life Spine products during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Life Spine Policies and Procedures; and
- 6) the identification of any potential improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 3 Observations during each Reporting Period.

Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives’ interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, Life Spine shall also review various types of records to assess sales representatives’ interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Life Spine shall develop and implement a plan for conducting Records Reviews associated

with at least 2 Government Reimbursed Product Lines<sup>1</sup>. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

- b. The Records Reviews shall include the monitoring and review of:
  - (i) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records relating to consulting and other fee-for-service arrangements, speaker program activities, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
  - (ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Product Lines under review;
  - (iii) sales representative call notes;
  - (iv) sales representatives' e-mails and other electronic records; and
  - (v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

4. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential noncompliance with Life Spine's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, Life Spine shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken,

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<sup>1</sup> The "Government Reimbursed Product Lines" are the categories of Life Spine products associated with their applications (e.g., Biologics, Cervical, Expandable, Lateral, interbody, MIS, OSSEO-LOC, SI Fixation, and Thoracolumbar).

including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.

L. Requirements Relating to Certain Non-Promotional Activities

Within 120 days after the Effective Date, Life Spine shall develop policies, procedures and systems to implement the requirements outlined below relating to the following types of activities: (1) consultant arrangement activities and (2) intellectual property agreements involving HCPs and HCIs.

1. *Consulting Arrangement Activities.* To the extent that Life Spine engages HCPs for consulting services (e.g., training and education services, speaker programs, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, and authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs shall be referred to as Consultants. Within 120 days after the Effective Date, Life Spine shall:

- a. Require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.
- b. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year and (ii) the budgeted amounts to be spent on Consultant-related activities. Life Spine compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Life Spine Policies and Procedures.
- c. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant

and provide specific details about the consulting arrangement (*e.g.*, information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Life Spine compliance personnel.

- d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant was engaged and that, as applicable, Life Spine receives the work product generated by the Consultant.

2. *Intellectual Property Agreements.* Within 120 days after the Effective Date, Life Spine shall develop policies, procedures, and systems relating to agreements with HCPs or HCIs for the purchase or licensing of intellectual property (including patents, patent applications, and the payment of royalties) (“Intellectual Property Agreements”) to comply with the following requirements:

- a. Life Spine shall ensure that any agreement or arrangement with an HCP or HCI for the purchase or licensing of intellectual property is in writing and describes the intellectual property to be licensed or purchased and the purchase price, licensing fees, or royalties to be paid. Any such purchase price, licensing fees, or royalty amounts must be determined based on an independent fair market value analysis.
- b. Life Spine shall establish a process to develop an annual budgeting plan for the purchase or licensing of intellectual property from HCPs or HCIs that identifies the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Intellectual Property Agreements to be entered into during the year. The annual budgeting plan shall also identify the budgeted amounts to be spent on Intellectual Property Agreements during the year. Life Spine compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan, for the purpose of ensuring that Intellectual Property Agreements are entered into for legitimate purposes in accordance with Life Spine Policies and Procedures and with Federal health care program and FDA requirements.

- c. Life Spine shall establish a process to ensure that a needs assessment has been completed to justify any Intellectual Property Agreement prior to entering into the Intellectual Property Agreement. The needs assessment shall identify the business or scientific need for the intellectual property to be licensed or purchased. Any deviations from the budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Life Spine compliance personnel.

M. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 120 days after the Effective Date, Life Spine shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). Life Spine also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Life Spine.

2. *Definitions.* For purposes of this Section III.M, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

IV. SUCCESSOR LIABILITY

A. Sale of Life Spine

In the event that, after the Effective Date, Life Spine proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Life Spine shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Life Spine wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Life Spine must notify OIG in writing of the

proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

## **V. IMPLEMENTATION AND ANNUAL REPORTS**

### **A. Implementation Report**

Within 120 days after the Effective Date, Life Spine shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (“Implementation Report”). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, 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.2;
3. the names of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B.1 and a statement that indicates which activities Life Spine is not currently engaged in;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the risk assessment and internal review process required by Section III.D;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Life

Spine that includes a summary of all current and prior engagements between Life Spine and the IRO;

9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;
11. a description of the FFMP required by Section III.K;
12. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.L;
13. a certification from the Compliance Officer that information regarding Payments has been posted on Life Spine's website as required by Section III.N;
14. a list of all of Life Spine's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;
15. a description of Life Spine's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
16. the certifications required by Section V.C.

B. Annual Reports

Life Spine shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods ("Annual Report"). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;
2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
4. the Board resolution required by Section III.A.3, a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and the Compliance Expert report as required in Section III.A.3.d.;
5. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;
6. a description of any changes to Life Spine's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;
7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
9. a complete copy of all reports prepared pursuant to Section III.E and Life Spine's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
10. a certification from the IRO regarding its professional independence and objectivity with respect to Life Spine, including a summary of all current and prior engagements between Life Spine and the IRO;
11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;
12. a description of any changes to the Ineligible Persons screening and

removal process required by Section III.G, including the reasons for such changes;

13. 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;

14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

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

16. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that Life Spine took as a result of such determinations;

17. a summary of any changes to the policies, procedures, and systems relating to the Requirements for Certain Non-Promotional Activities described in Section III.L, including the reasons for such changes;

18. a certification from the Compliance Officer that information regarding Payments has been posted on Life Spine's website as required by Section III.N;

19. a description of all changes to the most recently provided list of Life Spine's locations (including addresses) as required by Section V.A.13;

20. a description of any changes to Life Spine's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

21. the certifications required by Section V.C.

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

### C. Certifications

1. *Certifying Employees.* In each Annual Report, Life Spine shall

include the certifications of Certifying Employees as required by Section III.A.4;

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

- a. to the best of his or her knowledge, except as otherwise described in the report, Life Spine has implemented and is in compliance with all requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

Life Spine shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552. Life Spine 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

**Life Spine**

Jennifer Jesse

Corporate Compliance Officer

13951 S. Quality Drive

Huntley, IL 60142

Telephone: 847-884-6117

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Life Spine may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

**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 conduct interviews, examine and/or request copies of or copy Life Spine's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Life Spine's locations for the purpose of verifying and evaluating: (a) Life Spine's compliance with the terms of this CIA and (b) Life Spine's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Life Spine to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Life Spine's owners, employees, contractors and directors 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. Life Spine shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Life Spine's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Life Spine present.

**VIII. DOCUMENT AND RECORD RETENTION**

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

## **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Life Spine prior to any release by OIG of information submitted by Life Spine pursuant to its obligations under this CIA and identified upon submission by Life Spine as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Life Spine shall have the rights set forth at 45 C.F.R. § 5.42 (a).

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

Life Spine is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Life Spine 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 on Life Spine (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) per obligation for each day Life Spine fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations;
- d. the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report, as required by Section III.A.3.d;
- e. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- f. written Policies and Procedures;

- g. the development of a written training plan and the training and education of Covered Persons and Board members;
- h. a risk assessment and internal review process;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- l. notification of written communications with FDA;
- m. the FFMP;
- n. the Requirements Relating to Certain Non-Promotional Activities; and
- o. posting of any Payment-related information.

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 Life Spine fails to engage and use an IRO as required by Section III.E and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Life Spine fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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 Life Spine fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Life Spine as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day Life Spine fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day Life Spine fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix B; and

8. A Stipulated Penalty of \$1,000 for each day Life Spine fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Life Spine stating the specific grounds for its determination that it has failed to comply fully and adequately with the CIA obligation(s) at issue and steps it shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Life Spine 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

Life Spine 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 Life Spine 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 Life Spine 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 Life Spine 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 Life Spine of: (a) the identified failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

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

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Life Spine 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. repeated violations or a flagrant violation of any of the the obligations under this CIA, including, but not limited to, Life Spine's obligations addressed in Section X.A;
  - b. a failure by Life Spine to report a Reportable Event and take corrective action as required in Section III.I;
  - c. a failure by Life Spine to engage and use an IRO in accordance with Section III.E and Appendix B;
  - d. a failure by Life Spine to respond to a Demand Letter concerning the payment of its Stipulated Penalties in accordance with Section X.C.
  - e. failure by Life Spine to implement the requirements outlined in Section III.L relating to consultant arrangement activities and intellectual property agreements involving HCPs and HCIs; and

2. *Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Life Spine constitutes an independent basis for Life Spine's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion but not more than five years per material breach. Upon a determination by OIG that Life Spine has materially breached this CIA and that exclusion is the appropriate remedy, OIG will notify the relevant party of: (a) the 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.* Life Spine 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. the alleged Material Breach has been cured; or
- b. the alleged Material Breach cannot be cured within the 30 day period, but that: (i) Life Spine has begun to take action to cure the Material Breach; (ii) Life Spine is pursuing such action with due diligence; and (iii) Life Spine has provided to OIG a reasonable timetable for curing the Material Breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day opportunity to cure period for any Material Breach arising from Sections X.D.1.a-e, Life Spine fails to satisfy the requirements of Section X.D.3, OIG may exclude Life Spine from participation in the Federal health care programs. OIG will notify Life Spine in writing of its determination to exclude (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 the applicable party's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, the excluded party 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 Life Spine 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, Life Spine 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. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 Life Spine was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Life Spine 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 Life Spine to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Life Spine 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 whether Life Spine was in material breach of this CIA and, if so, whether:

- a. Life Spine cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following Life Spine's receipt of the Notice of Material Breach: (i) Life Spine had begun to take action to cure the material breach within that period; (ii) Life Spine pursued such action with due diligence; and (iii) Life Spine provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Life Spine, only after a DAB decision in favor of OIG. Life Spine's election of their contractual right to appeal to the DAB shall

not abrogate OIG's authority to exclude Life Spine 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 Life Spine 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. Life Spine 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 Life Spine, the prevailing party 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**

Life Spine and OIG agree as follows:

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

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

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Life Spine's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

D. The undersigned signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

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

**ON BEHALF OF LIFE SPINE, INC.**

/Michael Butler/  
MICHAEL BUTLER  
Chief Executive Officer  
Life Spine, Inc.

3/11/2021  
DATE

/Heather Glaser/  
HEATHER GLASER  
General Counsel  
Life Spine, Inc.

3/11/2021  
DATE

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

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

3/16/2021  
DATE

/Tamara Forys/  
TAMARA T. FORYS  
Deputy Branch Chief  
Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
U.S. Department of Health and Human Services

3/17/2021  
DATE

## APPENDIX A

### 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

1. Life Spine shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Life Spine in response to a request by OIG, whichever is later, OIG will notify Life Spine if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Life Spine may continue to engage the IRO.

2. If Life Spine 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, Life Spine shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Life Spine at the request of OIG, whichever is later, OIG will notify Life Spine if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Life Spine may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the medical device industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with medical device products and the Federal Anti-Kickback Statute and the False Claims Act.

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO Review;
3. respond to all OIG inquires in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Life Spine Responsibilities

Life Spine shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section III.E of this CIA and that all records furnished to the IRO are accurate and complete.

D. IRO Independence and Objectivity

The IRO must perform each IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Life Spine in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Life Spine shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's

qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Life Spine regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Life Spine in writing that Life Spine shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Life Spine must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Life Spine to engage a new IRO shall be made at the sole discretion of OIG.

## **APPENDIX B**

### **INDEPENDENT REVIEW ORGANIZATION REVIEWS**

#### **A. IRO Engagement, General Description**

As specified more fully below, Life Spine shall retain an IRO to perform engagements to assist Life Spine in assessing and evaluating certain of its systems, processes, policies, and procedures related to Life Spine's Covered Functions ("IRO Review"). The IRO Review shall consist of two components - a systems review ("Systems Review") and a transactions review ("Transactions Review") as described more fully below. Life Spine may engage, at its discretion, a single entity to perform both components of the IRO Reviews, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Life Spine's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods. If Life Spine materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

#### **B. IRO Systems Review**

The Systems Review shall be a review of Life Spine's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. Prior to the Systems Review, Life Spine shall certify to the IRO any activities listed below that it did not engage in during the applicable reporting period, and the IRO will not review systems related to activities Life Spine did not engage in. More specifically, the IRO shall review Life Spine's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Life Spine's systems, policies, processes, and procedures relating to conducting Covered Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False

Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

2. Life Spine's systems, policies, processes, and procedures relating to the development, implementation, and compliant use of promotional materials used by sales representatives (including any contract sales force) and other Life Spine representatives who promote and sell Government Reimbursed Products;
3. Life Spine's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
4. Life Spine's systems, policies, processes, and procedures relating to agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);
5. Life Spine's systems, policies, processes, and procedures relating to programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
6. Life Spine's systems, policies, processes, and procedures relating to the review and approval of, and payment for, travel and related expenses for HCPs including those in connection with an HCP's participation in educational, research, training, or other Life Spine-sponsored programs or activities;
7. Life Spine's systems, policies, processes, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions involving HCPs and HCIs;
8. Life Spine's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.4 and II.C. 5 of the CIA;

9. Life Spine's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and
10. Life Spine's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Life Spine's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

C. IRO Systems Review Report

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

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of Life Spine's systems, policies, processes, and procedures relating to the items identified in Sections B.1-10 above, including a general description of Life Spine's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections B.1-10 above are made known or disseminated within Life Spine;
4. findings and supporting rationale regarding any weaknesses in Life Spine's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
5. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

D. IRO Transactions Review

The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of agreements with HCPs or HCIs for the purchase or licensing of intellectual property, and (3) a sample of

Payments. The IRO shall report on all aspects of its reviews in the Transactions Review Report.

1. *Review of Consulting Activities.* For purposes of this Appendix B , the term “Consulting Activities” shall include all consulting and other fee for service arrangements entered with HCPs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship and authorship-related activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

- a. For the first Reporting Period, the IRO shall select and review a sample of 10 Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods, the IRO shall review a sample of 10 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG. Prior to the determination of the number of each type of Consulting Activity to be reviewed during the second and subsequent Reporting Periods, Life Spine shall provide to the OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.
- b. The IRO shall select its sample of Consulting Activities for review in consultation with OIG after the provision of information about the Consulting Activities to the OIG. Life Spine shall provide the following information to the OIG: 1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; 2) the number of each type of Life Spine Consulting Activity undertaken during the Reporting Period; and 3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period.
- c. For each Consulting Activity reviewed the IRO shall determine whether:
  - i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;

- ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Life Spine;
- iii. the rate structure was established based on an independent FMV analysis;
- iv. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Life Spine;
- v. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting Activity was completed prior to the initiation of the Consulting Activity;
- vi. the Consulting Activity was reviewed and approved in accordance with Life Spine Policies and Procedures;
- vii. Life Spine collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated by the HCP in connection with the Consulting Activity; and
- viii. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by Life Spine in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. *Review of Intellectual Property Arrangements.* For purposes of this Appendix B, the term “Intellectual Property Arrangement” shall include any arrangement pursuant to which Life Spines licenses or purchases intellectual property from an HCP or HCI. For each Reporting Period, the IRO shall select a random sample of 2 Intellectual Property Arrangements entered into with HCPs and HCIs. For each Intellectual Property Arrangement reviewed, the IRO shall determine whether:

- i. a written agreement was in place for each Intellectual Property Arrangement that describes the intellectual property to be purchased or licensed and the purchase price, licensing fees, or royalties to be paid;
- ii. the purchase price, licensing fees, or royalty amounts were determined based on an independent fair market value analysis;

- iii. the Intellectual Property Consulting Arrangement was identified in the annual budgeting plan developed by Life Spine;
- iv. a needs assessment that identifies the business need for the Intellectual Property Arrangement and provides details about the arrangement was completed prior to entering into the arrangement; and
- v. the Intellectual Property Arrangement was reviewed and approved in accordance with Life Spine Policies and Procedures.

In addition, for each Intellectual Property Arrangement selected for review, Life Spine shall provide the IRO with information about the total aggregate annual Payments (as defined in Section III.M of the CIA) by Life Spine to the associated HCP or HCI for any reason other than the Intellectual Property Arrangement selected for review. The IRO shall assess whether Life Spine paid the HCP or HCI an amount that exceeded any annual cap on compensation established in accordance with Life Spine's Policies and procedures

3. *Review of Payments.* For purposes of this Appendix B, the term "Control Documents" shall include all material documents or electronic records associated with each Life Spine Payment reflected in the Open Payments database for that calendar year. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of the Payment; contracts relating to the Payment; documents relating to the occurrence of Payment; documents reflecting any work product generated in connection with the Payment; documents submitted by sales representatives or headquarters personnel to request approval for the Payment; and business rationale or justification forms relating to the Payment.

- a. For each Reporting Period, the OIG shall have the discretion to identify up to 15 Covered Recipients who received Payments from Life Spine during the prior calendar year and will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select 15 Covered Recipients to be included in the review.
- b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments.

Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

- (i) whether Control Documents are available relating to each Payment;
- (ii) whether the Control Documents were completed and archived in accordance with the requirements set forth in Life Spine's policies;
- (iii) whether the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents; and
- (iv) whether the Control Documents reflect that Life Spine's policies were followed in connection with the Payment(e.g., all required written approvals for the activity were obtained in accordance with Life Spine's policies.)

E. Transactions Review Report

A. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

- 1. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- 2. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- 3. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

B. Results to be Included in Report. The following results shall be included in each Transactions Review Report:

1. Relating to the Review of Consulting Activities
  - a. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
  - b. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:
    - i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;
    - ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Life Spine;
    - iii. the rate structure was established based on an independent FMV analysis;
    - iv. the Consulting Activity was identified in the annual Consulting budgeting plan developed by Life Spine;
    - v. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;
    - vi. the Consulting Activity was reviewed and approved in accordance with Life Spine Policies and Procedures,
    - vii. Life Spine collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity; and
    - viii. the activity undertaken by the Consultant and/or the work product generated was used by Life Spine in a manner consistent with the needs assessment that was

completed prior to the initiation of the Consulting Activity;

- c. any weaknesses in Life Spine's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and
- d. any recommendations for improvements to Life Spine's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

2. Relating to the Review of Intellectual Property Arrangements

- a. a description of each Intellectual Property Arrangement reviewed and an identification of the types of documents and information reviewed for each Intellectual Property Arrangement.
- b. for each Intellectual Property Arrangement reviewed, information about the aggregate annual amount paid by Life Spine to the HCP or HCI for all purposes.
- c. for each Intellectual Property Arrangement reviewed, the IRO's findings and supporting rationale as to whether:
  - i. a written agreement was in place for each Intellectual Property Arrangement that describes the intellectual property to be purchased or licensed and the purchase price, licensing fees, or royalties to be paid;
  - ii. the purchase price, licensing fees, or royalty amounts were determined based on an independent fair market value analysis;
  - iii. the Intellectual Property Arrangement was identified in the annual budgeting plan developed by Life Spine;
  - iv. a needs assessment that identifies the business need for the Intellectual Property Arrangement and provides details about the arrangement was prepared prior to entering into the arrangement;

- v. the Intellectual Property Arrangement was reviewed and approved in accordance with Life Spine Policies and Procedures; and
  - vi. the aggregate amount paid by Life Spine to the HCP or HCI exceeded any applicable cap established under Life Spine's Policies and Procedures.
- d. any weaknesses in Life Spine's systems, processes, policies, procedures and/or practices relating to Intellectual Property Arrangements identified by the IRO; and
  - e. any recommendations for improvements to Life Spine's systems, processes, policies, procedures and/or practices relating to Intellectual Property Arrangements.

3. Relating to the Review of Payments

- a. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and
- b. for each sampled Payment, findings and supporting rationale as to whether:
  - i. all required Control Documents exist;
  - ii. each Control Document was completed in accordance with all of the requirements set forth in the applicable Life Spine policy;
  - iii. the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;
  - iv. each Control Document reflects that Life Spine's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and
  - v. any corrective action or disciplinary action was undertaken in those instances in which Life Spine policies were not followed.