

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ENDO PHARMACEUTICALS INC.**

I. PREAMBLE

Endo Pharmaceuticals Inc. (EPI) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). As set forth more fully below, the CIA will apply to EPI and any of its corporate sisters or subsidiaries (including Endo Pharmaceutical Solutions Inc. and Endo Pharmaceuticals Valera Inc.) that engage in a Covered Function (as defined below) and all such entities shall be referred to collectively hereafter as “Endo”.

Contemporaneously with this CIA, Endo is entering into a Settlement Agreement with the United States. Endo will also enter into settlement agreements with various States (State Settlement Agreements) and Endo’s agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, Endo initiated certain compliance measures and established a compliance program designed to address compliance with Federal health care program and FDA requirements (Compliance Program). Endo shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Endo may modify the Compliance Program as appropriate. However, at a minimum, Endo shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Endo 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) EPI’s final Annual Report; or (2) any additional materials submitted by EPI 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 directors of Endo Health Solutions Inc. (or any future parent company of Endo) (hereafter referred to as “EHS”) and Endo, and all owners of EHS and Endo 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 or in connection with the operation of employee incentive programs);
- b. all officers of EHS with responsibilities for Endo activities;
- c. all employees of EPI;
- d. all employees of Endo who are engaged in or have job responsibilities relating to any of the Covered Functions (as defined below in Section II.C.6); and
- e. all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Endo and in that capacity either: (i) interact directly with healthcare professionals (HCPs), healthcare institutions (HCIs), or consumers (including contract sales personnel); or (ii) perform activities, provide services, or create materials

relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by an Endo employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include: 1) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year; or 2) employees of Generics International, Inc. (US Parent) and its subsidiaries, American Medical Systems Holdings, Inc. and its subsidiaries, or HealthTronics, Inc. and its subsidiaries. The products of Generics International (US Parent), Inc. and its subsidiaries, American Medical Systems Holdings, Inc. and its subsidiaries, and HealthTronics Inc. and its subsidiaries are not considered Government Reimbursed Products (as defined below) for purposes of this CIA.

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 Endo human pharmaceutical products that are: (a) marketed or sold by Endo in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

4. The term “Promotional Functions” includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Endo’s review process for promotional materials and all applicable review committee(s) for promotional materials.

5. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to HCPs, HCIs, and payors about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions involved in scientific exchange (such as the Clinical Development and Medical Science Department (which is responsible for

medical affairs activities at Endo and is generally referred to in this CIA as “medical affairs”); (b) contracting with HCPs licensed in the United States to conduct Research (as defined in Section II.C.8 below); (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

6. The term “Covered Functions” refers to “Promotional Functions” and “Product Related Functions” collectively.

7. The term “Third Party Educational Activity” shall mean, as defined in Endo’s policies, professional education for HCPs intended to be independent of Endo’s control or influence and that are conducted by a third party and supported by Endo, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

8. The term “Research” shall mean sponsorship or support by Endo of post-marketing research involving human subjects and Government Reimbursed Products. This includes post-marketing clinical trials and other post-marketing studies sponsored by Endo (Endo-Sponsored Research) and support by Endo of investigator-sponsored studies (ISSs).

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer.* Prior to the Effective Date, EHS appointed a Covered Person to serve as its Chief Compliance Officer (Compliance Officer) and Endo and EHS shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements. The Compliance Officer shall be a member of senior management of EHS, shall report directly to the Chief Executive Officer of EHS, shall make periodic (at least quarterly) reports regarding compliance

matters directly to the Board of Directors of EHS, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer of EHS or EPI. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Endo 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.

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

2. *Compliance Committee.* Prior to the Effective Date, EHS appointed a Compliance Committee and EHS and Endo shall maintain the Compliance Committee during the term of the CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (*e.g.*, senior executives representing relevant departments, such as sales and marketing, human resources, finance, research and development, medical/scientific affairs, regulatory, legal, and other relevant departments). The Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (*e.g.*, shall assist in the analysis of the Endo's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

EPI 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 (or a committee or subcommittee of the Board) of EHS (Board) shall be responsible for the review and oversight of matters related to Endo's compliance with Federal health care program and FDA requirements and the obligations of this CIA. The Board must include independent (*i.e.*, non-executive) members.

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

- a. meeting at least quarterly to receive reports from the Compliance Officer regarding Endo's Compliance Program;
- b. reviewing and overseeing Endo's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- c. evaluating the effectiveness of the Compliance Program, including at a minimum, by receiving updates about the activities of the Compliance Officer and other compliance personnel and updates about the adoption and implementation of policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with applicable Federal health care program requirements, and FDA requirements; and
- d. for each Reporting Period of the CIA, adopting a resolution (for which the Board may rely on (without diminishing their obligations under law to provide adequate oversight) independent outside experts engaged to assist the Board with a review of the Compliance Program), signed by each member of the Board summarizing its review and oversight of Endo's and EPI's compliance with Federal health care program and FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board of Directors [or a Committee or subcommittee of the Board] has made a reasonable inquiry into the operations of Endo's Compliance Program for [insert a description of the time period reviewed] including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board [or Committee or subcommittee] has concluded that, to the best of its knowledge, Endo has implemented an effective Compliance Program to meet Federal health care program and FDA requirements and the obligations of the CIA.”

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 Endo.

EPI 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 EHS officers and Endo officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, consistent with the language set forth below, that the applicable Endo business unit or area of authority is compliant with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President and Chief Executive Officer of Endo Health Solutions (or parent company); Chief Operating Officer, Pharmaceuticals; Senior Vice President Branded Pharma; Vice President and General Manager, Urology; Sales Director, Urology; Vice President Business Operations and Planning; Marketing Director Pain; Sales Director Pain; Senior Director, Managed Markets and Trade; Senior Director and General Manager Supprelin LA; Executive Vice President, Research and Development and Chief Scientific Officer; Vice President Development Operations; Vice President, Regulatory Affairs; Senior Director Medical Affairs; Vice President PVRM and Senior Clinical Advisor; and, to the extent that an Endo business unit or functional area performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other Endo or EPI executives, vice-presidents, or leaders of an area of authority as would be necessary to ensure that there is a Certifying Employee from each such business unit or functional area engaged in Covered Functions.

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 Endo policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Endo 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 conclusion in the certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above and the steps being taken to address the issue(s) identified in the certification.

B. Written Standards

1. *Code of Conduct.* To the extent not already accomplished, within 120 days after the Effective Date, Endo shall develop, implement, and distribute (either in hardcopy or electronically) a written Code of Conduct to all Covered Persons. Endo shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees who are Covered Persons. The Code of Conduct shall, at a minimum, set forth:

- a. Endo’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to comply with all requirements relating to the Covered Functions;
- b. Endo’s requirement that all Covered Persons shall be expected to comply with all Federal health care program requirements, FDA requirements, and with Endo’s own Policies and Procedures;
- c. Endo’s requirement that all Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Endo, suspected violations of any Federal health care program requirements, FDA requirements, or of Endo’s Policies and Procedures;
- d. the personal obligations of each Covered Person to comply with Federal health care program requirements, FDA requirements, and Endo’s Policies and Procedures; and

- e. the right of all individuals to use the Disclosure Program described in Section III.F, and Endo's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by Endo's Code of Conduct. New Covered Persons shall receive (either in hardcopy or electronically) the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, Endo shall implement written Policies and Procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and Endo's compliance with Federal health care program and FDA requirements (Policies and Procedures). The Policies and Procedures shall address, at a minimum, the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional Functions in compliance with 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 in compliance with all applicable FDA requirements;
- c. appropriate ways to conduct Product Related Functions in compliance with 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 in compliance with all applicable FDA requirements;

- d. the materials and information that may be distributed by sales representatives about Government Reimbursed Products; and the manner in which sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage in off-label promotion of Government Reimbursed Products (*i.e.*, sales representatives shall not promote the products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been reviewed and approved by Endo; and (iii) refer all requests for information about off-label uses of Government Reimbursed Products to the Medical Information department (or other department that undertakes a medical affairs function);
- e. the materials and information that may be distributed by the Medical Information department (or other department that undertakes a medical affairs function) and the mechanisms through, and manner in which, medical affairs receives and responds to requests for information from an HCP, and HCI, or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by Endo or EPI in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Endo develop a database for use by medical affairs (Inquiries Database) to track all requests for information about Government Reimbursed Products made to medical affairs. The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Government Reimbursed Products: (i) date of Inquiry; (ii) form of Inquiry (*e.g.*, fax, phone, etc.); (iii) name of the requesting HCP, HCI, or other individual or entity; (iv) nature and topic of

request (including exact language of the Inquiry if made in writing); (v) an evaluation of whether the Inquiry relates to information about an off-label use for the product; (vi) nature/form of the response from Endo or EPI (including a record of the materials provided to the HCP or HCI in response to the request); and (vii) the name of the Endo or EPI representative who called on or interacted with the HCP, HCI, or other customer, if known;

- f. the manner and circumstances under which medical personnel from medical affairs interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with sales representatives or managed market representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products. These Policies and Procedures shall require that medical personnel not engage in the off-label promotion of Government Reimbursed Products and provide information about Government Reimbursed Products that is fair, accurate, and supported by clinically significant data;
- g. the materials and information about Government Reimbursed Products that may be distributed or made available by Endo through social media and/or direct-to-consumer advertising. These policies and procedures shall be designed to ensure that Endo'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 before they are disseminated;
- h. the development, implementation, and review of call plans for sales representatives and other field-based Endo representatives (including any contract sales force) who promote and sell Government Reimbursed Products. For each Government Reimbursed Product, the Policies and Procedures shall require that Endo review the call plans for the Government Reimbursed Product and the bases upon, and circumstances under which

HCPs and HCIs belonging to specified medical specialties or types of clinical practice are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Endo design and, when necessary, modify the call plans in a manner designed to ensure that Endo is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time when the FDA approves a new or additional indication for a Government Reimbursed Product;

- i. the development, implementation, and review of policies, procedures, and plans for the distribution of samples of, or (if any) coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under which, HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Endo. The Policies and Procedures shall also require that Endo design and, when necessary, modify the Sample Distribution Plans in a manner designed to ensure that Endo is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;
- j. consultant or other fee-for-service arrangements entered into with HCPs or HCIs relating to Covered Functions (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, and ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

- k. programs to educate Endo sales representatives or other Covered Persons, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities, if any. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;
- l. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Endo's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- m. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.7 above. These Policies and Procedures shall be designed to ensure that Endo's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: (1) all Third Party Educational Activity funding requests are reviewed, tracked, and evaluated through a process designed to ensure that the requests meet compliance criteria for providing the funding; (2) funding decisions are based on objective criteria such as the qualifications of the requestor, the quality of the Third Party Educational Activity program, and pre-established educational goals; (3) Third Party Educational Activity funding is provided only pursuant to a written agreement with the funding recipient, and payments to the Third Party Educational Activity funding recipient are consistent with the written agreement; (4) Endo disclose its financial support of the Third Party Educational Activity and, to the extent feasible consistent with subsection III.B.2.m.7 below, any financial relationships with faculty, speakers, or organizers at such Activity; (5) as a condition of funding, the third party shall agree to disclose Endo's financial

support of the Third Party Educational Activity and to require faculty, speakers, or organizers at such Activity to disclose any financial relationship with Endo; (6) the Third Party Educational Activity have an educational focus; (7) the content, organization, and operation of the Third Party Educational Activity (including the faculty, educational methods, materials, and venue) be independent of Endo's control; (8) Endo supports only Third Party Educational Activity that Endo understands will be non-promotional in tone/nature; and (9) Endo's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Third Party Educational that is fair, balanced, accurate and not misleading;

- n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Endo by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Endo's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information comply with all applicable Federal health care program and FDA requirements. Among other things, the Policies and Procedures shall require that: (i) applicable review committees review all promotional materials prior to the distribution or use of such materials; and (ii) deviations from the standard review committee practices and protocols (including timetables for the submission of materials for review) shall be documented and referred for appropriate follow-up;
- o. sponsorship, funding of, and disclosures relating to Product Related Functions. These Policies and Procedures shall be designed to ensure that Endo's funding, sponsorship, and disclosure complies with all applicable Federal health care program and FDA requirements;
- p. compensation (including through salaries, bonuses, contests, or other means) for Relevant Covered Persons who are sales

representatives or their direct 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 Government Reimbursed Products; and (ii) include mechanisms, where appropriate, that are designed to exclude from incentive compensation any sales for which Endo knows or should reasonably be aware were the result of the promotion of non-FDA-approved uses of Government Reimbursed Products or other improper promotion;

- q. the submission of information about any Government Reimbursed Product to any compendia, such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter “Compendia”). This includes any initial submission by Endo of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Endo’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results). The Policies and Procedures shall include a requirement that Endo conduct: (i) a review at the time of submission of information to Compendia, to verify that the information submitted to the Compendia by Endo (including information about clinical studies and other Research) is complete and accurate; (ii) an annual review of Government Reimbursed Product listings and monographs within the Compendia designed to identify errors or inaccuracies; and (iii) an annual review of all arrangements, processing fees, or other payments or financial support (if any) provided by Endo to any Compendia. Endo’s legal or compliance personnel shall be involved in this review;
- r. sponsorship or support by Endo of Research (as defined in Section II.C.8 above), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the

Research, including the publication of information about the Research results and trial outcomes; and uses made of publications relating to Research;

Policies/Procedures regarding Research:

Endo represents that it requires that all Research sponsored or funded by Endo address a legitimate scientific question or need, and be reviewed and approved by the relevant governance body within its research and development organization. Research and development (R&D) personnel are responsible for all steps of the design, conduct, and/or publication of Research. Commercial personnel do not participate in the decision to fund Research or in the approval of the publication of Research results.

Registration of Studies and Publication of Study Results:

Endo represents that it registers Endo-Sponsored Research that involves clinical trials and reports results of such clinical trials on the National Institutes of Health (NIH) sponsored website (www.clinicaltrials.gov) in accordance with Endo's Policies and Procedures governing clinical trial disclosure, which shall at minimum require registration consistent with all Federal requirements. Endo shall continue to comply with Federal requirements or other applicable requirements relating to the registration and results reporting of such Endo-Sponsored Research throughout the term of this CIA. In addition, if there is a change in Federal requirements or other applicable requirements relating to registration and results reporting of information about Endo-Sponsored Research, Endo shall comply with such requirements.

Endo represents that it has established policies, procedures and practices with respect to prematurely discontinued Endo - Sponsored Research, which require timely notification of the relevant institutional review board or ethics committee about the decision and reasons for premature discontinuation. As specified in Endo's Policies and Procedures governing clinical trial

disclosure, Endo posts status updates with respect to Endo - Sponsored Research (including discontinued studies) to the NIH sponsored website (www.clinicaltrials.gov).

Endo represents that it has established policies, systems and practices to ensure that adverse event information regarding its products is collected, processed, analyzed, communicated and reported to FDA.

Endo represents that it makes good faith efforts to publish information about the results of Endo-Sponsored Research in peer-reviewed journals and includes specified timeframes for the submission of manuscripts following completion of an Endo-Sponsored Research study in the publication plan for each Government Reimbursed Product. Endo's Policies and Procedures govern the publication of results from Endo-Sponsored Research. Endo further represents that its written agreements pertaining to ISSs require the investigator to exercise best efforts to publish the results of the ISS.

The standards, policies, and practices described above shall hereafter be referred to collectively as the "Research and Publication Practices." Endo shall maintain its Research and Publication Practices (or standards and practices substantively equivalent to those set forth above) for Research initiated, supported, or completed after the Effective Date for the term of the CIA;

- s. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Endo or other potential conflicts of interest that might bias the author's work, the identification of all authors or contributors (including professional writers) associated with a given publication, and the scope and breadth of research results made available to each author or contributor.

Authorship Requirements: Endo represents that it requires all authors of journal articles about Endo-Sponsored Research to adhere to International Committee of Medical Journal Editors (ICMJE) requirements regarding authorship. In addition, Endo requires all authors of articles about Research to disclose any Endo financial support for the study and any financial relationship with Endo (including any financial interest the author may have in Endo or an Endo product). In addition, Endo represents that individuals may be considered an “author” on a publication about Endo-Sponsored Research only if the individual has made substantial contributions to the study and has given final approval to the version of the publication ultimately published. Endo’s policies and procedures prohibit guest/honorary/gift authorship, ghostwriting, and plagiarism.

The standards, policies and practices described above shall be referred to collectively as “Authorship-Related Practices”; and

- t. disciplinary policies and procedures for violations of Endo’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 120 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.

At least annually (and more frequently, if appropriate), Endo shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, a description of the revisions shall be communicated to all affected Covered Persons and any revised Policies and Procedures shall be made available to all Covered Persons.

C. Training and Education

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

- a. CIA requirements; and
- b. Compliance Program, including the Code of Conduct.

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

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

- a. all applicable Federal health care program requirements relating to Covered Functions;
- b. all applicable FDA requirements relating to Covered Functions;
- c. all Endo Policies and Procedures and other requirements applicable to Covered Functions;
- d. the personal obligation of each individual involved in Covered Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. examples of proper and improper practices related to Covered Functions.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later.

After receiving the initial Specific Training described in this section, each Relevant Covered Person shall receive at least 3 hours of Specific Training, in addition to the General Training, in each subsequent Reporting Period.

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

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

4. *Certification.* Each Covered Person who is required to attend 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 the certifications, along with all course materials. These shall be made available to OIG, upon request.

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

6. *Update of Training.* Endo shall review the training annually, and, where appropriate, shall update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during internal audits or the IRO Reviews, and any other relevant information.

7. *Computer-based Training.* Endo may provide the training required under this CIA through appropriate computer-based training approaches. If Endo 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. Risk Assessment and Mitigation Process.

Within the first Reporting Period, Endo shall develop and begin to implement a standardized, centralized annual risk assessment and mitigation process (the “RAMP Program”), as further described in this Section III.D and Appendix B. The RAMP Program shall require compliance, legal and other relevant representatives as determined by Endo to assess and identify risks associated with Government Reimbursed Products that are marketed in the United States, including risks associated with the sales, marketing, and promotion of such products. The RAMP Program shall involve an evaluation, at least annually, of the risks associated with Government Reimbursed Products. Based on the outcomes of the risk-identification component of the RAMP Program, Endo and EPI 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 Product. Endo and EPI shall mitigate risks associated with marketing the Government Reimbursed Products in the United States, taking into account each risk assessment and applicable Federal health care program and FDA requirements. The RAMP Program shall be in effect no later than the first anniversary of the Effective Date of the CIA.

E. Review Procedure

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, EPI 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 Endo in assessing and evaluating its Covered Functions and its RAMP Program. More specifically, the IRO(s) shall conduct reviews that assess Endo’s systems, processes, policies, procedures, and practices relating to the Covered Functions and to Endo’s RAMP Program (IRO Reviews).

The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference. Each IRO engaged by EPI shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the IRO Review for

which the IRO is retained. Each IRO shall assess, along with Endo, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the IRO Review, taking into account any other business relationships or other engagements that may exist.

b. *Frequency and Brief Description of Reviews.*

Systems, Transactions, and Additional Items Reviews. As set forth more fully in Appendix B, the IRO Reviews shall consist of three components: 1) Systems Review to assess Endo's systems, processes, policies and procedures relating to the Covered Functions; 2) Systems Review to assess Endo's systems, processes, policies and procedures relating to the RAMP Program; and 3) Transaction Reviews (which may include Additional Items Reviews.)

If there are no material changes in Endo's relevant systems, processes, policies, and procedures, the Systems Review related to Covered Functions shall be performed for the first and fourth Reporting Periods, and the Systems Review related to the RAMP Program shall be performed for the second and fourth Reporting Periods. If Endo materially changes its relevant systems, processes, policies, or 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 as set forth above and 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 Endo 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 Endo and may consider internal audit and monitoring work conducted by Endo, the Government Reimbursed Product portfolio, the nature and scope of Endo’s promotional practices and arrangements with HCPs and HCIs, and other information known to it.

As set forth more fully in Appendix B, Endo 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 Endo’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Endo of the nature and scope of the IRO review for each of the Additional Items not later than 150 days prior to the end of each Reporting Period. Prior to undertaking the review of the Additional Items, the IRO and/or EPI 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.

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

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

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO’s

findings or IRO Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the IRO Review complied with the requirements of the CIA and/or the IRO's findings or IRO Review results are inaccurate (Validation Review). Endo 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 EPI's final Annual Report shall be initiated no later than one year after EPI's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Endo of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Endo may request a meeting with OIG to: (a) discuss the results of the IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. Endo agrees to provide any additional information as may be requested by OIG under this Section III.E.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with Endo prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

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

F. Disclosure Program

To the extent not already accomplished, within 120 days after the Effective Date, Endo 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 reporting line, any identified issues or questions associated with Endo's policies, conduct, practices, or procedures with respect to a Federal health care program requirement or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Endo shall appropriately publicize the existence of the disclosure mechanism (*e.g.*, via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and 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 he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Endo shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons

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

- a. an “Ineligible Person” shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's System for Award Management (available through the Internet at <http://www.sam.gov>).

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

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

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

3. *Removal Requirement.* If Endo has actual notice that a Covered Person has become an Ineligible Person, Endo shall remove such Covered Person from responsibility for, or involvement with, Endo's business operations related to the Federal

health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Endo 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, Endo shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings

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

I. Reportable Events

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

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

Government Reimbursed Products (including an FDA Warning Letter issued to Endo);

- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by EHS or Endo.

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

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

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

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

Endo shall not be required to report as a Reportable Event a matter which is the subject of an ongoing investigation or legal proceeding by a government entity or its agents previously disclosed under Section III.I above.

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

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

K. Field Force Monitoring and Review Efforts. Within 120 days after the Effective Date, Endo shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales representatives' interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales representatives; and (3) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.* With regard to speaker programs, Endo shall implement a process to require all speakers be qualified, complete training, and enter into written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements that the speaker may only use Endo approved materials and may not directly or indirectly promote the product for off-label uses.) Endo shall maintain processes designed to ensure that there is a legitimate need for each speaker program. Endo shall also maintain a centralized electronic system through which all speaker programs are initiated, tracked, and administered. This system shall include controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements.

The system shall establish controls regarding eligibility and qualifications of speakers and venues for the programs. The controls shall require that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair market value analysis conducted by Endo. Endo shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, Endo shall use its

centralized system to handle all logistics and spending associated with the speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs. Endo shall require certified evaluations by sales representatives or other Endo personnel regarding whether a speaker program complied with Endo requirements, or in the event of non-compliance, Endo shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

Endo shall institute a Speaker Monitoring Program under which Endo compliance or other appropriately trained personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend speaker programs during each Reporting Period and conduct live audits of 30 of such programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected both on a risk-based targeting approach and on a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and Endo representative activities during the program to assess whether the programs were conducted in a manner consistent with Endo's Policies and Procedures. Endo shall maintain the controls around speaker programs as described above and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Endo Monitoring Personnel shall conduct observations of sales representatives acting on behalf of Endo (including both Endo employees and contract sales force personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Endo's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and the HCPs or HCIs during the workday. The Observations shall be scheduled throughout the year, selected by Endo Monitoring Personnel both on a risk-based targeting approach and on a sampling approach, include review of each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States. At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;

- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Endo policy; and
- 6) the identification of any potential off-label or other potentially illegal promotional activity by the sales representative.

Endo Monitoring Personnel shall conduct at least 20 Observations during each Reporting Period.

3. *Records Reviews.* As a component of the FFMP, Endo shall also review various types of records to assess the interactions of sales personnel acting on behalf of Endo (including both employees and contractors) with HCPs and HCIs in order to identify potential or actual compliance violations. For each Reporting Period, Endo shall develop and implement a plan for conducting Records Reviews associated with at least three Government Reimbursed Products and a sampling of the representatives promoting the Government Reimbursed Products in every separate district/region of the United States. The OIG shall have the discretion to identify the Government Reimbursed Products to be reviewed for each Reporting Period. The OIG will select the Government Reimbursed Products based on information about Endo's Government Reimbursed Products provided by Endo no later than 60 days prior to the beginning of the Reporting Period and other information known to the OIG. If the OIG does not identify the Government Reimbursed Products to be reviewed during a given Reporting Period, Endo shall select the three Government Reimbursed Products to be reviewed.

These Records Reviews shall include the monitoring and review of: (1) records and systems relating to sales representatives' interactions with HCPs and HCIs (including, but not limited to, records from all available electronic detailing system(s), sales communications from managers, sample distribution records, and expense reports); (2) requests for, or inquiries relating to, medical information about Government Reimbursed Products; (3) tutorials and preceptorships (to the extent any are conducted); (4) to the extent they are available within Endo, message recall studies or similar records (such as Verbatims) purporting to reflect the details of sales representatives' interactions with HCPs and HCIs; (5) sales representative call notes; (6) sales representatives' e-mails and other electronic records; (7) records of promotional materials provided by sales personnel to HCPs and HCIs; and (8) recorded results of the Observations of sales representatives and applicable notes, coaching guides, or other information from the sales representatives' managers.

4. *Reporting and Follow-Up.* Personnel conducting the Speaker Program Audits, Observations and Records Reviews shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. Results from the FFMP audits shall be compiled and reported to the Compliance Officer (or designee) for review and remediation, as appropriate. In the event that a compliance issue, including but not limited to a potential improper promotion or noncompliance with Endo's legal requirements, compliance program requirements, or Policies and Procedures is identified during any portion of the FFMP review, Endo shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.I above, as applicable. Any compliance issues identified during a Speaker Program Audit, Observation and/or report from Records Review and any corrective action shall be recorded in the files of the Compliance Department.

EPI 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, EPI also shall provide the OIG with copies of the Observation Report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Endo took as a result of such determinations. EPI shall make the Observation reports for all other Observations available to the OIG upon request.

L. Monitoring of Non-Promotional Activities. Within 120 days after the Effective Date, Endo shall develop and implement a monitoring program for the following types of activities: 1) consultant arrangement activities; 2) research-related activities; 3) publication activities; and 4) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consultant Arrangement Activities.* To the extent that Endo engages U.S.-based HCPs or HCIs for services other than for speaker programs, research-related functions, or publication activities that relate to Promotional Functions or to Product Related Functions (*e.g.*, as a member of an advisory board or to attend consultant meetings), such HCPs or HCIs shall be referred to herein as Consultants. Endo shall require all Consultants to enter into written agreements describing the scope of work to be performed, the fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid

according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Endo.

Within 120 days after the Effective Date, Endo shall establish a process to develop periodic budgeting plans (at least annual budgeting plans) that identify the business needs for, and the estimated numbers of, various Consultant engagements and activities to occur during the following year (or period, if more frequent than annual). The Consultant budgeting plans shall also identify the budgeted amounts to be spent on Consultant-related activities. Endo's compliance and/or legal personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The review process shall be designed to ensure that Consultant arrangements and related events are used for legitimate purposes in accordance with applicable Endo Policies and Procedures and with applicable Federal health care program and FDA requirements.

Within 120 days after the Effective Date, Endo shall establish a process designed to ensure that a documented 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 or HCIs to be engaged, the agenda for proposed meeting(s), and a description of the proposed work to be done and type of work product to be generated.) Any deviations from the Consultant budgeting plans shall be documented in the needs assessment and shall be subject to review and approval by Endo compliance and/or legal personnel.

Within 120 days after the Effective Date, Endo shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Endo received the work product generated by the Consultant.

Within 120 days after the Effective Date, Endo shall establish a Consultant Monitoring Program through which it shall conduct audits for each Reporting Period (Consultant Program Audits) of at least 15 Consultant arrangements with HCPs. The Consultant Program Audits shall include at least 6 advisory board programs and 9 professional services agreements with HCPs. The Consultant Monitoring Program shall review Consultant arrangements both on a risk-based targeting approach and on a sampling approach.

Endo Monitoring Personnel shall conduct the Consultant Program Audits by reviewing needs assessment documents, consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Endo's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer or designee for review and follow-up as appropriate.

2. *Research-Related Activities.* To the extent that Endo or EPI engages U.S.-based HCPs or HCIs to conduct Research (as defined above in Section II.C.8 above) such HCPs and HCIs shall be referred to collectively as "Researchers". Endo shall require all Researchers to enter into written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid, and compliance obligations for the Researchers. Researchers shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Endo or industry standard databases or tools.

Within 120 days after the Effective Date, Endo shall establish an annual budgeting plan for Researchers that identifies the business or scientific need for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Endo compliance personnel and/or legal shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. This review shall be designed to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Endo Policies and Procedures and with applicable Federal health care program and FDA requirements.

Within 120 days after the Effective Date, Endo shall establish a process designed to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans

shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Endo compliance and/or legal personnel.

Within 120 days after the Effective Date, Endo shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.

Within 120 days after the Effective Date, Endo shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits) of at least 5 Researcher arrangements with HCPs or HCIs.

The Researcher Monitoring Program shall review Researcher arrangements both on a risk-based targeting approach and on a sampling approach. Endo Monitoring Personnel shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Endo and performed by the Researchers in a manner consistent with Endo's Policies and Procedures. Results from the Researcher Program Audits, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up as appropriate.

3. Publication Activities. To the extent that Endo engages HCPs or HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Endo shall require all Authors to enter into written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance obligations of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Endo.

Within 120 days after the Effective Date, Endo shall establish a process to develop annual plans that identify the business needs for and the estimated numbers of various Publication Activities (Publications Plans). The annual Publications Plans shall also identify the budgeted amounts to be spent on Publication Activities. Endo's compliance and/or legal personnel shall be involved in the review and approval of such annual Publications Plans, including any modification of an approved plan. This review process shall be designed to ensure that Publication Activities and related events are used for

legitimate purposes in accordance with Endo Policies and Procedures and with applicable Federal health care program and FDA requirements.

Within 120 days after the Effective Date, Endo shall establish a needs assessment process for Publication Activities. This process shall be designed to ensure that a needs assessment has been completed prior to the retention of an Author to undertake a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Endo compliance and/or legal personnel.

Within 120 days after the Effective Date, Endo shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 10 Publication Activities. The Publication Monitoring Program shall select publications for review both on a risk-based targeting approach and on a sampling approach.

Endo Monitoring Personnel shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Endo's Policies and Procedures. Results from the Publication Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up, as appropriate.

4. Medical Education Grant Activities. Within 120 days after the Effective Date, Endo shall establish a grants management system which shall be the exclusive mechanism through which requestors may seek or be awarded grants for independent medical education grants. Endo's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of medical education. Grant requests shall be submitted through the grants management system and processed in accordance with standardized criteria developed by Endo. Endo shall continue the grant process described above (or an equivalent process) throughout the term of the CIA, and shall notify the OIG in writing at least 30 days prior to the implementation of any new system subsequent to the Effective Date.

Within 120 days after the Effective Date, Endo shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 5 grants. The Grants Monitoring Program shall select grants for review both on a risk-based targeting approach and on a sampling approach.

Endo Monitoring Personnel conducting the Grants Monitoring Program shall review proposal documents (including grant requests), approval documents, contracts, payments, documents, and materials relating to the grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with Endo's Policies and Procedures. Results from the Grant Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or designee) for review and follow-up as appropriate.

5. Follow Up Reviews and Reporting. In the event that a potential violation of Endo's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any aspect of the NPMP, Endo shall investigate the incident consistent with established Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable. Any compliance issues identified during any portion of the NPMP referenced above, and any corrective action, shall be recorded in the files of the Compliance Department.

EPI shall include a summary of the NPMP and the results of the NPMP as part of each Annual Report. As part of each Annual Report, EPI also shall provide the OIG with descriptions of any instances identified through the NPMP in which it was determined that improper promotion of Government Reimbursed Products occurred or the activities violated Endo's requirements or Policies and Procedures, and a description of the action(s) that Endo took as a result of such determinations. EPI shall make the documents relating to the NPMP available to the OIG upon request.

M. Reporting of Physician Payments.

1. *Reporting of Payment Information.* Quarterly Reporting: On or before September 1, 2014, Endo shall post in a prominent position on its website an easily accessible and readily searchable listing of all U.S.-based physicians and Related Entities who or which received Payments (as defined in Section III.M.2) directly or indirectly

from Endo during the first full calendar quarter following the Effective Date and the aggregate value of such Payments. Thereafter, 60 days after the end of each calendar quarter during the term of the CIA, Endo shall post on its website a report of the cumulative value of the Payments provided to each physician and Related Entity during the preceding calendar quarter.

Annual Reporting: On or before March 31, 2015, and 90 days after the end of each subsequent calendar year during the term of the CIA, Endo shall post on its website a report of the cumulative value of the Payments provided to all U.S.-based physicians and Related Entities directly or indirectly from Endo during the prior applicable calendar year. Each quarterly and annual report shall be easily accessible and readily searchable.

Each listing made pursuant to this Section III.M shall include a complete list of all individual physicians or Related Entities to whom or which Endo made Payments in the preceding quarter or year (as applicable). Each listing shall be arranged alphabetically according to the physicians' last name or name of Related Entity. The Payment amounts in the lists shall be reported in the actual amount paid for all physicians or Related Entity on the listing. For each physician, the applicable listing shall include the following information: (i) physician's full name; (ii) name of any Related Entities (if applicable); (iii) city and state that the physician has provided to Endo for contact purposes; and (iv) the aggregate value of the payment(s) in the preceding quarter or year (as applicable). If payments for multiple physicians have been made to one Related Entity, the aggregate value of all payments to the Related Entity will be the reported amount.

2. *Definitions and Miscellaneous Provisions.*

(i) Endo shall continue to make each annual listing and the most recent quarterly listing of Payments available on its website during the term of the CIA. Endo shall retain and make available to OIG, upon request, all supporting documentation, correspondence, and records related to all applicable Payments and to the annual and/or quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Endo to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entity.

(ii) For purposes of Section III.M.1, "Payments" is defined to include all "payments or transfers of value" as that term is defined in §1128G(e)(10) under Section 6002 of the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) and any regulations promulgated thereunder. The term Payments

includes, by way of example, the types of payments or transfers of value enumerated in §1128G(a)(1)(A)(vi) of the Affordable Care Act. The term includes all payments or transfers of value made to Related Entities on behalf of, at the request of, for the benefit or use of, or under the name of a physician for whom Endo or EPI would otherwise report a Payment if made directly to the physician. The term Payments also includes any payments or transfers of value made, directly by Endo, EPI, or by a vendor retained by Endo or EPI to a physician or Related Entity in connection with, or under the auspices of, a co-promotion arrangement.

(iii) For purposes of its annual and quarterly website postings as described above, and only with regard to payments made pursuant to product research or development agreements and clinical investigations as set forth in § 1128G(c)(E) of the Affordable Care Act, Endo may delay the inclusion of such payments on its website listings consistent with § 1128G(c)(E) of the Act and any subsequent regulations promulgated thereunder.

(iv) The term “Payments” does not include transfers of value or other items that are not included in or are excluded from the definition of “payment” as set forth in § 1128G(e)(10) under Section 6002 of the Affordable Care Act and any regulations promulgated thereunder.

(v) For purposes of this Section III.M, the term “Related Entity” is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

N. Notices to Health Care Providers and Entities. Within 120 days after the Effective Date, Endo shall send, by first class mail, postage prepaid with delivery confirmation, a notice containing the language set forth below to all HCPs and HCIs who are currently detailed on behalf of Endo. This notice shall be dated and shall be signed by Endo’s Chief Executive Officer. The body of the letter shall state the following:

As you may be aware, Endo Pharmaceuticals Inc. recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with the promotion of one of its products (Lidoderm). This letter provides you with additional information about the settlement, explains the commitments of Endo going forward, and provides you with access to information about those commitments.

In general terms, the Government alleged that Endo unlawfully promoted

its product Lidoderm for intended uses not approved by the Food & Drug Administration (FDA) and that these activities violated the Federal Food, Drug, and Cosmetic Act and the False Claims Act. To resolve these matters, an Endo subsidiary, Endo Pharmaceuticals, Inc. (EPI) has entered into a deferred prosecution agreement and agreed to pay approximately \$20.8 million as a monetary penalty and forfeiture. In addition, Endo entered into a civil settlement and agreed to pay \$172.9 million to the Federal Government and State Medicaid programs to resolve False Claims Act allegations. More information about the deferred prosecution agreement and the civil settlement may be found at the following: <http://www.justice.gov/> and <http://endo.com/about-us/corporate-compliance-business-practices>.

As part of the global settlement, Endo also entered into a five-year corporate integrity agreement (CIA) with the Office of Inspector General of the U.S. Department of Health and Human Services. The CIA is available at <https://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>. Under this agreement, Endo agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. Endo also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by any of Endo's representatives to Endo's Compliance Department or the FDA using the information set forth below.

Please call Endo at 1-855-645-5591 if you have questions about the settlement referenced above or to report any instances in which you believe that an Endo representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Endo representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about the products to 1-800-462-3636.

The Compliance Officer 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, Endo shall provide to the OIG a summary of the calls and messages received.

O. Other Transparency/Disclosure Initiatives.

1. Medical Education Grants and Charitable Contributions.

Within 120 days after the Effective Date, Endo shall post summary information on its company website about medical education grants and charitable contributions made by Endo. This posting shall include information about the number of medical education grants and charitable contributions made in each calendar year and information about the aggregate value of such grants and charitable contributions. Endo shall notify the OIG in writing at least 60 days prior to any change in the substance of its policies regarding the funding of medical education grants or the posting of the above-referenced information about medical education grants and charitable contributions.

2. Consultant Disclosure Obligations.

Endo shall implement a requirement that all Consultants fully comply with all applicable disclosure obligations relating to their relationship with Endo or EPI that may be externally imposed on the Consultants based on their affiliation with formulary or Pharmacy & Therapeutics (P&T) committees or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. Within 120 days after the Effective Date, Endo shall amend its policies relating to Consultants to explicitly state that Endo requires all Consultants to fully comply with all applicable disclosure obligations relating to their relationship with Endo or EPI that may be externally imposed on the Consultants based on their affiliation with formulary, P&T committees, or committees associated with the development of treatment protocols or standards or that are required by any HCI, medical committee, or other medical or scientific organization with which the Consultants are affiliated. In addition, for any amendment to contracts with Consultants and in any new contracts with Consultants entered into after 120 days following the Effective Date, Endo and /or EPI shall include an explicit requirement that the Consultants fully comply with all applicable disclosure requirements, as referenced above in this paragraph. Endo shall continue these disclosure requirements throughout the term of this CIA.

3. Authors.

Endo shall implement a requirement that all Authors of biomedical manuscripts fully comply with the International Committee of Medical Journal Editors (ICMJE) criteria regarding authorship and disclosure of their relationship with Endo or EPI and to disclose any potential conflicts of interest, including any financial or personal relationships that might be perceived to bias their work. Within 120 days after the Effective Date, Endo and/or EPI, if necessary, shall amend its/their Author contracts or engagement letters to explicitly state Endo's requirement about full disclosure by Authors consistent with the requirements of any HCI, medical committee or other medical or scientific organization with which the Authors are affiliated. In addition, for any amendments to its contracts or engagement letters with Authors and in any new contracts or engagement letters with Authors entered into after 120 days following the Effective Date, Endo or EPI shall include an explicit requirement that Authors disclose in their manuscripts, journal submissions, and elsewhere as appropriate or required, any potential conflicts of interest, including their financial or personal relationship with Endo, the names of any individuals who have provided editorial support for any manuscript or other publication, and all funding sources for the study or publication.

4. Post-Marketing Commitments.

To the extent not already accomplished, within 120 days after the Effective Date, Endo shall post or make available information on its company website about post-marketing commitments (PMCs). The Endo website or links included therein shall provide access to general information about the PMC process, descriptions of ongoing Endo studies, and information about the nature and status of FDA post-marketing commitments. Endo shall continue to post or make available the above-described information about PMCs on its website or links included therein throughout the term of this CIA.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Business, Business Unit or Location.

In the event that, after the Effective Date, EHS or Endo 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, EPI shall notify OIG of the proposed sale no later than five business days after the date on which the sale is publicly

disclosed by Endo. 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 the business, business unit or location, unless otherwise determined and agreed to in writing by the OIG.

B. Change or Closure of Business, Business Unit or Location

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

C. Purchase or Establishment of New Business, Business Unit or Location

In the event that, after the Effective Date, EHS or Endo purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, EPI shall notify OIG no later than five business days after the date of such purchase or the date on which the operation of the new business, business unit or location is publicly disclosed by Endo. This notification shall include the address of the new business, business unit or location, phone number, fax number, the location's Federal health care program number and/or supplier number(s), if applicable; and the name and address of Federal health care program contractor(s) to which Endo currently submits claims (if applicable). 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 agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, EPI 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 Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Endo's Code of Conduct required by Section III.B.1;
6. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);
7. a summary of all Policies and Procedures required by Section III.B.2 (copies of the Policies and Procedures shall be made available to OIG upon request);
8. the following information regarding each type of training required by Section III.C:
 - a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

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

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

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

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

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

12. a certification from the Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Endo's website as required by Section III.M;

13. a certification by the Compliance Officer that the notice required by Section III.N was mailed to each applicable HCP and HCI, the number of HCPs and HCIs to whom the notice was mailed, a sample copy of the notice required by Section III.N, and a summary of the calls or messages received in response to this notice;

14. a list of all of Endo's locations (including locations and mailing addresses) engaged in Covered Functions; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider number and/or supplier number(s) (if applicable); and the name and address of each Federal health care program contractor to which Endo currently submits claims (if applicable);

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

16. the certifications required by Section V.C.

B. Annual Reports

EPI shall submit to OIG annually a report with respect to the status of, and findings regarding, Endo'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.2-III.A.4.;
2. a copy of the resolution by the Board or a Committee of the Board, required by Section III.A.3;
3. a summary of any changes or amendments to Endo's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;
4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);
5. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (*e.g.*, change in contractor policy);
6. the following information regarding each type of training required by Section III.C:
 - a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions; and

- b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions.

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

7. beginning for the second Reporting Period, a description of the RAMP Program required by Section III.D and a summary of any significant changes to the program during the applicable Reporting Period;

8. a complete copy of all reports prepared pursuant to Section III.E and Appendix B, along with a copy of the IRO's engagement letter;

9. Endo's response to the reports prepared pursuant to Section III.E and Appendix B, along with corrective action plan(s) related to any issues raised by the reports;

10. a summary and description of any and all current and prior engagements and agreements between Endo or EHS and the IRO (if different from what was submitted as part of the Implementation Report);

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

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

13. any changes to the process by which Endo fulfills the requirements of Section III.G regarding Ineligible Persons;

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

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

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

17. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Endo took as a result of such determinations;

18. a summary of the NPMP and the results of the NPMP program described in Section III.L, including detailed description of any identified instances in which it was determined that the activities violated Endo's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Endo took as a result of such determinations;

19. a certification from the Compliance Officer that, if required under Section III.M and to the best of his/her knowledge, information regarding Payments has been posted on Endo's website as required by Section III.M;

20. a summary of the calls and messages received in response to the notice required by Section III.N and the disposition of those calls and messages;

21. a certification from the Compliance Officer that, to the best of his/her knowledge, information required to be posted under Section III.O has been posted to Endo's website as required by Section III.O;

22. a description of all changes to the most recently provided list of Endo's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; and the corresponding phone and fax numbers;

23. a description of: (i) any additional, updated, supplemental or changed information submitted to any Compendia in accordance with Section III.B.2.q;

(ii) Endo's review of information submitted to the Compendia and Endo's conclusion as to whether information submitted to the Compendia and product listings and monographs contained in the Compendia about Government Reimbursed Products are accurate and complete and do not contain any errors; and (iii) all arrangements, processing fees, and other payments or financial support (if any) with or made to any Compendia that were evaluated during the annual review described in Section III.B.2.q; and

2. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 120 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

The following certifications shall be included in the Implementation Report and Annual Reports (as specified below):

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

2. Compliance Officer. In the Implementation Report and Annual Reports, EPI 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 applicable report, Endo is in compliance with all of the requirements of this CIA;

- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

- c. Policies and Procedures as referenced in Section III.B.2 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by legal counsel with experience regarding Federal health care program and FDA requirements and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Endo's promotional materials containing claims or

information about Government Reimbursed Products and other materials and information intended to be disseminated outside Endo have been reviewed by competent regulatory, medical, and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns are properly addressed by Endo and brought to the attention of the appropriate individuals when required, and that the materials and information when finally approved are, to the best of his or her knowledge, in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical, and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

d. Endo's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.2.h) and, for each product the call plans were found to be consistent with Endo's policy objectives as referenced above in Section III.B.2.h.

D. Designation of Information

EPI 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. EPI 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

Endo:

Jon Smollen
Executive Vice President and
Chief Compliance Officer
Endo Health Solutions Inc.
1400 Atwater Drive
Malvern, PA 19335
Telephone: 484.216.6811
Facsimile: 484.713.5204

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

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Endo's or EHS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Endo's locations for the purpose of verifying and evaluating: (a) Endo's and EHS's compliance with the terms of this CIA; and (b) Endo's compliance with the requirements of the Federal health care programs in which it participates and with applicable FDA requirements. The documentation described above shall be made available by Endo and/or EHS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Endo's employees, contractors, or agents who consent to be interviewed at the individual's place

of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Endo shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Endo's employees may elect to be interviewed with or without a representative of Endo present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

EPI and Endo are expected to fully and timely comply with all of their CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, EPI 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 Endo or EHS 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 of Directors compliance obligations, including the resolution of the Board;
- d. the management accountability and certification obligations;
- e. a written Code of Conduct;
- f. written Policies and Procedures;
- g. the training of Covered Persons, Relevant Covered Persons, and Board Members;
- h. a RAMP Program;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA as required by Section III.J;
- n. a program for FFMP as required by Section III.K;
- o. a program for NNMP as required by Section III.L;
- p. posting of any Payments as required by Section III.M;
- q. notification to HCPs and HCIs as required by Section III.N;
and

r. the implementation of the Other Transparency/Disclosure Initiatives as required by Section III.O.

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

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

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

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

7. A Stipulated Penalty of \$1,000 for each day Endo or EHS fail to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to EPI stating the specific grounds for its determination that Endo has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Endo or EHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Endo 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

EPI 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 EPI fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after EPI receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Endo or EHS 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 EPI of: (a) Endo or EHS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

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

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

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

affect or otherwise set a standard for OIG’s decision that Endo or EHS have materially breached this CIA, which decision shall be made at OIG’s discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by EPI to report a Reportable Event and take corrective action as required in Section III.I.
- c. a failure by EPI to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, and Appendix B; or
- e. a failure of the Board (or a Committee thereof) 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 Endo or EHS constitutes an independent basis for EPI’s exclusion from participation in the Federal health care programs. Upon a determination by OIG that Endo or EHS have materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify EPI of: (a) Endo’s or EHS’s material breach; and (b) OIG’s intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the “Notice of Material Breach and Intent to Exclude.”)

3. *Opportunity to Cure.* EPI 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. EPI or EHS is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30 day period, but that: (i) EPI has begun to take action to cure the material breach; (ii) EPI is pursuing such action with due diligence; and (iii) EPI has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, EPI or Endo fails to satisfy the requirements of Section X.D.3, OIG may exclude EPI from participation in the Federal health care programs. OIG shall notify EPI in writing of its determination to exclude EPI. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of EPI’s receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. After the end of the period of exclusion, EPI 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 EPI 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, EPI shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether EHS and Endo were in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. EPI shall have the burden of proving 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 EPI to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless EPI requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Endo and EHS were in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) EPI had begun to take action to cure the material breach within that period; (ii) EPI has pursued and is pursuing such action with due diligence; and (iii) EPI provided to OIG within that period a reasonable timetable for curing the material breach and Endo has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Endo, only after a DAB decision in favor of OIG. EPI's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude EPI 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 EPI 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. EPI 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 Endo, EPI 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

EPI 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 Endo 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 capacities 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 ENDO PHARMACEUTICALS INC.

/Jon Smollen/

2/18/2014

JON SMOLLEN
Executive Vice President
and Chief Compliance Officer
Endo Health Solutions Inc.

DATE

/John S. Rah/

2/21/2014

JOHN S. RAH
Morgan, Lewis & Bockius LLP
Counsel for Endo Health Solutions, Inc.

DATE

/Jennifer Clarke/

2/21/2014

JENNIFER CLARKE
Morgan, Lewis & Bockius LLP
Counsel for Endo Health Solutions, Inc.

DATE

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

/Robert K. DeConti/

2/18/14

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/

2/21/14

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

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. EPI 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.9 of the CIA or any additional information submitted by EPI in response to a request by OIG, whichever is later, OIG will notify EPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, EPI may continue to engage the IRO.

2. If EPI 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, EPI shall submit the information identified in Section V.A.9 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 EPI at the request of OIG, whichever is later, OIG will notify EPI if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, EPI 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 pharmaceutical industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions and the RAMP Program. The assigned individuals shall be experienced in risk identification and mitigation in relation to pharmaceutical product marketing and promotion. 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. if in doubt of the application of a particular Federal health care program or FDA requirement, policy or regulation, request clarification from the appropriate authority (*e.g.*, CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

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. *EPI and IRO.* If EPI terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, EPI 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. EPI 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 may, at its sole discretion, require EPI to engage a new IRO in accordance with Paragraph A of this Appendix. EPI must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring EPI to engage a new IRO, OIG shall notify EPI of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, EPI may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with EPI prior to requiring EPI to terminate the IRO. However, the final determination as to whether or not to require EPI to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for

I. IRO Engagement, General Description

As specified more fully below, EPI shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist Endo in assessing and evaluating certain of its systems, processes, policies, and procedures related to Endo's Covered Functions and Risk Assessment and Mitigation Process (RAMP) (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. EPI 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 Endo's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods and the Systems Review of the RAMP Program during the second and fourth Reporting Periods. If Endo materially changes its systems, processes, policies, and procedures relating to Covered Functions or its RAMP, 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; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) 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.

II. IRO Systems Review

The Systems Review shall be a review of Endo's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Covered Functions and the RAMP Program. Where practical, Endo personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Endo pursuant to the preceding sentence.

More specifically, the IRO shall review Endo's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Endo's systems, policies, processes, and procedures applicable to the manner in which Endo sales representatives and personnel from the Medical Information department (or other department that undertakes a medical affairs function (hereafter "Medical Information")) handle requests or inquiries relating to information about the uses of products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of products.

This review shall include an assessment of the following:

- a) the manner in which Endo sales representatives handle requests for information about off-label uses of products (*e.g.*, by referring all such requests to Medical Information), including any electronic system(s) that Endo uses to collect, process, and/or store such information;
 - b) the manner in which Medical Information personnel handle and respond to requests for information about off-label uses (including tracking the requests and using or distributing materials provided in response to the request);
 - c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, or other individuals or entities outside Endo;
 - d) Endo's systems, processes, and procedures (including the Inquiries Database) used to track requests for information about off-label uses of products and responses to those requests;
 - e) the manner in which Endo collects and supports information reported in any systems used to track and respond to requests for product information, including the Inquiries Database;
 - f) the processes and procedures by which Medical Information and Endo's Compliance Officer or compliance department monitor and identify situations in which it appears that improper promotion may have occurred; and
 - g) Endo's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;
- 2) Endo's systems, processes, policies and procedures applicable to the manner and circumstances under which personnel from Medical Information interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with sales representatives) and the role of the medical personnel at such meetings or events,

including the manner in which they handle responses to requests about off-label indications of Government Reimbursed Products;

- 3) Endo's systems, policies, processes, and procedures relating to Endo's internal review and approval of information and materials relating to Government Reimbursed Products that are disseminated to individuals or entities outside Endo (including HCPs, HCIs, and payors);
- 4) Endo's systems, processes, policies, and procedures relating to incentive compensation for Relevant Covered Persons who are sales representatives or their managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Endo establishes different systems, processes, policies, or procedures relating to compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;
- 5) Endo's systems, processes, policies, and procedures relating to the development and review of call plans (as described in Section III.B.2.h of the CIA). This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on, among other factors, expected utilization of products for FDA-approved uses or non-FDA-approved uses;
- 6) Endo's systems, processes, policies, and procedures relating to Sample Distribution Plans (as described in Section III.B.2.i of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from Endo (including, separately, from Endo sales representatives and other Endo personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Endo through sales representatives or are distributed from a central location and the rationale for the manner of distribution;
- 7) Endo's systems (including any centralized electronic system), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;
- 8) Endo's systems, processes, policies, and procedures relating to Consultant Arrangements entered into with HCPs or HCIs (including, but not limited to, presentations, consultant task force meetings, advisory boards, preceptorships, and ad hoc

advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;

9) Endo's systems, processes, policies and procedures relating to the funding, directly or indirectly, of Third Party Educational Activity (as defined in Section II.C.7 of the CIA) and all events and expenses relating to such activities;

10) Endo's systems, processes, policies and procedures relating to the submission of information about any product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the Product ("Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information, (*e.g.*, any changes based on Endo's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia.) The review shall also assess Endo's processes relating to its annual reviews of Compendia listings relating to Government Reimbursed Products and its annual reviews of all arrangements with, and processing fees or other payments or financial support (if any) provided by the company to any Compendia;

11) Endo's systems, processes, policies, and procedures relating to Research and Publication Practices (as defined in Section III.B.2.r of the CIA) including the decision to provide financial or other support for Research; the manner in which support is provided for the Research; and publication of the information about the Research, including publication of information about the trial outcomes and results and the uses made of publications relating to Research;

12) Endo's systems, processes, policies and procedures relating to Authorship-Related Practices (as defined in Section III.B.2.s of the CIA) including, but not limited to, the disclosure of any and all relationships between any author and Endo, the identification of all authors or contributors (including professional writer, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

13) Endo's systems, processes, policies and procedures relating to the RAMP, including but not limited to, a review of the: (i) the sources and types of information used in connection with the risk assessment (*e.g.*, the individual personnel, departments or functional areas, and/or any data and systems involved); and (ii) the timing for development of the risk assessment and risk mitigation plans;

14) An assessment of whether, in developing the risk assessment or risk mitigation plans: (i) additional or different sources of information should be utilized; (ii) additional or different types of data or information should be utilized; and (iii) additional or different timing cycles should be utilized;

- 15) A review of the experience and background of personnel responsible for the development of the risk assessment and risk mitigation plans; and an assessment of the completeness and appropriateness of the relevant training, policies, procedures, standard operating procedures, and guidance each such individual receives;
- 16) An assessment of whether risk monitoring and audit activities related to RAMP: (i) adequately monitor all relevant identified risks; (ii) identify any actual problems that have occurred in connection with the identified potential sales, marketing or promotional risk; and/or (iii) prevent reoccurrence of any problems associated with an identified risk;
- 17) An assessment of whether risk monitoring and audit activities related to the RAMP should be: (i) enhanced, revised, or refined; (ii) changed to include additional or different mitigation/monitoring options to be considered based upon specific identified risks; and/or (iii) tracked and reviewed more frequently than prescribed by current policies to ensure that the options address all relevant risks for the specific Endo products reviewed; and
- 18) A review of the systems, policies, procedures, and processes by which Endo tracks and manages RAMP activities and an assessment of whether the systems, policies, procedures and processes ensure that risk mitigations plans are appropriately implemented and completed (including by identifying individuals responsible for the follow-up action items).

III. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II 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 Endo's systems, policies, processes, and procedures relating to the items identified in Sections II.1-18 above, including a general description of Endo'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 II.1-18 above are made known or disseminated within Endo;

- 4) a detailed description of any system(s) used to track and respond to requests for information about Endo's products (including the Inquiries Database);
- 5) a detailed description of Endo's incentive compensation system for Relevant Covered Persons who are sales representatives and their managers, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Endo may establish compensation differently for different Government Reimbursed Products, the IRO shall report separately on each such type of compensation arrangement;
- 6) whether the risk monitoring and risk mitigation activities associated with RAMP identify relevant risks and address identified risks;
- 7) whether sufficient controls exist to ensure that all monitoring and mitigation activities are tracked and monitored appropriately;
- 8) whether the RAMP (including the options for risk mitigation activities) potentially mitigates identified risks;
- 9) whether sufficient controls exist to ensure that all agreed-upon risk monitoring activities and risk mitigation action items are implemented and completed as planned pursuant to the RAMP;
- 10) findings and supporting rationale regarding any weaknesses in Endo's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 11) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-E, the Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of Endo's call Plans and Endo's call plan review process; (3) a review of Sampling Events as defined below in Section IV.C; (4) a review of records relating to a sample of the Payments that are reported by Endo pursuant to Section III.M of the CIA; and (5) a review of up to three additional items identified by the OIG in accordance with Section III.E.1.b of the CIA (hereafter "Additional Items".) The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.2.e of the CIA, Endo shall establish a database (Inquiries Database) to track information relating to all requests for information received by Endo about its Government Reimbursed Products (Inquiries). Endo shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (*e.g.*, fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) an evaluation of whether the Inquiry relates to information about off-label use for the product; 6) nature/form of the response from Endo (including a record of any materials provided in response to the request); and 7) the name of the Endo representative who called upon or interacted with the HCP or HCI, if known.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer, or a designee, shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section IV.A.1 above for each Inquiry received during the preceding two quarters (Inquiry Report). The Compliance Officer, or a designee, shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper (including but not limited to off-label) promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer, or a designee, in consultation with other appropriate Endo personnel, suspects that improper promotion may have occurred in connection with any Inquiry, the Compliance Officer or a designee shall initiate a follow-up review of the Inquiry (Improper Promotion Review), make specific findings based on his/her Improper Promotion Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.I of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 50 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty of the Inquiries reviewed by the IRO shall be Inquiries for which Endo conducted an Improper Promotion Review, and the other 10 shall be Inquiries for which Endo did not conduct an Improper Promotion Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section IV.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer conducted an Improper Promotion Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Improper Promotion Review; the findings of the Compliance Officer as a result of the Improper Promotion Review; and any follow-up actions taken by Endo based on the Improper Promotion Review findings.

B. IRO Review of Endo’s Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Endo’s review of its call plans described in Section III.B.2.h of the CIA. Endo shall provide the IRO with: i) a list of Government Reimbursed Products promoted by Endo sales representatives (including contract sales representatives) during the Reporting Period; ii) information about the FDA-approved uses for each Government Reimbursed Product; and iii) the call plans for each Government Reimbursed Product. Endo shall also provide the IRO with information about the reviews of call plans that Endo conducted during the Reporting Period and any modifications to the call plans made as a result of Endo’s reviews.

For each call plan, the IRO shall randomly select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (*e.g.*, medical specialty or practice area) used by Endo in conducting its review and/or modification of the call plan in order to determine whether Endo followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with Endo’s criteria relating to the call plan and/or Endo’s Policies and Procedures. The IRO shall also note any instances in which it appears that Endo failed to follow its criteria or Policies and Procedures.

C. IRO Review of the Distribution of Samples of Government Reimbursed Products

The IRO shall conduct a review and assessment of Endo’s distribution of samples of Government Reimbursed Products to HCPs and HCIs. Endo shall provide the IRO with: (i) a list of Government Reimbursed Products for which Endo distributed samples during the Reporting Period; (ii) information about the FDA-approved uses for each such product; and (iii) information about Endo’s policies and procedures relating to the

distribution of samples of each such Government Reimbursed Product, including Endo's Sample Distribution Plan for each Government Reimbursed Product showing which types of samples may be distributed by sales personnel or other Endo personnel to HCPs and HCIs of particular medical specialties or types of clinical practices. Endo shall also provide the IRO with information about the reviews of Sample Distribution Plans that Endo conducted during the Reporting Period as set forth in Section III.B.2.i of the CIA and any modifications to the Sample Distribution Plans made as a result of Endo's reviews.

For each Government Reimbursed Product for which Endo distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Endo provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

For each Sampling Event, the IRO shall review all relevant documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: 1) the quantity, dosage, and form of the Endo product provided to the HCP or HCI; 2) the identity and type of medical specialty or clinical practice of the HCP or HCI; 3) which individual Endo sales personnel or other Endo personnel provided the sample to the HCP or HCI; and 4) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to Endo).

For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by an Endo representative in a manner consistent with Endo's Sample Distribution Plan for the Government Reimbursed Product. To the extent that a sample was provided to an HCP or HCI by a representative or agent of Endo other than a sales representative, the IRO shall review the proof of receipt form signed by the HCP or HCI. If no proof of receipt form is available, the IRO shall contact the HCP or HCI by letter. The letter shall request that the HCP or HCI: 1) verify that he/she/it received the quantity and type of samples identified by the IRO as the Sampling Event; 2) verify that he/she/it requested the samples provided during the Sampling Event; 3) explain or confirm its type of medical specialty or clinical practice; and 4) identify the basis for requesting the sample (e.g., conversations with an Endo sales representative, conversation with an Endo representative at headquarters, independent research, or knowledge of the HCP or HCI).

For each Sampling Event, the IRO shall compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample was not consistent with the uses of the Government

Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by Endo in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Endo failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

D. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Endo shall post listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from Endo. For purposes of the IRO Review described in this Section IV.D, each annual listing shall be referred to as the “Physician Payment Listing” or “Listing.” For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) physician’s full name; ii) name of Related Entity (if applicable); iii) city and state of the physician’s practice or the Related Entity; and iv) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO Review, the term “Control Documents” shall include all material documents or electronic records associated with each Payment reflected in the Physician Payment Listing for the sampled physician and/or Related Entity. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify up to 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the physicians and/or Related Entities subject to the IRO review.

If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity 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 reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Endo's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payment(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Endo's policies were followed in connection with Payment(s) reflected in the Listing (*e.g.*, all required written approvals for the activity were obtained in accordance with Endo's policies.)

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:
 - i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Endo otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Endo's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Endo has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Endo otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

E. IRO Review of Additional Items

As set forth in Section III.E.1.b 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 150 days prior to the end of the applicable Reporting Period, the OIG shall notify Endo 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 Endo 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 Endo’s systems, processes, policies, and procedures based on its review of each Additional Item.)

Endo may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Field Force Monitoring Program (FFMP) described in Section III.K of the CIA or the Non-Promotional Monitoring Program (NPMP) described in Section III.L of the CIA be substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Endo’s internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Endo’s planned monitoring activities and internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Endo’s demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Endo’s request to permit its internal audit work to be substituted for a portion of the IRO’s

review of Additional Items in a given Reporting Period, Endo shall engage the IRO to perform the Review as outlined in this Section IV.

If the OIG agrees to permit certain of Endo's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work shall be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review at least 20% of the sampling units reviewed by Endo in its internal audits.

F. Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Transactions Reviews. 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:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (*e.g.*, the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether:

- (i) each item of information listed in Section IV.A.1 is reflected in the Inquiries Database; and
 - (ii) for each Inquiry for which an Improper Promotion Review was conducted, the basis for suspecting that improper (including but not limited to off-label) promotion may have occurred; the steps undertaken as part of the Improper Promotion Review; the findings of the Compliance Officer as a result of the Improper Promotion Review; and any follow-up actions taken by Endo as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in Endo's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in Endo's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the Government Reimbursed Products promoted by Endo during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for Government Reimbursed Product promoted by Endo during the Reporting Period: i) a description of the criteria used by Endo in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Endo of the call plans and an indication of whether Endo reviewed the call plans as required by Section III.B.2.h of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Endo's criteria relating to the call plan and/or Endo's Policies and Procedures; and iv) a description of all instances in which it appears that Endo failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- h) the findings and supporting rationale regarding any weaknesses in Endo's systems, processes, policies, procedures, and practices relating to Endo's call plans or the review of the call plans, if any;
- i) recommendations, if any, for changes in Endo's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or

deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Sampling Event Reviews)

- j) for each Government Reimbursed Product for which samples were distributed during the Reporting Period: (i) a description of the applicable Sample Distribution Plan (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice sales representatives may provide samples); (ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by Endo in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and (iii) a detailed description of any instances in which it appears that Endo failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event;
- k) the findings and supporting rationale regarding any weaknesses in Endo's systems, processes, policies, procedures, and practices relating to Endo's distribution of samples of Government Reimbursed Products, if any;
- l) recommendations, if any, for changes in Endo's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples;

(Relating to the Physician Payment Listing Reviews)

- m) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;
- n) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Endo policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Endo's policies were followed in connection with the underlying activity reflected in the document (*e.g.*, all required approvals were obtained); and

(v) any corrective action or disciplinary action was undertaken in those instances in which Endo policies were not followed;

o) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;

p) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

q) for each Additional Item reviewed, a description of the review conducted;

r) for each Additional Item reviewed, the IRO's findings based on its review;

s) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Endo's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

t) for each Additional Item reviewed, recommendations, if any, for changes in Endo's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.