RESPIRONICS, INC.

CONTRACTING WITH HEALTHCARE PROFESSIONALS OR PROVIDERS AND REFERRAL SOURCES POLICY

I. Purpose

This document sets forth Respironics, Inc.’s (“Company”) policy for engaging United States (“U.S.”) Healthcare Professionals or Providers (“HCPs”) and Potential Referral Sources as advisors or Consultants to assure Company’s retention of HCPs and Potential Referral Sources conforms to Office of Inspector General (“OIG”) Compliance Program Guidance, the Company’s Code of Conduct, and relevant industry guidance. This policy also addresses situations in which referral sources or HCPs engage Company to perform consulting services for the benefit of the HCP or Potential Referral Source.

Company may seek expert advice on a variety of topics, including product development, clinical program design, and marketing from an HCP or Potential Referral Source, including individual experts and Key Opinion Leaders. The primary purpose of advisor/Consultant engagements is to obtain information from, rather than provide information to, the HCPs and Potential Referral Sources.

II. Scope

This Policy applies to:

- Company, including both its business group and U.S. sales activities, and their officers, directors, and employees, and Company’s consultants, contract workers, and temporary workers who provide services to Company which relate to government reimbursed products or services (collectively “Company Representatives”); and

- Consulting engagements with HCPs or Potential Referral Sources and the review and approval of such engagements.

III. Definitions

**Consultant:** For the purposes of this Policy, a Consultant is defined as an HCP or Potential Referral Source retained either directly or indirectly, by Company pursuant to a consulting or fee for service agreement.

**Consulting Engagement:** Company’s retention of Consultants for services related to or for the benefit of Company and any other services requested by a department within Company, such as speaker, advisory board, feedback, product marketing assessment, research or clinical trial services, or any other arrangement where a Potential Referral Source receives payment for services rendered to Company or where a Potential Referral Source retains and pays for consulting services rendered by Company.
**Contract:** A written legal agreement that documents the services the HCP or Potential Referral Source will provide to Company (or Company will provide HCP or Potential Referral Source), the compensation for such services, and the timeframe in which they will be completed. These agreements must be completed prior to delivery of any services or payment for such services.

**Covered Person:** 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 of less than 5% through public trading or in connection with the operation of employee incentive programs); b) officers, directors, and employees of the Company; c) all contractors, subcontractors, agents, and other persons, who furnish patient care items or related services, or who perform marketing, sales, or billing functions on behalf of the Company excluding both vendors, whose sole connection to Company is selling or otherwise providing medical supplies, equipment, services, or components to the Company and customers, whose sole connection to the Company is purchasing durable medical equipment related services.

**Fair Market Value ("FMV"):** For the purposes of this Policy, “Fair Market Value” is defined as

- The fee Company and a contracted HCP or Potential Referral Source agree upon to compensate the HCP or Potential Referral Source for legitimate and necessary services performed on behalf of Company.

- The fee Company and Referral Source agree upon to compensate Company for legitimate and necessary services performed on behalf of HCP or Referral Source.

The fee is determined without intent to reward or incentivize the HCP to advance Company’s business objectives, in accordance with the Company’s Code of Conduct.

**HCP Checklist:** A specific set of criteria and qualifications that are applied to HCPs to determine the Fair Market Value for compensation paid for services based upon experience, specialization, type of services provided, and medical and academic achievements.

**Key Opinion Leaders ("KOLs"):** A subset of HCPs or Potential Referral Sources meeting five (5) generally agreed-upon criteria: 1) Regularly sought out by their colleagues for opinions or advice; 2) Speak often at regional or national conferences; 3) Have published articles in a major journal during the past two (2) years; 4) Early adopters of new treatments or procedures; and 5) Help establish protocols for patient care.


**U. S. Health Care Professional or Provider ("HCP") or Potential Referral Source:** The term “U.S. Health Care Professional” is defined very broadly to cover any person or entity that is involved in the provision of health care services or items to patients, and that purchases, leases or recommends, uses or arranges for the purchase or lease, of Company medical products, services or solutions in the U.S. Practically, this includes, among others:
Clinicians, such as physicians, nurses, PhDs, technologists, pharmacists and medical, staff such as respiratory technologists or physician assistants, as well as clinicians in training.

- Hospitals, medical schools affiliated with hospitals, medical group practices, medical clinics, nursing homes, sleep diagnostic clinics, surgical centers, emergency medical services and home healthcare organizations, as well as nonmedical personnel in these facilities who make purchasing decisions.
- Medical device distributors and dealers, including Durable Medical Equipment (“DME”) suppliers, who sell to HCPs or bill Medicare and Medicaid for their items and services.
- Health care-related trade associations which serve HCPs or Potential Referral Sources or have a significant number of HCPs or Potential Referral Sources on its board, such as the American Sleep Association.
- Employees, administrators, officers and directors of HCPs are also considered HCPs, where involved in the decision to purchase or lease Company services or products.

IV. Policy

The Company will make payment or provide services to an HCP or a Potential Referral Source only when:

- The applicable arrangement is in writing and signed by both parties;
- The writing defines, specifically, the work to be performed;
- There is a bona fide reasonable need for the services of a HCP or Potential Referral Source; and
- Such services can be obtained at a reasonable cost consistent with the Fair Market Value of such services.

Company employees are expected to negotiate diligently and in good faith to achieve this goal in conformance with this Policy and its related procedures.

Consultants are chosen based on a clearly defined set of eligibility criteria, including academic and clinical or business credentials, and never as a reward or incentive for past, present, or future product purchases.

The identification, selection, and retention of Consultants and other aspects of the consulting service must comply with applicable laws, rules, regulations, Company policies or procedures, the Company Code of Conduct, and industry codes of conduct. Company employees or agents with sales responsibility may provide input about the suitability of a proposed Consultant, but may not control or unduly influence the decision to engage a particular HCP or Potential Referral Source as a Consultant.

Each party to a Consultant Engagement that meets the definition of a Covered Person shall complete one (1) hour of training regarding the Anti-Kickback Statute. Company will provide each party to a Consultant Engagement with a copy of its Code of Conduct and related Anti-Kickback statutes.
Statute policies, which may be provided via website. Written agreements for Consulting Engagements must include a certification by all parties that they agree to comply with the Anti-Kickback Statute with respect to performance of the activities related to the agreement. For more information on Covered Persons and Focus Arrangements procedures. See Focus Arrangement and Promotional Functions Policy RI-CP-002.

When Company is retained for consulting services, compensation received must be Fair Market Value.

A. Consulting Engagements

The purpose of Company engaging a Consultant is to fulfill a legitimate, unmet business need for information, advice, and feedback from Consultants regarding Company products and other topics relevant to Company’s business. This engagement type, as well as when an HCP or Referral Source engages Respironics, should be designed to obtain bona fide services to address identified, legitimate business, scientific or medical needs of relevant party.

Company must ensure that Consulting Engagements are neither inducements nor rewards for purchasing, leasing, using, or recommending the purchase, use, or lease of any Company product. The purpose of entering into a consulting arrangement must never be for any reason that could be perceived as inappropriate or unethical.

B. Selecting and Retaining Consultants

The Company Representative requesting consulting services from an HCP or Potential Referral Source shall complete an HCP Checklist and ensure that the following information is documented and in compliance with applicable Company policies and procedures prior to entering into an agreement with a Consultant:

- A legitimate, identified business need and rationale for the consulting services with an explanation of the justifiable value to the business that is not otherwise available through internal personnel or duplicative of services provided by other Consultants
- The selection criteria for the Consultant and a description as to how the criteria directly relates to the business purpose and need
- That each Consultant has the appropriate knowledge and expertise in the particular therapeutic area, and qualifications to act as a Consultant for Company, and appropriate licensure and good standing with professional and administrative agencies
- The estimated total fees for services for the consulting engagement and the support that the fees are Fair Market Value for the services

An HCP or Potential Referral Source may not provide consulting services on behalf of Company if he/she:

- Has been debarred by the U.S. Food and Drug Administration (“FDA”);
- Is on the OIG exclusion list;
• Is known to be under current government investigation;
• Has been cited for violations by the FDA/the Office of Prescription Drug Promotion; or
• Has violated his/her contract with Company.

C. Consultant Compensation

HCPs or Potential Referral Sources who participate in Consulting Engagements may be offered reasonable compensation for their time, considering the value of the type of services provided, and offered reimbursement for reasonable travel, lodging, and meal expenses. Such compensation and reimbursement can only be offered when:

• A legitimate need for the services has been clearly defined in advance of requesting the services and entering into the arrangement;
• There is a written contract specifying the nature of the consulting services to be provided and the basis for payment of those services; and
• The criteria for selecting the Consultant is directly related to the identified purpose and the persons responsible for selecting the Consultants have the expertise necessary to evaluate whether the particular HCPs or Potential Referral Sources meet those criteria as outlined in this document.

Any compensation or reimbursement made to an HCP or Potential Referral Source in conjunction with a Consultant arrangement should comply with Company’s Code of Conduct.

Payments will be made directly to Consultants or Consultant’s company following completion of an agreed-upon activity or service in accordance with the agreement, and all applicable Company policies and procedures.

In addition to compensation for service, preparation time, and travel time, Company may reimburse Consultants for reasonable out-of-pocket expenses incurred in connection with services provided to Company. All payments must be reasonable and represent FMV. The number of nights of lodging paid by Company may not exceed the number necessary for services. Company will not pay for any expenses incurred by a guest or anyone accompanying the Consultant.

D. Review and Approval

Transactions under this Policy shall be reviewed and approved in accordance with the Focus Arrangement Policy and related procedures. See Focus Arrangement and Promotional Functions Policy RI-CP-002.

E. Documentation of Consulting Activities

Documentation of deliverables or services received from an HCP or Potential Referral Source must be tracked in accordance with the Focus Arrangement Policy and related procedures. See Focus Arrangement and Promotional Functions Policy RI-CP-002.
F. Documentation and Tracking

Company is required to report payments made to U.S. HCPs and Potential Referral Sources pursuant to federal and state transparency requirements. Refer to the policies governing Transparency Reporting for more information.

All transactions under this Policy will be tracked and stored in accordance with the Focus Arrangement Policy and the Centralized Arrangements Tracking System (CATS) SharePoint Procedure. See Focus Arrangement Policy – RI-CP-002 and Centralized Arrangements Tracking System (CATS) SharePoint Procedure – RI-CPROC-002(b).

V. Appendices

Not Applicable

VI. References

Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
Respironics Inc. Code of Conduct
Philips Transparency Guide

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