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

I. PREAMBLE

EndoGastric Solutions, Inc. (EGS) 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). Contemporaneously with this CIA, EGS is entering into a Settlement Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), EGS established a voluntary compliance program applicable to EGS's directors, officers, managers, and employees (Compliance Program). EGS's Compliance Program includes, among other features, a Chief Compliance Officer; a code of conduct and written policies and procedures; educational and training initiatives; and a disclosure program.

EGS shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. EGS may modify its Compliance Program as appropriate, but at a minimum, EGS shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by EGS under this CIA shall be five years from the effective date of this CIA, except that if a specific code for Transoral Incisionless Fundoplication is first included in an annual version of the Current Procedural Terminology[1] ("CPT manual") during the fourth or fifth Reporting Period,

[1] Current Procedural Terminology is published by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures. Any use of the CPT outside of this CIA should refer to the most current version of the Current Procedural Terminology available from AMA.

then the compliance obligations shall continue for an additional two Reporting Periods after the Reporting Period in which publication in the CPT manual first occurred. Publication in the CPT Manual shall be referred to as "CPT Publication." The first Reporting Period after CPT Publication shall be referred to as the "Publication Reporting Period." The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

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

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

1. "Covered Persons" includes:

a. all owners of EGS who are natural persons (other than those 1) who have an ownership interest of less than 5%; and 2) are not involved in the business operations of EGS), officers, directors, and employees of EGS; and

b. all contractors, subcontractors, agents, and other persons who perform Promotional Functions or Advice Functions on behalf of EGS.

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. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional Functions or Advice Functions.

3. "Government Reimbursed Products" refers to all EGS devices that are marketed or sold by EGS in the United States and that are reimbursed by Federal health care programs or sold pursuant to contracts with the United States.

4. "Promotional Functions" includes the selling, marketing, detailing, advertising, or promoting of Government Reimbursed Products.

5. "Advice Functions" includes the provision of advice regarding the billing or coding of Government Reimbursed Products.

III. CORPORATE INTEGRITY OBLIGATIONS

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

A. Compliance Officer and Committee

1. *Compliance Officer*. EGS has appointed, and shall maintain during the term of the CIA, a Covered Person to serve as its Compliance Officer. 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 EGS, shall report directly to the Chief Executive Officer of EGS, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of EGS (or a Committee of the Board), and shall be authorized to report on such matters to the Board of Directors at any time. Written documentation of the Compliance Officer's reports to the Board of Directors (or its authorized and designated Committee) shall be made available to OIG upon request. The Compliance Officer shall not be, or be subordinate to, the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by EGS, as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

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

2. *Compliance Committee*. Within 90 days after the Effective Date, EGS 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 billing, clinical, human resources, audit, and operations). 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 EGS's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or an authorized and designated committee of the Board) of EGS (Board) shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board (or its authorized and designated Committee) shall, at a minimum, be responsible for the following:

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

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board (or its authorized and designated Committee) summarizing its review and oversight of EGS's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

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

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

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

B. Written Standards

1. *Code of Conduct*. Prior to the Effective Date, EGS developed, implemented, and distributed a written Code of Conduct to all Covered Persons who are EGS officers and employees. During the term of the CIA, EGS shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all officers and employees who are Covered Persons. The Code of Conduct includes, or within 60 days after the Effective Date, shall be revised to address or include the following:

a. EGS's commitment to full compliance with all Federal health care program requirements;

b. EGS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements, the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), and Federal anti-kickback statute (codified at 42 U.S.C. §§ 1320a-7b(b)), and with EGS's own Policies and Procedures;

c. the requirement that all of EGS's Covered Persons shall be expected to report to the Compliance Officer, or other appropriate individual designated by EGS, suspected violations of any Federal health care program requirements or of EGS's own Policies and Procedures; and

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

Within 90 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by EGS'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 90 days after the Effective Date, whichever is later.

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

2. *Policies and Procedures.* Prior to the Effective Date, EGS implemented written Policies and Procedures regarding the operation of its Compliance Program, including the Compliance Program requirements outlined in this CIA and EGS's compliance with Federal health care program requirements. The Policies and Procedures address, at a minimum, or within 90 days after the Effective Date shall address, the following:

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

b. appropriate ways to conduct the Promotional Functions in compliance with all applicable Federal health care program requirements, including but not limited to the False Claims Act and the Federal anti-kickback statute; and

c. appropriate ways to conduct the Advice Functions in compliance with all applicable Federal health care program requirements, including but not limited to the False Claims Act and the Federal anti-kickback statute.

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

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

C. Training and Education

1. *General Training*. Within 90 days after the Effective Date, EGS shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain EGS's:

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 90 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 90 days after the Effective Date, each Relevant Covered Person shall receive at least 90 minutes of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. how to perform Promotional Functions in compliance with Federal health care program requirements, the False Claims Act, and the Federal anti-kickback statute;

b. how to perform Advice Functions in compliance with the Federal health care program requirements regarding the accurate coding and submission of claims for Government Reimbursed Products;

c. applicable reimbursement statutes, regulations, and program requirements and directives;

d. the legal sanctions for violations of the Federal health care program requirements; and

e. examples of proper and improper claims submission practices.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 90 days after the Effective Date, whichever is later.

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

3. *Board Member Training*. Within 90 days after the Effective Date, EGS shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

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

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

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

6. *Update of Training.* EGS shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits, risk assessments, field force monitoring, the Systems Review, or the Encounters Review, and any other relevant information.

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

D. Notification of Publication

EGS shall notify OIG of CPT Publication within fifteen days after CPT Publication occurs.

E. Risk Assessment and Mitigation Process

Within 90 days after CPT Publication, EGS shall develop a standardized, centralized process to allow EGS in-house or outside legal counsel, compliance, and leaders of the relevant departments and functions to identify and assess risks associated with the sale, marketing, detailing, advertising, and promotion of Government Reimbursed Products, and to devise and implement specific measures to mitigate identified risks. This process shall focus on risks associated with Government Reimbursed Products, including, but not limited to, Promotional Functions and Advice Functions, related to compliance with Federal health care program requirements, the False Claims Act, and the Federal anti-kickback statute. EGS shall maintain the Risk Assessment and Mitigation Process for the duration of the CIA. The IRO shall perform a review of the effectiveness of the Risk Assessment and Mitigation Process at the OIG's request.

F. Field Force Monitoring

Within 90 days after the Effective Date, EGS shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales representatives' interactions with health care professionals (HCPs) and health care institutions (HCIs) and to identify potential improper conduct involving Promotional Functions. As described in more detail below, the FFMP shall include (1) direct field observations of sales representatives; and (2) the monitoring and review of other records relating to sales representatives' interactions with HCPs and HCIs (Record Reviews).

1. *Observations.* As a component of the FFMP, EGS compliance personnel and/or other appropriately trained EGS personnel who are not currently working in the marketing or field sales areas ("Monitoring Personnel") shall conduct observations of sales representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with applicable legal requirements and with EGS's Policies and Procedures. These observations shall be full day ride-alongs with sales representatives ("Observations"), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, selected by EGS compliance personnel both on a risk-based targeting approach and a sampling approach, and be

conducted across the United States. At the completion of each Observation, EGS Monitoring Personnel shall prepare a report that includes:

a. the identity of the sales representative;
b. the identity of the EGS Monitoring Personnel;
c. the date and duration of the Observation;
d. the product promoted during the Observation (if EGS is currently promoting more than one product);
e. an overall assessment of compliance with EGS policy; and
f. the identification of any potential improper conduct by the sales representative.

EGS Monitoring Personnel shall conduct Observations of at least 20 percent of the sales representatives or at least three sales representatives, whichever is greater, during each Reporting Period.

2. *Records Reviews.* As a component of the FFMP, EGS shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations. For each Reporting Period, EGS shall develop and implement a plan for conducting Records Reviews, which shall include a sampling of the representatives. These Records Reviews shall include the monitoring and review of: 1) records and systems relating to sales representatives' interactions with HCPs and HCIs (including sales representative corporate charge card expense records, and aggregate spend records concerning sales representatives' interactions with HCPs); 2) sales representatives' emails and other electronic records; 3) recorded results of the Observations of sales representatives and applicable notes or information from the sales representatives' managers; and 4) any other data that reflects or relates to sales representatives' interactions with HCPs and HCIs.

3. *Reporting and Follow-Up.* Personnel conducting the Observations and Records Reviews shall have access to all relevant records and information necessary to assess potential or actual compliance violations. Results from the FFMP audits, including the identification of potential violations of policies and/or legal requirements, shall be compiled and reported to the Compliance Department for review and follow-up as appropriate. In the event that a potential violation of EGS's Policies and Procedures or of legal or compliance requirements is identified during any aspect of the FFMP, EGS shall investigate the incident consistent with Policies and Procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.K below, if applicable. Any compliance issues identified in

Observation or Records Review and any corrective action shall be recorded in the files of the Compliance Department.

EGS shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, EGS also shall provide the OIG with copies of the Observation report for any instances in which was determined that improper conduct occurred and a description of the action(s) that EGS took as a result of such determinations. EGS shall make Observation reports for all other Observations available to the OIG upon request.

G. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, EGS shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.G. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the IRO Reviews shall consist of two components – a Systems Review and an Encounters Review, or an Alternate Review in lieu of an Encounters Review, as provided for in Section I.C of Appendix B. The Systems Review shall assess EGS's systems, processes, policies, and procedures relating to 1) Promotional Functions; 2) Advice Functions; and 3) the Risk Assessment and Mitigation Process (as applicable). The Encounters Review shall consist of a review of Promotional Functions and Advice Functions.

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

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

3. *Validation Review*. In the event OIG has reason to believe that: (a) an IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or IRO Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the IRO Review complied with the requirements of the CIA and/or the findings or the IRO Review results are inaccurate (Validation Review). EGS 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 EGS's final Annual Report shall be initiated no later than one year after EGS's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify EGS 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, EGS may request a meeting with OIG to: (a) discuss the results of any IRO Review submissions or findings; (b) present any additional information to clarify the results of the IRO Review or to correct the inaccuracy of the IRO Review; and/or (c) propose alternatives to the proposed Validation Review. EGS agrees to provide any additional information as may be requested by OIG under this Section III.G.3 in an expedited manner. OIG will attempt in good faith to resolve any IRO Review issues with EGS 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 EGS a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.G and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

H. Disclosure Program

Prior to the Effective Date, EGS established, and shall maintain during the term of the CIA, 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 EGS'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. EGS 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, EGS 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.

I. Ineligible Persons

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

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

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

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

b. "Exclusion Lists" include:

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

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

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

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

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

c. EGS shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

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

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

J. Notification of Government Investigation or Legal Proceedings

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

K. Reportable Events

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

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

b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.I.1.a; or

c. the filing of a bankruptcy petition by EGS.

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

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

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

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

b. a description of EGS's actions taken to correct the Reportable Event;

c. any further steps EGS plans to take to address the Reportable Event and prevent it from recurring; and

d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by EGS to identify and quantify the Overpayment.

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

IV. SUCCESSOR LIABILITY; CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Sale of Company, Business Unit or Location.

In the event that, after the Effective Date, EGS proposes to sell any or all of its company, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that are subject to this CIA, EGS shall notify OIG of the proposed sale at least 30 days prior to the sale of its company, business unit, or location. This notification shall include a description of the company, business unit, or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of the business,

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

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

In the event that, after the Effective Date, EGS changes locations or closes the company or a business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, EGS 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 company, business unit, or location.

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

In the event that, after the Effective Date, EGS purchases or establishes a new company, business unit, or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, EGS shall notify OIG at least 30 days prior to such purchase or the operation of the new company, business unit, or location. This notification shall include the address of the new company, business unit, or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which EGS currently submits claims. Each new company, business unit, or location and all Covered Persons at each new company, business unit, or location shall be subject to the applicable requirements of this CIA, unless otherwise agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 120 days after the Effective Date, EGS 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 Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. a copy of EGS's Code of Conduct required by Section III.B.1;

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

6. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

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

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

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

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

8. a description of the Risk Assessment and Mitigation Process required by Section III.E (if applicable);

9. a description of the Field Force Monitoring Program required by Section III.F;

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

11. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between

EGS and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to EGS;

12. a description of the process by which EGS fulfills the requirements of Section III.I regarding Ineligible Persons;

13. a list of all of EGS's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number and/or supplier number(s) (if applicable); and the name and address of each Medicare and state Medicaid program contractor to which EGS currently submits claims (if applicable);

14. a description of EGS's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business, any individual owners who are Covered Persons, and any entities that own an interest in EGS; and

15. the certifications required by Section V.C.

B. Annual Reports

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

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

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available upon request);

3. the Board resolution required by Section III.A.3;

4. a summary of any changes or amendments to EGS's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

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

6. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes;

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

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

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

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

8. a summary of the FFMP and the results of the FFMP required by Section III.F, including copies of the Observation report for any instances in which determined improper conduct occurred and a description of the action(s) that EGS took as a result of such determinations;

9. a complete copy of all reports prepared pursuant to Section III.G, along with a copy of the IRO's engagement letter;

10. EGS's response to the reports prepared pursuant to Section III.G, along with corrective action plan(s) related to any issues raised by the reports;

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

12. a certification from the IRO regarding its professional independence and objectivity with respect to EGS;

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

14. a summary of the disclosures in the disclosure log required by Section III.H that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

15. any changes to the process by which EGS fulfills the requirements of Section III.I regarding Ineligible Persons;

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

17. a description of all changes to the most recently provided list of EGS's locations (including addresses) as required by Section V.A.12; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s) (if applicable); and the name and address of each Medicare and state Medicaid program contractor to which EGS currently submits claims (if applicable); and

18. the certifications required by Section V.C.

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

C. Certifications

The Implementation Report and each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, EGS is in compliance with all of the requirements of this CIA;

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

3. to the best of his or her knowledge, EGS 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. Designation of Information

EGS 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. EGS 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

EGS:

Steven J. Hoffman
Sr. Director, Regulatory Affairs & Corporate Compliance Officer
EndoGastric Solutions
8210 154th Ave NE
Redmond, WA 90852
Telephone: 425.307.9226
Facsimile: 425.307.9201

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, EGS may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

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

VIII. DOCUMENT AND RECORD RETENTION

EGS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for one year after the end of the last Reporting Period (or longer if otherwise required by law).

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

EGS 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, EGS 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 EGS fails to establish and implement any of the following obligations as described in Section III:

   a. a Compliance Officer;

   b. a Compliance Committee;

   c. the Board of Directors compliance obligations;

   d. a written Code of Conduct;

   e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Covered Persons, and Board Members;

g. a Field Force Monitoring Program;

h. a Risk Assessment and Mitigation Program;

i. a Disclosure Program;

j. Ineligible Persons screening and removal requirements;

k. notification of Government investigations or legal proceedings; and

l. 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 EGS fails to engage and use an IRO, as required in Section III.G, Appendix A, and Appendix B.

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

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

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

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

B. Timely Written Requests for Extensions

EGS 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 EGS 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 EGS 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 EGS 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 EGS of: (a) EGS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, EGS 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 EGS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until EGS 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 EGS 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 EGS to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.K;

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

d. a failure to engage and use an IRO in accordance with Section III.G, Appendix A, and Appendix B.

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

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

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

EGS and OIG agree as follows:

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

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

C. OIG may agree to a suspension of EGS's obligations under this CIA based on a certification by EGS that it is no longer providing Government Reimbursed Products that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If EGS is relieved of its CIA obligations, EGS will be required to notify OIG in writing at least 30 days in advance if EGS plans to resume providing Government Reimbursed Products that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

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

E. 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 EGS

/Robert Michael Kleine/	2-6-2014
ROBERT MICHAEL KLEINE Executive Chairman EndoGastric Solutions Inc.	DATE
/Jonathan L. Diesenhaus/	2-7-14
JONATHAN L. DIESENHAUS Hogan Lovells US LLP Counsel for EndoGastric Solutions Inc.	DATE

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

/Robert K. DeConti/ 2/11/14

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

/Laura E. Ellis/ 2-7-14

LAURA E. ELLIS DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. EGS shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.11 of the CIA or any additional information submitted by EGS in response to a request by OIG, whichever is later, OIG will notify EGS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, EGS may continue to engage the IRO.

2. If EGS 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, EGS shall submit the information identified in Section V.A.11 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by EGS at the request of OIG, whichever is later, OIG will notify EGS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, EGS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Reviews who have expertise in all applicable Federal health care program requirements relating to Promotional Functions and Advice Functions performed; and for the Advice Functions, assign individuals who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

2. assign individuals to design and select the Encounters Review sample 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 Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare and Medicaid rules and reimbursement guidelines in making assessments in the Encounters Review;

3. if in doubt of the application of a particular Medicare or Medicaid policy or regulation, request clarification from the appropriate authority (e.g., Medicare contractor);

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

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

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

E. IRO Removal/Termination

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

2. *OIG Removal of IRO*. In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require EGS to engage a new IRO in accordance with Paragraph A of this Appendix. EGS must engage a new IRO within 60 days of termination of the IRO.

Prior to requiring EGS to engage a new IRO, OIG shall notify EGS 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, EGS may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with EGS prior to requiring EGS to terminate the IRO. However, the final determination as to whether or not to require EGS to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B
SYSTEMS REVIEW AND ENCOUNTERS REVIEW

I. General Description and Requirements

A. Retention of IRO

As specified more fully below, EGS shall retain an Independent Review Organization (IRO) to perform reviews to assist EGS in assessing and evaluating its systems, processes, policies, procedures, and practices related to EGS's Promotional Functions, Advice Functions, and, if applicable following CPT Publication, Risk Assessment and Mitigation Process. The IRO shall perform two reviews – a Systems Review and an Encounters Review or an Alternate Review in lieu of an Encounters Review, as described more fully below. EGS may engage, at its discretion, a single IRO to perform both Reviews provided that the entity has the necessary expertise and capabilities to perform both.

B. Performance of Systems Review

If there are no material changes in EGS's systems, processes, policies, and procedures relating to applicable Promotional Functions, Advice Functions, and/or the Risk Assessment and Mitigation Process, the IRO shall perform the Systems Review, as described in Section II.A of this Appendix B, for the first and fourth Reporting Periods, and for the Publication Reporting Period. If EGS materially changes its systems, processes, policies, and procedures relating to applicable Promotional Functions, Advice Functions, and/or the Risk Assessment and Mitigation Process, the IRO shall perform a Systems Review for Reporting Period(s) in which such changes were made in addition to conducting the Review for the Reporting Periods described above. The additional Systems Review(s) shall consist of: 1) an identification of the material changes, 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

C. Performance of Encounters Review and Opportunity to Request Alternate Review

The IRO shall conduct the Encounters Review, as described in Section III.B of this Appendix B, for each Reporting Period of the CIA unless the OIG grants a request by EGS to have the IRO perform a review of identified risks involving Government Reimbursed Products (Alternate Review). In any Reporting Period other than the first Reporting Period and the Publication Reporting Period, EGS and the IRO may submit a request and work plan to the OIG no later than 60 days prior to the end of the Reporting Period to perform an Alternate Review, consisting of a review of a risk identified by the

IRO or by EGS through its Risk Assessment and Mitigation Program in lieu of the Encounters Review. The work plan for the Alternate Review shall identify the subject of the review, how the review will be performed, and what will be contained in the Alternate Review Report. The OIG retains sole discretion over whether to allow the IRO to perform the Alternate Review instead of the Encounters Review.

D. OIG Review of Work Plans

The IRO shall provide OIG with its work plans for both Reviews 60 days prior to the end of each Reporting Period. If the IRO does not hear from the OIG before the end of the Reporting Period, it may assume that the OIG does not have any questions regarding the work plan for that Reporting Period. The lack of questions by the OIG regarding the work plan for a Reporting Period does not create a presumption regarding the acceptability of a work plan, even if unchanged, for subsequent Reporting Periods.

E. Supplemental Materials

The IRO shall request all documentation and materials required for its reviews at the start of the review. EGS shall furnish such documentation and materials to the IRO. If the IRO accepts any supplemental documentation or materials from EGS after the IRO has completed its initial review ("Supplemental Materials"), the IRO shall identify in its Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its Review. In addition, the IRO shall include a narrative in the applicable Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

II. Systems Review

A. Scope of Systems Review

The Systems Review shall be a review of EGS's systems, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to the following subjects ("Review Subjects"):

1. the performance and supervision of Promotional Functions;

2. the performance and supervision of Advice Functions; and

3. if applicable, the development and performance of the Risk Assessment and Mitigation Process.

Where practical, EGS 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 EGS pursuant to the preceding sentence.

B. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each Review Subject, 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 EGS's systems, policies, processes, and procedures relating to the Review Subject, including a general description of EGS's control and accountability systems and written policies regarding the Review Subject;

3. for the Promotional Functions and the Advice Functions, a description of the manner in which the control and accountability systems and written policies relating to the Review Subjects are made known or disseminated within EGS;

4. for the Promotional Functions and the Advice Functions, a detailed description of EGS's incentive compensation system for Relevant Covered Persons;

5. for the Advice Functions, a detailed description of the system used to track and respond to requests for billing and coding advice;

6. a description of any Supplemental Materials, as required by Section I.E above;

7. findings and supporting rationale regarding any weaknesses in EGS's systems, processes, policies, and procedures relating to the Review Subject, if any;

8. recommendations to improve any of the systems, policies, processes, or procedures relating to the Review Subject, if any; and

9. the names and credentials of the individuals who performed the Systems Review.

III. Encounters Review

The Encounters Review is comprised of two components: a review of the FFMP performed (FFMP Component) and a review of the billing and coding advice given regarding Government Reimbursed Products (Advice Component) during the relevant Reporting Period.

A. FFMP Component

The IRO shall review 100% of the Observations and Records Reviews conducted by the Monitoring Personnel. The review shall include, but is not limited to:

1. review of all reports, notes, records, and underlying documents; and

2. interviews of the Monitoring Personnel and, in the IRO's discretion, the sales representatives who were the subject of the Observation or Record Review and their managers.

B. Advice Component

The IRO shall randomly select and review a sample of up to 50 records of billing and coding advice provided about Government Reimbursed Products during the Reporting Period. The review shall include, but is not limited to:

1. review of all reports, notes, records, and underlying documents, including, at the IRO's discretion, records related to any Covered Person's Promotional Functions with the requestor;

2. interviews of the Covered Persons who provided the billing and coding advice, and their managers; and, at the IRO's discretion, the Covered Person who engages in Promotional Functions with the requestor; and

3. an assessment as to whether EGS relied on the relevant laws, regulations, CPT manual, and program guidance in providing the billing and coding advice.

C. IRO Encounters Review Report.

The IRO shall prepare a report based upon each Encounters Review. For each Component of the Review, the report shall include the following items:

1. a description of the documentation reviewed and personnel interviewed;

2. for the Advice Component, a description of the laws, regulations, CPT manual, and program guidance relied upon by the IRO;

3. a narrative description of how the Review was conducted and the IRO's findings, including providing, to the extent that the IRO disagrees with EGS's, the IRO's findings and the IRO's support for its findings.

4. a description of any Supplemental Materials, as required by Section I.E above,

5. the IRO's observations and recommendations for improvement of the FFMP, or the performance of the Promotional Functions or the Advice Functions, and

6. the names and credentials of the individuals who performed the Encounters Review.