

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
RESMED CORP.**

**I. PREAMBLE**

ResMed Corp. (“ResMed”) 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). Contemporaneously with this CIA, ResMed is entering into a Settlement Agreement with the United States.

ResMed represents that, prior to the Effective Date (as defined below), it implemented a compliance program that includes the following elements with regard to its business operations in the United States: a Chief Compliance Officer, a corporate compliance committee, training and education, Code of Conduct and Business Ethics, written policies and procedures, an ethics hotline for reporting compliance issues, and monitoring and auditing activities (the “Compliance Program”). ResMed shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. ResMed may modify its Compliance Program as appropriate but, at a minimum, ResMed shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

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

A. The period of the compliance obligations assumed by ResMed 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) ResMed’s final annual report; or (2) any additional materials submitted by ResMed pursuant to OIG’s request, whichever is later.

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

1. “Arrangements” shall mean every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and is between ResMed and any actual or potential source of health care business or referrals to ResMed or any actual or potential recipient of health care business or referrals from ResMed.

2. The term “source of health care business or referrals” shall mean any individual or entity that refers, recommends, arranges for, orders, leases, or purchases any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

3. The term “recipient of health care business or referrals” shall mean any individual or entity (1) to whom ResMed refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom ResMed purchases, leases, or orders or arranges for or recommends the purchasing, leasing, or ordering of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program.

4. “Focus Arrangements” means every Arrangement that is between ResMed and any actual source or recipient of health care business or referrals and involves, directly or indirectly, the offer, payment, or provision of anything of value.

5. “Invoiced Sales” means Focus Arrangements that involve the sale or rental of Government Reimbursed Products to a source of health care business or referrals at reduced prices where such prices are reflected on an invoice that includes the terms and conditions of sale.

6. “Covered Persons” includes:

- a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, directors, and employees of ResMed; and
- b. all contractors, subcontractors, agents, and other persons who furnish patient care items or services or who perform marketing, billing, collections, or sales functions on behalf of ResMed excluding vendors whose sole connection with ResMed is selling or otherwise providing medical supplies or equipment to ResMed.

Notwithstanding the above, the term “Covered Persons” does not include ResMed employees who work in ResMed’s distribution centers to the extent such employees do not perform any marketing, billing, collections or sales functions and do not interact with actual or potential customers. The term “Covered Persons” also does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work for ResMed more than 160 hours per year, except that any such individual shall become a “Covered Person” at the point when they work more than 160 hours for ResMed during the calendar year.

7. “Arrangements Covered Persons” includes each Covered Person who is involved with the development, approval, management, or review of ResMed’s Arrangements.

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

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

ResMed 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, ResMed 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 ResMed, shall report directly to the Chief Executive Officer of ResMed, Inc. and to the Compliance Oversight Committee of ResMed, Inc.'s Board of Directors (Compliance Oversight Committee) and shall not be or be subordinate to the ResMed 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 ResMed. The Compliance Officer shall be responsible for, without limitation:

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

ResMed 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, ResMed 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 billing and collections, clinical, human resources, audit, 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 ResMed'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.

ResMed shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or 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 Compliance Oversight Committee shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA. The Compliance Oversight Committee must include independent (i.e., non-employee and non-executive) members.

The Compliance Oversight Committee shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee ResMed's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to the OIG a description of the 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 Compliance Oversight Committee summarizing its review and oversight of ResMed's compliance with Federal health care program requirements and the obligations of this CIA.
- d. for the first and fourth Reporting Periods of the CIA, the Compliance Oversight Committee shall retain an individual or entity with expertise in compliance with Federal health care program requirements (Compliance Expert) to perform a review of the effectiveness of ResMed's Compliance Program (Compliance Program Review). The Compliance Expert shall create a work plan for the Compliance Program Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to ResMed's compliance program. The Compliance Oversight Committee shall review the Compliance Program Review Report as part of its review and oversight of ResMed's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by ResMed. In addition, copies of any materials provided to the Compliance Oversight Committee by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Compliance Oversight Committee, shall be made available to the OIG upon request.

At minimum, the resolution shall include the following language:

“The Compliance Oversight Committee has made a reasonable inquiry into the operations of ResMed's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Compliance Oversight Committee has concluded that, to the best of its knowledge, ResMed has implemented an

effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA.”

If the Compliance Oversight Committee is unable to provide such a conclusion in the resolution, the Compliance Oversight Committee 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 ResMed.

ResMed shall report to OIG, in writing, any changes in the composition of the Compliance Oversight Committee, or any actions or changes that would affect the Compliance Oversight Committee’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 ResMed employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable ResMed department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the following: President of Sleep Business, President of Respiratory Care Business, Chief Financial Officer, Vice President of Sales Management, Vice President of Operations, Vice President of Marketing, Vice President of Corporate Compliance. 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 department] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and ResMed policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of ResMed is in compliance with all applicable Federal health care program 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, ResMed 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

Within 90 days after the Effective Date, ResMed 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 ResMed's compliance with Federal health care program requirements (Policies and Procedures). The Policies and Procedures also shall address:

- a. 42 U.S.C. § 1320a-7b(b) (Anti-Kickback Statute), and the regulations and other guidance documents related to this statute, and business or financial arrangements or contracts that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute;
- b. and the requirements set forth in Section III.D (Compliance with the Anti-Kickback Statute).

The Policies and Procedures shall be made available to all Covered Persons. Throughout the term of this CIA, ResMed shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees.

At least annually (and more frequently, if appropriate), ResMed shall assess and update, as necessary, the Policies and Procedures. Any revised or new Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.



C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, ResMed shall develop a written plan (Training Plan) that outlines the steps ResMed will take to ensure that:

- a. all Covered Persons receive at least annual training regarding ResMed's CIA requirements and Compliance Program and the applicable Federal health care program requirements, including the requirements of the Anti-Kickback Statute.
- b. all Arrangements Covered Persons receive at least annual training regarding: (i) Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to these statutes; (ii) ResMed's policies, procedures, and other requirements relating to Arrangements and Focus Arrangements, including but not limited to the Focus Arrangements Tracking System, the internal review and approval process, and the tracking of remuneration to and from sources of health care business or referrals required by Section III.D of the CIA; (iii) the personal obligation of each individual involved in the development, approval, management, or review of ResMed's Arrangements to know the applicable legal requirements and the ResMed's policies and procedures; (iv) the legal sanctions under the Anti-Kickback Statute; and (v) examples of violations of the Anti-Kickback Statute.

The Training Plan shall include information regarding the following: training topics, identification of Covered Persons and Arrangements Covered Persons required to attend each training session, length of the training sessions(s), schedule for training, and format of the training. ResMed shall furnish training to its Covered Persons and Arrangements 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 of Directors of ResMed, Inc. (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 the 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.* ResMed 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. Compliance with the Anti-Kickback Statute

1. *Focus Arrangements Procedures.* Within 90 days after the Effective Date, ResMed shall create procedures reasonably designed to ensure that each existing and new or renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations and guidance related to this statute (Focus Arrangements Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Focus Arrangements and the information specified in Sections III.D.1.b-f below for each existing and new or renewed Focus Arrangement (Focus Arrangements Tracking System);
- b. documenting the names and positions of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of all Focus Arrangements;

- c. tracking all remuneration to and from all parties to Focus Arrangements to ensure that the parties are complying with the financial terms of the Focus Arrangements and that the Focus Arrangements are commercially reasonable;
- d. documenting all fair market value determination(s) for any Focus Arrangement, including the fair market value amount or range and corresponding time period(s), the date(s) of completion of the fair market valuation(s), the individuals or entities that determined the fair market value amount or range, and the names and positions of the Covered Person(s) who received and/or were otherwise involved with the fair market value determination(s);
- e. tracking service and activity logs to ensure that parties to the Focus Arrangement are performing the services required under the applicable Focus Arrangement(s) (if applicable);
- f. monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);
- g. establishing and implementing a written review and approval process for Focus Arrangements, the purpose of which is to ensure that all new and existing or renewed Focus Arrangements do not violate the Anti-Kickback Statute and that includes at least the following: (i) a legal review of all Focus Arrangements by counsel with expertise in the Anti-Kickback Statute, (ii) a process for specifying and documenting the business need or business rationale for all Focus Arrangements, and (iii) a process for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement;

- h. ensuring that all existing Focus Arrangements are subject to the review and approval process described in Section III.D.1.g above;
- i. requiring the Compliance Officer to review the Focus Arrangements Tracking System, internal review and approval process, and other Focus Arrangements Procedures on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- j. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

2. *Invoiced Sales Procedures.* Within 90 days after the Effective Date, ResMed shall create procedures reasonably designed to ensure that Invoiced Sales do not violate the Anti-Kickback Statute or the regulations and guidance related to this statute (Invoiced Sales Procedures). These procedures shall include the following:

- a. creating and maintaining a centralized system that reflects the single base price for each product subject to Invoiced Sales (“Base Price List”);
- b. creating and maintaining a centralized system for tracking all Invoiced Sales with prices that reflect a discount from the Base Price List, including the parties to such sales (“Discounted Price List”);
- c. establishing and implementing a written review and approval process for offering or approving any discounted prices for Invoiced Sales (“Pricing Protocol”) that is subject to legal review by counsel with expertise in the Anti-Kickback Statute, the purpose of which is to ensure that Invoiced Sales do not violate the Anti-Kickback Statute;
- d. ensuring that all Invoiced Sales are subject to the review and approval process described in Section III.D.2.c. above;

- e. requiring the Compliance Officer to review the Pricing Protocol on at least an annual basis and to provide a report on the results of such review to the Compliance Committee; and
- f. implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events.

3. *New or Renewed Focus Arrangements.* No later than 90 days after the Effective Date, and prior to entering into new Focus Arrangements or renewing existing Focus Arrangements, in addition to complying with the Focus Arrangements Procedures set forth above, ResMed shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that all written Focus Arrangements are signed by ResMed and the other party(ies) to the Focus Arrangement prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement;
- b. Ensure that all Focus Arrangements have been subject to the written review and approval process described in Section III.D.1.g prior to the payment or receipt of any remuneration pursuant to the Focus Arrangement, and that ResMed maintains appropriate documentation of the review and approval of such Focus Arrangement; and
- c. Include in any written agreement a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Arrangement.

4. *Records Retention and Access.* ResMed shall retain and make available to OIG, upon request, the Focus Arrangements Tracking System and all supporting documentation of the Focus Arrangements and Invoiced Sales subject to this Section and, to the extent available, all non-privileged communications related to the

Focus Arrangements and Invoiced Sales, and the actual performance of the duties under the Focus Arrangements.

E. Review Procedures

1. *General Description.*

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

2. *Arrangements Review.* The IRO shall perform an Arrangements Review and prepare an Arrangements Review Report as outlined in Appendix B to this CIA, which is incorporated by reference.

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

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, ResMed shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with Arrangements (as defined in Section II.C.1 above) and ResMed's participation in the Federal health care programs, including but not limited to the risks associated with the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted at least annually and shall require ResMed to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit 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. ResMed shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, ResMed 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 ResMed's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. ResMed shall appropriately publicize the existence of 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 ResMed's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by ResMed. 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, ResMed 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 the Federal health care programs) 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.

#### H. 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 any Federal health care program; 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.* ResMed shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

Nothing in this Section III.H affects ResMed’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. ResMed understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that ResMed may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether ResMed meets the requirements of Section III.H.

3. *Removal Requirement.* If ResMed has actual notice that a Covered Person has become an Ineligible Person, ResMed shall remove such Covered Person from responsibility for, or involvement with, ResMed’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 or the items or services furnished, ordered, or prescribed by the Covered

Person are paid in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s).

4. *Pending Charges and Proposed Exclusions.* If ResMed 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, ResMed 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.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, ResMed shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to ResMed conducted or brought by a governmental entity or its agents involving an allegation that ResMed 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. ResMed shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceeding, if any.

J. 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 FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;
- b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or
- d. the filing of a bankruptcy petition by ResMed.

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

2. *Reporting of Reportable Events.* If ResMed determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, ResMed shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Section III.J.1.a and III.J.1.b.* For Reportable Events under Section III.J.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 entities and individuals 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;
- d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- e. a description of ResMed's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.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 ResMed completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the Ineligible Persons screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

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

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

In the event that, after the Effective Date, ResMed proposes to (a) sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any business, business unit, or location and any new business, business unit, or location (and all Covered Persons at each new business, business unit, or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and

agreed to in writing by OIG. ResMed 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 proposed purchase, ResMed 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, ResMed 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, ResMed 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, 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;
3. the names of the Compliance Oversight Committee 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 all Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training, and when the training was provided);
7. a description of (a) the Focus Arrangements Tracking System required by Section III.D.1.a, (b) the internal review and approval process required by Section III.D.1.g; and (c) the tracking and monitoring procedures and other Focus Arrangements Procedures required by Section III.D.1;
8. a description of (a) the Base Price List and the Discounted Price List required by Section III.D.2.a and III.D.2.b; (b) the Pricing Protocol required by Section III.D.2.c and (c) the other Invoiced Sales Procedures required by Section III.D.2;
9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO that it does not have a prohibited relationship with ResMed as set forth in Section III.E.3 that includes a summary of any current and prior relationships between ResMed or its owners, officers, or directors and the IRO;
10. a description of the risk assessment and internal review process required by Section III.F;
11. a description of the Disclosure Program required by Section III.G;
12. a description of the Ineligible Persons screening and removal process required by Section III.H;
13. a description of ResMed's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;
14. a list of all of ResMed's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, and each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s) if any; and

15. the certifications required by Section V.C.

B. Annual Reports

ResMed shall submit to OIG a written report 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 Compliance Oversight Committee 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, Compliance Oversight Committee, 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 Compliance Oversight Committee resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Compliance Oversight Committee, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
5. a list of any new or revised Policies and Procedures developed during the Reporting Period;
6. a description of any changes to ResMed'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 (a) any changes to the Focus Arrangements Tracking System required by Section III.D.1.a; (b) any changes to the internal review and approval

process required by Section III.D.1.g; and (c) any changes to the tracking and monitoring procedures and other Arrangements Procedures required by Section III.D.1;

8. a description of (a) any changes to the Base Price List and the Discounted Price List required by Section III.D.2.a and III.D.2.b; (b) the Pricing Protocol required by Section III.D.2.c and (c) the other Invoiced Sales Procedures required by Section III.D.2;

9. a complete copy of all reports prepared pursuant to Section III.E and ResMed'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 that it does not have a prohibited relationship with ResMed, as described in Section III.E.3 above, including a summary of any current and prior relationships between ResMed or its owners, officers, or directors and the IRO;

11. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;

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

13. a summary of the disclosures in the disclosure log required by Section III.G that: (a) relate to Federal health care programs; or (b) involve allegations of conduct that may involve illegal remuneration or inappropriate referrals in violation of the Anti-Kickback Statute (the complete disclosure log shall be made available to OIG upon request);

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;



15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. 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;

16. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

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

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

19. 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, ResMed 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, ResMed is in compliance with all of the requirements of this CIA;
- b. to the best of his or her knowledge, ResMed has implemented procedures reasonably designed to ensure that all Focus Arrangements do not violate the Anti-Kickback Statute,

including the Focus Arrangements Procedures required in Section III.D of the CIA;

- c. to the best of his or her knowledge, ResMed has fulfilled the requirements for New and Renewed Focus Arrangements under Section III.D.3 of the CIA;
- d. 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
- e. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information

ResMed 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. ResMed 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

ResMed:

Jim Ellis, Chief Compliance Officer  
ResMed Corp.  
9001 Spectrum Center Blvd.  
San Diego, CA 92123  
Telephone: 858.836.6547  
Facsimile: 858.836.5518  
Email: [jim.ellis@resmed.com](mailto:jim.ellis@resmed.com)

Unless otherwise specified, all notifications and reports required by this CIA shall be made by overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, ResMed 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 ResMed's books, records, and other documents and supporting materials, and conduct on-site reviews of any of ResMed's locations for the purpose of verifying and evaluating: (a) ResMed's compliance with the terms of this CIA; and (b) ResMed's compliance with the requirements of the Federal health care programs. The documentation described above shall be made available by ResMed 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 ResMed's owners, who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading); employees, contractors, and 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. ResMed shall assist OIG or its duly authorized representative(s) in

contacting and arranging interviews with such individuals upon OIG's request. ResMed's owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading; employees, contractors, and directors may elect to be interviewed with or without a representative of ResMed present.

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

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

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

ResMed 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, ResMed 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 ResMed fails to establish, implement or comply with any of the following obligations as described in Sections III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report, as required by Section III.A.3;
- 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, Arrangements Covered Persons, and Board members;
- g. the Focus Arrangements Procedures, Invoiced Sales Procedures and/or Focus Arrangements Requirements;
- h. a risk assessment and internal review process;
- i. a Disclosure Program;
- j. Ineligible Persons screening and removal requirements;
- k. notification of Government investigations or legal proceedings; and
- l. reporting of Reportable Events

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 ResMed fails to engage and use an IRO, as required by Section III.E, Appendix A, or 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 ResMed 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 ResMed fails to submit any Arrangements Review Report in accordance with the requirements of Section III.E and Appendix B.

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

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

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

8. A Stipulated Penalty of \$1,000 for each day ResMed fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to ResMed stating the specific grounds for its determination that ResMed has failed to comply fully and adequately with the CIA obligation(s) at issue and steps ResMed shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date ResMed 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

ResMed 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 ResMed 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 ResMed 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 ResMed 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 ResMed of: (a) ResMed's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 business days after the receipt of the Demand Letter, ResMed 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 ResMed elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ResMed 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.c, these provisions for payment of Stipulated Penalties shall not

affect or otherwise set a standard for OIG’s decision that ResMed 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. a failure by ResMed to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.J;
- b. 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;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B.

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

3. *Opportunity to Cure.* ResMed shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) ResMed has begun to take action to cure the material breach; (ii) ResMed is pursuing such action with due diligence; and (iii) ResMed has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, ResMed fails to satisfy the requirements of Section X.D.3, OIG may exclude ResMed from participation in the Federal health care programs. OIG shall notify ResMed in writing of its determination to exclude ResMed. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of ResMed’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, ResMed 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 ResMed 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, ResMed 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 ResMed was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. ResMed 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 ResMed to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless ResMed 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 ResMed was in material breach of this CIA and, if so, whether:

- a. ResMed 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 ResMed's receipt of the Notice of Material Breach:
  - (i) ResMed had begun to take action to cure the material breach;
  - (ii) ResMed pursued such action with due diligence;
  - and (iii) ResMed provided to OIG 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 ResMed, only after a DAB decision in favor of OIG. ResMed's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude ResMed 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 ResMed 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. ResMed 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 ResMed, ResMed 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**

ResMed 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. OIG may agree to a suspension of ResMed's obligations under this CIA based on a certification by ResMed that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If ResMed is relieved of its CIA obligations, ResMed shall be required to notify OIG in writing at least 30 days in advance if ResMed plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

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

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

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

**ON BEHALF OF RESMED CORP.**

/David Pendarvis/  
DAVID PENDARVIS  
Secretary

12/16/2019  
DATE

/Laura F. Laemmle Weidenfeld/  
LAURA F. LAEMMLE-WEIDENFELD  
Jones Day  
Counsel for ResMed Corp.

12/16/2019  
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

12/09/2019  
DATE

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

12/18/2019  
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. ResMed shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall not have a prohibited relationship to ResMed as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by ResMed in response to a request by OIG, whichever is later, OIG will notify ResMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ResMed may continue to engage the IRO.

2. If ResMed engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, ResMed shall submit the information identified in Section V.A.9 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 ResMed at the request of OIG, whichever is later, OIG will notify ResMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ResMed may continue to engage the IRO.

#### B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Arrangements Review who are knowledgeable in the requirements of the Anti-Kickback Statute and the regulations and other guidance documents related to these statutes;

2. possess expertise in fair market valuation issues or have the ability to associate a valuation firm to assist in conducting the transactions review component of the Arrangements Review; 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 Arrangements Review in accordance with the specific requirements of the CIA;
2. respond to all OIG inquiries in a prompt, objective, and factual manner; and
3. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. ResMed Responsibilities

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

E. IRO Relationship to ResMed

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

F. Assertions of Privilege

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

G. IRO Removal/Termination

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

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, has a prohibited relationship as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify ResMed in writing regarding OIG's basis for determining



that the IRO has not met the requirements of this Appendix. ResMed shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, relationship or performance of its responsibilities in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by ResMed regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify ResMed in writing that ResMed shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. ResMed 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 ResMed to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### ARRANGEMENTS REVIEW

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

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

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

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

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

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

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

6. ResMed's systems, policies, processes, and procedures for monitoring the use of leased space, medical supplies, medical devices, equipment, or other patient care items to ensure that such use is consistent with the terms of the applicable Focus Arrangement(s) (if applicable);

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

8. ResMed's systems, policies, processes, and procedures for the internal review and approval of existing, new and renewed Focus Arrangements, including those policies that identify the individuals required to approve each type or category of Focus Arrangement entered into by ResMed, the internal controls designed to ensure that all required approvals are obtained, the processes for determining and documenting the business need or business rationale for all Focus Arrangements, the processes for determining and documenting the fair market value of the remuneration specified in the Focus Arrangement, and the processes for ensuring that all Focus Arrangements are subject to a legal review by counsel with expertise in the Anti-Kickback Statute;

9. the Compliance Officer's annual review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, ResMed's internal review and approval process, other Focus Arrangements systems, process, policies, and procedures, and the Pricing Protocol;

10. ResMed's systems, policies, processes, and procedures for implementing effective responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events when appropriate;

11. ResMed's systems, policies, processes, and procedures for ensuring that all new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.3 of the CIA;

12. ResMed's systems, policies, processes and procedures with respect to creating and maintaining a centralized system that reflects the single base price for each product subject to Invoiced Sales (Base Price List) and with respect to

creating and maintaining a centralized system for tracking all Invoiced Sales with prices that reflect a discount from the Base Price List (Discounted Price List), including a description of the information captured in the Base Price List and the Discounted Price List; and

13. ResMed's systems, policies, processes and procedures for establishing a written review and approval for offering any discounted prices for Invoiced Sales (Pricing Protocol), including the process for ensuring that the Pricing Protocol is subject to legal review by counsel with expertise in the Anti-Kickback Statute and that all Invoiced Sales are subject to the Pricing Protocol.

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

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

2. a detailed description of ResMed's systems, policies, processes, and procedures relating to the items identified in Section A.1-13 above;

3. findings and supporting rationale regarding weaknesses in ResMed's systems, processes, policies, and procedures relating to Arrangements described in Section A.1-13 above; and

4. recommendations to improve ResMed's systems, policies, processes, or procedures relating to Arrangements described in Section A.1-13 above.

C. Arrangements Transactions Review. The Arrangements Transactions Review shall consist of a review by the IRO of 50 randomly selected Focus Arrangements that were entered into or renewed by ResMed during the Reporting Period. The IRO shall assess whether ResMed has complied with the Focus Arrangements Procedures and the Focus Arrangements Requirements described in Sections III.D.1, III.D.2, and III.D.3 of the CIA, with respect to the selected Focus Arrangements.

In OIG's discretion, OIG may specify the categories of Focus Arrangements from which the IRO shall select the random sample for purposes of the Arrangements Transactions Review and notify ResMed and the IRO of its selection of such categories at least 30 days prior to the end of each Reporting Period. At least 90 days prior to the end of each Reporting Period, ResMed shall submit to OIG a description of the different categories of Focus Arrangements it has entered into or renewed during the preceding Reporting Period. ResMed, or its IRO on behalf of

ResMed, may submit proposals identifying suggestions for the categories of Focus Arrangements from which the random sample of Focus Arrangements shall be selected at least 60 days prior to the end of each Reporting Period. In connection with limiting the categories of Focus Arrangements to be reviewed as part of the Arrangements Transactions Review, OIG may consider (1) proposals submitted by ResMed or its IRO or (2) information furnished to OIG regarding the results of ResMed's risk assessment and internal review process. The determination of whether, and in what manner, to limit the Focus Arrangements subject to the Arrangements Transactions Review shall be made at the sole discretion of OIG.

1. The IRO's assessment with respect to each Focus Arrangement that is subject to review shall include:

a. for Focus Arrangements that are not Invoiced Sales, verifying that the Focus Arrangement is maintained in ResMed's centralized tracking system in a manner that permits the IRO to identify: (i) the parties to the Focus Arrangement, (ii) the name(s) and position(s) of the Arrangements Covered Person(s) involved in the negotiation, review, and approval of the Focus Arrangement; (iii) the relevant terms of the Focus Arrangement (i.e., the items, services, equipment, or space to be provided, the amount of compensation, the effective date, the expiration date, etc.); and (iv) the parties' performance under the Focus Arrangement (i.e, items or services actually provided, equipment or space actually provided or leased, amount of payments, dates of payment, etc.);

b. for Invoiced Sales, verifying that information about Invoiced Sales with prices that reflect a discount from the Base Price List are accurately reflected in the Discounted Price List;

c. verifying that the Focus Arrangement was subject to the internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented (or, in the case of Invoiced Sales, that it was subject to the Pricing Protocol);

d. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with ResMed's policies and procedures for determining and documenting the fair market value of the remuneration, that the remuneration is properly tracked, and that the parties to the Focus Arrangement are complying with the financial terms of the Focus Arrangement (if applicable);

e. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with ResMed's policies and procedures (if applicable);

f. verifying that the service and activity logs are properly completed and reviewed (if applicable);

g. verifying that leased space, medical supplies, medical devices, and equipment, and other patient care items are properly monitored (if applicable); and

h. verifying that the Focus Arrangement satisfies the applicable requirements of Section III.D. of the CIA.

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

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

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

1. *Review Methodology*.

- a. Review Protocol. A description of the process used by the IRO to identify the Focus Arrangements subject to review in the Arrangements Transactions Review.
- b. Sources of Data. A full description of the documentation and other information relied upon by the IRO in performing the Arrangements Transactions Review.
- c. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Focus Arrangements selected as part of the Arrangements Transactions Review and ResMed shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Focus Arrangements. If the IRO accepts any supplemental documentation or materials from ResMed after the IRO has completed its initial review of the Focus Arrangements (Supplemental Materials), the IRO shall identify in the Arrangements Transactions Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Arrangements Transactions Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

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

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