

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

**I. PREAMBLE**

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

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by RMS under this CIA shall be five years from the effective date of this CIA. The “Effective Date” shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) RMS’s final Annual Report; or (2) any additional materials submitted by RMS pursuant to OIG’s request, whichever is later.

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

1. For purposes of this CIA, the term “Covered Persons” includes: (a) all owners of RMS who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading or private placement) and all officers and directors of RMS; (b) all employees of RMS ; and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of RMS, and in that capacity either: (i) interact

directly with healthcare professionals (HCPs) and healthcare institutions (HCIs); or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by a RMS employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Person does not include part-time or per-diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become “Covered Persons” at the point when they work more than 160 hours during the calendar year.”

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

3. The term “Covered Functions” includes: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to RMS’s review and approval processes for promotional materials and any applicable review committee(s); (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to RMS’s review and approval process for any non-promotional materials and any applicable review committees; (d) contracting with health care professionals (HCPs) for consulting services (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and any research-related activities, and authorship of articles or other publications relating to Government Reimbursed Products), or other fee-for service arrangements relating to Government Reimbursed Products; (e) reviewing and/or approving requests for grants or charitable contributions.

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

5. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by

a third party and supported by RMS, including but not limited to, continuing medical education (CME), disease awareness, or symposia at medical conferences.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

RMS shall establish and maintain a Compliance Program that includes the following elements:

#### **A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations**

1. *Compliance Officer.* Within 90 days after the Effective Date, RMS shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of RMS; shall report directly to the Chief Executive Officer of RMS; 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 RMS. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters in person to the Board of Directors of RMS (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by RMS as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

RMS shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to

perform the duties necessary to meet the obligations in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, RMS shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of RMS's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

RMS shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

3. *Board Compliance Obligations.* The Board (or the Audit Committee of the Board of Directors) of RMS ("Board") shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include independent (i.e., non-employee and non-executive) members.

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

- a. meeting at least quarterly to review and oversee RMS's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as 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, signed by each member of the Board, summarizing its review and oversight of RMS's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of RMS'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, RMS has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at RMS.

RMS shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 business days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain RMS employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable RMS department is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: Chief Financial Officer; Vice President of Operations; Director of Marketing; Head of Sales for Dermatology. For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under

my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and RMS policies, and I have taken steps to promote such compliance. To the best of my knowledge, the \_\_\_\_\_ [insert name of department] of RMS is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

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

Within 90 days after the Effective Date, RMS shall develop and implement a written process for Certifying Employees 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 Employee making the required certification).

B. Written Standards

1. *Policies and Procedures.* Within 90 days after the Effective Date, RMS shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and RMS’s compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, RMS shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

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

- b. the materials and information that may be distributed by RMS sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which RMS sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products;
- c. the materials and information that may be distributed by RMS and the mechanisms through, and manner in which RMS receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by RMS in response to such requests; and the internal review process for the information disseminated;
- d. the manner and circumstances under which RMS medical and/ or regulatory personnel interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with RMS sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products;
- e. the materials and information that may be distributed or made available by RMS through social media and/or direct-to-consumer advertising;
- f. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other RMS representatives who promote and sell Government Reimbursed Products;
- g. the development, implementation, and review of all plans for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Products). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Products

(including, separately, from sales representatives or through other channels);

- h. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- i. agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including but not limited to, patents, patent applications, and the payment of royalties);
- j. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
- k. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCP participation in educational, research, training, or other RMS-sponsored programs or activities;
- l. sponsorship or funding of grants (including educational grants) or charitable contributions;
- m. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.4 and II.C.5 above;
- n. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside RMS by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to

ensure that legal, regulatory, and medical concerns are properly addressed during RMS's review and approval process and are elevated when appropriate;

- o. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representative and their managers;
- p. medical device reporting, including the development of medical device reporting procedures and establishing and maintaining medical device reporting event files, as required by 21 CFR Part 803 and other applicable FDA requirements; and
- q. disciplinary policies and procedures for violations of RMS's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), RMS shall assess and update, as necessary, the Policies and Procedures. 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, RMS shall develop a written plan (Training Plan) that outlines the steps RMS will take to ensure that: (a) all Covered Persons receive at least annual training regarding RMS's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all RMS Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. RMS shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the Board shall receive training regarding the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

D. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, RMS shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require RMS to: (1) identify and prioritize risks, (2) develop work plans related to the identified risk areas, (3) implement the work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. RMS shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, RMS shall engage an entity (or entities), such as an accounting, auditing, or consulting firm

(hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

- b. *Retention of Records.* The IRO and RMS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and RMS) related to the reviews.
- c. *Access to Records and Personnel.* RMS shall ensure 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. *System, Transaction, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of three components: Systems Reviews and Transactions Reviews relating to the Covered Functions and an Additional Items Review.

- a. *Systems Review.* The Systems Reviews shall assess RMS’s systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in RMS’s relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If RMS materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a 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, as set forth more fully in Appendix B.
- b. *Transactions Review.* The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.

- c. *Additional Items Review.* Each IRO review shall also include a review of up to three additional areas or practices of RMS identified by OIG in its discretion (hereafter “Additional Items”). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with RMS and may consider internal audit and monitoring work conducted by RMS, the Government Reimbursed Product portfolio, the nature and scope of RMS’s promotional and other practices, the nature and scope of RMS’s arrangements with HCPs and HCIs, and other information known to OIG.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

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

#### F. Disclosure Program

Within 90 days after the Effective Date, RMS shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual’s chain of command, any identified issues or questions associated with RMS’s policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. RMS shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall

include a requirement that all of RMS's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by RMS. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, RMS shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:
  - a. an "Ineligible Person" shall include an individual or entity who:
    - i. is currently excluded from participation in the Federal health care programs; or
    - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
  - b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* RMS shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

- a. RMS shall screen all prospective Covered Persons against the Exclusion List 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. RMS shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.
- c. RMS shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects RMS's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. RMS understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that RMS may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether RMS meets the requirements of Section III.G.

3. *Removal Requirement.* If RMS has actual notice that a Covered Person has become an Ineligible Person, RMS shall remove such Covered Person from responsibility for, or involvement with, RMS's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is 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).

4. *Pending Charges and Proposed Exclusions.* If RMS has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, RMS shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely

affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

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

Within 30 days after discovery, RMS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to RMS conducted or brought by a governmental entity or its agents involving an allegation that RMS has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. RMS also shall provide written notice to OIG within 30 days after the resolution of the matter and describe the findings and/or results of the investigation or proceeding, if any.

#### I. Reportable Events

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

- a. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by RMS.

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

2. *Reporting of Reportable Events.* If RMS determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, RMS shall notify OIG,

in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a and III.I.1.b.* For Reportable Events under Sections III.I.1.a and b, the report to OIG shall include:

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

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.1.c, 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 List screening that RMS 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.

5. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA requirements implicated.

J. Notification of Communications with FDA

Within 30 days after the date of any written or electronic report, correspondence, or communication between RMS and the FDA that materially discusses RMS's or a Covered Person's actual or potential unlawful or improper promotion of RMS's products (including any improper dissemination of information about off-label indications) or that involves adverse events required to be reported to the FDA under 21 C.F.R. Part 803, RMS shall provide a copy of the report, correspondence, or communication to OIG. RMS shall also provide written notice to OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts

Within 90 days after the Effective Date, RMS shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations (Observations) of sales personnel and (2) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Observations.* As a component of the FFMP, RMS compliance or other appropriately trained RMS personnel who are independent from the functional area

being monitored, or third party consultants appropriately trained by and under the supervision of RMS (Monitoring Personnel) shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with RMS's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the Government Reimbursed Product(s) promoted during the Observation;
- 5) an overall assessment of compliance with RMS Policies and Procedures; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least 3 Observations during each Reporting Period.

Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

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

- a. For each Reporting Period, RMS shall develop and implement a plan for conducting Records Reviews associated with at least 2 Government Reimbursed Products. The

Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.

- b. The Records Reviews shall include the monitoring and review of:
  - (i) records and systems associated with sales representatives' interactions with HCPs and HCIs (including records relating to consulting and other fee-for-service arrangements, speaker program activities, , travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers);
  - (ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;
  - (iii) sales representative call notes;
  - (iv) sales representatives' e-mails and other electronic records; and
  - (v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

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

L. Requirements Relating to Certain Promotional and Non-Promotional Activities

RMS shall develop policies, procedures, and systems to implement the requirements outlined below relating to the following types of activities: (1) arrangements with HCPs to serve as presenters on behalf of RMS or participate in training programs related to such presentations (Speaker Programs), (2) arrangements with HCPs for

services other than Speaker Programs, referred to herein as “consulting arrangement activities,” and (3) grant and charitable contribution activities

1. *Speaker Programs.* To the extent that RMS engages in Speaker Programs, RMS shall establish and implement the following requirements:

- a. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of RMS approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses).
- b. A centralized, electronic system to initiate and track all Speaker Programs that includes controls designed to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.
- c. A process to ensure speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.
- d. A comprehensive list of Speaker Program attendees through its centralized system. In addition, RMS shall use its centralized system to handle all logistics and spending associated with Speaker Programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with Speaker Programs.
- e. A requirement for certifications by sales representatives or other RMS personnel that a Speaker Program complied with RMS requirements, or in the event of non-compliance, RMS shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

2. *Consulting Arrangement Activities.* To the extent that RMS engages HCPs for services other than for speaker programs (e.g., training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, research and research-related activities, authorship activities, and any other financial engagement or arrangement with an HCP), such HCPs shall be referred to herein as Consultants. Within 90 days of the Effective Date, RMS shall:

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

documented in the needs assessment form and shall be subject to review and approval by RMS compliance personnel.

- d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, RMS receives the work product generated by the Consultant.

3. *Grant and Charitable Contribution Activities.* Within 90 days of the Effective date, RMS shall:

- a. Establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for Third Party Educational Activities, other grant activities involving HCPs and HCIs (referred to below as “Grants”), and charitable contributions supported by RMS (referred to below as “Contributions”).
- b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by RMS (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants or Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. RMS’s sales and marketing personnel shall have no involvement in, or influence over, the review and approval of requests for Grants or Contributions.

M. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, RMS shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS’s Open Payments Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). RMS also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from RMS.

2. *Definitions.* For purposes of this Section III.M, the terms “Payments” and “Covered Recipient” are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, RMS proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. RMS shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, RMS wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, RMS must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. 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 AND ANNUAL REPORTS**

##### **A. Implementation Report**

Within 120 days after the Effective Date, RMS shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, business address, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;

3. the names of the Board members who are responsible for satisfying the Board compliance obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B.1;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the risk assessment and internal review process required by Section III.D;
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 regarding its professional independence and objectivity with respect to RMS that includes a summary of all current and prior engagements between RMS and the IRO;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;
11. a description of the FFMP required by Section III.K;
12. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Promotional and Non-Promotional Activities outlined in Section III.L;
13. a certification from the Compliance Officer that information regarding Payments has been posted on RMS's website as required by Section III.M;

14. a list of all of RMS's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;

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

16. the certifications required by Section V.C.

B. Annual Reports

RMS shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other 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 obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;

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

4. the Board resolution required by Section III.A.3, a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution, and the Compliance Expert report as required in Section III.A.3.d.;

5. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;

6. a description of any changes to RMS's Training Plan developed pursuant to Section III.C and a summary of any Board training provided during the Reporting Period;
7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) any internal audits performed; (c) corrective action plans developed in response to any internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
9. a complete copy of all reports prepared pursuant to Section III.E and RMS's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
10. a certification from the IRO regarding its professional independence and objectivity with respect to RMS, including a summary of all current and prior engagements between RMS and the IRO;
11. a summary of the disclosures in the disclosure log required by Section III.F that relate to Federal health care programs, FDA requirements, or Government Reimbursed Products, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;
12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;
13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
14. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period;

15. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J. This summary shall include a description of each matter and the status of each matter;

16. a summary of any changes the FFMP and the results of the FFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper conduct occurred and a description of the action(s) that RMS took as a result of such determinations;

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

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

19. a description of all changes to the most recently provided list of RMS's locations (including addresses) as required by Section V.A.14;

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

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

### C. Certifications

1. *Certifying Employees.* In each Annual Report, RMS shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and Chief Executive Officer that:

a. to the best of his or her knowledge, except as otherwise

described in the report, RMS has implemented and is in compliance with all requirements of this CIA;

- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

RMS 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. RMS shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
Office of Inspector General  
U.S. Department of Health and Human Services  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

RMS:

Will McGuire

Chief Executive Officer  
Ra Medical Systems, Inc.  
2070 Las Palmas Drive  
Carlsbad, CA 92011  
Phone: (760) 804-1648  
Fax: (760) 804-1657  
[wmcguire@ramed.com](mailto:wmcguire@ramed.com)

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, RMS may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

## **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 RMS's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of RMS's locations for the purpose of verifying and evaluating: (a) RMS's compliance with the terms of this CIA and (b) RMS's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by RMS to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of RMS's owners (who are Covered Persons), employees, contractors and directors 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. RMS shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. RMS's owners, employees, contractors and directors may elect to be interviewed with or without a representative of RMS present.

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

RMS 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 RMS prior to any release by OIG of information submitted by RMS pursuant to its obligations under this CIA and identified upon submission by RMS as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, RMS shall have the rights set forth at 45 C.F.R. § 5.42 (a).

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

RMS is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, RMS and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) per obligation for each day RMS fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations;
- d. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training

and education of Covered Persons and Board members;

- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. notification of Government investigations or legal proceedings;
- k. reporting of Reportable Events;
- l. notification of written communications with FDA;
- m. the FFMP;
- n. the Requirements Relating to Certain Promotional and Non-Promotional Activities; and
- o. posting of any Payment-related information.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to engage and use an IRO as required by Section III.E and Appendix B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day RMS fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

date RMS fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of RMS as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day RMS fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day RMS fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix B; and

8. A Stipulated Penalty of \$1,000 for each day RMS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to RMS stating the specific grounds for its determination that RMS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps RMS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date RMS receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

RMS may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after RMS fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after RMS receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that RMS has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify RMS of: (a) RMS's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, RMS shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event RMS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until RMS cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that RMS has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by RMS to report a Reportable Event and take corrective action as required in Section III.I;

- c. a failure to engage and use an IRO in accordance with Section III.E and Appendix B; or
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by RMS constitutes an independent basis for RMS's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that RMS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify RMS of: (a) RMS's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* RMS shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) RMS has begun to take action to cure the material breach; (ii) RMS is pursuing such action with due diligence; and (iii) RMS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, RMS fails to satisfy the requirements of Section X.D.3, OIG may exclude RMS from participation in the Federal health care programs. OIG shall notify RMS in writing of its determination to exclude RMS (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of RMS's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, RMS may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to RMS of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, RMS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.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 RMS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. RMS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders RMS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless RMS requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether RMS was in material breach of this CIA and, if so, whether:

- a. RMS cured such breach within 30 days of its receipt of the Notice of Material Breach; or

- b. the alleged material breach could not have been cured within the 30 day period, but that, during the 30 day period following RMS's receipt of the Notice of Material Breach: (i) RMS had begun to take action to cure the material breach within that period; (ii) RMS pursued such action with due diligence; and (iii) RMS provided to OIG within that period a reasonable timetable for curing the material breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for RMS, only after a DAB decision in favor of OIG. RMS's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude RMS upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that RMS may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. RMS 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 RMS, RMS shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

RMS and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

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

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

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

E. 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 signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF RMS**

/Will McGuire/  
WILL MCGUIRE  
Chief Executive Officer  
Ra Medical Systems, Inc.

12/21/2020  
DATE

/Michael Theis/  
MICHAEL C. THEIS  
Hogan Lovells US LLP

December 21, 2020  
DATE

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

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

12/28/2020  
DATE

/Dennis Pangindian/  
DENNIS A. PANGINDIAN  
Associate Counsel  
Office of Counsel to the Inspector General  
U.S. Department of Health and Human Services

12/28/2020  
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. RMS shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by RMS in response to a request by OIG, whichever is later, OIG will notify RMS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, RMS may continue to engage the IRO.

2. If RMS engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, RMS 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 RMS at the request of OIG, whichever is later, OIG will notify RMS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, RMS may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the medical device industry and have expertise in all applicable Federal health care program and FDA requirements relating to Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with medical devices and the Federal Anti-Kickback Statute and False Claims Act;

2. assign individuals to design and select the samples for the Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. 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 IRO Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each IRO 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. IRO Independence and Objectivity

The IRO must perform each IRO Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *RMS and IRO.* If RMS terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, RMS must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. RMS must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify RMS in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. RMS shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by RMS regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify RMS in writing that RMS shall be required to engage a new

IRO in accordance with Paragraph A of this Appendix. RMS 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 RMS to engage a new IRO shall be made at the sole discretion of OIG.

## **APPENDIX B IRO REVIEWS**

### **A. IRO Engagement, General Description**

As specified more fully below, RMS shall retain an IRO to perform engagements to assist RMS in assessing and evaluating certain of its systems, processes, policies, and procedures related to RMS's Covered Functions (IRO Review). The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. RMS may engage, at its discretion, a single entity to perform both components of the IRO Reviews, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in RMS's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods. If RMS materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

### **B. IRO Systems Review**

The Systems Review shall be a review of RMS's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. More specifically, the IRO shall review RMS's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures):

1. RMS's systems, policies, processes, and procedures relating to the materials and information that may be distributed by RMS sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which RMS sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products;

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

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

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

5. RMS's systems, policies, processes, and procedures relating to the development, implementation, and review of policies relating to the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from RMS (including, separately, from sales representatives, or through other channels);

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

7. RMS's systems, policies, processes, and procedures relating to agreements or arrangements with HCPs or HCIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);

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

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

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

11. RMS's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.E.4 and II.E.5 of the CIA;

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

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

14. RMS's systems, policies, processes, and procedures relating to medical device reporting, including the development of medical device reporting procedures and establishing and maintaining medical device reporting event files, as required by 21 CFR Part 803 and other applicable FDA requirements; and

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

### C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review performed. For each of the Reviewed Policies and Procedures identified in Section B above, the report shall include the following items:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of RMS's systems, policies, processes, and procedures relating to the items identified in Sections B.1-15 above, including a general description of RMS's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections B.1-14 above are made known or disseminated within RMS;
4. findings and supporting rationale regarding any weaknesses in RMS's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
5. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

D. IRO Transactions Review

The Transactions Review shall include a review of: (1) a sample of consultant or other fee-for-service arrangements entered into with HCPs (including all events and expenses related to such engagements or arrangements), (2) a sample of Payments, and (3) up to three additional items identified by the OIG in accordance with Section III.E.2.c of the CIA (hereafter “Additional Items”). The IRO shall report on all aspects of its reviews in the Transactions Review Report.

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

- a. For the first Reporting Period, the IRO shall select and review a sample of 3 Consulting Activities entered into with HCPs and all related expenses. For the second and subsequent Reporting Periods,

the IRO shall review a total of at least 3 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG. Prior to the determination of the number of each type of Consulting Activity to be reviewed during the second and subsequent Reporting Periods, RMS shall provide to the OIG the information specified below in the next paragraph within 60 days prior to the end of the applicable preceding Reporting Period.

- b. The IRO shall select its sample of Consulting Activities for review in consultation with OIG after the provision of information about the Consulting Activities to the OIG. RMS shall provide the following information to the OIG: 1) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; 2) the number of each type of RMS Consulting Activity undertaken during the Reporting Period; and 3) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period.
- c. For each Consulting Activity reviewed the IRO shall determine whether:
  - i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;
  - ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by RMS;
  - iii. the rate structure was established based on an independent FMV analysis;
  - iv. the Consulting Activity was identified in the annual Consultant budgeting plan developed by RMS;
  - v. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting

Activity was completed prior to the initiation of the Consulting Activity;

vi. the Consulting Activity was reviewed and approved in accordance with RMS Policies and Procedures;

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

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

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

a. For each Reporting Period, the OIG shall have the discretion to identify up to 30 Covered Recipients who received Payments from RMS during the prior calendar year and will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO Review. If the OIG elects not to exercise its discretion, the IRO shall randomly select 30 Covered Recipients to be included in the review.

b. For each selected Covered Recipient, the IRO shall review the Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

i. whether Control Documents are available relating to each Payment;

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

3. *Review of Additional Items.* As set forth in Section III.E.2.c of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter “Additional Items”). No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify RMS of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or RMS shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in RMS's systems, processes, policies, and procedures based on its review of each Additional Item).

- a. RMS may propose to OIG that its internal audit(s), reviews, or monitoring activities, including those conducted as part of the Field Force Monitoring Program described in Section III. K and/or other reviews conducted by outside entities at RMS's request be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow RMS's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.
- b. In making its decision, the OIG agrees to consider, among other factors, the nature and scope of RMS's planned internal audit work or compliance monitoring or audit activities, the results of the Transactions Review(s) during prior Reporting Period(s), and RMS's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies RMS's request to permit its internal audit work or compliance

monitoring or audit activities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, RMS shall engage the IRO to perform the Review as outlined in this Section III. E.

- c. If the OIG agrees to permit certain of RMS's internal audit work or compliance monitoring or audit activities for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

E. Transactions Review Report

A. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
2. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
3. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

B. Results to be Included in Report. The following results shall be included in each Transactions Review Report:

1. Relating to the Review of Consulting Activities
  - a. a description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
  - b. for each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:

- i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;
  - ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by RMS;
  - iii. the rate structure was established based on an independent FMV analysis;
  - iv. the Consulting Activity was identified in the annual Consulting budgeting plan developed by RMS;
  - v. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;
  - vi. the Consulting Activity was reviewed and approved in accordance with RMS Policies and Procedures,
  - vii. RMS collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity; and
  - viii. the activity undertaken by the Consultant and/or the work product generated was used by RMS in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;
- c. any weaknesses in RMS's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and
  - d. any recommendations for improvements to RMS's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

## 2. Relating to the Review of Payments

- a. a description of the entry in the Open Payments Database for each Payment sampled and a description of Control Documents reviewed in connection with each sampled Payment; and
- b. for each sampled Payment, findings and supporting rationale as to whether:
  - i. all required Control Documents exist;
  - ii. each Control Document was completed in accordance with all of the requirements set forth in the applicable RMS policy;
  - iii. the aggregate value of the Payment as reflected in the Open Payments Database is consistent with the value of the Payment reflected in the Control Documents;
  - iv. each Control Document reflects that RMS's policies were followed in connection with the underlying activity reflected in the document (all required approvals were obtained); and
  - v. any corrective action or disciplinary action was undertaken in those instances in which RMS policies were not followed.

3. Relating to the Review of Additional Items. For each Additional Item reviewed:

- a. a description of the review conducted;
- b. the IRO's findings based on its review;
- c. the findings and supporting rationale regarding any weaknesses in RMS's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- d. recommendations, if any, for changes in RMS's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.