

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MMM HOLDINGS, LLC**

I. PREAMBLE

MMM Holdings, LLC (MMM) 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). Elevance Health owns and operates MMM as well as other entities that operate Medicare Advantage organizations. Elevance Health undertakes certain obligations under this CIA that relate to the operation and oversight of MMM. Contemporaneously with this CIA, MMM is entering into a Settlement Agreement with the United States.

MMM represents that, prior to this CIA, MMM voluntarily established a Compliance Program which provides for a Medicare Compliance Officer, a Medicare Compliance Committee, a compliance training and education program, a confidential disclosure reporting hotline, auditing and monitoring activities, and various policies and procedures aimed at ensuring MMM's compliance with Medicare Advantage organization requirements. MMM shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. MMM may modify its Compliance Program, as appropriate, but at a minimum, MMM shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

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) MMM'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 MMM complies with the decision.

C. Definitions.

1. “Arrangements” means: every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value and is between MMM and (i) any actual or potential source of health care business or referrals of Medicare beneficiaries to MMM or (ii) any actual or potential recipient of health care business or referrals of Medicare beneficiaries from MMM.

- i. “Source of health care business or referrals” means any individual or entity, including but not limited to, first tier, downstream, or related entities¹ (FDRs), providers, suppliers, and Third-Party Marketing Organizations² (TPMOs) that makes referrals or recommendations to Medicare beneficiaries for enrollment in or marketing by MMM Medicare Advantage plans or that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.
- ii. “Recipient of health care business or referrals” means any individual or entity (a) to whom MMM refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom MMM purchases, leases, orders, arranges for, or recommends the purchasing, leasing, or ordering of any good, facility, item, or service, for which payment may be made in whole or in part by a Federal health care program.

2. “Arrangements Covered Persons” means each Covered Person who is involved with the development, negotiation, approval, management, implementation, payment, or review of MMM’s Arrangements.

3. “Marketing Arrangements” means every Arrangement that is between MMM and any actual source or recipient of health care business or referrals, including sources of referrals of Medicare beneficiaries, and involves, directly or indirectly, the offer, compensation, or provision of anything of value to perform marketing³ related functions for the benefit of MMM.

4. “Certifying Covered Persons” means the following: MMM’s Chief Financial Officer, Vice President of Sales, Vice President of Marketing, Staff Vice President of Marketing Communications and Services, and Elevance Health’s Chief Compliance Officer.

¹ 42 C.F.R. sec. 422.2

² 42 C.F.R. sec. 422.2260

³ “Marketing” in this context is defined as activities related to the process of selling or promoting MMM’s Medicare Advantage plans.

5. “Covered Persons” means:

(a) all owners who are natural persons, (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, board members, and employees of MMM or any of its wholly-owned subsidiaries who are engaged in, supervise, or oversee personnel who are engaged in MMM’s Medicare Advantage business;

(b) all contractors who furnish patient care items or services or perform billing or coding functions on behalf of MMM; and

(c) all contractors, subcontractors, agents, brokers, and other persons who perform marketing and enrollment for MMM’s Medicare Advantage plans.

Covered Persons do not include active Medicare providers who are contracted with MMM or any of its wholly-owned subsidiaries pursuant to 42 C.F.R. sec. 422.200 et seq. to furnish Medicare-covered items and services unless such providers are employees of MMM or its wholly owned subsidiaries.

6. “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 MMM’s policies, conduct, practices, or procedures.

7. “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.

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. “Overpayment” means any funds that MMM receives or retains under any Federal health care program to which MMM, after applicable reconciliation, is not entitled under such Federal health care program.

10. “Reportable Event” means: (a) a substantial Overpayment; (b) 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 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; (c) the employment of or contracting with a Covered Person who is an Ineligible Person; or (d) the filing of a bankruptcy petition by MMM.

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

12. “Training Plan” means a written plan that outlines the steps MMM will take to ensure that: (a) Covered Persons receive training on a periodic basis during the term of the CIA regarding MMM’s CIA requirements and compliance program and the applicable Federal health care program requirements, including the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute); and (b) Arrangements Covered Persons receive at least annual training regarding (i) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to the statute; (ii) MMM’s policies, procedures, and other requirements relating to Arrangements and Marketing Arrangements, including but not limited to the Marketing Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of MMM’s Arrangements to know the applicable legal requirements and the MMM’s policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) examples of violations of the Anti-Kickback Statute.

13. “Transition Plan” means a plan to address whether and how MMM’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

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

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

1. *Compliance Officer.* Within 90 days after the Effective Date, MMM shall appoint a Compliance Officer who is an employee and a member of senior management of MMM. The Compliance Officer shall report directly to the Chief Executive Officer of MMM 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 MMM. The Compliance Officer shall be authorized to report to the Chief Compliance Officer for Elevance Health, the Board of Directors of Elevance Health (EH Board), and the Board of Directors of MMM (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 requirements;

- b. making at least quarterly reports regarding compliance matters to the Board.
- c. making at least semi-annual reports regarding compliance matters to the EH Board;
- d. monitoring the day-to-day compliance activities engaged in by MMM; and
- e. 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.

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

MMM 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 MMM's compliance with Federal health care program requirements and the requirements of this CIA. The Board must include at least one independent (e.g., non-owner, non-employee, and non-executive) member.

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

- a. meeting at least quarterly to review and oversee MMM's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the 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 MMM's compliance with Federal health care program 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 MMM'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, MMM has implemented an effective compliance program to meet Federal health care program requirements and the requirements of MMM'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 the Board is taking to implement an effective compliance program at MMM.

MMM 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 and oversee compliance within the divisions or departments for which they are responsible and annually certify that the applicable MMM division or department is in compliance with applicable Federal health care program 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, requirements of the Corporate Integrity Agreement, and MMM'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 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 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, MMM 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 90 days after the Effective Date, MMM shall develop and implement written policies and procedures (Policies and Procedures) that address the following: (1) the operation of MMM's compliance program, including the compliance program requirements outlined in this CIA; (2) MMM's compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute, and the regulations and other guidance documents related to these statutes, and business or financial arrangements that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute; (3) the requirements set forth in Section III.D below; and (4) the identification, quantification, and repayment of Overpayments. MMM 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 revised or new 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 and Arrangements Covered Persons Training.* Within 90 days after the Effective Date, MMM shall develop a Training Plan that includes the following information: (a) training topics; (b) identification of Covered Persons and Arrangements Covered Persons required to attend each training session; (c) length of the training sessions(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 90 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 the OIG's guidance on board member responsibilities. Each member of the Board also shall receive the training described in Section III.C.1.

New members of the Board shall receive the training described in this Section III.C.2 within 30 days after becoming a member or within 90 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.* MMM 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. Compliance with the Anti-Kickback Statute.

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

- a. creating and maintaining a centralized tracking system for all existing, new, or renewed Marketing Arrangements and the information specified in Sections III.D.1.b-f below for each existing, new, or renewed Marketing Arrangement (Marketing Arrangements Tracking System);
- b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Marketing Arrangements;
- c. tracking all remuneration, including any referral fees, administrative payments (not for enrollments), and other compensation to and from all parties to Marketing Arrangements to ensure that the parties are complying with the financial terms of the Marketing Arrangements and that the Marketing Arrangements are commercially reasonable;
- d. documenting all regulatory assessments⁴ and/or fair market value (FMV) determination(s) for any Marketing Arrangement, including the FMV amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the FMV amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the FMV determination(s);
- e. tracking service and activity logs to ensure that parties to the Marketing Arrangement are performing the services required under the applicable Marketing Arrangement(s) (if applicable);

⁴ CMS regulates agent, broker, and other third-party requirements applicable to Medicare Advantage organizations in CMS's marketing regulations. See 42 C.F.R. § 422.2274. "Regulatory assessments" here include but are not necessarily limited to MMM's assessments regarding compliance with CMS's requirements.

- f. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Marketing Arrangement(s) (if applicable);
- g. establishing and implementing a written review and approval process for Marketing Arrangements, the purpose of which is to ensure that all existing, new, or renewed Marketing Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Marketing Arrangements by counsel with expertise in the Anti-Kickback Statute; (ii) a process for specifying and documenting the business need or business rationale for all Marketing Arrangements; and (iii) a process for determining and documenting the FMV of the remuneration specified in the Marketing Arrangement;
- h. ensuring that all existing Marketing Arrangements are subject to the review and approval process described in Section III.D.1.g above;
- i. requiring the Compliance Officer to review the Marketing Arrangements Tracking System, internal review and approval process, and other Marketing Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- j. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate.

2. *New or Renewed Marketing Arrangements.* No later than 120 days after the Effective Date, and prior to entering into new Marketing Arrangements or renewing existing Marketing Arrangements, in addition to complying with the Marketing Arrangements Procedures set forth above, MMM shall comply with the following requirements (Marketing Arrangements Requirements):

- a. ensure that all written Marketing Arrangements are signed by MMM and the other party(ies) to the Marketing Arrangement prior to the payment or receipt of any remuneration pursuant to the Marketing Arrangement;
- b. ensure that all Marketing Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remuneration pursuant to the Marketing Arrangement, and that MMM maintains appropriate

documentation of the review and approval of such Marketing Arrangement; and

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

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

E. Review Procedures.

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, MMM shall engage a lawyer, law firm, or consulting firm (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.E.
- b. *Retention of Records.* The IRO and MMM shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and MMM related to the reviews described in this Section III.E.
- c. *Responsibilities and Liabilities.* Nothing in this Section III.E affects MMM’s responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute.
- d. *Access to Records and Personnel.* MMM shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E and that all records furnished to the IRO are accurate and complete.

2. *Marketing Systems and Transactions Reviews.* The IRO shall perform Marketing Systems and Transactions Reviews and shall prepare Review Reports, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Certification Regarding Prohibited Relationships.* The IRO shall include in its report(s) to MMM a certification that the IRO (a) does not currently represent or is not currently employed or engaged by MMM or Elevance Health and (b) does not have a current or prior relationship to MMM or Elevance Health or their owners, officers, or Board members that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by this Section III.E. The IRO's certification shall include a summary of any current and prior relationships between MMM, Elevance Health, or their owners, officers, or Board members and the IRO.

F. Risk Assessment and Internal Review Process. Within 120 days after the Effective Date, MMM shall develop and implement a centralized annual risk assessment and internal review process to identify and address the Anti-Kickback Statute risks associated with Arrangements and MMM's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. 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 MMM 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.

G. Disclosure Program. Within 90 days after the Effective Date, MMM shall establish a Disclosure Program. MMM 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 the use of the Disclosure Program and MMM 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 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) 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.

H. Ineligible Persons.

1. *Screening Requirements.* MMM 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 on a monthly basis thereafter;
- c. screen all prospective and current Covered Persons against the Preclusion List as appropriate and in accordance with the Centers for Medicare & Medicaid Services (CMS's) requirements; and
- d. require all Covered Persons to disclose immediately to the Compliance Officer (or designee) if they become an Ineligible Person.

2. *Removal Requirement.* If MMM has actual notice that a Covered Person has become an Ineligible Person, MMM 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 MMM may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether MMM meets the requirements of Section III.H.

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

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

1. *Substantial Overpayment.* 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 entities and individuals believed to be implicated, including an explanation of their roles in the Reportable Event;

- b. the Federal health care programs affected by the Reportable Event;
- c. a description of the steps taken by MMM to identify and quantify the Overpayment; and
- d. a description of MMM's actions taken to correct the Reportable Event and prevent it from recurring.

Within 60 days of identification of the substantial Overpayment, MMM shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS's guidance, and provide OIG with documentation of the repayment.

- 2. *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 the steps taken by MMM to identify and quantify any Overpayments; and
 - e. a description of MMM's actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, MMM shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and CMS guidance, and provide OIG with documentation of the repayment.

- 3. *Ineligible Persons.* 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 MMM completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons 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 authorities implicated.

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

IV. SUCCESSOR LIABILITY

If, after the Effective Date, MMM 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 the furnishing of items or services that may be reimbursed by a Federal health care program; or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, 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. MMM 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 MMM wishes to obtain a determination by OIG that a proposed purchaser or proposed acquisition will not be subject to the CIA requirements, MMM 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, MMM shall submit a written report (Implementation Report) to OIG that includes, at a minimum, the following information:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3;
4. the names and positions of the Certifying Covered Persons required by Section III.A.4 and a copy of the written process for Certifying Covered Persons to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
7. a description of (a) the Marketing Arrangements Tracking System required by Section III.D.1.a; (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Marketing Arrangements Procedures required by Section III.D.1;
8. 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 that it does not have a prohibited relationship with MMM or its owners, officers, or Board members (as set forth in Section III.E.3) that includes a summary of any current and prior relationships between MMM or its owners, officers, or Board members, and the IRO;
9. a description of the risk assessment and internal review process required by Section III.F;
10. a description of the Disclosure Program required by Section III.G;
11. a description of the Ineligible Persons screening and removal process required by Section III.H;
12. a description of MMM's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
13. a list of all of MMM's locations (including mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and

- that:
14. a certification by the Compliance Officer and Chief Executive Officer
 - a. to the best of their knowledge, except as otherwise described in the report, MMM is in compliance with all of the requirements of this CIA;
 - b. to the best of their knowledge, MMM has implemented procedures reasonably designed to ensure that all Marketing Arrangements do not violate the Anti-Kickback Statute, including the Marketing Arrangements Procedures required in Section III.D of the CIA;
 - c. to the best of their knowledge, MMM has fulfilled the requirements for new or renewed Marketing Arrangements under Section III.D.2 of the CIA;
 - d. they have reviewed the report and have made reasonable inquiry regarding its content and believe that the information in the report is accurate and truthful; and
 - e. they understand that the certification is being provided to and relied upon by the United States.

B. Annual Reports. MMM 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 Board members who are responsible for satisfying the Board compliance requirements, and a current list of the Certifying Covered Persons, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, or Certifying Covered Persons;
2. the dates of each meeting of the Compliance Committee (copies of the meeting minutes shall be made available to OIG upon request);
3. the dates of each report made by the Compliance Officer to the Board and the EH Board (written documentation of such reports shall be made available to OIG upon request);
4. the Board resolution required by Section III.A.3 and 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.4;
7. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
8. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons, Arrangements Covered Persons, and Board members during the Reporting Period;
9. a description of (a) any changes to the Marketing Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Marketing Arrangements Procedures required by Section III.D.1;
10. a complete copy of all reports prepared pursuant to Section III.E and MMM's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
11. a certification from the IRO that it does not have a prohibited relationship with MMM or Elevance Health, as described in Section III.E.3 above, including a summary of any current and prior relationships between MMM or Elevance Health or their owners, officers, or Board members and the IRO;
12. a description of any changes to the risk assessment and internal review process required by Section III.F, 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 actions plans shall be made available to OIG upon request;
14. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs including those that involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute, 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.H, 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.I 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.J during the Reporting Period;

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

19. a description of all changes to the most recently provided list of MMM's locations (including addresses) as required by Section V.A.13;

20. a description of any changes to MMM'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 Chief Executive Officer that:

- a. to the best of their knowledge, except as otherwise described in the report, MMM is in compliance with all of the requirements of this CIA;
- b. to the best of their knowledge, MMM has implemented procedures reasonably designed to ensure that all Marketing Arrangements do not violate the Anti-Kickback Statute, including the Marketing Arrangements Procedures required in Section III.D of the CIA;
- c. to the best of their knowledge, MMM has fulfilled the requirements for new or renewed Marketing Arrangements under Section III.D.2 of the CIA;
- d. they have reviewed the report and have made reasonable inquiry regarding its content and believe that the information in the report is accurate and truthful; and
- e. they understand 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 90 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. MMM 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. MMM 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

MMM:

Chief Compliance Officer
MMM Holdings LLC
350 Av. Carlos E. Chardón #500
San Juan, Puerto Rico 00918
Telephone: (787) 398-4855
Email: chiefcomplianceofficer@mmmhc.com

Unless otherwise requested by OIG, all notifications and reports required by this CIA shall be submitted electronically. OIG shall notify MMM in writing of any changes to the OIG contact information listed above. MMM shall notify OIG in writing within two business days of any changes to the MMM 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 MMM's books, records, and other documents and supporting materials, and conduct on-site reviews of any of MMM's locations for the purpose of evaluating: (a) MMM's compliance with the requirements of this CIA and (b) MMM's compliance with the requirements of the Federal

health care programs. The documentation described above shall be made available by MMM 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 MMM's owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), employees, contractors, and Board members who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. MMM shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. MMM's owners, employees, contractors, and Board members may elect to be interviewed with or without a representative of MMM present.

VIII. DOCUMENT AND RECORD RETENTION

MMM 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 MMM prior to any release by OIG of information submitted by MMM pursuant to its requirements under this CIA and identified upon submission by MMM as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, MMM 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 MMM fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.E;

6. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section III.K;
12. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section IV;
13. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section V;
14. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section VII;
15. A Stipulated Penalty of up to \$2,500 for each day MMM fails to comply with Section VIII; or
16. A Stipulated Penalty of up to \$50,000 for each false certification or false statement made to OIG by or on behalf of MMM under this CIA.

B. Timely Written Requests for Extensions. MMM 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 MMM 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 MMM 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 MMM of: (a) MMM'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, MMM 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 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.E;
- e. failure to comply with Section III.J;
- f. failure to comply with Section V;
- g. failure to respond to a Demand Letter in accordance with Section X.C.;
- h. a false statement or false certification made to OIG by or on behalf of MMM under this CIA;
- i. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering MMM 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

- j. failure to come into compliance with a requirement for which the 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 MMM constitutes an independent basis for MMM'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 MMM has materially breached this CIA, OIG shall notify MMM of: (a) MMM's material breach; and (b) OIG's intent to exclude MMM. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice.* MMM 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 MMM in writing of its determination to exclude MMM. (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 MMM, 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, MMM 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 MMM, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, MMM 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. § 1005.1: (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 MMM was in full and

timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. MMM shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that MMM has breached this CIA and orders MMM to pay Stipulated Penalties, MMM 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 MMM 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, MMM 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 MMM 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. MMM 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 MMM, MMM 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 MMM 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

MMM 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) MMM'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 MMM 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 MMM HOLDINGS, LLC

/Ricardo Rivera Cardona/
RICARDO RIVERA CARDONA
President and Chief Executive Officer
MMM Holdings LLC

December 20, 2024
DATE

/Benjamin D. Singer/
BENJAMIN D. SINGER
Counsel for MMM Holdings LLC
O'Melveny & Myers LLP

December 20, 2024
DATE

/Caitlin M. Bair/
CAITLIN M. BAIR
Counsel for MMM Holdings LLC
O'Melveny & Myers LLP

December 20, 2024
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

12/19/24
DATE

/Sarah Kessler/
SARAH KESSLER
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

2024.12.20
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. MMM 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 not have a prohibited relationship to MMM or Elevance Health as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by MMM in response to a request by OIG, whichever is later, OIG will notify MMM if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MMM may continue to engage the IRO.

2. If MMM 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, MMM shall submit the information identified in Section V.A.8 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 MMM at the request of OIG, whichever is later, OIG will notify MMM if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, MMM may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Marketing Arrangements Systems and Marketing Arrangements Transactions Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to the statute;
2. assign individuals to conduct the Marketing Arrangements Systems and Marketing Arrangements Transactions Review who are knowledgeable in the marketing, contracting, enrollment, and other requirements of the Medicare Advantage program;
3. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Marketing Arrangements Systems and Marketing Arrangements Transactions Review; and
4. 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 Marketing Arrangements Systems and Marketing Arrangements Transactions Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. MMM Responsibilities

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

E. IRO Relationship to MMM

The IRO shall not (1) currently represent or currently be employed or engaged by MMM or Elevance Health or (2) have a current or prior relationship to MMM or Elevance Health or their owners, officers, or Board members that would cause a reasonable person to question the IRO's objectivity in performing the reviews required by Appendix B to this CIA.

F. Assertions of Privilege

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

G. IRO Removal/Termination

1. *MMM and IRO.* If MMM terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, MMM 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. MMM 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 that the IRO does not possess the qualifications described in Paragraph B, has a prohibited relationship as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify MMM in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. MMM shall have 30 days from the date of OIG's written notice

to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by MMM regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify MMM in writing that MMM shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. MMM 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 MMM to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

MARKETING ARRANGEMENTS REVIEW

The Marketing Arrangements Review shall consist of a Systems Review and a Transactions Review. If there are no material changes to MMM's systems, processes, policies, and procedures relating to Marketing Systems, the Marketing Arrangements Systems Review shall be performed for the first and fourth Reporting Periods. If MMM materially changes the systems, processes, policies and procedures related to Marketing Arrangements, the IRO shall perform a Marketing Arrangements Systems Review for the Reporting Period in which such changes were made in addition to conducting the systems review for the first and fourth Reporting Periods. The Marketing Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

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

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

2. MMM's systems, policies, processes, and procedures for documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Marketing Arrangements;

3. MMM's systems, policies, processes, and procedures for tracking all remuneration to and from all parties to Marketing Arrangements to ensure that the parties are complying with the financial terms of the Marketing Arrangements and that the Marketing Arrangements are commercially reasonable;

4. MMM's systems, policies, processes and procedures for documenting all fair market value (FMV) determination(s) for any Marketing Arrangement, including the FMV amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the FMV amount or range, and the names and positions of the Arrangements Covered Person(s) who received or were otherwise involved with the FMV determination(s);

5. MMM's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in sales or marketing with regard to whether the systems, policies, processes, and procedures comply with applicable Federal healthcare program laws and regulations, including Medicare Advantage marketing requirements, and are, when applicable, designed to meet a safe harbor to the Federal

anti-kickback statute. To the extent that MMM establishes different methods of compensation for different Medicare Advantage plans, the IRO shall review each type of compensation arrangement separately;

6. MMM's systems, policies, processes, and procedures applicable to the marketing materials and information that may be distributed or made available by MMM's sales representatives (including any contract sales force) about MMM's Medicare Advantage plans and the methods by which the materials and information are distributed or made available;

7. MMM's systems, policies, processes, and procedures relating to the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other MMM's representatives who promote and sell MMM Medicare Advantage plans;

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

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

10. MMM's systems, policies, processes, and procedures for the internal review and approval of existing, new, and renewed Marketing Arrangements, including those policies that identify the individuals required to approve each type or category of Marketing Arrangement entered into by MMM, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Marketing Arrangements, the processes for determining and documenting the FMV of the remuneration specified in the Marketing Arrangement, and the processes for ensuring that all Marketing Arrangements are subject to a legal review by counsel with expertise in the applicable Federal healthcare program rules including Medicare Advantage marketing requirements, the Anti-Kickback Statute, and the beneficiary inducement prohibition (codified at 42 C.F.R. sec. 1320a-7a(a)(5));

11. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Marketing Arrangements Tracking System, MMM's internal review and approval process, and other Marketing Arrangements systems, process, policies, and procedures; and

12. MMM's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Federal requirements are discovered, including disclosing Reportable Events and quantifying and repaying Overpayments when appropriate.

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

1. a description of the documentation (including policies) reviewed and personnel interviewed;
2. a detailed description of MMM's systems, policies, processes, and procedures relating to the items identified in Section A.1-12 above;
3. findings and supporting rationale regarding weaknesses in MMM's systems, processes, policies, and procedures relating to Marketing Arrangements described in Section A.1-12 above; and
4. recommendations to improve MMM's systems, policies, processes, or procedures relating to Marketing Arrangements described in Section A above.

C. Marketing Arrangements Transactions Review. The Marketing Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Marketing Arrangements that were entered into or renewed by MMM during the Reporting Period. Ten of the 50 Marketing Arrangements will be randomly selected from a subset of the Marketing Arrangements between MMM or its wholly owned subsidiaries and its Covered Persons who are bona fide employees; the remaining 40 Marketing Arrangements will be randomly selected from the remaining population of Marketing Arrangements (excluding the subset of the Marketing Arrangements between MMM or its wholly owned subsidiaries and its Covered Persons who are bona fide employees). The IRO shall assess whether MMM has complied with the Marketing Arrangements Procedures and the Marketing Arrangements Requirements described in Sections III.D.1 and III.D.2 of the CIA, with respect to the selected Marketing Arrangements.

1. The IRO's assessment with respect to each Marketing Arrangement that is subject to review shall include:
 - a. verifying that the Marketing Arrangement is maintained in MMM's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Marketing Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Marketing Arrangement; (iii) the relevant terms of the Marketing Arrangement (i.e., the services to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) service and activity logs associated with the parties' performance under the Marketing Arrangement (i.e., services actually provided, amount of payments, any relevant enrollment data, dates of payment, etc.);
 - b. verifying that the Marketing Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented;

c. verifying that the remuneration related to the Marketing Arrangement has been determined in accordance with MMM's policies and procedures for determining and documenting regulatory compliance and/or the FMV of the remuneration, that the remuneration is properly tracked, and that the parties to the Marketing Arrangement are complying with the financial terms of the Marketing Arrangement; and

d. verifying that the Marketing Arrangement complies with CMS's Marketing requirements, including those at Subpart V of Part 422 of Title 42 of the Code of Federal Regulations.

2. For any Marketing Arrangement for which the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above, the IRO shall identify and review the system(s) and/or process(es) that resulted in the identified non-compliance and recommend improvements to such system(s) and/or process(es). The IRO may need to review additional documentation and/or interview personnel to identify the system(s) and/or process(es) that resulted in the identified non-compliance.

3. If the IRO cannot verify compliance with each of the applicable requirements specified in Section C.1 above with respect to at least 90% of the Marketing Arrangements subject to the Marketing Arrangements Transactions Review, then, at its discretion, within 60 days of receipt of the Marketing Arrangements Transactions Review Report, the OIG may require the IRO to select an additional sample of Marketing Arrangements, not to exceed the number of Marketing Arrangements initially reviewed by the IRO, that will be subject to the Marketing Arrangements Transactions Review (Additional Marketing Arrangements Transactions Review) and complete and submit to MMM and OIG an Additional Marketing Arrangements Transactions Review Report that includes the information specified in Section D below, within 60 days of the date the OIG notifies MMM and its IRO that an Additional Marketing Arrangements Transactions Review will be required.

D. Marketing Arrangements Transactions Review Report. The IRO shall prepare a report based on each Marketing Arrangements Transactions Review performed. The Marketing Arrangements Transaction Review Report shall include the following information:

1. *Review Methodology*.

a. Review Protocol. A description of the process used by the IRO to identify the Marketing Arrangements subject to review in the Marketing Arrangements Transactions Review.

b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Marketing Arrangements Transactions Review.

c. Supplemental Materials. The IRO shall request all documentation required for its review of the Marketing Arrangements selected as part of the Marketing Arrangements Transactions Review and MMM shall

furnish such documentation to the IRO prior to the IRO initiating its review of the Marketing Arrangements. If the IRO accepts any supplemental documentation from MMM after the IRO has completed its initial review of the Marketing Arrangements (Supplemental Materials), the IRO shall include the following in the Marketing Arrangements Transactions Review Report: (i) a description of the Supplemental Materials, (ii) the date the Supplemental Materials were accepted, (iii) the IRO's reason(s) for accepting the Supplemental Materials, and (iv) the relative weight the IRO gave to the Supplemental Materials in its review.

2. *Review Findings.* The IRO's findings with respect to whether MMM has complied with the Marketing Arrangements Procedures and Marketing Arrangements Requirements with respect to each of the randomly selected Marketing Arrangements reviewed by the IRO, including findings for each item listed in Sections C.1.a-d above. In addition, as applicable, the Marketing Arrangements Transactions Review Report shall include the IRO's recommendations as required by Section C.2 above.

3. *Names and Credentials.* The names and credentials of the individuals who conducted the Marketing Arrangements Systems Review and the Marketing Arrangements Transactions Review.