

**CORPORATE INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
PHILIPS RS NORTH AMERICA LLC, F/K/A RESPIRONICS, INC.**

**I. PREAMBLE**

Philips RS North America LLC, f/k/a Respironics, Inc. (“Respironics”) 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, Respironics is entering into a Settlement Agreement with the United States.

Respironics 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. Respironics shall continue its compliance program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Respironics may modify its compliance program as appropriate but, at a minimum, Respironics 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 Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The term of this CIA shall be five years from the Effective Date. 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) Respiroics' final Annual Report; or (2) any additional materials submitted by Respiroics 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 Respiroics 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); (b) all officers, directors and employees of Respiroics; and (c) all contractors, subcontractors, agents and other persons who furnish patient care items or services, who perform billing or coding functions, or who perform any of the Covered Functions on behalf of Respiroics excluding vendors whose sole connection with Respiroics is selling or otherwise providing medical supplies or equipment to Respiroics.

Notwithstanding the above, the term "Covered Persons" does not include (a) employees at Respiroics' manufacturing or 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 source of health care business or referrals or (b) part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work for Respiroics 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 Respiroics during the calendar year.

2. "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 Respiroics and any actual or potential source of health care business or referrals to Respiroics or any actual or potential recipient of health care business or referrals from Respiroics.

3. 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.

4. The term "recipient of health care business or referrals" shall mean any individual or entity (a) to whom Respiroics refers an individual for the furnishing or arranging for the furnishing of any item or service, or (b) from whom Respiroics

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.

5. “Focus Arrangements” means every Arrangement that is between Respiroics 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.

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

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

8. 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; (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to Respiroics’ review and approval process for any non-promotional materials; (d) contracting with durable medical equipment suppliers (DME Suppliers) or 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) entering into arrangements with HCPs or DME Suppliers for any Co-Marketing Activity (as defined in Section II.C.11 below) and (f) reviewing and/or approving requests for grants or charitable contributions.

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

10. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for DME Suppliers or HCPs conducted by a third party and supported by Respirationics, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

11. The term “Co-Marketing Activity” shall mean any marketing or other promotional activity that Respirationics performs with or on behalf of (in addition to itself) one or more HCPs, health care institutions (HCIs), or DME Suppliers involving a Government Reimbursed Product.

### **III. COMPLIANCE PROGRAM REQUIREMENTS**

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

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

1. *Compliance Officer.* Within 90 days after the Effective Date, Respirationics 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 Respirationics; shall report directly to the Chief Executive Officer of Respirationics; 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 Respirationics. 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 in person to the Board of Directors (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 Respiroics as well as any reporting requirements 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.

Respiroics 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 requirements in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Respiroics 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 Respiroics' risk areas and shall oversee monitoring of internal and external audits and investigations) and shall review any Monitor reports issued pursuant to Section III.E.4 of this CIA, as well as any Respiroics response to such reports, prior to submission of such response to the Monitor and OIG. The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Respiroics 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 requirements in this CIA, within 15 business days after such a change.

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

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

- a. meeting at least quarterly to review and oversee Respirationics' compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. reviewing all Monitor reports issued pursuant to Section III.E.4 of this CIA (or summaries thereof), as well as any Respirationics' responses to such reports prior to the submission of such response to the Monitor and OIG;
- c. 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
- d. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Respirationics' compliance with Federal health care program requirements, and the requirements of this CIA.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Respirationics' 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, Respirationics has implemented an effective compliance program to meet Federal health care program requirements, and the requirements 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 Respirationics.

Respironics 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 requirements 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 Respironics employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Respironics business unit is in compliance with applicable Federal health care program requirements and with the requirements of this CIA. These Certifying Employees shall include, at a minimum, the following: Business Leader, Sleep & Respiratory Care (SRC); National Business Leader, SRC; Senior Director – Marketing; Global Marketing Leader; Business Sales Leader, Sleep and Home Respiratory; Customer Solutions Leader; and Director of Clinical Affairs. 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, requirements of the Corporate Integrity Agreement, and Respironics policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Respironics complies with all applicable Federal health care program requirements, and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying 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, Respironics 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, Respironics 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 Respironics' compliance with Federal health care program requirements, including but not limited to compliance with the Anti-Kickback Statute, and the regulations and other guidance documents related to these statutes, and business or financial arrangements that generate unlawful Federal health care program business in violation of the Anti-Kickback Statute (Policies and Procedures). Throughout the term of this CIA, Respironics shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

- a. the requirements set forth in Section III.D below;
- b. appropriate ways to conduct Covered Functions in compliance with all 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);
- c. the materials and information that may be distributed by Respironics sales representatives (including any contract sales force) about Government Reimbursed Products;
- d. the manner and circumstances under which Respironics medical personnel interact with or participate in meetings or events with DME Suppliers, HCPs, HCIs, or payors (either alone or with Respironics sales representatives) and the role of Respironics medical personnel at such meetings or events;
- e. the materials and information that may be distributed or made available by Respironics through social media and/or direct-to-consumer advertising;
- f. the development, implementation, and review of policies for 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 Respirationics (including, separately, from sales representatives, or through other channels);

- g. consultant or other fee-for-service arrangements entered into with DME Suppliers, 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 a DME Supplier, HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- h. programs by DME Suppliers or HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
- i. review and approval of, and payment for, travel and related expenses for DME Suppliers or HCPs including those in connection with DME Suppliers or HCP participation in educational, research, training, or other Respirationics-sponsored programs or activities;
- j. sponsorship or funding of grants (including educational grants), Co-Marketing Activities or charitable contributions involving DME Suppliers, HCPs and HCIs;
- k. funding of, or participation in, any Sponsorships or Third Party Educational Activity or Co-Marketing Activity as defined in Sections II.C above;
- l. review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated

outside Respiroics 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 Respiroics' review and approval process and are elevated when appropriate;

- m. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers;
- n. disciplinary policies and procedures for violations of Respiroics' Policies and Procedures, including policies relating to Federal health care program requirements; and
- o. Respiroics' involvement with Focus Arrangements that involve financing by a third-party financial institution for the purchase of Government Reimbursed Products, including any role of Respiroics sales representatives in informing sources of health care business or referrals (e.g., DME Suppliers) of the availability of such financing arrangements, the negotiation of any finance charges of third-party financial institutions, and the creation of and compliance with loss pool allocations between Respiroics and third-party financial institutions that provide such financing arrangements.

At least annually (and more frequently, if appropriate), Respiroics 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, Respiroics shall develop a written plan (Training Plan) that outlines the steps Respiroics will take to ensure that:

- a. all Covered Persons receive at least annual training regarding Respiroics' CIA requirements and compliance program;

- b. all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program requirements relating to Covered Functions and (ii) all Respironics' Policies and Procedures and other requirements applicable to Covered Functions; and
- c. 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) Respironics' 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 Respironics' Arrangements to know the applicable legal requirements and the Respironics' 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, categories of Covered Persons and Arrangements Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. Respironics 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 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 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.* Respirationics 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, Respirationics shall create procedures reasonably designed to identify each existing and new Focus Arrangement and ensure that each existing, new, and renewed Focus Arrangement does not violate the Anti-Kickback Statute or the regulations and guidance related to that 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. *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, Respiroics shall comply with the following requirements (Focus Arrangements Requirements):

- a. Ensure that all written Focus Arrangements are signed by Respiroics 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 Respiroics 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.

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

E. Independent Monitor

Within 60 days after the Effective Date, Respiroics shall retain an appropriately qualified monitoring team (the “Monitor”), selected by OIG after consultation with Respiroics. The Monitor may retain additional personnel, including but not limited to independent consultants, if needed to help meet the Monitor’s requirements under this CIA, provided the Monitor first consults with Respiroics and OIG to explain the need for the additional personnel. The Monitor may confer and correspond with Respiroics or OIG individually or together. The Monitor and Respiroics shall not negotiate or enter into a financial relationship, other than the

monitoring engagement required by this section, and the Monitor shall refrain from recruiting or hiring any employee of Respiroics during the term of this CIA.

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

1. *Systems Review.* The Monitor shall be responsible for assessing the following:

- a. Whether Respiroics has procedures in place for accurately identifying all existing and new Focus Arrangements;
- b. Whether Respiroics' Focus Arrangements Tracking System includes all existing, new, and renewed Focus Arrangements and, with respect to those Focus Arrangements, accurately and completely captures the information required by Section III.D.b-f;
- c. Whether Respiroics has established and implemented a written review and approval process for Focus Arrangements that meets all the requirements of Section III.D.1.g and that such written review and approval process has been followed with respect to all new, existing, or renewed Focus Arrangements;
- d. Whether Respiroics is following its internal 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, and the internal systems, policies, processes, and controls designed to ensure that all required approvals are obtained for an Arrangement;
- e. The accuracy and completeness of the Compliance Officer's review of and reporting to the Compliance Committee on the Focus Arrangements Tracking System, Respiroics' internal

review and approval process, and other Focus Arrangements systems, process, policies, and procedures;

- f. Respirationics' responses when suspected violations of the Anti-Kickback Statute are discovered, including disclosing Reportable Events. In connection with the Monitor's review of Respirationics' responses to suspected violations of the Anti-Kickback Statute, the Monitor shall have the authority to conduct an independent investigation of any suspected violations of the Anti-Kickback Statute for which the Monitor, after discussions with Respirationics regarding the suspected violation, continues to have concerns regarding the thoroughness, integrity, or adequacy of Respirationics' review of the suspected violation. Where appropriate, the Monitor shall assess whether the arrangement prompting its investigation presents a low or high risk of violating the Anti-Kickback Statute, or whether the Monitor is unable to make such a conclusion;
- g. Whether new and renewed Focus Arrangements comply with the Focus Arrangements Requirements set forth in Section III.D.2 of the CIA;
- h. Whether Respirationics has appropriately identified all Covered Persons who engage in Covered Functions and whether the training provided to Covered Persons who engage in Covered Functions adequately addresses the topics identified in Section III.C.1.b of the CIA;
- i. Whether Respirationics has appropriately identified all Arrangements Covered Persons and whether the training provided to such Arrangements Covered Persons adequately addresses the topics identified in Section III.C.1.c of the CIA;
- j. With respect to the Disclosure Program required by Section III.G of this CIA, whether (a) Respirationics has adequately publicized the existence of the Disclosure Program and the available disclosure mechanisms, (b) the Disclosure Program emphasizes a nonretribution, nonretaliation policy, (c)

Respironics is ensuring that, within two business days of receipt, all disclosures are recorded in a written disclosure log that includes 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; and (d) Respironics is conducting appropriate reviews of the allegations set forth in disclosures that are sufficiently specific to permit a determination of the appropriateness of the alleged improper practice and provide an opportunity for taking corrective action, and that proper follow-up is conducted.

- k. With respect to the Risk Assessment and Internal Review Process required by Section III.F of this CIA, the Monitor shall assess whether Respironics' risk assessment and internal review process identifies and addresses relevant and appropriate risks for Respironics' compliance with Federal health care program requirements, including the Anti-Kickback Statute risks associated with Arrangements, and the risks associated with each Government Reimbursed Product, including the risks associated with the Covered Functions; and
- l. With respect to the FFMP required by Section III.K of the CIA, the Monitor shall assess whether the FFMP is designed to effectively identify potential improper promotional activities or other improper conduct by Respironics sales personnel and whether any remediation undertaken by the Compliance Officer in connection with the reporting of the results of the FFMP was appropriate. In connection with this assessment, the Monitor shall be permitted to participate in up to fifty percent of any Observations conducted as part of the FFMP and shall have access to all records relied on by the Monitoring Personnel in completing the Observation reports required by Section III.K.1 of the CIA and the underlying records and systems reviewed by Respironics in connection with the Records Reviews required by Section III.K.2 of the CIA, including those identified in Section III.K.2.b.(i)-(v).

2. *Arrangements Transactions Review.* For each Reporting Period of the CIA, the Monitor shall perform the Arrangements Transactions Review, and prepare an Arrangements Transactions Review Report as outlined in Appendix A to this CIA, which is incorporated by reference.

3. *Timely Access to Records and Personnel.* Respiroics shall ensure that the Monitor has timely access to all records, personnel, systems, data, non-privileged communications, and documents necessary, in the Monitor's discretion, to perform the reviews described in this Section III.E and that all records, data, non-privileged communications, and documents furnished to the Monitor are accurate and complete. The Monitor may conduct interviews of Respiroics' personnel, in the Monitor's discretion, to perform the reviews described in this section III.E with such interviews to be conducted at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the Monitor. The Monitor shall be permitted to attend meetings of the Compliance Committee and the Board meetings relating to the oversight activities of the Board described in Section III.A.3 of this CIA and shall be permitted to meet independently with the Compliance Committee or the Board. The Monitor also shall be permitted to attend and/or review all Respiroics training provided under Section III.C of the CIA.

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

4. *Monitor Reports; Respiroics' Response to Monitor Reports.*

- a. Within 6 months following the Effective Date, the Monitor shall prepare an initial written report (Initial Monitor Report) that will be submitted to both Respiroics and the OIG. The Initial Monitor Report shall include: (a) a summary of the Monitor's activities in conducting its review of each of the items listed in Section III.E.1 above, including but not limited to a description of the documents and systems reviewed and the personnel interviewed; and (b) the Monitor's findings and recommendations regarding each of the items listed in Section III.E.1 above.

- b. Within 60 days following its receipt of the Initial Monitor Report, Respiroics shall prepare and submit to both the Monitor and the OIG a written response to the findings and recommendations in the Initial Monitor Report that indicates (i) the steps Respiroics will take to implement the Monitor's recommendations, or (ii) that Respiroics disagrees with the Monitor's recommendations. Respiroics shall implement the Monitor's recommendations no later than 120 days after Respiroics' response. In the event that Respiroics disagrees with the Monitor's findings and recommendations, Respiroics and the Monitor shall in good faith attempt to resolve the disagreement within 45 days of Respiroics' response under this section. In the event that Respiroics and the Monitor cannot come to an agreement on the issue, the Monitor's findings and recommendations and Respiroics' response, must be promptly submitted to OIG for review. Respiroics shall implement any determination made by OIG no later than 120 days after notice of OIG's determination.
  
- c. Within 60 days following the end of each Reporting Period during the term of the CIA, the Monitor shall issue a written report (Annual Monitor Report) to both Respiroics and the OIG. The Annual Monitor Report shall include: (a) a summary of the Monitor's activities in conducting its review of each of the items listed in Section III.E.1 above during the applicable Reporting Period, including but not limited to a description of the documents and systems reviewed and the personnel interviewed; (b) the Monitor's findings and recommendations regarding each of the items listed in Section III.E.1 above; and (c) the Monitor's assessment of whether Respiroics has implemented the Monitor's recommendations from the Initial Monitor Report or any prior Annual Monitor Report in the timeline specified by Respiroics in its response to the Initial Monitor Report or Annual Monitor Report, as applicable.
  
- d. Within 60 days following its receipt of each Annual Monitor Report, Respiroics shall prepare and submit to both the

Monitor and the OIG a written response to the findings and recommendations in the Annual Monitor Report that indicates (i) the steps Respiroics will take to implement the Monitor's recommendations, or (ii) if Respiroics disagrees with the Monitor's findings and recommendations. Respiroics shall implement the Monitor's recommendations within 120 days of Respiroics' written response. In the event that Respiroics disagrees with the Monitor's findings and recommendations, Respiroics and the Monitor shall in good faith attempt to resolve the disagreement within 45 days of Respiroics' response under this section. In the event that Respiroics and the Monitor cannot come to an agreement on the issue, the Monitor's findings and recommendations and Respiroics' response must be promptly submitted to OIG for review. Respiroics shall implement any determination made by OIG no later than 120 days after notice of OIG's determination.

- e. The Monitor may issue ad hoc written reports of its findings and recommendations relating to the items listed in Section III.E.1 above at any time during the term of the CIA. Such written reports shall be submitted to both Respiroics and OIG. Respiroics shall be required to provide a written response to any such ad hoc reports, to both the Monitor and the OIG, within 60 days of receipt of such report.
- f. The Monitor shall clearly identify any portions of its reports 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.

5. *Financial Requirements of Respiroics and the Monitor.*

Respiroics shall be responsible for all reasonable costs incurred by the Monitor in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).

- a. The Monitor shall submit invoices to Respiroics that reflect the costs incurred by the Monitor with a reasonable level of detail reflecting the costs billed. Respiroics shall remit payment to the Monitor within 60 days of receipt of any Monitor invoice. Respiroics may bring any disputed Monitor costs or bills to OIG's attention for purposes of facilitating the resolution of any such dispute.
- b. In connection with each Annual Monitor Report, the Monitor shall submit a written accounting of its costs incurred during the Reporting Period to Respiroics and to OIG. This report shall reflect, on a cumulative basis, all costs included on any periodic invoices. OIG will consider concerns raised by Respiroics, if any, associated with the Monitor's costs in the prior Reporting Period.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, Respiroics shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with its participation in the Federal health care programs, including the Anti-Kickback Statute risks associated with Arrangements and the risks associated with each Government Reimbursed Product, including the 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 Respiroics 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. Respiroics 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, Respiroics 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 Respironics' policies, conduct, practices, or procedures with respect to a Federal health care program requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Respironics 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 Respironics' 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 Respironics. 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, Respironics 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 program 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.

#### 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 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.* Respiroics shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

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

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

3. *Removal Requirement.* If Respiroics has actual notice that a Covered Person has become an Ineligible Person, Respiroics shall remove such Covered Person from responsibility for, or involvement with, Respiroics’ 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 Respiroics 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, Respiroics 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, Respiroics shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Respiroics conducted or brought by a governmental entity or its agents involving an allegation that Respiroics 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. Respiroics 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.

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 criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;
- b. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or

- c. the filing of a bankruptcy petition by Respiroics.

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

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

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

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

4. *Reportable Events under Section III.J.1.b.* For Reportable Events under Section III.J.1.b, 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 Respirationics 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.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

K. Field Force Monitoring and Review Program

Within 120 days after the Effective Date, Respirationics shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with DME Supplier staff, HCPs, and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with DME Suppliers staff, HCPs and HCIs and to identify potential improper 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 DME Supplier staff, HCPs, and HCIs (Records Reviews) by Respirationics compliance or other appropriately training Respirationics personnel who are independent from the sales and marketing function (Monitoring Personnel).

1. *Observations.* As a component of the FFMP, Monitoring Personnel shall conduct observations of sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to DME Supplier staff, HCPs and HCIs are consistent with applicable legal requirements and with Respirationics' Policies and Procedures. These observations shall be full day ride-alongs with sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and DME Supplier staff, HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year,

judgmentally selected by Monitoring Personnel, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes: (a) the identity of the sales representative; (b) the identity of the Monitoring Personnel who conducted the Observation; (c) the date and duration of the Observation; (d) the product(s) promoted during the Observation; (e) an overall assessment of compliance with Respiroics Policies and Procedures; and (f) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least eight 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, Respiroics shall also review various types of records to assess sales representatives' interactions with DME Supplier staff, HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Respiroics shall develop and implement a plan for conducting Records Reviews associated with at least two Government Reimbursed Product Lines.<sup>1</sup> 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 DME Supplier staff, HCPs and HCIs (including records relating to

---

<sup>1</sup> The "Government Reimbursed Product Lines" are the categories of Respiroics' products associated with their applications (e.g., CPAPs, ventilators, patient interface (masks), nebulizers).

consulting and other fee-for-service arrangements, speaker program activities, travel and entertainment, expense reports, any payments to DME Supplier staff, HCPs or HCIs, and sales communications from managers);

- ii. records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Product Lines 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.

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

#### M. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Respironics shall post on its website a description of the types of Payments made to Covered Recipients and include a link to CMS's Open Payments Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). Respironics 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 Respironics.

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, Respironics 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. Respirationics 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, Respirationics 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, Respirationics 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, Respirationics 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 requirements 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 of Directors 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 the risk assessment and internal review process required by Section III.F;
9. a description of the Disclosure Program required by Section III.G;
10. a description of the Ineligible Persons screening and removal process required by Section III.H;
11. a description of the FFMP required by Section III.K;
12. a certification from the Compliance Officer that information regarding Payments has been posted on Respironics' website as required by Section III.M;
13. a list of all of Respironics' 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;
14. a description of Respironics' corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and
15. the certifications required by Section V.C.

B. Annual Reports

Respironics 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 requirements; 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;
5. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period;
6. a description of any changes to Respironics' Training Plan developed pursuant to Section III.C and a summary of any Board of Directors 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 any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;
9. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b)

internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;

10. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs 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;

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

12. 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;

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

14. 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 Respiroics took as a result of such determinations;

15. a certification from the Compliance Officer that information regarding Payments has been posted on Respiroics' website as required by Section III.L;

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

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

18. 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, Respirationics 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, Respirationics has implemented and complies with is in compliance with all requirements of this CIA;
- b. to the best of his or her knowledge, Respirationics 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, Respirationics has fulfilled the requirements for new or renewed Focus Arrangements under Section III.D.2 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

Respirationics 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. Respironics 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

### Respironics:

Carol Roney, Compliance Officer  
Philips RS North America LLC  
6501 Living Place  
Pittsburgh, PA 15206  
Telephone:  
carol.roney@philips.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, Respironics 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 Respironics' books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Respironics' locations for the purpose of verifying and evaluating: (a) Respironics' compliance with the terms of this CIA and (b) Respironics' compliance with Federal health care program requirements. The documentation described above shall be made available by Respironics 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 Respironics' owners 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), 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. Respironics shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Respironics' owners, employees, contractors and directors may elect to be interviewed with or without a representative of Respironics present.

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

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

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

##### **A. Stipulated Penalties**

OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.F;
7. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.G;
8. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.H;
9. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.I;
10. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.J;
11. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.K;
12. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.L;
13. A Stipulated Penalty of up to \$2,500 for each day Respiration fails to comply with Section III.M;

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

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

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

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

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

B. Timely Written Requests for Extensions

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

C. Payment of Stipulated Penalties

1. *Demand Letter.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Respiroics of: (a) Respiroics' failure to comply; and (b) OIG's demand for payment of Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Respiroics shall either: (a) pay the applicable Stipulated

Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E.

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

D. Exclusion for Material Breach of this CIA

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C;
- b. failure to comply with Section III.A.1;
- c. failure to comply with Section III.D;
- d. failure to comply with Section III.E;
- e. failure to comply with Section III.J;
- f. failure to comply with Section V;
- g. failure to respond to a Demand Letter in accordance with Section X.C;
- h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Respiroics to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.C.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Respiroics constitutes an independent basis for

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

3. *Response to Notice.* Respironics shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Respironics in writing of its determination to exclude Respironics (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Respironics, including administrative and management services, except as stated in regulations found at 42 C.F.R. §1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, Respironics may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-3004.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Respironics shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. The procedures relating to the filing of a request for a

hearing can be found at  
<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 Respironics was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b) the period of noncompliance. Respironics shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Respironics has breached this CIA and orders Respironics to pay Stipulated Penalties, Respironics must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties, and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Respironics properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Respironics must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties, and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Respironics was in material breach of this CIA. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Respironics shall waive its right to any notice by OIG of the exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Respironics, Respironics shall be reinstated effective on the date of the exclusion.

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

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

Respironics 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) Respironics' 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.

D. The undersigned Respironics 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.

**PHILIPS RS NORTH AMERICA LLC**

/David Ferguson/  
DAVID FERGUSON  
President and Chief Executive Officer

8/22/2022  
DATE

/Stuart Cashman/  
STUART CASHMAN  
Vice President and Treasurer

8/22/2022  
DATE

/Howard J. Young/  
HOWARD J. YOUNG  
Morgan Lewis  
Counsel to Philips RS North America LLC

8/16/2022  
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

8/24/2022  
DATE

/Sarah Kessler/  
SARAH KESSLER  
Senior Counsel  
Administrative and Civil Remedies Branch  
Office of Counsel to the Inspector General  
U.S. Department of Health and Human Services

8/25/22  
DATE

## APPENDIX A

### ARRANGEMENTS TRANSACTIONS REVIEW

The Monitor shall perform all components of each Arrangements Transactions Review. The Arrangements Transactions Review shall be performed annually and shall cover each of the five Reporting Periods.

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

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

a. verifying that the Focus Arrangement is maintained in Respironics' centralized tracking system in a manner that permits the Monitor 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. 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;

c. verifying that the remuneration related to the Focus Arrangement has been determined in accordance with Respironics' 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;

d. verifying that the business need or business rationale for the Focus Arrangement is specified and is consistent with Respirationics' policies and procedures;

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

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

g. verifying that the Focus Arrangement satisfies the Focus Arrangements Requirements of Section III.D.2 of the CIA.

2. For any Focus Arrangement for which the Monitor cannot verify compliance with each of the applicable requirements specified in Section A.1 above, the Monitor 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 Monitor 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 Monitor cannot verify compliance with each of the applicable requirements specified in Section A.1 above with respect to 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 Monitor to select an additional sample of Focus Arrangements, not to exceed the number of Focus Arrangements initially reviewed by the Monitor, that will be subject to the Arrangements Transactions Review (Additional Transactions Review) and complete and submit to Respirationics and OIG an Additional Transactions Review Report that includes the information specified in Section B below, within 60 days of the date the OIG notifies Respirationics and its Monitor that an Additional Transactions Review will be required.

B. Arrangements Transactions Review Report. The Monitor shall prepare a report based on each Arrangements Transactions Review performed. The Arrangements Transactions Review Report shall include the following information:

1. *Review Methodology*.

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

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

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