CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
QOL MEDICAL, LLC, AND FREDERICK E. COOPER

I. PREAMBLE

QOL Medical, LLC (Manufacturer) and Frederick E. Cooper (collectively "QOL") hereby enter 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, QOL 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) QOL'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 QOL complies with the decision.

C. Definitions.

1. "Certifying Covered Persons" means the following: all members of senior management and the leaders of all business units, divisions or departments with operations that relate to the Covered Functions, including Chief Executive Officer, Chief Operating Officer, Vice President of Marketing, National Sales Director, Controller, and Deputy General Counsel.

2. "Covered Functions" means "Promotional Functions" and "Product Related Functions," collectively.

3. "Covered Persons" means: (a) all owners of QOL who are natural persons;

(b) all officers, board members, and employees of QOL; and (c) all contractors who perform any of the Covered Functions on behalf of QOL.

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 QOL'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) and state Medicaid program exclusion lists that are publicly available.

7. "Government Reimbursed Products" means to all QOL products that are: (a) marketed or sold by QOL 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. "Promotional Functions" means: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to QOL's review and approval processes for promotional materials and any applicable review committee(s).

11. "Product Related Functions" means: (a) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to any applicable review committees and medical affairs/medical information services or involved in scientific exchange; (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to Compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

12. "Reportable Event" means: "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 QOL.

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

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

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

16. "Training Plan" means a written plan that outlines the steps QOL will take to ensure that: all Covered Persons receive training on a periodic basis during the term of the CIA regarding QOL'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 QOL Policies and Procedures and other requirements applicable to Covered Functions.

17. "Transition Plan" means a plan to address whether and how QOL'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

QOL 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 120 days after the Effective Date, QOL shall appoint a Compliance Officer who is an employee and a member of senior management of QOL. The Compliance Officer shall report directly to the Chief Executive Officer of QOL 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 QOL. The Compliance Officer shall be authorized to report to the Board of Directors of QOL (Board) 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 QOL; 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.

QOL 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, QOL shall appoint a Compliance Committee that is chaired by the Compliance Officer. 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. The Compliance Committee 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.O below. The Compliance Committee shall meet at least quarterly.

QOL 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 shall be responsible for the review and oversight of QOL'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 QOL'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 QOL'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 QOL'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, QOL has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of QOL's Corporate Integrity Agreement with the Office of Inspector General of 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 QOL.

QOL shall report to OIG, in writing, any changes in 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 QOL 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 [insert name of business unit]'s compliance with all applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, and QOL's policies and procedures. To the best of my knowledge, the [insert name of business unit] of QOL 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, QOL 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, QOL 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) QOL's compliance with Federal health care program and FDA requirements. QOL 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: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

2. the materials and information that may be distributed by QOL sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which QOL 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 by Medical Information and the mechanisms through, and manner in which, Medical Information 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 QOL in response to such requests; and the internal review process for the information disseminated;

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

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

6. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other QOL representatives who promote and sell Government Reimbursed Products;

7. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from QOL (including, separately, from sales representatives, from Medical Information, or through other channels);

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

9. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

10. sponsorship or funding of grants (including educational grants) or charitable contributions;

11. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.14 and II.C.15 above;

12. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside QOL 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 QOL's review and approval process and are elevated when appropriate;

13. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions;

14. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any

changes based on QOL's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.);

15. sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of ISSs (collectively, "Research"), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research;

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

17. disciplinary policies and procedures for violations of QOL'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, QOL shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of Covered Persons 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 Board Training described in this Section III.C.2 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*. QOL 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 as required.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 120 days after the Effective Date, QOL shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications and requirements 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 QOL shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and QOL related to the reviews described in this Section III.D.

c. *Access to Records and Personnel*. QOL 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. *System Review, Transactions Review, and Additional Items Review.* The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions, and (if required) an Additional Items Review, and shall prepare a Systems Review Report, a Transactions Review Report, and (if applicable) an Additional Items 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 QOL 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 QOL and the IRO.

E. Risk Assessment and Internal Review Process. Within 120 days after the Effective Date, QOL 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 QOL to: (1) identify and prioritize risks, (2) develop work plans or internal audit plans (as appropriate) related to the identified 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, QOL shall establish a Disclosure Program. QOL 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 QOL 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.* QOL 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 an annual 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 QOL has actual notice that a Covered Person has become an Ineligible Person, QOL 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 QOL may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether QOL meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. QOL shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that QOL has committed a crime or has engaged in fraudulent activities, within 30 days of QOL 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, QOL shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. QOL 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 QOL's actions taken to correct the Reportable Event and prevent it from recurring.

2. *Probable Violation of FDA Requirements.* 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 FDA requirements probably violated by the Reportable Event, if any; and

c. a description of QOL'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 QOL 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 QOL and the FDA that materially discusses QOL's or a Covered Person's actual or potential unlawful or improper promotion of QOL's products (including any improper dissemination of information about non-FDA approved uses), QOL shall provide a copy of the report, correspondence, or communication to OIG. Within 30 days after resolution of the matter, QOL shall notify OIG, in writing, of the resolution.

K. Requirements Relating to Speaker Programs. Within 120 days following the Effective Date, QOL shall establish and implement the following requirements relating to arrangements with HCPs to serve as presenters on behalf of QOL or participate in training programs related to such presentations (Speaker Programs).

1. An annual budget and needs assessment process that identifies the business needs for, and the estimated numbers of, Speaker Programs for the following year. As part of the process, QOL shall identify the business need for the planned Speaker Programs and shall collect specific details about the Speaker Programs (e.g., the expected number of programs, the topics of the programs, and the identity and qualifications of the proposed speakers.) The annual Speaker Programs budget shall identify the total budgeted amounts to be spent on

Speaker Programs. QOL compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of approved plans. The purpose of this review shall be to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and QOL Policies and Procedures.

2. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance requirements for the speakers (including requirements regarding the use of QOL approved materials and requirements that speakers may not directly or indirectly promote the product for non-FDA approved uses.).

3. A centralized, electronic system to initiate and track all Speaker Programs that includes controls designed to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

4. A process to ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.

5. A comprehensive list of Speaker Program attendees through its centralized system. In addition, QOL shall use its centralized system to handle all logistics and spending associated with Speaker Programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with Speaker Programs.

6. A requirement for certifications by sales representatives or other QOL personnel that Speaker Programs comply with QOL requirements, or in the event of non-compliance, QOL shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

7. A Speaker Monitoring Program under which QOL compliance or other appropriately trained QOL personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend five Speaker Programs during each Reporting Period and conduct live audits of the Speaker Programs (Speaker Program Audits). The Speaker Programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each Speaker Program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the Speaker Program, speaker statements made during the program, and QOL sales representative activities during the Speaker Program to assess whether the Speaker Programs were conducted in a manner consistent with QOL's Policies and Procedures. Results from the Speaker Monitoring Program shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

L. Field Force Monitoring and Review Efforts. Within 120 days after the Effective Date, QOL 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 inappropriate 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 field 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 QOL's Policies and Procedures. These observations shall be full day ride-alongs with field 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 QOL Policies and Procedures; and (f) the identification of any potential inappropriate promotional activity or other improper conduct by the field sales representative.

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

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

a. For each Reporting Period, QOL shall develop and implement a plan for conducting Records Reviews associated with one or two Government Reimbursed Products, one of which is always Sucraid. (At OIG's discretion, OIG may require another Government Reimbursed Product Records Review. The specific additional product would be determined by OIG.) 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 field sales representatives' interactions with HCPs and HCIs

(including records relating to consulting and other fee-for-service arrangements, speaker program activities, samples, 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 field sales force representatives, coaching guides, and district 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.

M. Requirements Relating to Certain Non-Promotional Activities. To the extent that QOL engages HCPs for services other than for speaker programs, Research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants. To the extent that QOL engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.15), such HCPs and HCIs shall be referred to collectively as "Researchers." To the extent that QOL engages HCPs or HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Within 120 days after the Effective Date, QOL shall implement the requirements outlined below relating to the following types of activities: (1) consultant arrangement activities; (2) Research-related activities; (3) publication activities; and (4) medical education grants.

1. *Consulting Arrangement Activities*. QOL shall:

a. 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.

b. 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. QOL 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 QOL Policies and Procedures.

c. 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 QOL compliance personnel.

d. 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, QOL receives the work product generated by the Consultant.

e. Establish a Consultant Monitoring Program through which it shall conduct audits of at least two Consultant arrangements during each Reporting Period. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with QOL's Policies and Procedures. Results from the Consultant Monitoring Program, including the identification of potential violations of QOL policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Research-Related Activities.* QOL shall:

a. Require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid or support to be given, and compliance requirements for the Researchers. Researchers retained to conduct

Research shall be paid according to a centrally managed system and a rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop an annual budgeting plan for Researchers that specifies (i) the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year; and (ii) the budgeted amounts to be spent on Researcher-related activities during the year. QOL compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan, for the purpose of ensuring that Research arrangements and related events are used for legitimate purposes in accordance with QOL Policies and Procedures and with Federal health care program and FDA requirements.

c. Establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the Research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by QOL compliance personnel.

d. Amend its policies and procedures in a manner designed to ensure that each Researcher performs the work for which the Researcher was engaged.

e. Establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period. QOL shall review two Researcher arrangements with HCPs or HCIs for each Reporting Period. The Researcher Monitoring Program shall select Researcher arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel conducting the Researcher Monitoring Program shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by QOL and performed by the Researchers in a manner consistent

with QOL's Policies and Procedures. Results from the Researcher Monitoring Program, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Publication Activities.* QOL shall:

   a. Require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance requirements of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

   b. Establish a process to develop annual plans that specify: (i) the business needs for and the estimated number of various Publication Activities (Publication Plans), and (ii) the budgeted amounts to be spent on Publication Activities. QOL's compliance personnel shall be involved in the review and approval of such annual Publication Plans, including any modification of an approved plan, for the purpose of ensuring that Publication Activities and related events are used for legitimate purposes in accordance with QOL Policies and Procedures and with Federal health care program and FDA requirements.

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

   d. Establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least two Publication Activities. The Publication Monitoring Program shall select publications for review on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were

conducted in a manner consistent with QOL's Policies and Procedures. Results from the Publication Monitoring Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Grant and Charitable Contribution Activities.* QOL shall:

a. Establish a centralized system which shall be the exclusive mechanism though which requestors may request or be awarded amounts for independent medical education, amounts for other educational activities, and other grant activities involving HCPs and HCIs (referred to below as "Grants"), and health care related charitable contributions supported by QOL (referred to below as "Contributions").

b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by QOL (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants and Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. QOL's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of requests for Grants or Contributions.

c. Establish a Grants and Contributions Monitoring Program through which it shall conduct audits for each Reporting Period of at least two Grants and Contributions. The Grants and Contributions Monitoring Program shall select Grants and Contributions for review on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including requests), approval documents, contracts, payments and materials relating to the review of the requests, and documents and materials relating to the Grants or Contributions and any events or activities funded through the Grants or Contributions to assess whether the activities were conducted in a manner consistent with QOL's Policies and Procedures. Results from the Grants and Contributions Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

N. Reporting of Physician Payments. Within 120 days after the Effective Date, QOL 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). QOL 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 QOL.

O. Transition Plan. Prior to the end of the fourth Reporting Period, QOL 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 QOL's approved Transition Plan shall be included in QOL's fourth Annual Report.

IV. SUCCESSOR LIABILITY

If, after the Effective Date, QOL 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 are subject to this CIA; 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. QOL 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 QOL wishes to obtain a determination by OIG that a proposed purchase or proposed acquisition will not be subject to the CIA requirements, QOL 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, QOL 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 summary 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.1;

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 QOL that includes a summary of all current and prior engagements between QOL 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 policies, procedures, and systems implemented pursuant to the Speaker Program Requirements outlined in Section III.K;

12. description of the FFMP required by Section III.L;

13. a description of the policies, procedures and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.M;

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

15. a list of all of QOL'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;

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

17. 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, QOL has implemented and complies with and 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. QOL 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, and 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.1 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.E and QOL'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 QOL, including a summary of all current and prior engagements between QOL and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reasons 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 reasons 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. a summary of any changes to the policies, procedures, and systems relating to Speaker Programs required by Section III.K, including the reason(s) for such changes, and a summary of the results of the Speaker Monitoring Program described in Section III.K;

19. the results of the FFMP required by Section III.L, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action (s) that QOL took as a result of such determinations;

20. a summary of any changes to the policies, procedures, and systems relating to Certain Non-Promotional Activities required by Section III.M, including the reason(s) for such changes, and a summary of results of the Consultant Monitoring Program, Researcher Monitoring Program, Publication Monitoring Program, and Grants and Contributions Monitoring Program described in Section III.M;

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

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

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

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

25. 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, QOL 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. QOL 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. QOL 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

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
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: 202.619.2078
Email Address: officeofcounsel@oig.hhs.gov

QOL:

QOL Medical
Attn: Legal Department
3405 Ocean Drive
Vero Beach, FL 32963
Telephone: 866.469.3773 ext. 1067
Email Address: legal@qolmed.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify QOL in writing of any changes to the OIG contact information list above. QOL shall notify OIG in writing within two business days of any changes to the QOL 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 QOL's books, records, and other documents and supporting materials, and conduct on-site reviews of any of QOL's locations, for the purpose of evaluating: (a) QOL's compliance with the terms of this CIA and (b) QOL's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by QOL to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of QOL's owners, 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. QOL shall assist OIG or its duly authorized representative(s) in

contacting and arranging interviews with such individuals upon OIG's request. QOL's owners, employees, contractors and Board members may elect to be interviewed with or without a representative of QOL present.

VIII. DOCUMENT AND RECORD RETENTION

QOL 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 QOL prior to any release by OIG of information submitted by QOL pursuant to its requirements under this CIA and identified upon submission by QOL as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, QOL 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 QOL fails to comply with Section III.A;

2. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.B;

3. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.C;

4. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.D;

5. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.E;

6. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.F;

7. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.G;

8. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.H;

9. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.I;

10. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.J;

11. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.K;

12. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.L;

13. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.M;

14. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.N;

15. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section III.O;

16. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section IV;

17. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section V;

18. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section VII;

19. A Stipulated Penalty of up to $2,500 for each day QOL fails to comply with Section VIII; or

20. A Stipulated Penalty of up to $50,000 for each false certification or false statement made to OIG by or on behalf of QOL under this CIA.

B. Timely Written Requests for Extensions. QOL 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 QOL 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 QOL 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 QOL of: (a) QOL'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, QOL 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 of this CIA

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. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering QOL 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

h. 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 QOL constitutes an independent basis for QOL'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 QOL has materially breached this CIA, OIG shall notify QOL of: (a) QOL's material breach and (b) OIG's intent to exclude QOL (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Response to Notice*. QOL 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 QOL in writing of its determination to exclude QOL (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 QOL, 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, QOL 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, QOL 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 QOL was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b)

the period of noncompliance. QOL shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that QOL has breached this CIA and orders QOL to pay Stipulated Penalties, QOL 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 QOL 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, QOL 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 QOL 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. QOL shall waive its right to any notice of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of QOL, QOL 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 QOL 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

QOL 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) QOL'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 QOL 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 QOL

/Frederick Cooper/ 11/1/24

FREDERICK E. COOPER
On behalf of himself and QOL Medical, LLC
Chief Executive Officer
QOL Medical, LLC

DATE

/Michael Packard/ 11/01/2024

WILLIAM A. BURCK
MICHAEL T. PACKARD
Quinn Emanuel Urquhart & Sullivan, LLP
Counsel for Defendants

DATE

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

/Susan Gillin/ 11/01/24
SUSAN E. GILLIN DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

/Sandra Jean Sands/ November 1, 2024
SANDRA JEAN SANDS DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. QOL 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 QOL in response to a request by OIG, whichever is later, OIG will notify QOL if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, QOL may continue to engage the IRO.

2. If QOL 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, QOL 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 QOL at the request of OIG, whichever is later, OIG will notify QOL if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, QOL 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 pharmaceutical 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 pharmaceutical products 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 inquires 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. QOL Responsibilities

QOL 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 IRO Reviews 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. *QOL and IRO*. If QOL terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, QOL 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. QOL 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 QOL in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. QOL 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 QOL regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify QOL in writing that QOL shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. QOL 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 QOL 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 the applicable systems, processes, policies, and procedures of QOL relating to reviewed Policies and Procedures described below, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If QOL materially changes applicable systems, processes, policies, and procedures, the IRO shall perform an additional Systems Review for the Reporting Period(s) 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 systems, processes, policies, and procedures of QOL associated with the following (hereafter "Reviewed Policies and Procedures"):

1. QOL's systems, policies, and procedures applicable to the materials and information that may be distributed or made available by QOL sales representatives (including any contract sales force) about Government Reimbursed Products and the methods by which the materials and information are distributed or made available;

2. QOL's systems, policies, and procedures relating to the manner in which sales representatives and personnel from Medical Information handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include: (a) the manner in which QOL sales representatives handle requests for information about non-FDA approved uses of Government Reimbursed Products, (b) the manner in which Medical Information personnel, including those at QOL's headquarters, handle and respond to requests for information about non-FDA approved uses of Government Reimbursed Products; (c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, payors, and formulary decision-makers by QOL; (d) the systems, processes, policies, and procedures to track requests to Medical Information for information about non-FDA approved uses of products and responses to those requests; (e) the manner in which QOL collects and supports information reported in any systems used to track and respond to requests to Medical Information for Government Reimbursed Product information; (f) the processes and procedures by which Medical Information or other appropriate individuals within QOL identify situations in which it appears that inappropriate or improper promotion may have occurred; and (g) QOL's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

3. QOL's systems, policies, and procedures applicable to the manner and circumstances under which QOL's medical personnel (including those from Medical Information) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products, and the role of the medical personnel at such meetings or events;

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

5. QOL's systems, policies, and procedures relating to the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other QOL representatives who promote and sell Government Reimbursed Products;

6. QOL's systems, policies, and procedures relating to the development, implementation, and review of all plans for the distribution of samples of Government Reimbursed Products**,** including samples given either directly or indirectly to patients (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from QOL (including, separately, from sales representatives, from Medical Information, or through other channels);

7. QOL's systems (including any centralized systems), policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

8. QOL's systems, policies, and procedures relating to the engagement of non-speaker related consultants or other fee-for-service arrangements (including, but not limited to, presentations, advisory boards, preceptorships, mentorships, and ad hoc advisory activities, and any other financial engagement) that QOL entered with HCPs or HCIs and all events and expenses associated with such activities;

9. QOL's systems, policies, and procedures applicable to programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

10. QOL's systems, policies, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions;

11. QOL's systems, policies, and procedures applicable to the funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Sections II.C.14 and II.C.15 of the CIA;

12. QOL's systems, policies, and procedures applicable to the review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside

QOL 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 QOL's review and approval process and are elevated when appropriate;

13. QOL's systems, policies, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in or tolerate the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that QOL establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

14. QOL's systems, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"), including any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on QOL's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.);

15. QOL's systems, policies, and procedures applicable to sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of ISSs (collectively, "Research"), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research; and

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

B. Systems Review Report. The IRO shall prepare a Systems Review Report based on 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 systems, policies, processes, and procedures relating to the items identified in Section A above, including a general description of the 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 Section A above are made known or disseminated within QOL;

4. a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products;

5. a detailed description of the incentive compensation system for Covered Persons who are sales representatives and their direct managers, including a description of the bases upon which compensation is determined. To the extent that QOL may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures identified in Section A above, if any; and

7. recommendations to improve any of the systems, policies, processes, or procedures relating to any of the Reviewed Policies and Procedures identified in Section A above, if any.

C. Transactions Review. The Transactions Review shall include: (1) a review of QOL's call plans and the call plan review process; (2) a review of Consulting Activities; and (3) a review of up to three additional items identified by the OIG in accordance with Section III.D of the CIA (hereafter "Additional Items").

1. *Review of Call Plans and Call Plan Review Process*. The IRO shall conduct a review and assessment of QOL's review of its call plans for Government Reimbursed Products.

a. QOL shall provide the IRO with: (a) a list of Government Reimbursed Products promoted by QOL during the Reporting Period; (b) information about the FDA-approved uses for each such product; and (c) the call plans for each such product. QOL shall also provide the IRO with information about the reviews of call plans that QOL conducted during the relevant Reporting Period (if any) and any modifications to the call plans made as a result of QOL's reviews.

b. For each call plan, the IRO shall select a sample of 40 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or

practice area) used by QOL in conducting its review and/or modifying the call plan. The IRO shall seek to determine whether QOL followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

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

2. *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 or HCIs. This shall include, but not be limited to, speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, research and development meetings, product training and education sessions, ad hoc advisory activities, research and any other financial engagements or arrangements with an HCP or HCI and all expenses relating to the engagements or arrangements.

a. For the first Reporting Period, the IRO shall select and review a sample of ten of the Consulting Activities for which QOL retained HCPs or HCIs and all related expenses. For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, QOL shall provide the following information to OIG: (a) 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; (b) the number of each type of Consulting Activity undertaken during the Reporting Period; and (c) the overall budgeted amount 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 Periods, the OIG shall select the number of each type of Consulting Activity to be reviewed by the IRO during the second and subsequent Reporting Periods, up to a total sample size of ten.

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 paid for the Consulting Activity was determined in accordance with a centrally managed rate structure established by QOL based on an independent fair market value analysis;

iii. the Consulting Activity was identified in the annual Consultant budgeting plan developed by QOL;

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 QOL Policies and Procedures;

vi. QOL collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated by the HCP or HCI in connection with the Consulting Activity; and

vii. the activity undertaken by the Consultant and/or the work product generated by the HCP or HCI was used by QOL in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

In addition, for each Consulting Activity selected for review, QOL shall provide the IRO with information about the total aggregate annual amount paid by QOL to the associated HCP or HCI for all purposes (including, e.g., payments in connection with Speaker Programs.) The IRO shall assess whether QOL paid the HCP or HCI an amount that exceeded the annual cap on compensation established in accordance with QOL's Policies and Procedures.

3. *Review of Additional Items*. As set forth in Section III.D of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items").

a. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify QOL of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or QOL shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in QOL's systems, policies, and procedures based on its review of each Additional Item).

b. QOL may propose to the OIG that its internal audit(s), reviews, or monitoring activities, be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow QOL's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

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 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 documentation and other information relied on by the IRO in performing the Transactions Review.

2. *Transactions Review Findings*.

a. Relating to the Call Plan Review

i. a list of the Government Reimbursed Products promoted by QOL during the Reporting Period and a summary of the FDA-approved uses for such products;

ii. for each Government Reimbursed Product which was promoted during the Reporting Period: (a) a description of the criteria used by QOL in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; (b) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with QOL's criteria relating to the call plan and/or QOL's Policies and Procedures; and (c) a description of all instances in which it appears that QOL failed to follow its criteria or Policies and Procedures relating to call plans;

iii. the findings and supporting rationale regarding any weaknesses in QOL's systems, policies, procedures, and practices relating to call plans, if any; and

iv. recommendations, if any, for changes in QOL's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.

b. 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, the aggregate annual amount paid by QOL to the associated HCP or HCI for all purposes;

iii. 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 rate structure set by QOL that was established based on an independent fair market value analysis;

c. the Consulting Activity was identified in the annual Consulting budgeting plan developed by QOL;

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 QOL Policies and Procedures, including Policies and Procedures relating to the identification, selection and approval of a given HCP or HCI;

f. QOL collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated in connection with the Consulting Activity;

g. the activity undertaken by the Consultant and/or the work product generated was used by QOL in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;

h. the aggregate amount paid by QOL to the HCP or HCI exceeded the applicable cap established under QOL's Policies and Procedures;

iv. any weaknesses in QOL's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and

v. any recommendations for improvements to QOL's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

c. Relating to the Review of Additional Items

i. for each Additional Item reviewed, a description of the review conducted;

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

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

iv. for each Additional Item reviewed, recommendations, if any, for changes in QOL's systems, processes, policies, and

procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

E. Review of the Distribution of Samples of Government Reimbursed Products.

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs**,** HCIs and/or patients (directly or indirectly).

1. *Provision of Materials to the IRO.* QOL shall provide the IRO with: (a) a list of Government Reimbursed Products for which QOL distributed samples during the Reporting Period; (b) information about the FDA-approved uses for each such product; and (c) information about QOL's Sample Distribution Plans.

2. *Selection of Sample*. For each Government Reimbursed Product for which QOL distributed samples during the Reporting Period, the IRO shall randomly select a sample of 40 separate instances in which QOL provided samples of the product to HCPs, HCIs, and patients, directly or indirectly (i.e., through another entity, such as a specialty pharmacy). Each such instance shall be known as a "Sampling Event."

3. *Materials to Be Reviewed*. For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP, HCI, or patient. The reviewed materials shall include materials about the following: (a) the quantity, dosage, and form of the Government Reimbursed Product samples provided to the HCP, HCI, or patient; (b) the identity and type of medical specialty or clinical practice of the HCP, HCI, or patient; (c) which individual QOL sales representatives or other QOL personnel provided the sample or the sample order form to the HCP, HCI, or patient; and (d) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to QOL or the specialty pharmacy).

4. *Scope of Review for Sampling Events*. For each Sampling Event, the IRO shall:

a. evaluate whether the sample was provided to an HCP, HCI, or ordered for a patient by an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA;

b. evaluate whether the sample or the sample form was distributed by a QOL representative or the sample itself was distributed by a third party in a manner consistent with the Sample Distribution Plan for the product(s) provided during the Sampling Event;

c. compare the medical specialty and type of clinical practice of the HCPs and HCIs whose patients received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical

specialty or clinical practice of the HCPs or HCIs whose patients received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by QOL in determining that it was appropriate to provide a sample or sample form to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that QOL failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

5. *Relating to Sampling Event Review*

i. for each Government Reimbursed Product distributed during the Reporting Period: (a) a description of Sample Distribution Plans (including whether sales representatives may provide samples or sample forms for the product and, if so, to HCPs or HCIs (or their patients) of which medical specialty or type of clinical practice a sales representative may provide samples or sample forms); (b) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample or the sample form during a Sampling Event was not consistent with the uses of the Government Reimbursed Product approved by the FDA. This description shall include a description of the process followed by QOL in determining that it was appropriate to provide a sample or sample form to such HCP or HCI and the basis for such determination; and (c) a detailed description of any instances in which it appears that QOL failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;

ii. the findings and supporting rationale regarding any weaknesses in QOL's systems, processes, policies, procedures, and practices relating to the distribution of samples of Government Reimbursed Products, if any; and

iii. recommendations, if any, for changes in QOL's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples or sample forms.