

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

I. PREAMBLE

Endoscopic Technologies, Inc. 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). On June 15, 2009, Endoscopic Technologies, Inc. entered into a Settlement Agreement with the United States.

II. TERM AND SCOPE OF THE CIA

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

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

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

1. "Covered Persons" includes:
 - a. all owners (natural persons with an ownership stake greater than 5%), officers, directors, and employees of Endoscopic Technologies, Inc.; and
 - b. all contractors, subcontractors, agents, and other persons who perform Promotion and Product Services Related Functions (as defined below in Section II.C.3) on behalf of Endoscopic Technologies, Inc.

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

2. "Government Reimbursed Products" refers to all Endoscopic Technologies, Inc. products that are reimbursed by Federal health care programs and subject to FDA approval or clearance.
3. The term "Promotional and Product Services Related Functions" includes: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products; and (b) the preparation or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products that are distributed in the United States.
4. "Relevant Promotional and Product Services Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.

III. CORPORATE INTEGRITY OBLIGATIONS

Endoscopic Technologies, Inc. shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* Within 90 days after the Effective Date, Endoscopic Technologies, Inc. shall appoint an individual to serve as its Compliance Officer and 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 requirements. The Compliance Officer shall be a member of senior management of Endoscopic Technologies, Inc., shall report directly to the Chief Executive Officer of Endoscopic Technologies, Inc., shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Endoscopic Technologies, Inc., 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. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Endoscopic Technologies, Inc. as well as for any reporting obligations created under this CIA. Any non-compliance job responsibilities of the Compliance Officer must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, Endoscopic Technologies, Inc. shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as legal, human resources, sales and marketing). 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 organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Endoscopic Technologies, Inc. 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.* A Committee of the Board of Directors (Committee) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Committee shall, at a minimum, be responsible for the following:

a. The Committee shall meet at least quarterly to review and oversee Endoscopic Technologies, Inc.'s Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of the Chief Compliance Officer and other compliance personnel.

b. The Committee shall consist of at least three members, at least one of whom shall be an independent director. The Chief Compliance Officer is required to make at least four reports a year to the Committee or more often, if requested by the Committee or the Chief Compliance Officer.

c. The Committee shall arrange for the performance of a review on the effectiveness of Endoscopic Technologies, Inc.'s Compliance Program (Compliance Program Review) for each Reporting Period of the CIA and shall review the results of the Compliance Program Review as part of the review and assessment of Endoscopic Technologies, Inc.'s Compliance Program. A copy of the Compliance Program Review Report shall be provided to OIG in each Annual Report submitted by Endoscopic Technologies, Inc.

d. For each Reporting Period of the CIA, the Committee shall adopt a resolution, signed by each individual member of the Committee, summarizing its review and oversight of Endoscopic Technologies, Inc.'s compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The [insert name of Committee] Committee of the Board of Directors has made a reasonable inquiry into the operations of Endoscopic Technologies, Inc.’s Compliance Program, including but not limited to evaluating its effectiveness and receiving updates about the activities of its Chief Compliance Officer and other compliance personnel. The Board also has arranged for the performance of, and reviewed the results of, the Compliance Program Review. Based on its inquiry, the Committee has concluded that, to the best of its knowledge, Endoscopic Technologies, Inc. has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Committee is unable to provide such a conclusion in the resolution, the Committee 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 assure implementation by Endoscopic Technologies, Inc. of an effective Compliance Program.

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

The Board of Directors may by resolution reserve to itself the powers and responsibilities assigned to the Committee under this CIA. In that event, all references in this CIA to the Committee shall be deemed to be references to the Board of Directors.

4. *Management Accountability and Certifications:* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Endoscopic Technologies, Inc. employees (“Certifying Employees”) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify, in writing or electronically, that the applicable Endoscopic Technologies, Inc. component is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following individuals from Endoscopic Technologies, Inc.: the “Leadership Team”; the “Marketing Team”; and the “Domestic Sales Team.”

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 [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.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Endoscopic Technologies, Inc. is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

B. Written Standards.

1. *Code of Conduct.* Within 120 days after the Effective Date, Endoscopic Technologies, Inc. shall develop, implement, and distribute a written Code of Conduct to all Covered Persons. Endoscopic Technologies, Inc. shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

- a. Endoscopic Technologies, Inc.’s commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health care program and FDA requirements and to prepare and submit accurate claims consistent with such requirements;
- b. Endoscopic Technologies, Inc.’s requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Endoscopic Technologies, Inc.’s own Policies and Procedures;
- c. the requirement that all of Endoscopic Technologies, Inc.’s Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by Endoscopic Technologies, Inc., suspected violations of any Federal health care

program and FDA requirements and of Endoscopic Technologies, Inc.'s own Policies and Procedures; and

d. the right of all individuals to use the Disclosure Program described in Section III.E, and Endoscopic Technologies, Inc.'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, that he or she has received, read, understood, and shall abide by Endoscopic Technologies, Inc.'s Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* Within 120 days after the Effective Date, Endoscopic Technologies, Inc. shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA, and Endoscopic Technologies, Inc.'s compliance with Federal health care program and FDA requirements. At a minimum, the Policies and Procedures shall address:

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

b. appropriate ways to conduct Promotional and Product Services 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), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);

c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements, including FDA regulatory approval requirements;

d. the materials and information that may be distributed by Endoscopic Technologies, Inc. sales representatives and account executives about Endoscopic Technologies, Inc.'s Government Reimbursed Products and the manner in which Endoscopic Technologies, Inc. sales representatives and account executives respond to requests for information about non-FDA approved (or "off-label") uses of Endoscopic Technologies, Inc.'s Government Reimbursed Products; the form and content of information disseminated by Endoscopic Technologies, Inc. in response to such requests; and the internal review process for the information disseminated.

If, at any time during the term of the CIA, Endoscopic Technologies, Inc., acquires, develops, or otherwise obtains a line of Government Reimbursed Products (other than the "COBRA" line of radio-frequency ablation devices), then the obligations set forth in the remainder of this paragraph shall immediately come into effect with respect to such products, and shall remain in effect during any period that Endoscopic Technologies, Inc., continues to promote and sell Government Reimbursed Products. The Policies and Procedures shall include a requirement that Endoscopic Technologies, Inc. develop a database to track requests for information about Endoscopic Technologies, Inc.'s Government Reimbursed Products that involve non-FDA approved (or "off-label") uses. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Endoscopic Technologies, Inc.'s products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Endoscopic Technologies, Inc. (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Endoscopic Technologies, Inc. representative who called on or

interacted with the HCP or HCI. Any response from Endoscopic Technologies, Inc. to an HCP or HCI shall identify whether the information provided addresses an indication that is part of the approved product label. The status and findings of any follow-up review conducted by Endoscopic Technologies, Inc. in situations in which it appears that the Inquiry may have related to improper off-label promotion shall be maintained by the Chief Compliance Officer and the information shall be included in the Inquiry Reports further discussed in Section III.A.2 of Appendix B;

e. review of all call plans to ensure that Endoscopic Technologies, Inc. is promoting its Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements and is consistent with representations made by Endoscopic Technologies, Inc. to the FDA. 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;

f. review of all promotional and written materials and information intended to be disseminated outside Endoscopic Technologies, Inc., including promotional and written materials and information related to the coding of Government Reimbursed Products by health care professionals and health care institutions, to ensure that legal, regulatory, and medical concerns are properly addressed during Endoscopic Technologies, Inc.'s review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, as approved, comply with all applicable Federal health care program and FDA requirements;

g. Medical device reporting procedures, including those procedures required by 21 U.S.C. § 360i and 21 C.F.R. Part 803;

h. Post-approval medical device reporting procedures, including those required by 21 U.S.C. §§ 360i and 360l and 21 C.F.R. §§ 814.80, 814.82, and 814.84;

- i. Policies and procedures for the protections of human subjects required by 45 C.F.R. § Part 46;
- j. Policies and procedures for seeking clearance or approval of devices and uses of devices consistent with FDA statutes and regulations, including Investigational Device Exemption policies and procedures, required by 21 U.S.C. § 360j(g) and 21 C.F.R. Part 812; and
- k. disciplinary policies and procedures for violations of Endoscopic Technologies, Inc.'s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed 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), Endoscopic Technologies, Inc. shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be distributed to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

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

- a. CIA requirements; and
- b. Endoscopic Technologies, Inc.'s 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 Promotional and Product Services Covered Person shall receive at least three hours of Specific Promotional and Product Services Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions;
- b. all Endoscopic Technologies, Inc. Policies and Procedures and other requirements applicable to Promotional and Product Services Related Functions;
- c. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements, as well as Endoscopic Technologies, Inc.'s Policies and Procedures;
- d. the legal sanctions for violations of the applicable Federal health care program and FDA requirements, the False Claims Act, and the Anti-kickback statute;
- e. examples of proper and improper practices related to Promotional and Product Services Related Functions;
- f. the dissemination of information regarding Federal health care program requirements concerning the accurate coding and submission of claims;
- g. the legal sanctions to both Endoscopic Technologies, Inc. and Relevant Covered Promotional and Product Services Persons of failure to comply with Federal health care program and FDA requirements and with Endoscopic Technologies, Inc.'s own Policies and Procedures and the failure to report such non-compliance.

New Relevant Promotional and Product Services Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming a Relevant Promotional and Product Services Covered Person, or within 120 days after the Effective Date, whichever is later. An Endoscopic Technologies, Inc. employee who has completed the Specific Training shall review or supervise (as applicable) a new Relevant Promotional and Product Services Covered Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Promotional and Product Services Covered Person completes his or her Specific Training.

After receiving the initial Specific Training described in this Section, each Relevant Promotional and Product Services Covered Person shall receive at least three hours of Specific Training in each subsequent Reporting Period.

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

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, and/or outside consultant trainers selected by Endoscopic Technologies, Inc., or may be satisfied by relevant continuing education programs provided they cover the topics outlined above in Section III.C.2.

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

6. *Computer-based Training.* Endoscopic Technologies, Inc. may provide the training required under this CIA through appropriate computer-based training approaches. If Endoscopic Technologies, Inc. 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 Covered Persons receiving such training.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Endoscopic Technologies, Inc. shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Endoscopic Technologies, Inc., whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Endoscopic Technologies, Inc.’s systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Endoscopic Technologies, Inc.’s systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in Endoscopic Technologies, Inc.’s

systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Endoscopic Technologies, Inc. materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to Endoscopic Technologies, Inc.'s marketing and outreach efforts concerning atrial fibrillation, Endoscopic Technologies, Inc.'s product-approval efforts, and a review of records relating to information disseminated regarding the correct or proper coding of Endoscopic Technologies, Inc.'s Government Reimbursed Products

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

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

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 Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review).

Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc.'s final Annual Report shall be initiated no later than one year after Endoscopic Technologies, Inc.'s final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Endoscopic Technologies, Inc. agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Within 120 days after the Effective Date, Endoscopic Technologies, Inc. shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Endoscopic Technologies, Inc.'s policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. 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. The disclosure log shall be made available to OIG upon request.

F. 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 List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

a. Endoscopic Technologies, Inc. shall screen all prospective and current Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. Endoscopic Technologies, Inc. shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. Endoscopic Technologies, Inc. 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 this Section affects the responsibility of (or liability for) Endoscopic Technologies, Inc. to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Endoscopic Technologies, Inc. understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Endoscopic Technologies, Inc. may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Endoscopic Technologies, Inc. meets the requirements of Section III.F.

3. *Removal Requirement.* If Endoscopic Technologies, Inc. has actual notice that a Covered Person has become an Ineligible Person, Endoscopic Technologies, Inc. shall remove such Covered Person from responsibility for, or involvement with, Endoscopic Technologies, Inc.'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 Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. 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.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at Endoscopic Technologies, Inc., Endoscopic Technologies, Inc. shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Endoscopic Technologies, Inc. conducted or brought by a governmental entity or its agents involving an allegation that Endoscopic Technologies, Inc. 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. Endoscopic Technologies, Inc. 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.

H. Reporting.

1. *Reportable Events.*

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

- i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Endoscopic

Technologies, Inc. Government Reimbursed Products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Endoscopic Technologies, Inc.

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

b. *Reporting of Reportable Events.* If Endoscopic Technologies, Inc. determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Endoscopic Technologies, Inc. shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

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

ii. a description of Endoscopic Technologies, Inc.'s actions taken to correct the Reportable Event; and

iii. any further steps Endoscopic Technologies, Inc. plans to take to address the Reportable Event and prevent it from recurring.

iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.

v. Endoscopic Technologies, Inc. shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G.

I. Notification of Communications with FDA.

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

Within 30 days after the date of any written report, correspondence, or communication between Endoscopic Technologies, Inc. and the FDA that materially discusses the status of Endoscopic Technologies, Inc.'s application for FDA approvals of Government Reimbursed Products, including the status of studies related to the FDA approval process, Endoscopic Technologies, Inc. shall provide the OIG with a description of such written report, correspondence, or communication.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Endoscopic Technologies, Inc. changes locations or closes a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Endoscopic Technologies, Inc. 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 location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Endoscopic Technologies, Inc. purchases or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Endoscopic Technologies, Inc. shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Endoscopic Technologies, Inc. proposes to sell any or all of its business units or locations that manufacture or sell FDA cleared or approved products and are subject to this CIA, Endoscopic Technologies, Inc. shall notify OIG of the proposed sale at least 30 days prior to the closing of the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Endoscopic Technologies, Inc. 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, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A;
3. the names of the members of the Committee of the Board referenced in Section III.A.3
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Endoscopic Technologies, Inc.'s Code of Conduct required by Section III.B.1;
6. a copy of all Policies and Procedures required by Section III.B.2;
7. 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);

8. 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 supporting this information shall be available to OIG, upon request.

9. a description of the Disclosure Program required by Section III.E;

10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Endoscopic Technologies, Inc. and the IRO;

11. a certification from the IRO regarding its professional independence and objectivity with respect to Endoscopic Technologies, Inc.;

12. a description of the process by which Endoscopic Technologies, Inc. fulfills the requirements of Section III.F regarding Ineligible Persons;

13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;

14. a list of all of Endoscopic Technologies, Inc.'s U.S. locations (including locations and mailing addresses) at which it performs Promotional and Product Services Related 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 or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Endoscopic Technologies, Inc. currently submits claims (if applicable);

15. a description of Endoscopic Technologies, Inc.'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. Endoscopic Technologies, Inc. shall submit to OIG annually a report with respect to the status of, and findings regarding, Endoscopic Technologies, Inc.'s compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Committee, the compliance Committee of the Board of Directors, or the group of Certifying Employees described in Section III.A.4, and a copy of the Compliance Program Review Report described in Section III.A.3;

2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

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

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

a. a description of 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 supporting this information shall be available to OIG, upon request.

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

6. Endoscopic Technologies, Inc.'s response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

7. a summary and description of any and all current and prior engagements and agreements between Endoscopic Technologies, Inc. and the IRO, if different from what was submitted as part of the Implementation Report;

8. a certification from the IRO regarding its professional independence and objectivity with respect to Endoscopic Technologies, Inc.;

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

10. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;

11. any changes to the process by which Endoscopic Technologies, Inc. fulfills the requirements of Section III.F regarding Ineligible Persons;

12. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; and the actions taken by Endoscopic Technologies, Inc. in response to the screening and removal obligations set forth in Section III.F;

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

14. a description of all changes to the most recently provided list of Endoscopic Technologies, Inc.'s locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; and the corresponding phone numbers and fax numbers;

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

16. the certifications required by Section V.C.

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

C. Certifications. The following certifications shall be included in the Implementation Report and each Annual Report:

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

2. Chief Compliance Officer: In the Implementation Report and Annual Reports, Endoscopic Technologies, Inc. shall include the following individual certification by the Chief Compliance Officer:

a. 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;

b. to the best of his or her knowledge, except as otherwise described in the report, Endoscopic Technologies, Inc. is in compliance with the Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Endoscopic Technologies, Inc. has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

d. Endoscopic Technologies, Inc.'s: 1) 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 competent legal counsel and/or legal personnel working at their direction and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Endoscopic Technologies, Inc.'s promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Endoscopic Technologies, Inc. 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 and are elevated when appropriate, and that the materials and information when finally approved are 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

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

f. Endoscopic Technologies, Inc. is making good-faith efforts to obtain all necessary approvals for each of its Government Reimbursed Products.

D. Designation of Information. Endoscopic Technologies, Inc. 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. Endoscopic Technologies, Inc. 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

Provider: Chief Compliance Officer
Endoscopic Technologies, Inc.
2603 Camino Ramon
Suite 100
San Ramon, CA 94583
Phone: 925-866-7111
Facsimile: 925-866-7117

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, Endoscopic Technologies, Inc. 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), either instead of or in addition to, a paper copy.

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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 Endoscopic Technologies, Inc.'s books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Endoscopic Technologies, Inc.'s locations for the purpose of verifying and evaluating: (a) Endoscopic Technologies, Inc.'s compliance with the terms of this CIA; and (b) Endoscopic Technologies, Inc.'s compliance with the requirements of the Federal health care programs and FDA applicable to its Government Reimbursed Products. The documentation described above shall be made available by Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc.'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. Endoscopic Technologies, Inc. shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Endoscopic Technologies, Inc.'s employees may elect to be interviewed with or without a representative of Endoscopic Technologies, Inc. present.

VIII. DOCUMENT AND RECORD RETENTION

Endoscopic Technologies, Inc. shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) 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 Endoscopic Technologies, Inc. prior to any release by OIG of information submitted by Endoscopic Technologies, Inc. pursuant to its obligations under this CIA and identified upon submission by Endoscopic Technologies, Inc. as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Endoscopic Technologies, Inc. shall have the rights set forth at 45 C.F.R. § 5.65(d).

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X. BREACH AND DEFAULT PROVISIONS

Endoscopic Technologies, Inc. is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. fails to establish and implement any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. a written Code of Conduct;
- d. written Policies and Procedures;
- e. the training of Covered Persons and Relevant Covered Persons;
- f. a Disclosure Program;
- g. Ineligible Persons screening and removal requirements;
- h. notification of Government investigations or legal proceedings;
and
- i. reporting of Reportable Events.

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 Endoscopic Technologies, Inc. fails to engage an IRO, as required in Section III.D and 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 Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. fails to submit the annual IRO Review Report(s) in accordance with the requirements of Section III.D and Appendices A and B.

5. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day Endoscopic Technologies, Inc. employees or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Endoscopic Technologies, Inc.'s business operations related to Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered or ordered by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which Endoscopic Technologies, Inc. can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person.

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

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

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

after Endoscopic Technologies, Inc. receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

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

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

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

- a. a 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 Endoscopic Technologies, Inc. to report a Reportable Event or take corrective action, as required in Section III.H
- c. a failure to engage and use an IRO in accordance with Section III.D and Appendices A and B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

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

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

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Endoscopic Technologies, Inc. fails to satisfy the requirements of Section X.D.3, OIG may exclude Endoscopic Technologies, Inc. from participation in the Federal health care programs. OIG shall notify Endoscopic Technologies, Inc. in writing of its determination to exclude Endoscopic Technologies, Inc. (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Endoscopic Technologies, Inc.'s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Endoscopic Technologies, Inc. shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Endoscopic Technologies, Inc. to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. was in material breach of this CIA;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Endoscopic Technologies, Inc. had begun to take action to cure the material breach within that

period; (ii) Endoscopic Technologies, Inc. has pursued and is pursuing such action with due diligence; and (iii) Endoscopic Technologies, Inc. provided to OIG within that period a reasonable timetable for curing the material breach and Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc., only after a DAB decision in favor of OIG. Endoscopic Technologies, Inc.'s election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc. 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. Endoscopic Technologies, Inc. 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 Endoscopic Technologies, Inc., Endoscopic Technologies, Inc. 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

Endoscopic Technologies, Inc. and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of Endoscopic Technologies, Inc.;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;
- C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

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D. OIG may agree to a suspension of Endoscopic Technologies, Inc.'s obligations under the CIA in the event of Endoscopic Technologies, Inc.'s cessation of participation in Federal health care programs. If Endoscopic Technologies, Inc. ceases participating in Federal health care programs and is relieved of its CIA obligations by OIG, Endoscopic Technologies, Inc. shall notify OIG at least 30 days in advance of Endoscopic Technologies, Inc.'s intent to resume participating as a provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

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

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

ON BEHALF OF ENDOSCOPIC TECHNOLOGIES, INC.

_____/John Pavlidis/

John Pavlidis/
President and Chief Executive Officer

1/13/10
DATE

_____/Tamer Ibrahim/

Tamer Ibrahim
Compliance Officer

1/14/10
DATE

_____/Roger Goldman/

Roger Goldman
Latham & Watkins LLP

1/12/10
DATE

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

/Gregory E. Demske/

2/2/10

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

DATE

CORPORATE INTEGRITY AGREEMENT
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APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

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

If Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Endoscopic Technologies, Inc. if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Endoscopic Technologies, Inc. may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Endoscopic Technologies, Inc. products are reimbursed;
2. assign individuals to design and select the samples for the Transaction 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 Promotional and Product Services 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 Promotional and Product Services 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 the Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Endoscopic Technologies, Inc.

E. IRO Removal/Termination.

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

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

Prior to requiring Endoscopic Technologies, Inc. to engage a new IRO, OIG shall notify Endoscopic Technologies, Inc. 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, Endoscopic Technologies, Inc. may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its responsibilities and to present additional information regarding these matters. Endoscopic Technologies, Inc. shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Endoscopic Technologies, Inc. prior to requiring Endoscopic Technologies, Inc. to terminate the IRO. However, the final determination as to whether or not to require Endoscopic Technologies, Inc. to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA for Estech, Inc.
Promotional and Product Services Review**

I. Promotional and Product Services Review, General Description

As specified more fully below, Endoscopic Technologies, Inc. (Estech) shall retain an Independent Review Organization (IRO) to perform reviews to assist Estech in assessing and evaluating its systems, processes, policies, procedures, and practices related to Estech's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. Estech may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Estech's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Estech materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. 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 Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Estech's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, Estech 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 Estech pursuant to the preceding sentence.

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

- 1) Estech's systems, policies, processes, and procedures applicable to the manner in which Estech representatives (including sales representatives and marketing personnel) handle requests or inquiries relating to information about the uses of Estech products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:
 - a) the manner in which Estech sales representatives and marketing personnel handle requests for information about off-label uses of Estech products;
 - b) the form and content of information and materials related to Estech's products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions ("HCIs") by Estech;
 - c) Estech's systems, processes, and procedures (including the Inquiries Database if required by paragraph III.B.2.d of the CIA) to track requests for information about off-label uses of products and responses to those requests;
 - d) the manner in which Estech collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database if required by paragraph III.B.2.d of the CIA;
 - e) the processes and procedures by which the Compliance Officer (and other appropriate individuals within Estech) identify situations in which it appears that improper off-label promotion may have occurred; and
 - f) Estech's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;

2) Estech's systems, policies, processes, and procedures relating to Estech's internal review and approval of information and materials related to Estech's products disseminated to HCPs or HCIs by Estech;

3) Estech's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, 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 Estech's 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;

4) Estech's systems, policies, processes and procedures relating to its efforts to obtain FDA-required approvals for its Government Reimbursed Products;

and

5) Estech's systems, processes, policies, and procedures relating to the development and review of call plans for Estech's products. 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 expected utilization of Estech products for FDA-approved uses or non-FDA-approved uses.

B. Promotional and Product Services 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.A 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 Estech's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-5 above, including a general description of Estech'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.A.1-5 above are made known or disseminated within Estech;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Estech's products (including the Inquiries Database);
- 5) a detailed description of Estech's incentive compensation system for Covered Persons who are sales representatives, 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 Estech may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Estech's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-E, the Promotional and Product Services Transactions Review shall include the following: (1) a review of a sample of Inquiries reflected in the Inquiries Database (if required by paragraph III.B.2.d of the CIA); (2) a review of Estech's call plans and Estech's call plan review process; (3) a review of records relating to Estech's good-faith efforts to obtain FDA approval for its Government Reimbursed Products; and (4) a review of the coding information Estech provides to HCPs and HCIs. The IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.2.d of the CIA, Estech may be required to establish a database to track information relating to requests for information received by Estech about its products (hereafter “Inquiries”). To the extent such a requirement is imposed, Estech shall document and record all Inquiries received from HCPs or HCIs regarding Estech’s products in a database (the “Inquiries Database”). Estech 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) nature/form of the response from Estech (including a record of any materials provided in response to the request); and 6) the name of the Estech sales representative or marketing department employee who called upon or interacted with the HCP or HCI. Any response from Estech to an HCP or HCI shall identify whether the information provided addresses an indication that is part of an approved product label. The status and findings of any follow-up review conducted by Estech in situations in which improper off-label promotion is suspected shall be maintained by Global Compliance.

2) Internal Review of Inquiries Database

If an Inquiries Database is required, on a semi-annual basis, the Chief Compliance Officer or other appropriate personnel shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters (“Inquiry Report”). The Chief Compliance Officer or other appropriate personnel shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Chief Compliance Officer or other appropriate personnel, in consultation with other appropriate Estech personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Chief Compliance Officer or other appropriate personnel shall undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label 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.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 20 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period that such a Database is required. Ten of the Inquiries reviewed by the IRO shall be Inquiries for which Estech conducted an Off-Label Review, and the other 10 shall be Inquiries for which Estech did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

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

B. IRO Review of Estech's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Estech's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.e of the CIA. Estech shall provide the IRO with: i) a list of products promoted by Estech during the Reporting Period; ii) information about the FDA-approved uses for each Estech product; and iii) the call plans for each product. Estech shall also provide the IRO with information about the reviews of call plans that Estech conducted during the Reporting Period and any modifications to the call plans made as a result of Estech's reviews.

For each call plan, the IRO shall select a sample of 10 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 Estech in conducting its review and/or modification of the call plan

in order to determine whether Estech 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 Estech's criteria relating to the call plan and/or Estech's Policies and Procedures. The IRO shall also note any instances in which it appears that Estech failed to follow its criteria or Policies and Procedures.

C. IRO Review of Estech Materials Concerning Coding of Government Reimbursed Products

The IRO shall conduct a review and assessment of Estech's documents and materials related to the coding of its Government Reimbursed Products. Estech shall provide the IRO with: i) a list of Government Reimbursed Products promoted by Estech during the Reporting Period; ii) information about the CMS-approved coding for each Estech product; and iii) any materials produced or disseminated to HCIs and HCPs by Estech regarding coding for each product.

D. IRO Review of Estech's Efforts To Obtain FDA Approval for Government Reimbursed Products

The IRO shall conduct a review and assessment of Estech's efforts to obtain all necessary approvals to market from the FDA for each of its Government Reimbursed Products for any intended use. Estech shall provide the IRO with sufficient information for the IRO to assess whether Estech has adequate approvals to support its marketing for each of its Government Reimbursed Products. If Estech does not have adequate approvals, Estech shall further provide the IRO with sufficient information for the IRO to assess whether Estech 1) has set realistic internal goals and timelines to obtain FDA approvals; 2) is making a good-faith effort to initiate studies or other clinical trials necessary to obtain FDA approvals; and 3) is marketing its products in a manner consistent with each product's then-current approval or clearance by the FDA.

E. Promotional and Product Services Transactions Review Report

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

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
 - c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report to the extent required:

(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 III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label

promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Estech as a result of the Compliance Officer's findings;

- d) the findings and supporting rationale regarding any weaknesses in Estech's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;
- e) recommendations for improvement in Estech'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 products promoted by Estech during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Estech product: i) a description of the criteria used by Estech 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 Estech of the call plans and an indication of whether Estech reviewed the call plans as required by Section III.B.3.e 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 Estech's criteria relating to the call plan and/or Estech's Policies and Procedures; and iv) a description of all instances in which it appears that Estech 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 Estech's systems, processes, policies, procedures, and practices relating to Estech's call plans or the review of the call plans, if any; and
- i) recommendations, if any, for changes in Estech'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;