

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MCKINSEY & COMPANY, INC. UNITED STATES**

I. PREAMBLE

McKinsey & Company, Inc. United States (McKinsey) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). McKinsey is a subsidiary of McKinsey & Company, Inc. and is entering this CIA pursuant to authority granted by the Shareholders Council of McKinsey & Company, Inc. Contemporaneously with this CIA, McKinsey is entering into a Settlement Agreement with the United States.

Prior to the Effective Date, McKinsey established a compliance program that McKinsey represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program requirements (Compliance Program). McKinsey shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. McKinsey may modify the Compliance Program as appropriate. However, at a minimum, McKinsey shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The “Effective Date” of this CIA shall be the signature date of the final signatory to 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) McKinsey’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 is completed, and McKinsey complies with the decision.

C. Definitions.

1. “Engagement” means each unique registered project, study, or report undertaken, conducted, or produced by McKinsey for a private client.
2. “Certifying Covered Persons” means the following: the designated practice leaders for McKinsey’s Healthcare and Life Sciences practices, the designated risk partners for McKinsey’s Healthcare and Life Sciences practices, and McKinsey’s Director of Client Service Compliance.
3. “Covered Persons” means: (a) officers and Shareholders Council members who are involved with or oversee specific Life Sciences and Healthcare Sector Engagements (as defined below); (b) those partners and employees of McKinsey and McKinsey & Co., Inc. who are client-serving personnel staffed on Life Sciences and Healthcare Sector Engagements to provide substantive client support; and (c) all contractors who are retained for, and staffed on, Life Sciences and Healthcare Sector Engagements in a client-serving role.
4. “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, Regulated Industry Requirements (as defined below in Section II.C.8), or any issues or questions associated with McKinsey’s policies, conduct, practices, or procedures.
5. “Exclusion Lists” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at <http://www.oig.hhs.gov>); the General Services Administration’s System for Award Management (SAM) (available at <http://www.sam.gov>); and state Medicaid program exclusion lists that are publicly available.
6. “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.
7. “Life Sciences and Healthcare Sector Engagements” means Engagements in the Life Sciences or Healthcare practice areas for U.S.-based clients and Engagements that otherwise pertain to Federal health care programs.
8. “Regulated Industry Requirements” means requirements applicable to Life Sciences and Healthcare Sector Engagements, including the following to the extent applicable to McKinsey: i) Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute), the False Claims Act (codified at 31 U.S.C. §§ 3729-3733), the Civil Monetary Penalties Law (codified at 42 U.S.C. § 1320a-7a), the exclusion statute (codified at 42 U.S.C. § 1320a-7), and the Stark Law (codified at 42 U.S.C. § 1395nn); ii) statutes, regulations, and written directives of the Centers for Medicare & Medicaid Services

(CMS requirements); iii) statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements); iv) statutes, regulations, and written directives of other HHS components (including, but not limited to, the Health Resources and Services Administration, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration); v) the Controlled Substances Act and associated regulations and written directives; vi) other health care fraud statutes and associated regulations and written directives; and vii) professional responsibility standards applicable to McKinsey.

9. “Reportable Event” means: (a) a matter that a reasonable person would consider a probable violation by McKinsey of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties 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) the employment of or contracting with a Covered Person who is an Ineligible Person; or (c) the filing of a bankruptcy petition by McKinsey.

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

11. “Training Plan” means a written plan that outlines the steps McKinsey will take to ensure that Covered Persons receive training on a periodic basis during the term of the CIA regarding McKinsey’s CIA requirements and compliance program and requirements potentially applicable to Life Sciences and Healthcare Sector Engagements, including but not limited to Regulated Industry Requirements.

12. “Transition Plan” means a plan to address whether and how McKinsey’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

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

A. Compliance Officer, Compliance Committee, Shareholders Council Oversight, and Management Certifications.

1. *Compliance Officer.* Within 90 days after the Effective Date, McKinsey shall appoint a Chief Ethics and Compliance Officer (Compliance Officer) who is an employee and a member of senior management of McKinsey & Co., Inc. The Compliance Officer shall report directly to the Global Managing Partner of McKinsey & Co., Inc. and shall also report functionally to the Chair of the Risk, Audit & Governance Committee (RAGC) of the Shareholders Council. The Compliance Officer shall not be or be subordinate to the Chief Legal Officer, Chief Financial Officer, or Chief Risk Officer of McKinsey or McKinsey & Co, Inc. or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal

counsel functions for either entity. The Compliance Officer shall be authorized to report to the Shareholder's Council 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, Federal health care program requirements, Regulated Industry Requirements, and any professional standards applicable to McKinsey and Covered Persons;
- b. making at least quarterly reports regarding compliance matters to the RAGC and shall be authorized to report on such matters to the RAGC or broader Shareholder's Council at any time. Written documentation of the Compliance Officer's reports to the Shareholders' Council shall be made available to OIG upon request;
- c. monitoring the day-to-day compliance activities engaged in by McKinsey; 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.

McKinsey 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 90 days after the Effective Date, McKinsey shall appoint a Compliance Committee that is chaired by the Compliance Officer. The Compliance Committee shall include, at a minimum, the members of senior management necessary to meet the requirements of this CIA. The Compliance Committee shall meet at least quarterly.

The Compliance Committee shall be responsible for, among other things, reviewing the policies and procedures required by Section III.B below at least annually, reviewing the training required by Section III.C below at least annually, implementation and oversight of the risk assessment and internal review process required by Section III.E below, and the development and implementation of the Transition Plan required by Section III.J below.

The Compliance Committee shall also ensure that, within 120 days after the Effective Date, McKinsey establishes and implements a client and engagement risk evaluation process and a Client Service Risk Committee (CSRC) review process whereby quarterly, McKinsey escalates to CSRC (or a subcommittee thereof) all final material recommendations

and interim and/or final deliverables (if applicable) provided to (or that will be provided to) clients within that prior quarter under Life Sciences and Healthcare Sector Engagements identified as “High Risk” in accordance with McKinsey risk-related controls or identified as high risk for purposes of the CIA as described in Appendix B (collectively hereafter “High Risk Engagements”) (hereinafter collectively “Quality Review Program”).

The Quality Review Program shall make findings as to whether McKinsey: i) conducted a client and engagement risk evaluation for all potential Life Sciences and Healthcare Sector Engagements; ii) reviewed Life Sciences and Healthcare Sector Engagements to ensure they were conducted in accordance with risk-related controls (including risk compacts and guardrails) established for such engagements; iii) conducted a quarterly CSRC review of all final material recommendations and interim and/or final deliverables (if applicable) provided to clients (or that will be provided to clients) under Life Sciences and Healthcare Sector Engagements that are identified as High Risk Engagements to assess compliance with Regulated Industry Requirements and validate that such recommendations and deliverables did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements; and iv) developed corrective action plans in response to any identified findings or deficiencies and tracked the implementation, effectiveness, and completion of those plans.

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

3. *Shareholders Council/RAGC Oversight.* The RAGC of the Shareholders Council shall be responsible for the review and oversight of McKinsey’s compliance with Federal health care program requirements, Regulated Industry Requirements, and the requirements of this CIA. The RAGC should be readily available to the Compliance Officer and the independent Compliance Expert required under Section III.D to respond to any issues or questions that might arise.

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

- a. meeting at least quarterly to review and oversee McKinsey’s compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. reviewing the adequacy of McKinsey’s Quality Review Program and ensuring that the firm implements effective responses when findings from the Quality Review Program indicate deficiencies in McKinsey’s practices as it relates to Life Sciences and Healthcare Sector Engagements;
- c. 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 Quality Review Program and in

support of making the resolution below during each Reporting Period; and

- d. for each Reporting Period of the CIA, adopting a resolution approved by each member of the RAGC regarding its review and oversight of McKinsey's compliance with Federal health care program requirements, Regulated Industry Requirements, and the requirements of this CIA.

At minimum, the resolution shall include the following language:

"The Shareholders Council's Risk, Audit, and Governance Committee has made a reasonable inquiry into the operations of McKinsey's compliance program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Shareholders Council has concluded that, to the best of its knowledge, McKinsey has implemented an effective compliance program to meet Federal health care program requirements, Regulated Industry Requirements, and the requirements of McKinsey's Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

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

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

4. *Management Certifications.* The Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable McKinsey division or department is in compliance with applicable Federal health care program requirements, Regulated Industry Requirements, and 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 division or department], an area under my supervision. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, Regulated Industry Requirements, Corporate Integrity Agreement requirements, and McKinsey's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements, Regulated Industry Requirements, and Corporate Integrity Agreement requirements. 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 this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

Within 90 days after the Effective Date, McKinsey 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, McKinsey shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of McKinsey's compliance program, including the compliance program requirements outlined in this CIA; and (2) McKinsey's compliance with Regulated Industry Requirements. McKinsey shall enforce its Policies and Procedures and 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.

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 90 days after the Effective Date, McKinsey 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. *RAGC Training.* Within 120 days after the Effective Date, all members of the RAGC shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall also address the specific responsibilities of RAGC members relating to assessing compliance program effectiveness and undertaking effective risk assessment and mitigation programs and shall include a discussion of the OIG's guidance on board member responsibilities. Each member of the RAGC also shall receive the training described in Section III.C.1.

New members of the RAGC shall receive the 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 RAGC training at least annually and update the RAGC training as necessary.

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

D. Independent Compliance Expert.

1. *General Description.*

- a. *Engagement of Independent Compliance Expert.* Within 90 days after the Effective Date, McKinsey shall retain an appropriately qualified independent compliance expert (the “Compliance Expert”), as set forth in Appendix A to this CIA, selected by OIG after consultation with McKinsey. The Compliance Expert may retain additional personnel meeting the qualifications and requirements outlined in Appendix A if needed to help meet the Compliance Expert’s requirements under this CIA provided the Compliance Expert first consults with McKinsey and OIG to explain the need for the additional personnel.

The Compliance Expert may confer and correspond with McKinsey or OIG individually or together. The Compliance Expert and McKinsey shall not negotiate or enter into a financial relationship, other than the expert engagement required by this section, and the Compliance Expert shall refrain from recruiting or hiring any employee of McKinsey until after the date of OIG’s CIA closure letter to McKinsey or six months after the expiration of this CIA, whichever is later.

The Compliance Expert is not an agent of OIG. However, the Compliance Expert may be removed by OIG at its sole discretion. If the Compliance Expert resigns or is removed by OIG prior to the termination of the CIA, McKinsey shall retain, within 60 days of the resignation or removal, another Compliance Expert selected by OIG, with the same functions and authorities.

- b. *Retention of Records.* The Compliance Expert and McKinsey shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the Compliance Expert and McKinsey related to the reviews described in this Section III.D.
- c. *Timely Access to Records and Personnel.* McKinsey shall ensure that the Compliance Expert has access to all records, personnel, systems, data, non-privileged communications, and documents necessary, in the Compliance Expert’s discretion, to perform the

reviews described in this Section III.D and Appendix B and that all records, data, non-privileged communications, and documents furnished to the Compliance Expert are accurate and complete. The Compliance Expert may conduct interviews of McKinsey's personnel, in the Compliance Expert's discretion, to perform the reviews described in this Section III.D and Appendix B with such interviews to be conducted 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 the Compliance Expert. The Compliance Expert shall be permitted to attend meetings of the Compliance Committee and the RAGC meetings relating to the oversight activities of the RAGC described in Section III.A.3 of this CIA and shall be permitted to meet independently with the Compliance Committee or the RAGC. The Compliance Expert also shall be permitted to attend and/or review all McKinsey's training provided under Section III.C of the CIA.

Notwithstanding the above, McKinsey may require the Compliance Expert to execute a non-disclosure agreement and/or undertake such other precautions reasonable and necessary to protect McKinsey's confidential and/or proprietary information, provided that such non-disclosure agreement and/or precautions shall not in any way limit the disclosure of any information by the Compliance Expert to OIG.

2. *Quality Systems Review and Transactions Review.* The Compliance Expert shall perform a Quality Systems Review and a Transactions Review and shall prepare a Quality Systems Review Report and a Transactions Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

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

E. Risk Assessment and Internal Review Process. Within 90 days after the Effective Date, McKinsey shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Regulated Industry Requirements. 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 at least annually and shall require McKinsey to: (1) identify and prioritize risks, (2)

develop work plans or audit plans (as appropriate) related to the identified risk areas, (3) implement the work plans and 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 90 days after the Effective Date, McKinsey shall establish a Disclosure Program. McKinsey shall appropriately publicize the existence of the Disclosure Program (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 use of the Disclosure Program and McKinsey 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 the Federal health care programs or Regulated Industry 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*. McKinsey 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 90 days after the Effective Date and annually 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 McKinsey has actual notice that a Covered Person has become an Ineligible Person, McKinsey 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 for 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 McKinsey may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing an Ineligible Person as a Covered Person or contracting with an Ineligible Person in connection with a Life Sciences or Healthcare Sector Engagement regardless of whether McKinsey meets the requirements of Section III.G.

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

I. Reportable Events. McKinsey 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;
 - c. the Federal health care programs affected by the Reportable Event;
 - d. a description of McKinsey's actions taken to correct the Reportable Event and prevent it from recurring.
2. *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 McKinsey 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.

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

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

IV. SUCCESSOR LIABILITY

If, after the Effective Date, McKinsey 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) relating to its Life Sciences or Healthcare practices for U.S.-based clients or service lines that otherwise potentially pertain to Federal health care programs; or (b) purchase or establish a new business, business unit, or location relating to Life Sciences or Healthcare practices for U.S.-based clients or service lines that otherwise potentially pertain to Federal health care programs, 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. McKinsey 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 McKinsey wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, McKinsey 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, McKinsey shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. a description of the Quality Review Program required by Section III.A.2;
4. the names of the RAGC members who are responsible for satisfying the Shareholders Council compliance requirements described in Section III.A.3;
5. 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;
6. a list of the Policies and Procedures required by Section III.B;
7. the Training Plan required by Section III.C.1 and a description of the RAGC 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);
8. the following information regarding the Compliance Expert(s): (a) a copy of the engagement letter; (b) information to demonstrate that the Compliance Expert has the qualifications outlined in Appendix A to this CIA; and (c) a certification from the Compliance Expert regarding its professional independence and objectivity with respect to McKinsey that includes a summary of all current and prior engagements between McKinsey and the Compliance Expert;
9. a description of the risk assessment and internal review process required by Section III.E;
10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;
12. a description of McKinsey's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

13. a list of all of McKinsey's locations (including mailing addresses), the corresponding name under which each location is doing business; and

14. a certification by the Compliance Officer and Global Managing Partner that:

- a. to the best of his or her knowledge, except as otherwise described in the report, McKinsey has implemented and is in compliance with all of the 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. McKinsey shall submit to OIG a written report (Annual Report) 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 RAGC members who are responsible for satisfying the Shareholders Council 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, Shareholders Council, or Certifying Covered Persons;

2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);

3. the dates of each report made by the Compliance Officer to the Shareholders Council (written documentation of such reports shall be made available to OIG upon request);

4. a summary of activities and findings under McKinsey's Quality Review Program and a summary of any corrective action taken in response to any findings or deficiencies identified through its Quality Review Program as required by Section III.A.2;

5. the RAGC resolution required by Section III.A.3 and a description of the materials reviewed by the RAGC and any additional steps taken in its oversight of the compliance program and in support of making the resolution;

6. 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;
7. the certifications of Certifying Covered Persons required by Section III.A.4;
8. a list of any new or revised Policies and Procedures required by Section III.B. developed during the Reporting Period;
9. 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 RAGC members during the Reporting Period;
10. a complete copy of all reports prepared pursuant to Section III.D and McKinsey's response to the reports, along with corrective action plan(s) related to any issues raised by the report;
11. a certification from the Compliance Expert regarding its professional independence and objectivity with respect to McKinsey, including a summary of all current and prior engagements between McKinsey and the Compliance Expert;
12. a description of any changes to the risk assessment and internal review process required by Section III.E, including the reason(s) for such changes;
13. 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, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
14. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs or Regulated Industry Requirements, 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;
15. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reason(s) for such changes;
16. a summary of 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;

17. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period;
18. (in the fourth Annual Report), a copy of the Transition Plan required by Section III.J;
19. a description of all changes to the most recently provided list of McKinsey's locations (including addresses) as required by Section V.A.13;
20. a description of any changes to McKinsey's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and
21. a certification by the Compliance Officer and Global Managing Partner that:
 - a. to the best of his or her knowledge, except as otherwise described in the report, McKinsey has implemented and is in compliance with all of the 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. McKinsey 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. McKinsey 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

McKinsey:

Daniel Trujillo
Partner, Global Chief Ethics & Compliance Officer
McKinsey & Company, Inc.
1221 S. Congress Ave Building 1, Suite 200
Austin, TX 78704
Telephone: (314) 793-1955
Email Address: Daniel_Trujillo@mckinsey.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify McKinsey in writing of any changes to the OIG contact information listed above. McKinsey shall notify OIG in writing within two business days of any changes to the McKinsey 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 McKinsey's books, records, and other documents and supporting materials, and conduct on-site reviews of any of McKinsey's locations, for the purpose of evaluating: (a) McKinsey's compliance with the requirements of this CIA and (b) McKinsey's compliance with Federal health care program requirements, and Regulated Industry Requirements. The documentation described above shall be made available by McKinsey to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. For purposes of this provision, OIG or its duly authorized representative(s) may interview any of McKinsey's owners, employees, contractors, and Shareholders Council 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. McKinsey shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. McKinsey's owners, employees, contractors, and Shareholders Council members may elect to be interviewed with or without a representative of McKinsey present.

VIII. DOCUMENT AND RECORD RETENTION

McKinsey shall maintain for inspection all documents and records relating to reimbursement (if any) 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 McKinsey prior to any release by OIG of information submitted by McKinsey pursuant to this CIA and identified upon submission by McKinsey as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, McKinsey 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 McKinsey fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day McKinsey fails to comply with Section III.I;

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

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

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

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

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

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

B. Timely Written Requests for Extensions. McKinsey 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 McKinsey 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 McKinsey 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 McKinsey of: (a) McKinsey's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, McKinsey shall either: (a) pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

D. Exclusion for Material Breach.

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

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

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by McKinsey constitutes an independent basis for McKinsey's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that McKinsey has materially breached this CIA, OIG shall notify McKinsey of: (a) McKinsey's material breach and (b) OIG's intent to exclude McKinsey. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice.* McKinsey 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 McKinsey in writing of its determination to exclude McKinsey. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of 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 McKinsey, 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, McKinsey 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 to McKinsey, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, McKinsey 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 McKinsey was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. McKinsey shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG’s determination that McKinsey has breached this CIA and orders McKinsey to pay Stipulated Penalties, McKinsey must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless McKinsey 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, McKinsey must (a) come into compliance with the requirement(s) 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 McKinsey 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. McKinsey shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of McKinsey, McKinsey shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. 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 McKinsey 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

McKinsey 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) McKinsey's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

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

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 MCKINSEY & COMPANY, INC.
AND MCKINSEY & COMPANY, INC. UNITED STATES**

/Jonathan Slonim/
Jonathan Slonim
Deputy General Counsel, Head of Legal, Americas
Partner of McKinsey & Company, Inc. and Vice President
Authorized Corporate Representative
for McKinsey & Company, Inc. United States

12/11/24
DATE

/Pierre Gentin/
Pierre Gentin
Senior Partner and Chief Legal Officer of
McKinsey & Company, Inc.
Authorized Corporate Representative
for McKinsey & Company, Inc.

12/11/24
DATE

/Peter J. Eyre/
Peter J. Eyre
Troy A. Barsky
M. Yuan Zhou
Crowell & Moring
Counsel for McKinsey & Company Inc.
and McKinsey & Company, Inc. United States

12/11/24
DATE

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

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

12/10/24
DATE

/Mary E. Riordan/
Mary E. Riordan
Meredith Williams
Senior Counsel
Office of Counsel to the Inspector General

12/11/2024
DATE

APPENDIX A

COMPLIANCE EXPERT

This Appendix contains the requirements relating to the Compliance Expert required by Section III.D of the CIA.

A. Engagement

1. McKinsey shall engage a Compliance Expert selected by OIG that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The Compliance Expert shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E.

B. Qualifications

The Compliance Expert shall:

1. have the expertise in the Regulated Industry Requirements relating to the Life Sciences and Healthcare Sector Engagements (as defined in Section II of the CIA) necessary to conduct the Quality Systems Review and Transactions Review; and
2. have sufficient resources to conduct the reviews required by the CIA on a timely basis.

C. Responsibilities

The Compliance Expert shall conduct the Quality Systems Review and the Transactions Review as described more fully in Appendix B to the CIA. The Compliance Expert shall:

1. perform each component of the Quality Systems Review and Transactions Review in accordance with the specific requirements of the CIA;
2. follow all applicable Regulated Industry Requirements in making assessments in the Quality Systems Review and Transactions Review;
3. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. McKinsey Responsibilities

McKinsey shall ensure that the Compliance Expert has access to all records and personnel necessary to complete the reviews described in Section III.D and Appendix B of the CIA and that all records furnished to the Compliance Expert are accurate and complete.

McKinsey shall not assert claims of attorney-client privilege to avoid disclosing to OIG information related to or resulting from the Compliance Expert's engagement. McKinsey's engagement letter with the Compliance Expert shall include a provision stating that the Compliance Expert agrees not to assert claims of work product privilege to avoid disclosing to OIG information related to or resulting from its engagement.

E. Independence and Objectivity

The Compliance Expert must perform each component of the Compliance Expert 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. In addition, the Compliance Expert must perform its responsibilities in an ethical and professional manner in accordance with applicable Rules of Professional Conduct and have an appropriate process to assess conflicts of interest between (i) the Compliance Expert (and its employer and firm, if any) and (ii) McKinsey or current or prospective clients of McKinsey for whom McKinsey may perform Life Sciences and Healthcare Sector Engagements.

F. Removal/Termination

1. *Termination by McKinsey.* If McKinsey proposes to terminate its Compliance Expert, McKinsey must submit a written request to OIG explaining its reasons for termination and requesting a determination by OIG whether a new Compliance Expert may be selected. McKinsey may propose a selection for the Compliance Expert. OIG will notify McKinsey in writing of its determination within 30 days of receiving McKinsey's request and may at OIG's discretion, select a new Compliance Expert.

2. *Withdrawal by Compliance Expert.* If the Compliance Expert resigns or withdraws from the engagement during the term of the CIA, McKinsey must provide OIG with notice of the Compliance Expert's resignation and McKinsey's proposed selection for a new Compliance Expert within 30 days of resignation or withdrawal. OIG will notify McKinsey within 30 days following receipt of McKinsey's proposal: a) whether the proposal is acceptable or unacceptable; and b) whether OIG has selected an alternative Compliance Expert.

3. *OIG Removal of Compliance Expert.* In the event OIG has reason to believe the Compliance Expert 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 McKinsey in writing regarding OIG's basis for determining that the Compliance Expert has not met the requirements of this Appendix.

McKinsey shall have 30 days from the date of OIG's written notice to provide information regarding the Compliance Expert'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 McKinsey regarding the Compliance Expert, OIG determines that the Compliance Expert has not met the requirements of this Appendix, OIG shall notify McKinsey in writing that McKinsey shall be required to engage a new Compliance Expert. McKinsey must provide OIG with McKinsey's proposed selection for a new Compliance Expert within 30 days of receipt of OIG's determination. OIG will notify McKinsey within 30 days following receipt of McKinsey's proposal: a) whether the proposal is acceptable or unacceptable; and b) whether OIG has selected an alternative Compliance Expert. The final determination as to whether or not to require McKinsey to engage a new Compliance Expert shall be made at the sole discretion of OIG.

G. Financial Requirements of McKinsey and Compliance Expert

McKinsey shall be responsible for all reasonable costs incurred by the Compliance Expert in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous). The Compliance Expert shall submit invoices to McKinsey that reflect the costs incurred by the Compliance Expert with a reasonable level of detail reflecting the costs billed. McKinsey shall remit payment to the Compliance Expert within 60 days of receipt of any Compliance Expert invoice. McKinsey may bring any disputed Compliance Expert costs or bills to OIG's attention for purposes of facilitating the resolution of any such dispute. In connection with each Quality Systems Review Report and Transactions Review Report, the Compliance Expert shall submit a written accounting of its costs incurred during the Reporting Period to McKinsey and to OIG. This report shall reflect, on a cumulative basis, all costs included on any periodic invoices. OIG will consider concerns raised by McKinsey, if any, associated with the Compliance Expert's costs in the prior Reporting Period.

H. Confidentiality and Non-Disclosure

The Compliance Expert agrees that any non-public information disclosed by or on behalf of McKinsey including its affiliates, employees, officers, contractors, agents, clients, and advisors, or by OIG to the Compliance Expert in connection with or related to the CIA or the business of McKinsey are confidential (collectively "Confidential Information"). The Compliance Expert shall take such steps as may be reasonably necessary to protect and maintain confidentiality of all Confidential Information.

Nothing in this Section shall prevent the Compliance Expert from sharing with OIG work papers, information, data, books, records, and other documents and supporting materials of

McKinsey or the Compliance Expert related to the reviews described in Section III.D and Appendix B.

The Compliance Expert shall retain all documentation that contains or reflects Confidential Information for a period consistent with the retention requirements set forth in Section VIII of the CIA. Within 90 days after the expiration of such period, the Compliance Expert agrees that it will, to the extent practicable, return to McKinsey or destroy all documentation that contains or reflects Confidential Information.

APPENDIX B

COMPLIANCE EXPERT REVIEW

The Compliance Expert shall perform all components of the Quality Systems Review and the Transactions Review. The Quality Systems Review shall be performed for at least two Reporting Periods as outlined below. The Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

I. Quality Systems Review

A. Quality Systems Review

The Quality Systems Review shall be a review of McKinsey's systems, processes, policies, and procedures relating to McKinsey's: i) evaluation of risks associated with potential clients and potential engagements; ii) the assignment of and adherence to risk-related controls implemented for Life Sciences and Healthcare Sector Engagements (as defined in Section II.C.7 of the CIA); iii) evaluation of potential conflicts of interest between clients and with regard to the staffing of engagements; iv) review of interim and final deliverables and final material recommendations for Life Sciences and Healthcare Sector Engagements; and iv) identification and implementation of corrective action in response to deficiencies.

If there are no material changes in the applicable systems, processes, policies, and procedures of McKinsey relating to Reviewed Policies and Procedures described below, the Compliance Expert shall perform the Quality Systems Review for the second and fourth Reporting Periods. If McKinsey materially changes applicable systems, processes, policies, and procedures, the Compliance Expert shall perform a Quality Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the second and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed.

1. The Compliance Expert shall review the systems, processes, policies, and procedures (hereafter collectively "Reviewed Policies and Procedures") that McKinsey uses to:

- a. evaluate potential clients in the Life Sciences and Healthcare practice areas prior to McKinsey's agreement to perform engagements for such clients, including the evaluation of risks associated with the potential clients;
- b. evaluate potential Life Sciences and Healthcare Sector Engagements prior to McKinsey's agreement to undertake the engagements, including the evaluation of risks associated with the engagements and the application to the engagements of controls that McKinsey refers to as "risk compacts, subcompacts, and guardrails";
- c. develop, update, approve, and implement risk compacts, subcompacts, and guardrails applicable to Life Sciences and Healthcare Sector Engagements;
- d. assess whether Life Sciences and Healthcare Sector Engagements were conducted in accordance with all applicable risk compacts, subcompacts and guardrails assigned to each such engagement;
- e. identify, manage, and disclose potential conflicts of interest between the potential clients or engagements in the Life Sciences and Healthcare practice areas and existing McKinsey clients or engagements;
- f. evaluate and manage conflicts of interest associated with Covered Persons (as defined in Section II.C.3 of the CIA) assigned to or involved with Life Sciences and Healthcare Sector Engagements;
- g. validate that Covered Persons assigned to or involved with Life Sciences and Healthcare Sector Engagements have appropriate expertise in, training on, and knowledge of Regulated Industry Requirements applicable to the engagements;
- h. validate that the quarterly reviews by the Client Service Risk Committee (Quarterly CSRC Reviews) appropriately assessed and confirmed that all final material recommendations and interim and/or final deliverables (if applicable) associated with Life Sciences Engagements and Healthcare Sector Engagements complied with Regulated Industry Requirements, and did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements;
- i. conduct other internal reviews (e.g., by the Client Services Team or the Risk or Legal Teams) during the course of Life Sciences Engagements and

Healthcare Sector Engagements to assess whether material recommendations and interim and/or final deliverables (if applicable) associated such engagements complied with Regulated Industry Requirements and did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements;

j. take remedial action in any situations in which interim or final deliverables and/or material recommendations associated with Life Sciences and Healthcare Sector Engagements violated Regulated Industry Requirements or were identified as providing or assisting clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements; and

k. identify, track, and remediate any deficiencies associated with the Reviewed Policies and Procedures described above in Sections I.A.1.a-j.

2. Quality Systems Review Report

The Compliance Expert shall prepare a Quality Systems Review Report based upon each Quality Systems Review. For each of the Reviewed Policies and Procedures identified in Section I.A.1 above, the report shall include the following items:

a. A description of the systems, processes, policies, and procedures used to evaluate potential Life Sciences and Healthcare Sector Engagement clients prior to McKinsey's agreement to perform engagements for such clients, including the evaluation of risks associated with the potential client;

b. A description of the systems, processes, policies and procedures used to evaluate potential Life Sciences and Healthcare Sector Engagements prior to McKinsey's agreement to undertake the engagements, including the evaluation of risks associated with the engagements and the assignment of risk compacts, subcompacts, and guardrails to the engagements;

c. A description of the systems, processes, policies and procedures used to develop, update, approve, and implement risk compacts, subcompacts, and guardrails applicable to Life Sciences Engagements and Healthcare Sector Engagements;

d. A description of the systems, processes, policies, and procedures used to assess whether Life Sciences Engagements and Healthcare Sector Engagements were

conducted in accordance with applicable risk compacts, subcompacts, and guardrails assigned to each such engagement;

e. A description of the systems, processes, policies, and procedures used to identify, manage, and disclose potential conflicts of interest between potential clients or engagements in the Life Sciences and Healthcare Sector and existing McKinsey clients or engagements;

f. A description of the systems, processes, policies and procedures used to evaluate and manage conflicts of interest associated with Covered Persons assigned to or involved with Life Sciences and Healthcare Sector Engagements;

g. A description of the systems, processes, policies and procedures used to validate that Covered Persons assigned to or involved with Life Sciences and Healthcare Sector Engagements have appropriate expertise in, training on, and knowledge of Regulated Industry Requirements applicable to the engagements;

h. A description of the systems, processes, policies and procedures associated with the Quarterly CSRC Reviews;

i. A description of the systems, processes, policies, and procedures relating to other assessments (apart from the Quarterly CSRC Reviews) of material recommendations and interim and/or final deliverables (if applicable) associated with Life Sciences and Healthcare Sector Engagements as to whether the recommendations and/or deliverables complied with Regulated Industry Requirements and did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements

j. A description of the systems, processes, policies and procedures followed in any situations in which interim or final deliverables and/or material recommendations associated with Life Sciences Engagements and Healthcare Sector Engagements provided or assisted clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements;

k. A description of the systems, processes, policies and procedures used to identify, track, and remedy any deficiencies associated with the Reviewed Policies and Procedures;

l. Observations, findings, and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

m. Recommendations for the improvement of systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

II. Transactions Review

For each Reporting Period of the CIA, the Compliance Expert shall perform the Transactions Review. The Transactions Review shall be based on a review of a sample of Life Sciences and Healthcare Sector Engagements completed during the applicable Reporting Period. The Compliance Expert shall report on all aspects of each Transaction Review in each Transactions Review Report.

A. Compliance Expert Transactions Review.

1. *Identification of High Risk Engagements.* Beginning with the second Reporting Period, McKinsey shall work with OIG to identify subcategories of Life Sciences and Healthcare Sector Engagements that are deemed to be “High Risk Engagements” for purposes of the CIA. At least 45 days before the start of each Reporting Period, McKinsey shall provide OIG with a list of the subcategories of work performed under Life Sciences and Healthcare Sector Engagements that it recommends be considered High Risk Engagements for purposes of the subsequent Reporting Period. In its sole discretion, OIG may agree with McKinsey’s identification of High Risk Engagements or may modify the subcategories of work included in Life Sciences and Healthcare Sector Engagements that are deemed to be High Risk Engagements for purposes of the CIA.

2. *Selection of Sample.* For each Reporting Period, the Compliance Expert shall review a sample of 50 High Risk Engagements from among the Life Sciences and Healthcare Sector Engagements that were completed during the Reporting Period. The sample shall be drawn from the subcategories of work included in Life Sciences and Healthcare Sector Engagements deemed to be High Risk Engagements as described above in Section II.A.1. OIG shall have the discretion to identify which subcategories shall be included and how many engagements shall be reviewed from each subcategory. If OIG elects to exercise this discretion, it shall notify McKinsey and the Compliance Expert at least 30 days prior to the end of the Reporting Period. In such an instance, McKinsey and the Compliance expert may submit proposals identifying

suggestions for the subcategories to be included and the number of engagements to be included from each subcategory. The determination of whether, and in what manner, to limit the selection of samples shall be made at the sole discretion of OIG.

If OIG elects not to exercise its discretion as described above, the Compliance Expert shall randomly select at least one engagement from each subcategory of work included in the High Risk Engagements. Each engagement selected for review shall be referred to hereafter as a “Reviewed Engagement”.

3. *Scope of Review.* For each Reviewed Engagement, the Compliance Expert shall:

- a. Review the consulting agreement, Master Service Agreement, and Statement of Work associated with the Reviewed Engagement and any agreed modifications, extensions, or renewals;
- b. Review all final material recommendations and key interim deliverables and/or final deliverables (if applicable) associated with the Reviewed Engagement;
- c. Review documentation of any client disagreement associated with the Reviewed Engagement and how any such disagreement was resolved;
- d. Identify all risk compacts, subcompacts, and guardrails applicable to the Reviewed Engagement;
- e. Assess whether the Reviewed Engagement was conducted in accordance with the applicable risk compacts, subcompacts, and guardrails as required;
- f. In the Compliance Expert’s discretion, conduct interviews of McKinsey personnel involved with the Reviewed Engagements;
- g. Assess whether the Reviewed Engagement was subject to the Quarterly CSRC Review. If so, the Compliance Expert shall

evaluate CSRC's findings and any remedial action taken in response to the CSRC's findings;

- h. Determine whether material recommendations and key interim and/or final deliverables (if applicable) associated with Reviewed Engagement were subject to any other internal McKinsey reviews (apart from the Quarterly CSRC Review) to assess whether they complied with Regulated Industry Requirements and did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements. If so, the Compliance Expert shall review the findings from the internal McKinsey reviews and any remedial action taken in response to the findings; and
- i. Assess whether all material recommendations and key interim and final deliverables (if applicable) associated with Reviewed Engagement complied with Regulated Industry Requirements and did not provide or assist clients with the implementation of plans, advice, or strategies that violate Regulated Industry Requirements.

B. Transactions Review Report. For each Reporting Period, the Compliance Expert shall prepare a report based on its Transactions Review. The report shall include the following:

- 1. *Transactions Review Methodology*
 - a. Review Objectives: 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 Transaction Review was performed and what was evaluated; and
 - c. Sources of Data: A full description of documentation, other information, and interviews (if applicable) relied upon by the Compliance Expert in performing the Transactions Review.

2. *Results to be Included in Report.* The following results shall be included in each Transaction Review Report:

- a. For each Reviewed Engagement:
 - i. a summary description of the Reviewed Engagement and the documentation and information reviewed in accordance with Sections II.A.2.a-c above;
 - ii. a description of risk compacts, subcompacts, and guardrails applicable to the Reviewed Engagement;
 - iii. a determination of whether the Reviewed Engagement was conducted in accordance with the applicable risk compacts, subcompacts, and guardrails;
 - iv. a description of whether the Reviewed Engagement was subject to the Quarterly CSRC Review. If so, the Compliance Expert shall describe the CSRC's findings and provide an assessment of whether any remedial action taken in response to the CSRC's findings was appropriate;
 - v. a description of whether the material recommendations and key interim and/or final deliverables (if applicable) associated with Reviewed Engagement were subject to any other internal McKinsey reviews as described above in Section II.A.2.h above. If so, the Compliance Expert shall describe the findings from the internal McKinsey review and provide an assessment of whether any remedial action taken in response to the internal McKinsey review findings was appropriate;
 - vi. an assessment of whether all material recommendations and all key interim and/or final deliverables (if applicable) associated with Reviewed Engagement complied with Regulated Industry Requirements and did not provide or assist clients with

the implementation of plans, advice or strategies that violate Regulated Industry Requirements;

- vii. findings and supporting rationale regarding any overall weaknesses in McKinsey's systems, processes, policies, procedures, and practices relating to identifying, minimizing, and remediating risks associated with Life Sciences and Healthcare Engagements;
- viii. findings and supporting rationale regarding any overall weaknesses in McKinsey's systems, processes, policies, procedures, and practices relating to ensuring that material recommendations and key interim and final deliverables comply with Regulated Industry Requirements and provide clients with plans, advice, and strategies that comply with Regulated Industry Requirements;
- ix. recommendations, if any, for changes in McKinsey's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies described above in Section II.B.2.a.vii; and
- x. recommendations, if any, for changes in McKinsey's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies described above in Section II.B.2.a.viii.