

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
OLYMPUS CORPORATION OF THE AMERICAS**

**I. PREAMBLE**

Olympus Corporation of the Americas and its subsidiaries that market, sell, or lease medical and surgical products in the United States, including Olympus America, Inc.; Spiration, Inc.; Gyrus ACMI, Inc.; Olympus Latin America, Inc. and Olympus Scientific Solutions Americas, Inc. (referred to collectively as "OCA") hereby enter 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). Contemporaneously with this CIA, OCA is entering into a Settlement Agreement with the United States. OCA is also entering settlement agreements with various states and OCA's agreement to this CIA is a condition precedent to those agreements.

OCA has represented the following: In 2008, OCA incorporated principles of the AdvaMed Code of Ethics on Interactions with Health Care Professionals into its Code of Ethics. In 2009, OCA began to commit increased resources and improve the internal infrastructure devoted to compliance. OCA appointed its first Compliance Officer and undertook a number of initiatives to strengthen compliance processes and remediate specific self-identified issues. Beginning in August 2010, OCA has undertaken additional reforms and remedial actions with respect to its compliance processes.

In this regard, OCA represents that it has implemented a compliance program that includes the following elements: a compliance officer, a compliance committee, training and education, policies and procedures, a hotline for reporting compliance issues, and monitoring and auditing activities. OCA shall continue its compliance program throughout the term of this CIA and shall do so in accordance with the terms set forth below. OCA may modify its compliance program as appropriate but, at a minimum,

OCA shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

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

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

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

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

1. "Covered Persons" includes:

- a. all owners of OCA 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);
- b. all officers, directors, and employees of OCA ; and
- c. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions (as defined below in Section II.C.4) on behalf of OCA, and in that capacity interact directly with healthcare professionals (HCPs) (which includes healthcare institutions) or consumers.

Notwithstanding the above, the term Covered Persons 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 the Reporting Period.

2. “Relevant Covered Persons” includes all Covered Persons who engage in any of the Covered Functions and all individuals who supervise Covered Persons who engage in any of the Covered Functions.

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

4. The term “Covered Functions” includes: (a) selling, leasing, marketing, advertising, or promoting Government Reimbursed Products; (b) performing activities or providing services involving or relating to asset management of Government Reimbursed Products, (c) contracting with HCPs for consulting services, research services or other fee-for-service arrangements related to Government Reimbursed Products; (d) reviewing and/or approving requests from HCPs for grants or charitable contributions, (e) performing any other activities or providing any other services directly relating to selling, leasing, marketing, advertising, or promoting of Government Reimbursed Products, and (f) the preparation or external dissemination of promotional materials about Government Reimbursed Products, including those functions relating to OCA’s review and approval processes for promotional materials and any applicable review committee(s).

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

6. The term “Third Party Educational Activity” shall mean any scientific, educational or professional program, meeting or event for HCPs that is organized, controlled, and conducted by an independent third party, including but not limited to, accredited and non-accredited medical education (CME and non-CME), disease awareness, or medical conferences.

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

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

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

1. *Compliance Officer.* Prior to the Effective Date, OCA appointed a Chief Compliance Officer for the Americas (Compliance Officer). OCA shall continue to maintain a Compliance Officer for the term of the CIA. The Compliance Officer is and shall continue to be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall continue to be an employee and a member of senior management of OCA. The Compliance Officer shall report directly to the President and Chief Executive Officer of OCA and also shall report to the Board of Directors of Olympus Corporation of the Americas (Board), and the Global Chief Compliance Officer of Olympus Corporation. The Compliance Officer shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board; and shall be authorized to report on such matters to the Board at any time. The Compliance Officer is a member of the Global Compliance Committee and has access to the Board of Directors of Olympus Corporation (OCA's parent company).

Written documentation of the Compliance Officer's reports to the Board of Directors shall be made available to OIG upon request. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer of any OCA entity or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for OCA. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by OCA as well as for any reporting obligations created under this CIA. Any job responsibilities of the Compliance Officer unrelated to compliance shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* To the extent not already accomplished, within 90 days after the Effective Date, OCA 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 co-chair the Compliance Committee with the CEO. The Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of OCA's risk areas and shall oversee monitoring of compliance-related audits and compliance investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors of OCA (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 an independent (i.e., non-executive) member.

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

- a. meeting at least quarterly to review and oversee OCA's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the 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 individual member of the Board, summarizing its review and oversight of OCA's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors has made a reasonable inquiry into the operations of OCA’s Compliance Program during the preceding twelve-month period 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, OCA 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 OCA.

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

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain OCA officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable OCA business unit is compliant with applicable Federal health care program requirements and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following:

- a. President and Chief Executive Officer, Olympus Corporation of the Americas
- b. President, Olympus America, Inc. (OAI) Medical Systems Group (MSG)
- c. Group Vice President, Commercial Operations, OAI MSG
- d. Group Vice President, Endoscopy, OAI, MSG
- e. Group Vice President, Surgical, OAI, MSG
- f. Chief Financial Officer, Olympus Corporation of the Americas
- g. President, Olympus Scientific Solutions Americas Corp.
- h. President, Olympus Latin America, Inc.

- i. President, Spiration, Inc.
- j. President, Gyrus ACMI, Inc.

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 or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and OCA policies applicable to [department or function], and I have taken steps to promote such compliance. To the best of my knowledge, the \_\_\_\_\_ [insert name of department or functional area] of OCA 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 and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards.

1. *Health Care Compliance Code of Conduct (Code of Conduct).* To the extent not already accomplished, within 90 days after the Effective Date, OCA shall develop, implement, and make available a written Code of Conduct to all Covered Persons. OCA shall make the performance of job responsibilities in a manner consistent with the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct shall include, at a minimum, the following:

- a. OCA’s commitment to full compliance with all Federal health care program requirements and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;

- b. OCA's requirement that all of its Covered Persons shall be expected to comply with all applicable Federal health care program requirements and FDA requirements, and with OCA's own policies and procedures;
- c. OCA's requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by OCA, suspected violations of any Federal health care program requirements, FDA requirements, or of OCA's own Policies and Procedures; and
- d. the right of all individuals to use the Disclosure Program described in Section III.G, and OCA's commitment to non-retaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

OCA shall review the Code of Conduct at least annually to determine if revisions are appropriate and shall make any necessary revisions based on such review. The Code of Conduct shall be made available at least annually to all Covered Persons.

2. *Policies and Procedures.* To the extent not already accomplished, within 90 days after the Effective Date, OCA shall implement written policies and procedures regarding the operation of its Compliance Program, including the compliance program requirements outlined in this CIA and OCA's compliance with Federal health care program requirements and FDA requirements (Policies and Procedures). Throughout the term of this CIA, OCA shall enforce and comply with its Policies and Procedures and shall make such compliance an element in evaluating the performance of all employees. At a minimum, the Policies and Procedures shall address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Covered Functions in compliance with (i) all 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;

- c. consultant or other fee-for-service arrangements entered into with HCPs (including but not limited to speaker programs, advisory boards, research and development meetings, product training and education sessions, presentations, ad hoc advisory activities, research and any other financial engagement or arrangement with an HCP) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events. The Policies and Procedures shall include requirements designed to ensure that the HCP performed the work for which the HCP was engaged and that, as applicable, OCA received the work product generated by the HCP;
- d. funding of grants (including CME and non-CME third party educational grants, research and “in-kind” grants) and charitable contributions. These Policies and Procedures shall be designed to ensure that OCA’s funding complies with all applicable Federal health care program and FDA requirements;
- e. review and approval of travel and related expenses for HCPs, including those in connection with HCPs’ participation in educational, research or other OCA -sponsored programs or activities;
- f. identification and tracking of medical and surgical equipment and products provided to HCPs on a temporary basis for any reason, including (i) demonstration or evaluation, (ii) medical education purposes, (iii) as a replacement for a product or equipment that requires repair, and (iv) trade shows and conference displays (collectively, “Field Assets”);

- g. identification, tracking, and reporting to the Centers for Medicare & Medicaid Services (CMS) of Payments pursuant to Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, and the related regulations and guidance (including FAQs) published by CMS;
- h. disciplinary policies and procedures for violations of OCA's Policies and Procedures, including policies relating to Federal health care program and FDA requirements;
- i. materials and information that may be distributed by OCA sales representatives (including any contract sales representatives) about Government Reimbursed Products and materials and information that may be distributed or made available by OCA through social media and/or direct-to-consumer advertising. These Policies and Procedures shall be designed to ensure that OCA's activities in this area and the information distributed or made available comply with all applicable Federal health care program and FDA requirements, and have been reviewed and approved by the applicable review committee(s) at OCA before they are posted or disseminated;
- j. funding of, or participation in, any Sponsorships, as defined in II.C.5. These Policies and Procedures shall be designed to ensure that OCA's funding of or participation in such Sponsorships involves fair market value transactions and is for a legitimate business purpose and satisfies all applicable Federal health care program and FDA requirements;
- k. funding of, or participation in, any Third Party Educational Activity, as defined in Section II.C.6 above. These Policies and Procedures shall be designed to ensure that the Third Party Educational Activity has a genuine educational purpose and function, appropriate disclosures of OCA's funding or participation are made, and that OCA's funding of or participation in such Third Party Educational Activity

satisfies all applicable Federal health care program and FDA requirements and

1. compensation (including through salaries, bonuses, or other means) for Relevant Covered Persons who are sales representatives and their field-based managers. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of OCA's Government Reimbursed Products and (ii) include mechanisms, where appropriate, to exclude from incentive compensation sales that may indicate improper promotion, sales, or marketing of Government Reimbursed Products.

Within 90 days after the Effective Date, the Policies and Procedures shall be made available to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

On a rolling three-year cycle, (and more frequently, if appropriate), OCA shall assess and update, as necessary, all the Policies and Procedures. Within 30 days after the effective date of any revisions or addition of new Policies and Procedures, any new or revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, OCA shall develop a written plan (Training Plan) that outlines the steps OCA will take to ensure that: (a) all Covered Persons receive adequate training regarding OCA's CIA requirements and Compliance Program, including the Code of Conduct and (b) all Relevant Covered Persons receive adequate training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions; (ii) all OCA Policies and Procedures and other requirements applicable to Covered Functions; (iii) the personal obligation of each individual involved in Covered Functions to comply with all applicable Federal health care program and all other applicable legal requirements; (iv) the legal sanctions for violations of the applicable Federal health care program; and (v) examples of proper and improper practices related to Covered Functions.

The Training Plan shall include information regarding the training topics, the categories of Covered Persons and Relevant Covered Persons required to attend each training session, the length of the training, the schedule for training, and the format of the training. Within 30 days of the OIG's receipt of OCA's Training Plan, OIG will notify OCA of any comments or objections to the Training Plan. Absent notification by the OIG that the Training Plan is unacceptable, OCA may implement its Training Plan. OCA shall furnish training to its Covered Persons and Relevant Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, OCA shall provide at least two hours of training to each member of the Board of Directors. This training shall address OCA's CIA requirements and Compliance Program (including the Code of Conduct), 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 industry 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 the OIG's guidance on Board member responsibilities.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a board member or within 90 days after the Effective Date, whichever is later.

3. *Certification.* Each Covered Person, Relevant Covered Person, and Board member who is required to complete training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain these certifications, along with all course materials.

4. *Qualifications of Trainer.* Persons responsible for providing training shall be knowledgeable about the subject area of the training, including about applicable Federal health care program and FDA requirements.

5. *Update of Training Plan.* OCA shall review the Training Plan annually, and, where appropriate, update the Training Plan to reflect changes in Federal health care program and FDA requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information. Any updates to the Training Plan must be reviewed and approved by the OIG prior to the implementation of the

revised Training Plan. Within 30 days of OIG's receipt of any updates or revisions to OCA's Training Plan, OIG will notify OCA of any comments or objections to the revised Training Plan. Absent notification from the OIG that the revised Training Plan is unacceptable, OCA may implement the revised Training Plan.

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

D. Requirements for Consulting Arrangements, Grants and Charitable Contributions, Management of Field Assets, and Review of Travel Expenses.

1. *Consulting Arrangements.* To the extent that OCA engages HCPs for consulting activities (e.g., as a member of an advisory board or a speaker, to develop sales and marketing materials, to serve as a faculty member for product training or education sessions) or research services (e.g., to assist in the research or development of medical or surgical products, clinical studies/clinical trials), such HCPs shall be referred to herein as Consultants. OCA shall require all Consultants to enter written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultant. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by OCA.

Within 90 days after the Effective Date, OCA shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. OCA compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and OCA Policies and Procedures.

Within 90 days after the Effective Date, OCA shall 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 to be engaged 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 OCA compliance personnel.

2. *Grants and Charitable Contributions.* Within 120 days after the Effective Date, OCA shall establish a grants management system which shall be the exclusive mechanism through which requestors may request or be awarded grants for independent medical education grants, other grant activities (including in-kind grants involving equipment loans), and healthcare-related charitable contributions supported by OCA. OCA's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of medical education grants or healthcare-related charitable contribution requests. Grant and healthcare-related charitable contribution requests shall be submitted through a centralized grants management system and processed in accordance with standardized, objective criteria developed by OCA (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant). In addition, the grants or healthcare-related charitable contributions shall be provided only pursuant to a written agreement with the funding recipient. OCA shall continue the grant and healthcare-related charitable contribution process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

3. *Management of Field Assets.* Within 90 days after the Effective Date, OCA shall establish a system for the management of Field Assets (as defined in Section III.B.2.f above). The Field Asset management system shall have the capability to identify, track, and monitor Field Assets and to ensure that such Field Assets are being used in a manner consistent with OCA's Policies and Procedures and Federal health care program and FDA requirements. OCA has designated a team of individuals with responsibility for managing and controlling Field Assets. The team's responsibilities include fulfilling requests for Field Assets, analysis and reporting of Field Assets, monitoring the return of Field Assets, and auditing of Field Assets in the possession of sales representatives. OCA's management system collects and records information about the following: 1) the consignment of Field Assets to OCA personnel, customers, prospective customers, and third parties; 2) the reason for the consignment; 3) the length of the consignment; and 4) information about the date on which the Field Assets were retrieved by OCA following the consignment. OCA shall continue the Field Asset management system (including the team of individuals responsible for managing and

controlling Field Assets) described above (or an equivalent system) throughout the term of the CIA, and shall notify the OIG in writing at least 60 days prior to the implementation of any new system subsequent to the Effective Date.

4. *Review of Travel Expenses.* Within 90 days after the Effective Date, OCA shall establish a process or processes for the review and approval of travel and related expenses for HCPs in connection with HCPs' attendance and participation in OCA-conducted product training and education programs, or OCA sales, promotional and other business meetings (e.g., plant tours, demo of non-portable equipment), other than travel and travel-related expenses incurred by HCP consultants in connection with consulting arrangements. The purpose of this process shall be to ensure that such travel and related expenses are appropriate and limited to those expenses necessary to facilitate the HCP's attendance and participation in the program or activity, in compliance with applicable Federal health care program requirements and OCA Policies and Procedures.

E. Risk Assessment and Mitigation Process. Within 90 days after the Effective Date, OCA shall implement a standardized, centralized annual risk assessment and mitigation process to evaluate and identify risks associated with its Covered Functions. The risk assessment and mitigation process shall require compliance, legal and business unit leaders, at least annually, to evaluate and identify risks associated with Government Reimbursed Products, including risks associated with the sales, marketing, and promotion of such products. Based on the outcomes of the risk-identification component of the risk assessment and mitigation process, OCA legal, compliance and other personnel shall centrally develop and implement specific plans designed to mitigate or reduce the identified risks. The risk mitigation plans shall be developed annually and a plan shall be developed for each Government Reimbursed Products category: Medical – GI & Respiratory; Medical – EndoTherapy; Medical – Respiratory; Surgical – Surgical Endoscopy; Surgical – Urology/Gynecology; Surgical – ENT; and Surgical – Energy. OCA shall implement the risk mitigation plans and shall track the implementation of the mitigation plans. OCA shall maintain the risk assessment and mitigation process for the duration of the CIA.

F. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, OCA shall engage an entity (or entities), such as an accounting, auditing, or consulting firm

(hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist OCA in assessing and evaluating its Covered Functions. More specifically, the IRO(s) shall conduct reviews that assess OCA’s systems, processes, policies, procedures, and practices relating to the Covered Functions (collectively, “IRO Reviews”). 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 OCA shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and OCA) related to the IRO Reviews.

2. *Systems Transactions, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components: Systems Reviews and Transactions Reviews relating to the Covered Functions. The Systems Reviews shall assess OCA’s systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in OCA’s relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If OCA 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 second and fourth Reporting Periods, as set forth more fully in Appendix B.

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 Transactions Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

In addition, as set forth in Appendix B, each Transactions Review shall also include a review of up to three additional areas or practices of OCA identified by the OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with OCA and may consider internal audit and monitoring work conducted by OCA, the Government Reimbursed Product portfolio, the nature and



scope of OCA's promotional practices and arrangements with HCPs , and other information known to it.

As set forth more fully in Appendix B, OCA may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow OCA's internal audit and monitoring work to be substituted for any portion of the Additional Items review conducted by the IRO.

The OIG shall notify OCA of the nature and scope of the IRO review for each of the Additional Items not later than 120 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or OCA shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

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 Appendix B.

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

Prior to initiating a Validation Review, OIG shall notify OCA in writing of its intent to do so and provide an explanation of the reasons OIG has determined a Validation Review is necessary. OCA shall have 30 days following the date of the OIG's written notice to submit a written response to OIG that includes any additional or relevant information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review and/or propose alternatives to the proposed Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

5. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to OCA a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.F; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A.

6. *Suspension of Requirements of Section III.F.* The requirements of this Section III.F shall be suspended during the first Reporting Period of the CIA. OCA may submit a request in writing to OIG at least 30 days prior to the end of the first Reporting Period that this suspension be extended beyond the first Reporting Period (but, in any event, no longer than the term of the Deferred Prosecution Agreement (DPA) entered into between OCA and the United States Attorney's Office for the District of New Jersey). Any determination as to whether to extend the suspension shall be made at the sole discretion of OIG. OCA shall have 90 days following the end of the suspension to engage an IRO as required by this Section III.F.

G. Disclosure Program.

To the extent not already accomplished, within 90 days after the Effective Date, OCA 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 OCA's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. OCA 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. 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 it obtains all necessary information 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, OCA shall conduct an internal

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

OCA shall maintain a disclosure log which includes a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The Compliance Officer (or designee) shall record each disclosure in the disclosure log within two business days of receipt of the disclosure.

H. Ineligible Persons.

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

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded, debarred, or suspended from participation in the Federal health care programs or in Federal procurement or non-procurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>); and
  - ii. the General Services Administration’s System for Award Management (SAM) (available through the Internet at <http://www.sam.gov>).

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

- a. OCA shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. OCA shall screen all current Covered Persons against the Exclusion Lists within 120 days after the Effective Date and thereafter shall screen against the LEIE on a quarterly basis and screen against SAM on an annual basis.
- c. OCA shall maintain a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

4. *Pending Charges and Proposed Exclusions.* If OCA 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, OCA 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.

I. Notification of Government Investigation or Legal Proceeding.

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

J. 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 or FDA requirements for which penalties or exclusion may be authorized;
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or
- c. the filing of a bankruptcy petition by OCA.

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

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

3. *Reportable Events under Section III.J.1.a.* For Reportable Events under Section III.J.1.a, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the conduct giving rise to the

Reportable Event, the period during which the conduct occurred, and the names of entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. the Federal health care program authorities or FDA requirements affected by or related to the Reportable Event;
- c. a description of OCA's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, 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 Persons employment or contractual relationship;
- c. a description of the Exclusion Lists screening that OCA completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Reportable Event was discovered; 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.J.1.c.* For Reportable Events under Section III.J.1.c, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

K. Field Force Monitoring.

Within 90 days after the Effective Date, OCA shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and to identify improper conduct. As described in more detail below, the FFMP shall consist of (1) direct field observations (Observations) of sales personnel and (2) the monitoring and review of records relating to sales personnel's interactions with HCPs (Records Review).

1. *Observations.* OCA compliance or other appropriately trained OCA personnel who are independent from the medical and surgical product sales and marketing function, or appropriately trained consultants engaged by OCA compliance (Monitoring Personnel) shall conduct Observations of sales representatives (including any contract sales personnel) to assess whether practices of the sales representatives, the messages delivered, and materials distributed to HCPs are consistent with applicable legal requirements and with OCA's Policies and Procedures. These Observations shall be full day ride-alongs with sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of activities related to all Government Reimbursed Product categories (*i.e.*, Medical – GI & Respiratory; Medical – EndoTherapy; Medical – Respiratory; Surgical – Surgical Endoscopy; Surgical – Urology/Gynecology; Surgical – ENT; and Surgical – Energy) 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 Government Reimbursed Product(s) promoted during the Observation;
- 5) an overall assessment of compliance with OCA Policies and Procedures; and
- 6) the identification of any potential improper conduct by the sales representative.

Monitoring Personnel shall conduct at least 25 Observations during the first Reporting Period. For the second and subsequent Reporting Periods, OIG may increase the number of Observations required to be conducted by Monitoring Personnel, up to a maximum of 50 Observations in any Reporting Period. OIG shall notify OCA at least 60 days prior to the start of each upcoming Reporting Period of the number of Observations that will be required in that Reporting Period.

2. *Records Reviews.* OCA shall also review various types of records to assess sales representatives' interactions with HCPs and to identify potential or actual compliance violations. For each Reporting Period, OCA shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products. The Records Reviews shall include a review of records relating to activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

These Records Reviews shall include the monitoring and review of (1) records and systems associated with sales representatives' interactions with HCPs (including records relating to consulting arrangements, travel and entertainment, expense reports, any payments to HCPs, and sales communications from managers); (2) sales representative notes or other records from sales calls with HCPs, (3) sales representative emails and other electronic records, and (4) recorded results of the Observations of sales representatives, coaching guides, and manager notes.

3. *Reporting and Follow-up.* Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and to identify potential or actual compliance violations. 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 noncompliance with OCA's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, OCA 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, including the disclosure of Reportable Events pursuant to Section III.J above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.



OCA shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, OCA also shall provide the OIG with copies of the Observation report for any instances in which a compliance issue was identified and a description of the action(s) that OCA took to address the compliance issue. OCA shall make the Observation reports for all other Observations available to the OIG upon request.

L. Notice to Health Care Providers and Entities. Within 30 days after the Effective Date, OCA shall post in a prominent place on the main page of the medical and surgical product section of its company website (or other placement agreed to in advance by the OIG), a copy of a letter signed by OCA's Chief Executive Officer containing the language set forth below:

As you may be aware, Olympus Corporation of the Americas (OCA) recently entered into civil, criminal, and administrative settlements with the United States in connection with the sales and marketing of certain OCA products. This letter provides you with additional information about the settlements, explains OCA's commitments going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that OCA unlawfully provided inducements to doctors, hospitals, and other health care providers in the United States to buy OCA products by giving various types of remuneration including grants, payments for travel and recreational activities, consulting payments, and gifts or no-charge loans of OCA equipment, in violation of the Federal Anti-kickback Statute. To resolve these matters, OCA entered into a civil settlement with the United States for \$306 million. In addition, OCA entered into a three-year Deferred Prosecution Agreement (DPA), pursuant to which OCA agreed to pay an additional \$306 million and to undertake certain compliance obligations, including the retention of an outside, independent monitor who will oversee OCA's compliance with the DPA. More information about this settlement may be found at the following: **[OCA shall include a link to the USAO website in the letter.]**

As part of the settlement, OCA also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity

agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, OCA agreed to undertake certain obligations to promote compliance with Federal health care program and FDA requirements. OCA also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by OCA representatives using the information set out below.

Please call OCA at [insert toll free number] if you have questions about the settlement referenced above. Please call OCA at 1-844-277-1698 or visit us at <http://olympusamerica.ethicspoint.com> to report any instances in which you believe that an OCA sales representative inappropriately promoted a product or engaged in other questionable conduct.

The notice shall remain posted for a period of at least 180 days. The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request. As part of the Implementation Report and each Annual Report, OCA shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, OCA shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to the Centers for Medicare & Medicaid Services (CMS) Open Payments Data website ([www.cms.gov/openpayments](http://www.cms.gov/openpayments)). OCA 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 OCA.

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; CHANGES TO BUSINESS UNITS OR LOCATIONS**

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

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

##### **B. Purchase or Establishment of New Unit or Location.**

In the event that, after the Effective Date, OCA purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, OCA shall notify OIG at least 30 days prior to such purchase or the operation of the new business, business unit or location. This notification shall include the address of the new business, business unit or location, phone number, and fax number. Each 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.

##### **C. Sale of Unit or Location.**

In the event that, after the Effective Date, OCA proposes to 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, OCA shall notify OIG of the proposed sale at least 30 days prior to the closing of the sale of its business, business unit, or location. This notification shall include a description of the business, business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by OIG.

## V. IMPLEMENTATION AND ANNUAL REPORTS

### A. Implementation Report.

Within 150 days after the Effective Date, OCA shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the 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 members of the Board of Directors who are responsible for satisfying the obligations referenced in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of OCA's Code of Conduct required by Section III.B.1;
6. a summary of all Policies and Procedures required by Section III.B.2 (copies of such Policies and Procedures shall be made available to OIG upon request);
7. the Training Plan required by Section III.C.1 and a description of the Board of Directors 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);
8. a summary of the policies, processes and systems relating to consulting arrangements, grants and charitable contributions, the management of field assets and the review of travel expenses implemented by OCA pursuant to Section III.D;
9. a description of the risk assessment and mitigation process required by Section III.E;
10. 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; (d) a summary and description of any and all current and prior engagements and agreements between OCA and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to OCA;

11. a description of the Disclosure Program required by Section III.G;
12. a certification that OCA has implemented the screening requirements described in Section III.H regarding Ineligible Persons, or a description of why OCA cannot provide such a certification;
13. a certification by the Compliance Officer that the notice required by Section III.L was posted in the manner required by Section III.L and a summary of the calls or messages received in response to the notice;
14. a certification from the Compliance Officer that the information regarding Payments and the link to CMS's Open Payments Data website has been posted on OCA's website as required by Section III.M;
15. a list of all of OCA's locations in the United States (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers;
16. a description of OCA's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
17. the certifications required by Section V.C.

B. Annual Reports.

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the Board of Directors, or the group of Certifying Employees described in Sections III.A.1-III.A.4;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);
3. a copy of the Board resolution required by Section III.A.3;
4. a summary of any changes or amendments to OCA's Code of Conduct required by Section III.B.1 and the reasons for such changes, along with a copy of the revised Code of Conduct;
5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in applicable requirements);
6. a copy of OCA's Training Plan developed under Section III.C and the following information regarding each type of training required by the Training Plan: a description of the training, including a summary of the topics covered, the length of sessions, a schedule of training sessions, a general description of the categories of individuals required to complete the training, and the process by which OCA ensures that all Covered Persons receive appropriate training. A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.
7. a summary of any changes in the policies, processes and systems relating to consulting arrangements, grants and charitable contributions, the review of travel expenses, and the management of field assets implemented by OCA pursuant to Section III.D;
8. a summary of any changes to the risk assessment and mitigation process required by Section III.E, and the reasons for such changes;
9. a summary of the risk mitigation plans for OCA's Government Reimbursed Product categories (*i.e.*, Medical – GI & Respiratory; Medical – EndoTherapy; Medical – Respiratory; Surgical – Surgical Endoscopy; Surgical – Urology/Gynecology; Surgical – ENT; and Surgical – Energy) developed and implemented during the Reporting Period, pursuant to Section III.E, and a description of OCA's efforts to track the implementation of such mitigation plans;

10. a complete copy of all reports prepared pursuant to Section III.F and Appendix B, along with a copy of the IRO's engagement letter, and OCA's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

11. a summary and description of any and all current and prior engagements and agreements between OCA and the IRO (if different from what was submitted as part of the Implementation Report) and a certification from the IRO regarding its professional independence and objectivity with respect to OCA;

12. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs or Government Reimbursed Products (the complete disclosure log shall be made available to OIG upon request);

13. a certification that OCA has completed the screening required by Section III.H regarding Ineligible Persons;

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

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

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 potential violations of Federal health care program or FDA requirements or other compliance issues were identified and a description of the action (s) that OCA took as a result;

17. for the first Reporting Period, a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages;

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

19. a description of all changes to the most recently provided list of OCA's locations (including addresses) as required by Section V.A.16;

20. the certifications required by Section V.C.

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

C. Certifications.

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

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

- a. to the best of his or her knowledge, except as otherwise described in the report, OCA is in compliance with the requirements of this CIA; and
- 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.

D. Monitor Reports.

1. OCA shall submit to OIG any report or written recommendations provided to OCA by the Monitor (as that term is defined in the DPA) pursuant to the DPA within 10 days after OCA receives such report or written recommendations from the Monitor.

2. OCA shall submit to OIG a copy of any report or written response to recommendations made by the Monitor that OCA provides to the Monitor pursuant to the DPA at the same time OCA submits such report or written response to recommendations to the Monitor.

3. Any documentation submitted to the Monitor by OCA pursuant to the DPA shall be made available to OIG upon request.

The documents described in paragraphs 1-3 above shall be referred to collectively



as "Monitor Reports."

E. Designation of Information.

OCA 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. OCA 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

OCA:

Caroline H. West  
Chief Compliance Officer for the Americas  
Olympus Corporation of the Americas  
3500 Corporate Parkway  
Center Valley, PA 18034-0610  
Telephone: (484) 896-3303  
Facsimile: (484) 896-7135

Unless otherwise specified, all notifications and reports required by this CIA may

*OCA Corporate Integrity Agreement*

be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, OCA may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

## **VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS**

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

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

OCA 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 OCA prior to any release by OIG of information submitted by OCA pursuant to its obligations under this CIA and identified upon submission by OCA as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, OCA shall have the rights set forth at 45 C.F.R. § 5.65(d).

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

OCA 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, OCA and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OCA fails to establish and implement any of the following obligations as described in Section III:
  - a. a Compliance Officer;
  - b. a Compliance Committee;
  - c. the Board’s compliance obligations, including the resolution from the Board;
  - d. the management accountability and certification obligations;
  - e. a written Code of Conduct;
  - f. written Policies and Procedures;
  - g. the development and/or implementation of a Training Plan for the training of Covered Persons, Relevant Covered Persons, and Board Members;
  - h. the requirements for consulting arrangements, grants and charitable contributions, management of field assets and review of travel expenses required by Section III.D;
  - i. a risk assessment and mitigation process as required in Section III.E;

- j. a Disclosure Program;
- k. Ineligible Persons screening and removal requirements;
- l. notification of Government investigations or legal proceedings;
- m. reporting of Reportable Events;
- n. the FFMP required by Section III.K;
- o. notification to HCPs as required by Section III.L;
- p. posting of any Payment-related information as required by Section III.M; and
- q. disclosure of changes to business units or locations.

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 OCA fails to engage and use an IRO as required by Section III.F, Appendix A 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 OCA fails to submit the Implementation Report, any Annual Reports, or the Monitor Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day OCA fails to submit any IRO Review report in accordance with the requirements of Section III.F, Appendix A, and Appendix B.

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

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

required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day OCA fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to OCA stating the specific grounds for its determination that OCA has failed to comply fully and adequately with the CIA obligation(s) at issue and steps OCA shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date OCA receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions. OCA 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 OCA 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 days after OCA 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 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 OCA 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 OCA of: (a) OCA's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, OCA 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 OCA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until OCA 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 OCA 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 obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by OCA to report a Reportable Event and take corrective action as required in Section III.J;
- c. a failure to engage and use an IRO in accordance with Section III.F, Appendix A, and Appendix B;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by OCA constitutes an independent basis for OCA's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that OCA has materially breached this CIA and

that exclusion is the appropriate remedy, OIG shall notify OCA of: (a) OCA's 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.* OCA 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) OCA has begun to take action to cure the material breach; (ii) OCA is pursuing such action with due diligence; and (iii) OCA has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, OCA fails to satisfy the requirements of Section X.D.3, OIG may exclude OCA from participation in the Federal health care programs. OIG shall notify OCA in writing of its determination to exclude OCA (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 OCA'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, OCA 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 OCA 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, OCA 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 OCA was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. OCA 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 OCA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless OCA 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 OCA was in material breach of this CIA and, if so, whether:

- a. OCA 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 OCA receipt of the Notice of Material Breach: (i) OCA had begun to take action to cure the material breach within that period; (ii) OCA pursued such action with due diligence; and (iii) OCA 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 OCA only after a DAB decision in favor of OIG. OCA's election of its contractual right to appeal to the DAB shall not



abrogate OIG's authority to exclude OCA 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 OCA 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. OCA 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 OCA, OCA 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**

OCA 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. The undersigned OCA 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.

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

**ON BEHALF OF OLYMPUS CORPORATION OF THE AMERICAS**

/Nacho Abia/

  
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**NACHO ABIA**  
President and Chief Executive Officer  
Olympus Corporation of the Americas

2/29/16  
DATE

/Thomas M. Gallagher/

**THOMAS M. GALLAGHER**  
Pepper Hamilton LLP  
Counsel for Olympus Corporation of the Americas

2/29/16  
DATE

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

/Robert K. DeConti/

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ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

2/26/16  
\_\_\_\_\_  
DATE

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MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

\_\_\_\_\_  
DATE

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NICOLE CAUCCI  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

\_\_\_\_\_  
DATE

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

\_\_\_\_\_  
ROBERT K. DECONTI  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U. S. Department of Health and Human Services

\_\_\_\_\_  
DATE

/Mary E. Riordan/

\_\_\_\_\_  
MARY E. RIORDAN  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

\_\_\_\_\_  
DATE

2/29/16

/Nicole Caucci/

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NICOLE CAUCCI  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

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DATE

2/29/2016

## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement

1. OCA 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.10 of the CIA or any additional information submitted by OCA in response to a request by OIG, whichever is later, OIG will notify OCA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, OCA may continue to engage the IRO.

2. If OCA 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, OCA shall submit the information identified in Section V.A.10 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 OCA at the request of OIG, whichever is later, OIG will notify OCA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, OCA 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 the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)). The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Government Reimbursed Products are reimbursed;

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 inquiries 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. 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. *OCA and IRO.* If OCA terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, OCA 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. OCA 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 OCA in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. OCA 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 OCA regarding the IRO, OIG determines that the IRO has not met the requirements of

this Appendix, OIG shall notify OCA in writing that OCA shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. OCA 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 OCA to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### IRO REVIEWS

#### A. IRO Engagement, General Description

As specified more fully below, OCA shall retain an IRO to perform engagements to assist OCA in assessing and evaluating certain of its systems, processes, policies, and procedures related to OCA'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. OCA 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 OCA'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 second and fourth Reporting Periods. If OCA 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 OCA's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. More specifically, the IRO shall review OCA's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. consultant or other fee-for-service arrangements entered into with HCPs (including, but not limited to, speaker programs, advisory boards, research and development meetings, product training and education sessions, presentations, ad hoc advisory activities, research and any other financial engagement or arrangement with an HCP) and all events and expenses relating to such engagements or arrangements;

2. funding of grants (including CME and non-CME third party educational activities, research and "in-kind" grants) and healthcare-related charitable contributions;



3. review and approval of travel and related expenses for HCPs including those in connection with HCPs' participation in educational, research, or other OCA-sponsored programs or activities;

4. identification, tracking, and management of Field Assets (as defined in Section III.B.2.f of the CIA);

5. identification, tracking, and reporting to the CMS of Payments pursuant to Section 6002 of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, and the related regulations and guidance (including FAQs) published by CMS;

6. materials and information about Government Reimbursed Products that may be distributed by OCA sales representatives (including any contract sales representatives) and materials or information that may be distributed or made available by OCA through social media and/or direct-to-consumer advertising, including OCA's internal review and approval of such materials and information;

7. funding of, or participation in, any Sponsorships (as defined in Section II.C.5 of the CIA); and

8. funding of, or participation in, any Third Party Educational Activity (as defined in Section II.C.6 of the CIA) and all events and expenses relating to any such activity.

#### 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 OCA's systems, policies, processes, and procedures relating to the items identified in Sections B.1-8 above, including a general description of OCA'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.1-8 above are made known or disseminated within OCA;

4. findings and supporting rationale regarding any weaknesses in OCA'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 grants and healthcare-related charitable contributions, (3) a sample of travel and related expenses for HCPs in connection with the HCP's participation in educational, research or other OCA-sponsored programs or activities, (4) a review of a sample of Field Assets; (5) a sample of Payments, and (6) up to three additional items identified by the OIG in accordance with Section III.F.2 of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Report.

1. *Review of Consulting Activities.* For purposes of this CIA, the term "Consulting Activities" shall include all consulting and other fee for service arrangements entered with HCPs including but not limited to speaker programs, advisory boards, research and development meetings, product training and education sessions, presentations, ad hoc advisory activities, research and any other financial engagement or arrangement and all related expenses.

For the first Reporting Period, the IRO shall select and review a sample of 60 Consulting Activities entered into with HCPs and all related expenses. More specifically, the IRO shall review: 20 advisory board arrangements; 20 general consulting arrangements; and 20 arrangements relating to professional education. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 60 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, OCA 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.

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. OCA 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

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.

For each Consulting Activity reviewed the IRO shall determine whether:

- a. 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;
- b. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by OCA;
- c. the rate structure was established based on a FMV analysis conducted by OCA;
- d. the Consulting Activity was identified in the annual Consultant budgeting plan developed by OCA;
- e. 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;
- f. the Consulting Activity was reviewed and approved in accordance with OCA Policies and Procedures;
- g. OCA 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
- h. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by OCA in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. *Review of Grants and Healthcare-Related Charitable Contributions.* For the first Reporting Period, the IRO shall select and review a sample of 60 grants and healthcare-related charitable contributions. More specifically, the reviewed grants and charitable contributions shall include 20 monetary grants; 20 monetary and equipment

grants; 10 equipment grants; and 10 healthcare-related charitable contributions. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 60 grants and healthcare-related charitable contributions which shall include a review of specified numbers of each type of grant and healthcare-related charitable contribution as determined by the OIG. Prior to the determination of the number of each type of grant and healthcare-related charitable contribution to be reviewed during the second and subsequent Reporting Periods, OCA 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.

The IRO shall select its sample of grants and healthcare-related charitable contributions for review in consultation with OIG after the provision of information about the grants and healthcare-related charitable contributions to the OIG. OCA shall provide the following information to the OIG: 1) a description of each type of grant and healthcare-related charitable contribution provided during the Reporting Period and a description of the purpose of, and activity to be undertaken in connection with, each type of grant or healthcare-related charitable contribution; 2) the numbers of each type of grant and healthcare-related charitable contribution provided during the Reporting Period; and 3) the budgeted amount to be spent on each type of grant and healthcare-related charitable contribution during the Reporting Period.

For each grant or healthcare-related charitable contribution reviewed, the IRO shall determine whether:

- a. the request for the grant or healthcare-related charitable contribution was submitted through OCA's centralized grants management system and processed in accordance with standardized objective criteria;
- b. the terms of the grant or healthcare-related charitable contribution are reflected in a written agreement between OCA and the recipient of the grant or contribution;
- c. the grant or healthcare-related charitable contribution was reviewed and approved in accordance with OCA policies and procedures;
- d. OCA records identify the purpose or use for which the grant or healthcare-related charitable contribution was requested; and
- e. applicable documents or other records verify that the purpose or use for which the grant or healthcare-related charitable contribution was requested occurred or was satisfied (e.g., if a grant was provided to

sponsor an event, the IRO shall assess whether the event, in fact, occurred.)

3. *Review of Travel Expenses.* For the first Reporting Period, the IRO shall select and review a sample of 50 payments for travel expenses made to HCPs in connection with HCPs' attendance and participation in OCA-conducted product training and education programs or OCA sales, promotional and other business meetings (e.g., plant tours, demo of non-portable equipment), other than travel and travel-related expenses incurred by HCP consultants in connection with consulting arrangements (Travel Payments). More specifically, the IRO shall review Travel Payments from the following categories: 25 Travel Payments relating to OCA-conducted product training and education programs and 25 Travel Payments relating to OCA sales, promotional, and other business meetings (e.g., plant tours, demo of non-portable equipment). For the second and subsequent Reporting Periods, the IRO shall review a total of 50 Travel Payments which shall include a review of specified numbers of each type of Travel Payments as determined by the OIG. Prior to the determination of the number of each type of Travel Payment to be reviewed during the second and subsequent Reporting Periods, OCA 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.

The IRO shall select its sample of Travel Payments for review in consultation with OIG after the provision of information about the Travel Payments to the OIG. OCA shall provide the following information to the OIG: 1) a description of each type of Travel Payment made during the Reporting Period and the circumstances under which each type of Travel Payment is made; 2) the number of each type of Travel Payment made during the Reporting Period; and 3) the overall amount spent on each type of Travel Payment during the Reporting Period.

For each Travel Payment reviewed the IRO shall:

- a. review the circumstances under which the Travel Payment was made, including a description of the activities undertaken by the HCP in connection with the Travel Payment and determine whether the activities were undertaken pursuant to a written agreement between OCA and the HCP;
- b. determine whether the amount of the Travel Payment was consistent with the actual travel expenses incurred by the HCP and was supported by receipts or other records of the actual travel expenses incurred; and
- c. determine whether the Travel Payment was reviewed, approved, and paid in accordance with OCA Policies and Procedures.

4. *Review of Payments.*

a. For purposes of this IRO Review, the term “Control Documents” shall include all material documents or electronic records associated with each OCA 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.

b. The IRO shall randomly select a total of 30 Payments to be included in the review, from the following payment categories: (i) Consulting Fee, (ii) Compensation for Services; (iii) Honoraria; (iv) Gift; (v) Grant, (vi) Space Rental or Facility Fees; and (vii) Education (collectively, “Reviewed Categories”). For each selected Payment, the IRO shall review the entry in the Open Payments Database and the Control Documents relating to the Payment identified by the IRO as necessary and sufficient to validate the Payment information in the Open Payments Database.

c. For each Payment 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 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 OCA’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 OCA’s policies were followed in connection with the Payment (e.g., all required written approvals for the activity were obtained in accordance with OCA’s policies.)

5. *Review of Field Assets.* For the first Reporting Period, the IRO shall select and review records relating to a sample of 150 activities in which Field Assets are provided to customers. More specifically, the IRO shall review records relating to the following: i) 80 product evaluations; ii) 20 demonstrations; iii) 25 loaner program transactions; and iv) 25 Placed Asset agreements. For the second and subsequent Reporting Periods, the IRO shall review records relating to a total of at least 150 activities in which Field Assets are provided to customers, which shall include a review of specified numbers of each category of activity in which Field Assets are used, as determined by the OIG. Prior to the determination of the number of each type of Field Asset to be reviewed during the second and subsequent Reporting Periods, OCA 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.

The IRO shall select its sample of records relating to Field Assets in consultation with OIG after the provision of information about the Field Assets to the OIG. OCA shall provide the following information to the OIG: 1) a description of each category of Field Assets; 2) the number of Field Assets in each category for the applicable Reporting Period; and 3) the estimated value of the Field Assets in each category during the Reporting Period.

The purpose of the IRO's review shall be to verify that OCA is managing and controlling its Field Assets in accordance with its Policies and Procedures for the fulfilling of requests, the analysis and reporting of Field Assets, the return of Field Assets, and the audit of Field Assets. The IRO's review shall also verify that all Field Assets are managed through the company's SAP and Elton systems (as applicable to the type of Field Asset) and that such systems accurately record: (1) the consignment of Field Assets to OCA personnel, customers, prospective customers and third parties; (2) the reason for consignment, (3) the length of consignment, and (4) the date on which the Field Assets were retrieved by OCA following the consignment.

6. *Review of Additional Items.* As set forth in Section III.F.2 of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify OCA of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or OCA shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in OCA's systems, processes, policies, and procedures based on its review of each Additional Item).

7. *OIG Review of Proposed Work Plan.* At least 30 days prior to the end of each Reporting Period, the IRO shall submit to OIG a work plan outlining the methodology for each element of the Transactions Review described above. The OIG shall have 30 days to provide any comments regarding the work plan; if no comments are provided, the IRO may proceed with the work plan as proposed.

E. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. *General Elements to Be Included in Report.*
  - a. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
  - b. 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
  - c. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.
2. *Results to be Included in Report.* The following results shall be included in each Transactions Review Report:
  - a. Relating to the Review of Consulting Activities
    - (i) in connection with the review of Consulting Activities, 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;
    - (ii) for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:
      - (1) 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;
      - (2) the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by OCA;



- (3) the rate structure was established based on a FMV analysis conducted by OCA;
- (4) the Consulting Activity was identified in the annual Consulting budgeting plan developed by OCA;
- (5) 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;
- (6) the Consulting Activity was reviewed and approved in accordance with OCA Policies and Procedures,
- (7) OCA 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;
- (8) the activity undertaken by the Consultant and/or the work product generated was used by OCA in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;
- (9) the IRO identified any weaknesses in OCA's systems, processes, policies, procedures and/or practices relating to Consulting Activities; and
- (10) the IRO has recommendations for improvements to OCA's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

b. Relating to the Review of Grants and Healthcare-Related Charitable Contributions

- (i) in connection with the review of grants and healthcare-related charitable contributions, a description of each type of grant or healthcare-related charitable contribution reviewed, including the number of each type of grant and healthcare-related charitable contribution reviewed and an identification of the types of documents and information reviewed for each grant and healthcare-related charitable contribution reviewed;

- (ii) for each grant or healthcare-related charitable contribution reviewed, the IRO's findings and supporting rationale as to whether:
  - (1) the request for the grant or healthcare-related charitable contribution was submitted through the OCA centralized grants management system and processed in accordance with standardized objective criteria;
  - (2) the terms of the grant or healthcare-related charitable contribution are reflected in a written agreement between OCA and the recipient of the grant or contribution;
  - (3) the grant or healthcare-related charitable contribution was reviewed and approved in accordance with OCA policies and procedures;
  - (4) the purpose or use for which the grant or healthcare-related charitable contribution was requested is identified in OCA records;
  - (5) records verify that the purpose or use for which the grant or healthcare-related charitable contribution was requested occurred or was satisfied;
  - (6) the IRO identified any weaknesses in OCA systems, processes, policies, procedures and/or practices relating to grants and healthcare-related charitable contributions; and
  - (7) the IRO has recommendations for improvements to OCA's systems, processes, policies, procedures and/or practices relating to grants and healthcare-related charitable contributions.

c. Relating to the Review of Travel Payments

- (i) in connection with the review of Travel Payments, a description of each type of Travel Payment reviewed, including the number of each type of Travel Payment reviewed and an identification of the types of documents and information reviewed for each Travel Payment;
- (ii) for each Travel Payment reviewed, a description of the circumstances under which each Travel Payment was made;

- (iii) for each Travel Payment reviewed, the IRO's findings and supporting rationale as to whether:
  - (1) the activities performed by the HCP in connection with the Travel Payment were undertaken pursuant to a written agreement in place between OCA and the HCP;
  - (2) the amount of the Travel Payment was consistent with the actual travel expenses incurred by HCP and was supported by receipts or other records;
  - (3) the Travel Payment was reviewed, approved, and paid in accordance with OCA Policies and Procedures;
  - (4) the IRO identified any weaknesses in OCA's systems, processes, policies, procedures and/or practices relating to Travel Payments; and
  - (5) the IRO has recommendations for improvements to OCA's systems, processes, policies, procedures and/or practices relating to Travel Payments.

d. Relating to the Review of Payments

- (i) in connection with the review of Payments, 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
- (ii) for each sampled Payment, findings and supporting rationale as to whether:
  - (1) all required Control Documents exist;
  - (2) each Control Document was completed in accordance with all of the requirements set forth in the applicable OCA policy;
  - (3) 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;

- (4) each Control Document reflects that OCA's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and
  - (5) any corrective action or disciplinary action was undertaken in those instances in which OCA policies were not followed.
- e. Relating to the Review of Field Assets.
- (i) in connection with the IRO's review of Field Assets, a description of each type of activity in which Field Assets are provided to customers that was reviewed, including the number of each type of activity reviewed and an identification of the types of documents and information reviewed for each activity;
  - (ii) for each activity reviewed, the IRO's findings and supporting rationale as to whether:
    - (1) OCA is managing its Field Assets in accordance with its Policies and Procedures for: 1) fulfilling consignment requests only when the requests meet applicable requirements; 2) the analysis and reporting of Field Assets, 3) the return of Field Assets to OCA on a timely basis consistent with OCA's policies, and 4) the auditing of Field Assets;
    - (2) the Field Asset is tracked in OCA's SAP or Elton system (as applicable) and that such tracking accurately records: 1) consignment to OCA personnel, customers, prospective customers, and third parties; 2) the reason for the consignment; 3) the length of consignment; 4) and the date on which the Field Assets were retrieved by OCA following the consignment;
    - (3) the IRO identified any weaknesses in OCA systems, processes, policies, procedures and/or practices relating to Field Assets; and
    - (4) the IRO has recommendations for improvements to OCA's systems, processes, policies, procedures and/or practices relating to Field Assets.

f. Relating to the Review of Additional Items

- (i) for each Additional Item reviewed, a description of the review conducted;
- (ii) for each Additional Item reviewed, the IRO's findings based on its review;
- (iii) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in OCA's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- (iv) for each Additional Item reviewed, recommendations, if any, for changes in OCA's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.