

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

**I. PREAMBLE**

ELA Medical, Inc. (ELA) 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, ELA is entering into a Settlement Agreement with the United States.

Prior to the effective date of this CIA, ELA, established a voluntary compliance program, which includes a Compliance Officer, a Compliance Committee, a compliance hotline, a non-retaliation policy, sanctions for compliance-related violations, compliance training (including training in ELA's Code of Conduct and Compliance Program, the AdvaMed Code of Ethics on Interactions with Health Care Professionals, the Antikickback Statute, and HIPAA), auditing and monitoring, and other policies. ELA shall continue to apply the voluntary compliance program to its operations throughout the term of the CIA and shall do so in accordance with the terms set forth below. The voluntary compliance program may be modified, as deemed appropriate by ELA, but at a minimum, ELA shall ensure that, during the term of this CIA, it shall comply with the obligations as set forth herein.

## II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by ELA 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, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) ELA's final annual report; or (2) any additional materials submitted by ELA pursuant to OIG's request, whichever is later.

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

1. "Arrangements" shall mean every arrangement or transaction entered into by or on behalf of ELA that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between ELA and any actual or potential source of referrals or sales of Government Reimbursed Products. The term "source" shall include any distributor, physician or other health care provider, contractor, vendor, or agent; and the term "referrals or sales" shall be read to include referring, recommending, arranging for, ordering, prescribing, or purchasing of Government Reimbursed Products.

2. "Focus Arrangements" means every Arrangement that is between ELA and any actual source of Government Reimbursed Product referrals or sales and involves, directly or indirectly, the offer, payment, or provision of anything of value. Focus Arrangements include, but are not limited to: speaker fees and speaker-related fees; honoraria; consultant fees; personal service arrangements; management or administrative arrangements; educational grants; charitable contributions; clinical or research grants; clinical or research agreements; advisory boards; continuing medical education sponsorships; marketing service fees; reimbursement support programs; data purchasing arrangements; and any other Arrangement that involves payment to any individuals or entity, including but not limited to

any distributor, wholesaler, supplier, physician, or other health care provider pursuant to a fee for service agreement

3. "Covered Persons" includes:

- a. all owners who are natural persons, officers, directors, and employees of ELA;
- b. all contractors, subcontractors, agents, and other persons who, on behalf of ELA perform functions related to the sale or marketing of Government Reimbursed Products; and
- c. all individuals that sell or market, on behalf of ELA, Government Reimbursed Products.

Notwithstanding the above, this term does not include: (1) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year; or (2) employees, contractors, subcontractors, agents, and other persons who, on behalf of ELA, perform only (i) product building, movement, inspection, manufacturing, or warehouse functions, including product builders, inspectors, and material handlers; (ii) physical plant maintenance and janitorial duties, cafeteria-related duties, and/or similar non-core ELA business related duties.

4. "Arrangements Covered Persons" includes each Covered Person who is involved with the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of ELA's Arrangements.

5. "Government Reimbursed Products" refers to all devices and other items that are marketed, distributed, sold, or promoted by ELA and reimbursed, in whole or in part, by Federal health care programs.

### III. CORPORATE INTEGRITY OBLIGATIONS

ELA shall continue to maintain a Compliance Program that includes the following elements:

#### A. Compliance Officer and Committee.

1. *Compliance Officer.* ELA has appointed 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 ELA, shall report directly to the President of ELA, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of ELA, 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 ELA 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.

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

2. *Compliance Committee.* Within 90 days after the Effective Date, ELA 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 finance, billing, human resources, audit, sales and marketing, 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 ELA's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

ELA 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.

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, ELA developed, implemented, and distributed a written Code of Conduct to all Covered Persons. ELA shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all Covered Persons. The Code of Conduct shall, at a minimum, continue to set forth:

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

To the extent not already accomplished, 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 ELA'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.

ELA 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.* Prior to the Effective Date, ELA implemented written Policies and Procedures regarding the operation of ELA's compliance program, including the compliance program requirements outlined in this CIA, and ELA's compliance with Federal health care program requirements. The Policies and Procedures also shall address:

a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute) and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute; and

b. the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute).

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), ELA shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all Covered Persons whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days after the Effective Date, ELA shall provide at least one hour of General Training to each Covered Person. This training, at a minimum, shall explain ELA's:

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

For Covered Persons who have received general training within the 60 days prior to the Effective Date, the initial General Training described above need only address ELA's CIA requirements and any changes to its Compliance Program as a result of the CIA. 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. *Arrangements Training.* Within 120 days after the Effective Date, each Arrangements Covered Person shall receive at least two hours of Arrangements Training, in addition to the General Training required above. The Arrangements Training shall include a discussion of:

- a. Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to these statutes;
- b. ELA's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA;

- c. the personal obligation of each individual involved in the development, approval, management, or review of ELA's Arrangements to know the applicable legal requirements and the ELA's policies and procedures;
- d. the legal sanctions under the Anti-Kickback Statute; and
- e. examples of violations of the Anti-Kickback Statute.

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

After receiving the initial Arrangements Training described in this Section, each Arrangements Covered Person shall receive at least two hours of Arrangements 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.

5. *Update of Training.* ELA 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 or the Arrangements Review, and any other relevant information.

6. *Computer-based Training.* ELA may provide the training required under this CIA through appropriate computer-based training approaches. If ELA 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. Compliance with the Anti-Kickback Statute.

1. *Focus Arrangements Procedures.* Within 120 days after the Effective Date, ELA shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations, directives, and guidance related to this statute (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements (Focus Arrangements Tracking System);
- b. tracking remuneration to and from all parties to Focus Arrangements;
- c. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s);
- d. establishing and implementing a written review and approval process for all Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute, and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) a process for specifying the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;
- e. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and

f. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events pursuant to Sections III.I when appropriate.

2. *New or Renewed Arrangements.* Prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, ELA shall comply with the following requirements (Focus Arrangements Requirements):

a. Ensure that each Focus Arrangement is set forth in writing and signed by ELA and the other parties to the Focus Arrangement;

b. Include in the written agreement a requirement that each party to a Focus Arrangement who meets the definition of a Covered Person shall complete the Arrangements Training required by Section III.C.2 of this CIA. Additionally, ELA shall provide each party to the Focus Arrangement with a copy of its Code of Conduct and Anti-Kickback Statute Policies and Procedures;

c. Include in the written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

3. *Records Retention and Access.* ELA shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

#### E. Review Procedures.

##### 1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, ELA shall engage an individual or entity (or entities), such as an accounting, auditing, law, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the following reviews: (i) a review to assist ELA in assessing its compliance with the obligations pursuant to Section III.D of this CIA (Arrangements Review). The IRO engaged by ELA to perform the Arrangements Review shall be knowledgeable about the Anti-Kickback Statute and the regulations and other guidance documents related to these statutes.

The IRO shall assess, along with ELA, whether it can perform the IRO review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or other engagements that may exist. The engagement of the IRO for the Arrangements Review shall not be deemed to create an attorney-client relationship between ELA and the IRO. The other applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

b. *Frequency of Arrangements Review.* The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Arrangements Review.

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

e. *Responsibilities and Liabilities.* Nothing in this Section III.E affects ELA's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.

2. *Arrangements Review.* The IRO shall perform a review to assess whether ELA is complying with the Focus Arrangements Procedures and Focus Arrangements Requirements required by Sections III.D.1 and III.D.2 of this CIA (Arrangements Review). The Arrangements Review shall consist of two components – a systems review and a transactions review. The Arrangements Systems Review shall assess ELA's systems, processes, policies, and procedures relating to Arrangements, including ELA's implementation of the Focus Arrangements Procedures (including the Focus Arrangement Tracking System) and Focus Arrangements Requirements. If there are no material changes to ELA's systems, processes, policies, and procedures relating to Arrangements, the Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If ELA materially changes the relevant Arrangements systems, processes, policies and procedures, the IRO shall perform an Arrangements 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 Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO shall perform all components of each Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review of a randomly selected sample of 40 Focus Arrangements that were entered into or renewed during the Reporting Period. The IRO shall assess for each selected Focus Arrangement whether ELA has complied with the Focus Arrangements Procedures and Focus Arrangements Requirements specifically with respect to that Focus Arrangement. The applicable procedures and reporting requirements for the Arrangements Review are outlined in Appendix B to this CIA which is incorporated by reference.

3. *Arrangements Review Report.* The IRO shall prepare a report based upon the Arrangements Review performed (Arrangements Review Report). The information to be included in the Arrangements Review Report is described in Appendix B.

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

Prior to initiating a Validation Review, OIG shall notify ELA 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, ELA may request a meeting with OIG to: (a) discuss the results of any Arrangements Review submissions or findings; (b) present any additional information to clarify the results of the Arrangements Review or to correct the inaccuracy of the Arrangements Review; and/or (c) propose alternatives to the proposed Validation Review. ELA agrees to provide any additional information as may be requested by OIG under this Section III.E.8 in an expedited manner. OIG will attempt in good faith to resolve any Arrangements Review issues with ELA 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.

*5. Independence and Objectivity Certification.* The IRO shall include in its report(s) to ELA 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 Arrangements Review and that it has concluded that it is, in fact, independent and objective.

#### F. Disclosure Program.

Prior to the Effective Date, ELA established 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 ELA'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. ELA shall continue to 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 continue to 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, ELA 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.

G. Ineligible Persons.

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

- a. an "Ineligible Person" shall include an individual or entity who:
  - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include:
  - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).

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

a. ELA shall screen all 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. ELA shall screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on an annual basis thereafter.

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

3. *Removal Requirement.* If ELA has actual notice that a Covered Person has become an Ineligible Person, ELA shall remove such Covered Person from responsibility for, or involvement with, ELA'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 ELA 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 of during the term of a physician's or other practitioner's medical staff privilege, ELA shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

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

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

#### I. Reportable Events.

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

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

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

2. *Reporting of Reportable Events.* If ELA determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, ELA shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. 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 ELA's actions taken to correct the Reportable Event;
- c. any further steps ELA plans to take to address the Reportable Event and prevent it from recurring; and
- d. if the Reportable Event relates to the filing of a bankruptcy petition, the report to the OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program authorities implicated.

#### IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, ELA changes locations or closes a business unit or location related to the sales and marketing of Government Reimbursed Products, ELA 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, ELA purchases or establishes a new business unit or location related to the sales and marketing of Government Reimbursed Products, ELA 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, the 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 ELA currently submits claims (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, ELA proposes to sell any or all of its business units or locations that are subject to this CIA, ELA shall notify OIG of the proposed sale at least 30 days prior to 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.

D. For purposes of this Section IV, "business unit or location" shall mean physical places of business where employees routinely carry out job responsibilities and does not include non-ELA-owned or leased properties such as offices operated out of individuals' residences.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 180 days after the Effective Date, ELA 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. a copy of ELA's Code of Conduct required by Section III.B.1;
4. a summary of all Policies and Procedures required by Section III.B.2 (a

copy of such Policies and Procedures shall be made available to OIG upon request);

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

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

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

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

7. a description of the Focus Arrangements Tracking System required by Section III.D.1.a;

8. a description of the internal review and approval process required by Section III.D.1.d;

9. a description of the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;

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

11. 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 ELA and the IRO;

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

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

14. a list of all of ELA's locations (including locations and mailing addresses, but excluding the non-ELA owned or leased properties such as offices operated out of individuals' residences); 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 ELA currently submits claims (if applicable);

15. a description of ELA'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. ELA shall submit to OIG annually a report with respect to the status of, and findings regarding, ELA'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. 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 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);

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 description of any changes to the Focus Arrangements Tracking System required by Section III.D.1.a;

6. a description of any changes to the internal review and approval process required by Section III.D.1.d;

7. a description of any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

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

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

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

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

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

13. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remunerations or inappropriate referrals in violation of the Anti-Kickback Statute;

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

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

17. a description of all changes to the most recently provided list of ELA's locations (including addresses, but excluding the non-ELA owned or leased properties such as offices operated out of individuals' residences) as required by Section V.A.14; 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 ELA 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 Annual Reports shall include a

certification by the Compliance Officer that:

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

2. to the best of his or her knowledge, ELA has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute, including the Focus Arrangements Procedures required in Section III.D of the CIA;

3. to the best of his or her knowledge, ELA has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.2 of the CIA;

4. 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

5. to the best of his or her knowledge, ELA 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. ELA 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. ELA 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

ELA:

Ted S. Biderman  
Compliance Officer  
14401 W. 65<sup>th</sup> Way  
Arvada, CO 80004  
Telephone: 303.425.5508  
Facsimile: 303.467.6584

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, ELA 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.

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

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

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

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

ELA 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, ELA 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 ELA 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 Arrangements Covered Persons;
- f. the Focus Arrangements Procedures and/or Focus Arrangements Requirements described in Sections III.D.1 and III.D.2;
- g. a Disclosure Program;
- h. Ineligible Persons screening and removal requirements;
- i. notification of Government investigations or legal proceedings;  
and
- j. 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 ELA fails to engage an IRO, as required in Section III.E and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day ELA 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 ELA fails to submit the annual

Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of ELA 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 ELA fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to ELA stating the specific grounds for its determination that ELA has failed to comply fully and adequately with the CIA obligation(s) at issue and steps ELA shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after ELA 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. ELA 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 ELA 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 ELA 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 ELA 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 ELA of: (a) ELA'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, ELA 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 ELA elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ELA 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 ELA 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 failure by ELA to report a Reportable Event and take corrective action, as required in Section III.I;
  - b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

- 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.D and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by ELA constitutes an independent basis for ELA's exclusion from participation in the Federal health care programs. Upon a determination by OIG that ELA has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify ELA of: (a) ELA'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.* ELA 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. ELA 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) ELA has begun to take action to cure the material breach; (ii) ELA is pursuing such action with due diligence; and (iii) ELA has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, ELA fails to satisfy the requirements of Section X.D.3, OIG may exclude ELA from participation in the Federal health care programs. OIG shall notify ELA in writing of its determination to exclude ELA (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 ELA'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, ELA 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 ELA 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, ELA 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 ELA was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. ELA 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 ELA to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless ELA 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 ELA 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) ELA had begun to take action to cure the material breach within that period; (ii) ELA has pursued and is pursuing such action with due diligence; and (iii) ELA provided to OIG within that period a reasonable timetable for curing the material breach and ELA 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 ELA, only after a DAB decision in favor of OIG. ELA's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude ELA 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 ELA 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. ELA 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 ELA, ELA 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**

ELA and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of ELA;
- 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;
- D. OIG may agree to a suspension of ELA's obligations under this CIA based on a certification by ELA that it is no longer providing health care items or services 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 ELA is relieved of its CIA obligations, ELA will be required to notify OIG in writing at least 30 days in advance if ELA plans to resume providing health care items or services 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.
- E. The undersigned ELA 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 ELA

/Ted S. Biderman/

\_\_\_\_\_  
TED. S. BIDERMAN  
Compliance Officer

10-21-10

\_\_\_\_\_  
DATE

/Heidi A. Sorensen/

\_\_\_\_\_  
HEIDI A. SORENSEN  
Foley & Lardner LLP  
Counsel for ELA

10 / 21 / 2010  
\_\_\_\_\_  
DATE



## APPENDIX A

### INDEPENDENT REVIEW ORGANIZATION

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

#### A. IRO Engagement.

ELA 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 and Section V.A.12 of the CIA, OIG will notify ELA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ELA may continue to engage the IRO.

If ELA 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, ELA shall submit the information identified in Section V.A.11 and Section V.A.12 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information, OIG will notify ELA if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ELA may continue to engage the IRO.

#### B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Arrangements Review engagement who are knowledgeable in the requirements of the Anti-Kickback Statute and the Stark Law and the regulations and other guidance documents related to these statutes; and

2. 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 Arrangements Review in accordance with the specific requirements of the CIA;

2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. 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 Arrangements 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 ELA.

E. IRO Removal/Termination.

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

Prior to requiring ELA to engage a new IRO, OIG shall notify ELA 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, ELA 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. ELA 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 ELA prior to requiring ELA to terminate the IRO. However, the final determination as to whether or not to require ELA to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### ARRANGEMENTS REVIEW

A. Arrangements Systems Review. The Arrangements Systems Review shall be a review of ELA's systems, processes, policies, and procedures relating to the initiation, review, approval, and tracking of Arrangements. Specifically, the IRO shall review the following:

1. ELA's systems, policies, processes, and procedures with respect to creating and maintaining a centralized tracking system for all existing and new and renewed Focus Arrangements (Focus Arrangements Tracking System), including a detailed description of the information captured in the Focus Arrangements Tracking System;

2. ELA's systems, policies, processes, and procedures for tracking remuneration to and from all parties to Focus Arrangements;

3. ELA's systems, policies, processes, and procedures for tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);

4. ELA's systems, policies, processes, and procedures for initiating Arrangements, including those policies that identify the individuals with authority to initiate an Arrangement and that specify the business need or business rationale required to initiate an Arrangement;

5. ELA's systems, policies, processes, and procedures for the internal review and approval of all Arrangements, including those policies that identify the individuals required to approve each type or category of Arrangement entered into by ELA, the internal controls designed to ensure that all required approvals are obtained, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

6. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, ELA's internal review and approval process, and other Arrangements Procedures;

7. ELA's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events; and

8. ELA's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA.

B. Arrangements Systems Review Report. The IRO shall prepare a report based upon each Arrangements Systems Review performed. The report shall include the following items:

1. a description of the documentation (including policies) reviewed and personnel interviewed;

2. a detailed description of ELA's systems, policies, processes, and procedures relating to the items identified in Section A.1-9 above;

3. findings and supporting rationale regarding weaknesses in ELA's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-9 above; and

4. recommendations to improve ELA's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-9 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 40 randomly selected Focus Arrangements that were entered into or renewed by ELA during the Reporting Period. The IRO shall assess whether ELA has complied with the Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Focus Arrangements.

The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

1. verifying that the Focus Arrangement is maintained in ELA's centralized tracking system in a manner that permits the IRO to identify the parties to the Focus Arrangement and the relevant terms of the Focus Arrangement (i.e., the items/services/equipment/space to be provided, the amount of compensation, the effective date, the expiration date; etc.)

2. verifying that the Focus Arrangement was subject to the internal review and approval process (including both the legal review and business needs process as set forth in Section III.D.1.d of the CIA) and obtained the necessary approvals and that such review and approval is appropriately documented;

3. verifying that the remuneration related to the Focus Arrangement is properly tracked;

4. verifying that the service and activity logs are properly completed and reviewed (if applicable);

5. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

D. Arrangements Transaction Review Report. The Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

a. 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 the sample reviewed.

b. Sources of Data: A full description of the documentation and other information, if applicable, relied upon by the IRO in performing the Arrangements Transaction Review.

2. *Review Findings*. The IRO's findings with respect to whether ELA has complied with the Arrangements Procedures and Focus Arrangements Requirements with respect to each of the randomly selected Focus Arrangements reviewed by the IRO. In addition, the Arrangements Transactions Review Report shall include observations, findings and recommendations on possible improvements to ELA's policies, procedures, and systems in place to ensure that all Focus Arrangements comply with the Arrangements Procedures and Focus Arrangements Requirements.