

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

I. PREAMBLE

Semler Scientific, Inc. and its wholly-owned subsidiary CardioVanta, Inc. (collectively “Semler”) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Semler is entering into a Settlement Agreement with the United States.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The “Effective Date” of this CIA shall be the signature date of the final signatory of this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG’s receipt of: (1) Semler’s final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. In addition, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.E.2 prior to the expiration of the 120-day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 has been completed, and Semler complies with the decision.

C. Definitions.

1. “Certifying Covered Persons” means the following: Chief Technology Officer, Chief Operating Officer, Chief Financial Officer, Vice President of Manufacturing and Engineering, Chief Innovation Officer, Senior Vice President of Business Development, Vice President of Regulatory Affairs, Quality Assurance, and Compliance.

2. “Covered Functions” means: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to Semler’s review and approval processes for promotional materials; (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to Semler’s review and approval process for any non-promotional materials; and (d) contracting with health care professionals (HCPs) for consulting services (including but not limited to training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating to Government Reimbursed Products), or other fee-for service arrangements relating to Government Reimbursed Products.

3. “Covered Persons” means: (a) all owners of Semler who are natural persons are (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading); (b) all officers, board members, and employees of Semler who are engaged in or supervise personnel who are engaged in Covered Functions; and (c) all contractors who perform any of the Covered Functions on behalf of Semler. Covered Person 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.

4. “Covered Recipient” is defined for purposes of Section III.N of this CIA, as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by the Centers for Medicare and Medicaid Services (CMS).

5. “Disclosure Program” means a program that enables individuals to disclose to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command any potential violations of criminal, civil or administrative law related to the Federal health care programs or any issues or questions associated with Semler’s policies, conduct, practices, or procedures.

6. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at <http://www.oig.hhs.gov>).

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

8. “Ineligible Person” means an individual or entity who: (a) is currently excluded from participation in any Federal health care program or (b) has been convicted of a

criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a) (mandatory exclusion) but has not yet been excluded from participation in any Federal health care program.

9. “Payments” is defined for purposes of Section III.N of the CIA as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

10. “Reportable Event” means: (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 criminal or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the “Act”) or exclusion under Section 1128 of the Act may be authorized; (b) a matter that a reasonable person would consider a probable violation of FDA requirements relating to the marketing or sale of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by Semler.

11. “Reporting Period” means each one-year period during the term of this CIA, beginning with the one-year period following the Effective Date.

12. “Sponsorships” means support for a program, event, or organization in return for the advertisement, or promotion of Semler products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

13. “Third Party Educational Activity” means any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Semler, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

14. “Training Plan” means a written plan that outlines the steps Semler will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding Semler’s CIA requirements and compliance program, and that all Covered Persons who engage in Covered Functions receive training on a periodic basis during the term of the CIA regarding: (a) all applicable Federal health care program and FDA requirements relating to Covered Functions and (b) all Semler Policies and Procedures and other requirements applicable to Covered Functions.

15. “Transition Plan” means a plan to address whether and how Semler’s compliance program will continue to include the compliance program requirements set forth in Section III of the CIA, following the end of the CIA’s term.

III. COMPLIANCE PROGRAM REQUIREMENTS

Semler shall establish and maintain a compliance program that includes the following elements:

A. Compliance Officer, Compliance Committee, Board Oversight, and Management Certifications.

1. *Compliance Officer.* Within 90 days after the Effective Date, Semler shall appoint a Compliance Officer who is an employee and a member of senior management of Semler. The Compliance Officer shall report directly to the Chief Executive Officer of Semler and shall not be or be subordinate to the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Semler. The Compliance Officer shall be authorized to report to the Board of Directors of Semler regarding compliance matters at any time. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making at least quarterly reports regarding compliance matters to the Board;
- c. monitoring the day-to-day compliance activities engaged in by Semler; and
- d. all reporting requirements of this CIA.

The Compliance Officer shall not have any noncompliance job responsibilities that, in OIG's discretion, may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

Semler shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five business days after such a change.

2. *Compliance Committee.* Within 120 days after the Effective Date, Semler shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.N below. The Compliance Committee shall meet at least quarterly.

Semler shall report to OIG, in writing, any changes to the membership of the Compliance Committee within 15 business days after such a change.

3. *Board Oversight.* The Board (or a committee of the Board) (“Board”) shall be responsible for the review and oversight of Semler’s compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

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

- a. meeting at least quarterly to review and oversee Semler’s compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the materials it reviewed, and any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; and
- c. for each Reporting Period of the CIA, adopting a resolution, approved by each member of the Board regarding its review and oversight of Semler’s compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Semler’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, Semler has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of Semler’s Corporate Integrity Agreement with the Office of Counsel to the Inspector General for the Department of Health and Human Services.”

If the Board is unable to adopt such a resolution, the Board shall provide a written explanation of the reasons why it is unable to adopt the resolution and the steps it is taking to implement an effective compliance program at Semler.

Semler shall report to OIG, in writing, any changes to the membership of the Board, within 15 business days after such a change.

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the business unit for which they are responsible and annually certify that the applicable Semler business unit is in compliance with applicable Federal health care program and FDA requirements and with the requirements of this CIA. For each Reporting Period, each Certifying Covered Person shall certify as follows:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of business unit], an area under my supervision. My job responsibilities include ensuring [business unit]’s compliance with all applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, and Semler’s policies and procedures. To the best of my knowledge, the [insert name of business unit] of Semler is in compliance with all applicable Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Covered Person is unable to provide such a certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 120 days after the Effective Date, Semler shall develop and implement a written process for Certifying Covered Persons to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Covered Person making the required certification).

B. Written Standards. Within 120 days after the Effective Date, Semler shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of its compliance program, including the compliance program requirements outlined in this CIA and (2) Semler’s compliance with Federal health care program and FDA requirements. Semler shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

1. appropriate ways to conduct Covered Functions in compliance with all: (a) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the False Claims Act, 31 U.S.C. §§ 3729-3733, and (b) all applicable FDA requirements;

2. the materials and information that may be distributed by Semler sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Semler sales representatives respond to requests for information about uses

of Government Reimbursed Products that are not FDA approved, cleared or exempt (“non-FDA approved uses”);

3. the materials and information that may be distributed and the mechanisms through, and manner in which, Semler receives and responds to requests for information from an HCP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Semler in response to such requests; and the internal review process for the information disseminated;

4. the manner and circumstances under which Semler medical personnel interact with or participate in meetings or events with HCPs, health care institutions (HCIs), or payors (either alone or with Semler sales representatives) and the role of Semler medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

5. the materials and information that may be distributed or made available by Semler through social media and/or direct-to-consumer advertising;

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

7. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCP participation in educational, research, training, or other Semler-sponsored programs or activities;

8. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.10 and II.C.11 above;

9. review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Semler by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Semler’s review and approval process and are elevated when appropriate;

10. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

11. disciplinary policies and procedures for violations of Semler’s Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

The Compliance Committee shall review the Policies and Procedures at least annually and update the Policies and Procedures, as necessary. Any new or revised Policies and Procedures shall be made available to all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, Semler shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of Covered Persons and required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Compliance Committee shall review the Training Plan at least annually and update the Training Plan as necessary.

2. *Board Training.* Within 120 days after the Effective Date, members of the Board shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity and shall include a discussion of OIG's guidance on board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C. 2 above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

3. *Training Records.* Semler shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Semler shall engage an entity ("Independent Review Organization" or "IRO") that meets the qualifications outlined in Appendix A to this CIA, which is incorporated by reference, to perform the reviews described in this Section III.D.

b. *Retention of Records.* The IRO and Semler shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged

between the IRO and Semler related to the reviews described in this Section III.D.

- c. *Access to Records and Personnel.* Semler shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.D, and that all records furnished to the IRO are accurate and complete.

2. *Systems Review and Transactions Review.* The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions and shall prepare a Systems Review Report and a Transactions Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Semler a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.D; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between Semler and the IRO.

E. Risk Assessment and Internal Review Process. Within 120 days after the Effective Date, Semler shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Semler to: (1) identify and prioritize risks, (2) develop work plans or internal audit plans (as appropriate) related to the prioritized risk areas, (3) implement the work plans and internal audit plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the work plans and any corrective action plans and assess the effectiveness of such plans.

F. Disclosure Program. Within 120 days after the Effective Date, Semler shall establish a Disclosure Program. Semler shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas). The Disclosure Program shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program shall prohibit retaliation against Covered Persons relating to the use of the Disclosure Program and Semler shall not retaliate against Covered Persons for use of the Disclosure Program. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering all relevant information from the disclosing individual, and ensure that appropriate follow-up is conducted.

The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements) in a written disclosure log within two business days of receipt of the disclosure. The disclosure log shall include the following information: (1) a summary of each disclosure received (whether anonymous or not), (2) the date the disclosure was received, (3) the individual or department responsible for reviewing the disclosure, (4) the status of the review, (5) any corrective action taken in response to the review, and (6) the date the disclosure was resolved.

G. Ineligible Persons.

1. *Screening Requirements.* Semler shall:

- a. 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. screen all Covered Persons against the Exclusion Lists within 120 days after the Effective Date and on a monthly basis thereafter; and
- c. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement.* If Semler has actual notice that a Covered Person has become an Ineligible Person, Semler 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 any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and Semler may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Semler meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Semler shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Semler has committed a crime or has engaged in fraudulent activities, within 30 days of Semler receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of the investigation or legal proceeding. Within 30 days after resolution of the matter, Semler shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Semler shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Probable Violation of Law*. The report to OIG shall include:
 - a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
 - b. a statement of the Federal criminal, civil or administrative laws that are probably violated by the Reportable Event, if any;
 - c. the Federal health care programs affected by the Reportable Event, if any; and
 - d. a description of Semler's actions taken to correct the Reportable Event and prevent it from recurring.

include:

2. *Probable Violation of FDA Requirements*. The report to OIG shall

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;
- b. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- c. a description of Semler's actions taken to correct the Reportable Event and prevent it from recurring.

3. *Ineligible Person*. The report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;

- c. a description of the Exclusion Lists screening that Semler completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

4. *Bankruptcy*. The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program or FDA requirements implicated.

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Semler and the FDA that materially discusses Semler's or a Covered Person's actual or potential unlawful or improper marketing or sale of Semler's products, Semler shall provide a copy of the report, correspondence, or communication to OIG. Within 30 days after resolution of the matter, Semler shall notify OIG, in writing, of the resolution.

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

1. *Observations*. As a component of the FFMP, Monitoring Personnel shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered, and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Semler'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 and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes: (a) the identity of the sales representative; (b) the identity of the Monitoring Personnel who conducted the Observation; (c) the date and duration of the Observation; (d) the product(s) promoted during the Observation; (e) an overall assessment of compliance with

Semler Policies and Procedures; and (f) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 5 Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, Semler shall also review various types of records to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Semler shall develop and implement a plan for conducting Records Reviews associated with at least two Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.
- b. The Records Reviews shall include the monitoring and review of:
 - (i) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records relating to consulting and other fee-for-service arrangements, speaker program activities, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
 - (ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;
 - (iii) sales representative call notes;
 - (iv) sales representatives' e-mails and other electronic records; and
 - (v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

3. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

L. Requirements Relating to Certain Non-Promotional Activities. To the extent that Semler engages HCPs for services other than for speaker programs (e.g., training and education

services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs shall be referred to herein as Consultants. Within 120 days after the Effective Date, Semler shall develop the following for all Consultant activities

1. Require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance requirements for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.
2. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year and (ii) the budgeted amounts to be spent on Consultant-related activities. Semler compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Semler Policies and Procedures.
3. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by Semler compliance personnel.
4. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, Semler receives the work product generated by the Consultant.

M. Reporting of Physician Payments. Within 120 days after the Effective Date, Semler shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). Semler also shall include on its website instructions

regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Semler.

N. Transition Plan. Prior to the end of the fourth Reporting Period, Semler shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be implemented following the end of the CIA's term. A copy of Semler's approved Transition Plan shall be included in Semler's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, Semler proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that engage in any of the Covered Functions; or (b) purchases or establishes a new business, business unit or location relating to or that will engage in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location and any new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Semler shall notify OIG, in writing, of such sale or purchase within 30 days following the closing of the transaction and shall notify OIG, in writing, within 30 days of establishing such new business, business unit or location.

If Semler wishes to obtain a determination by OIG that a proposed purchase or proposed acquisition will not be subject to the CIA requirements, Semler must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, Semler shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;

4. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. 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; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Semler that includes a summary of all current and prior engagements between Semler and the IRO;
8. a description of the risk assessment and internal review process required by Section III.E;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;
11. a description of the FFMP required by Section III.K;
12. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.L;
13. a certification from the Compliance Officer that information regarding Payments has been posted on Semler's website as required by Section III.M;
14. a list of all of Semler's locations (including mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s), if any;
15. a description of Semler's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

- that:
16. a certification by the Compliance Officer and Chief Executive Officer
 - a. to the best of his or her knowledge, except as otherwise described in the report, Semler has implemented and complies with is in compliance with all requirements of this CIA;
 - b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
 - c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Semler shall submit a written report (Annual Report) to OIG for each of the five Reporting Periods that includes, at a minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance requirements; and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;
2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);
3. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
4. the Board resolution required by Section III.A.3, a description of the materials reviewed by the Board and any additional steps taken in its oversight of the compliance program and in support of making the resolution;
5. a description of any changes to the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;
6. the certifications of Certifying Covered Persons required by Section III.A.4;
7. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;

8. a description of any changes to the Training Plan required by Section III.C and a summary of all training furnished to Covered Persons and Board members during the Reporting Period;

9. a complete copy of all reports prepared pursuant to Section III.D and Semler's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

10. a certification from the IRO regarding its professional independence and objectivity with respect to Semler, including a summary of all current and prior engagements between Semler and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;

12. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (b) internal audits performed, (c) corrective action plans developed in response to internal audits, and (d) steps taken to track the implementation of the work plans and any corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

13. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;

15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

16. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;

17. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J that includes a description of each matter and the status of each matter;

18. the results of the FFMP required by Section III.K, including copies of the

Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that Semler took as a result of such determinations;

19. a summary of any changes to the policies, procedures, and systems relating to the Requirements for Certain Non-Promotional Activities described in Section III.L, including the reason(s) for such changes;

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

21. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.N;

22. a description of all changes to the most recently provided list of Semler's locations (including addresses) as required by Section V.A.15;

23. a description of any changes to Semler's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

24. a certification by the Compliance Officer and Chief Executive Officer that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Semler has implemented and complies with is in compliance with all requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States.

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. Designation of Information. Semler 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. Semler 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 using the following contact information:

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
Telephone: 202.619.2078
Email Address: officeofcounsel@oig.hhs.gov

Semler:

Gena D. Parker Vice President, RA/QA & Compliance
Semler Scientific Inc.
Telephone: (669) 230-2729
Email Address: gparker@semlerscientific.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify Semler in writing of any changes to the OIG contact information listed above. Semler shall notify OIG in writing within two business days of any changes to the Semler contact information listed above.

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 conduct interviews, examine and/or request copies of or copy Semler's books, records, and other documents and supporting materials, and conduct on-site reviews of any of Semler's locations, for the purpose of evaluating: (a) Semler's compliance with the terms of this CIA and (b) Semler's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Semler to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Semler's owners (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members 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. Semler shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Semler's owners, employees, contractors and Board members may elect to be interviewed with or without a representative of Semler present.

VIII. DOCUMENT AND RECORD RETENTION

Semler shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Semler prior to any release by OIG of information submitted by Semler pursuant to its requirements under this CIA and identified upon submission by Semler as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Semler shall have the rights set forth at 45 C.F.R. § 5.42(a).

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.I;

10. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.K;
12. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.L;
13. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.M;
14. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section III.N;
15. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section IV;
16. A Stipulated Penalty of up to \$2,500 for each day Semler fails to comply with Section V;
17. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of Semler under this CIA.

B. Timely Written Requests for Extensions. Semler 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. 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 Semler fails to meet the revised deadline set by OIG. 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 Semler 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.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Semler of: (a) Semler's failure to comply and (b) OIG's demand for payment of Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Semler shall either: (a) 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.

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.

D. Exclusion for Material Breach

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;
- d. failure to comply with Section III.I;
- e. failure to comply with Section V;
- f. failure to respond to a Demand Letter in accordance with Section X.C;
- g. a false statement or false certification made to OIG by or on behalf of Semler under this CIA;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Semler to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

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

Upon a preliminary determination by OIG that Semler has materially breached this CIA, OIG shall notify Semler of: (a) Semler’s material breach and (b) OIG’s intent to exclude Semler (this notification is hereinafter referred to as the “Notice of Material Breach and Intent to Exclude”).

3. *Response to Notice.* Semler shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Semler in writing of its determination to exclude Semler (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 the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Semler, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Semler 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 issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Semler 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. 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 DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a hearing can be found at <https://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-alj/procedures/index.html>.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Semler was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Semler shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG’s determination that Semler has breached this CIA and orders Semler to pay Stipulated Penalties, Semler must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Semler properly and

timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Semler must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Semler was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. 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. Semler shall waive its right to any notice of such exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Semler, Semler shall be reinstated effective on the date of the 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. 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 and Semler agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Semler and OIG agree as follows:

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

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Semler's responsibility to follow all applicable Federal health care program and FDA requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program or FDA requirements.

C. The undersigned Semler signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

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

ON BEHALF OF SEMLER

/Gena D. Parker/
GENA D. PARKER
Vice President, RA/QA & Compliance
Semler Scientific, Inc.

09/03/2025
DATE

/Eliza Andonova/
ELIZA ANDONOVA
MICHELE SARTORI
Hogan Lovells US LLP
Counsel for Semler Scientific, Inc

9/3/2025
DATE

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

/Susan E. Gillin/
SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

2025.09.05
DATE

/T. Keusseyan/
TONYA KEUSSEYAN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

9/4/25
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. Semler 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 E. Within 30 days after OIG receives the information identified in Section V.A.7 of the CIA or any additional information submitted by Semler in response to a request by OIG, whichever is later, OIG will notify Semler if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Semler may continue to engage the IRO.

2. If Semler engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Semler shall submit the information identified in Section V.A.7 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 Semler at the request of OIG, whichever is later, OIG will notify Semler if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Semler may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Systems Review and Transactions Review who have expertise in the medical device industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions (as defined in Section II.C of the CIA), including but not limited to expertise relating to marketing and promotional activities associated with medical devices and the Federal Anti-Kickback Statute and False Claims Act; 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 component of the Systems Review and Transactions Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program and FDA requirements in making assessments in the Systems Review and Transactions Review;
3. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Semler Responsibilities

Semler shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.D of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the Systems Review and Transactions Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. *Semler and IRO.* If Semler terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Semler must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Semler 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 E or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Semler in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Semler shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Semler regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Semler in writing that Semler shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Semler must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Semler to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions (as defined in Section II.C of the CIA). If there are no material changes in Semler's systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Semler materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform an additional Systems Review for the Reporting Period(s) in which such changes were made that identifies the material changes and reviews the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

A. Systems Review. For the Systems Review, the IRO shall review Semler's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Semler's systems, policies, processes, and procedures relating to the materials and information that may be distributed by Semler sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Semler sales representatives respond to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared, or exempt ("non-FDA approved uses");

2. Semler's systems, policies, processes, and procedures relating to the materials and information that may be distributed and the mechanisms through, and manner in which, Semler receives and responds to requests for information from an HCP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Semler in response to such requests; and the internal review process for the information disseminated;

3. Semler's systems, policies, processes, and procedures relating to the manner and circumstances under which Semler medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with Semler sales representatives) and the role of Semler medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

4. Semler's systems, policies, processes, and procedures relating to the materials and information that may be distributed or made available by Semler through social media and/or direct-to-consumer advertising;

5. Semler's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc

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

6. Semler's systems, policies, processes, and procedures relating to the review and approval of, and payment for, travel and related expenses for HCPs including those in connection with an HCP's participation in educational, research, training, or other Semler-sponsored programs or activities;

7. Semler's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships, or Third Party Educational Activities, as defined in Section II.C.12, and II.C.13 of the CIA;

8. Semler's systems, policies, processes, and procedures relating to the review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Semler by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Semler's review and approval process and are elevated when appropriate;

9. Semler's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

10. Semler's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Semler's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

B. Systems Review Report. The IRO shall prepare a Systems Review Report for each Systems Review that includes the following information:

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

2. a detailed description of Semler's systems, policies, processes, and procedures relating to the items identified in Sections A.1-10 above, including a general description of Semler's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections A.1-10 above are made known or disseminated within Semler;

4. findings and supporting rationale regarding any weaknesses. in Semler's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

5. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

C. Transactions Review. The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of Payments.

1. *Review of Consulting Activities*. For purposes of this Appendix B, the term “Consulting Activities” shall include all consulting and other fee for service arrangements entered with HCPs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship and authorship-related activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

- a. For the first Reporting Period, the IRO shall randomly select and review a sample of three (3) Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, Semler shall provide the following information to OIG: (1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (2) the number of each type of Consulting Activity undertaken during the Reporting Period; and (3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period. At least 30 days prior to the end of the applicable Reporting Period, the OIG shall select the number of each type of Consulting Activity to be reviewed by the IRO during the second and subsequent Reporting Period, up to a total sample size of three (3).
- b. For each Consulting Activity reviewed, the IRO shall determine whether:
 - i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;
 - ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Semler based on an independent fair market value analysis;
 - iii. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Semler;

- iv. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting Activity was completed prior to the initiation of the Consulting Activity;
- v. the Consulting Activity was reviewed and approved in accordance with Semler Policies and Procedures;
- vi. Semler collected and retained a record of the specific activity performed by the HCP, and if applicable, a copy of the work product generated by the HCP in connection with the Consulting Activity; and
- vii. the activity undertaken by the Consultant and/or the work product generated by the HCP was used by Semler in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

2. *Review of Payments.* For purposes of this Appendix B, the term “Control Documents” shall include all material documents or electronic records associated with each Semler Payment reflected in the Open Payments database. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of the Payment; contracts relating to the Payment; documents relating to the occurrence of Payment; documents reflecting any work product generated in connection with the Payment; documents submitted by sales representatives or headquarters personnel to request approval for the Payment; and business rationale or justification forms relating to the Payment.

- a. For each Reporting Period, the OIG shall have the discretion to identify up to three (3) Covered Recipients who received Payments from Semler, as reflected in the most recent data available in the Open Payments database. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select three (3) Covered Recipients to be included in the review.
- b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:
 - i. whether Control Documents are available relating to each Payment;

- ii. whether the Control Documents were completed and archived in accordance with the requirements set forth in Semler's policies;
- iii. whether the aggregate value of the Payment as reflected in the Open Payments database is consistent with the value of the Payment reflected in the Control Documents; and
- iv. whether the Control Documents reflect that Semler's policies were followed in connection with the Payment (e.g., all required written approvals for the activity were obtained in accordance with Semler's policies.)

D. Transactions Review Report. The IRO shall prepare a Transactions Review Report for each Transactions Review that includes the following information:

1. *Transactions Review Methodology*.

- a. Review Objective: A statement of the objective intended to be achieved by each part of the Transactions Review;
- b. Review Protocol: A detailed narrative description of how the Transactions Review was performed and what was evaluated; and
- c. Sources of Data: A description of the documentation and other information relied on by the IRO in performing the Transactions Review.

2. *Transactions Review Findings*.

- a. Relating to the Review of Consulting Activities
 - i. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
 - ii. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:
 - (a) a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;

- (b) the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Semler that was established based on an independent FMV analysis;
 - (c) the Consulting Activity was identified in the annual Consulting budgeting plan developed by Semler;
 - (d) a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;
 - (e) the Consulting Activity was reviewed and approved in accordance with Semler Policies and Procedures,
 - (f) Semler collected and retained a record of the specific activity performed by the HCP, and if applicable, a copy of the work product generated in connection with the Consulting Activity; and
 - (g) the activity undertaken by the Consultant and/or the work product generated was used by Semler in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.
- iii. any weaknesses in Semler's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and
 - iv. any recommendations for improvements to Semler's systems, processes, policies, procedures and/or practices relating to Consulting Activities.
- b. Relating to the Review of Payments
- i. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and
 - ii. for each sampled Payment, findings and supporting rationale as to whether:
 - (a) all required Control Documents exist;

- (b) each Control Document was completed in accordance with all of the requirements set forth in the applicable Semler policy;
- (c) the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;
- (d) each Control Document reflects that Semler's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and
- (e) any corrective action or disciplinary action was undertaken in those instances in which Semler policies were not followed.