

RESPIRONICS, INC.

FOCUS ARRANGEMENTS AND PROMOTIONAL FUNCTIONS POLICY

I. Purpose

Respironics, Inc. (the “Company”) is committed to ensuring that its sales and contracting practices comply with federal and state laws, regulations, guidelines and policies. All Promotional Functions, Arrangements and Focus Arrangements (as defined below) must be conducted in accordance with all regulatory healthcare requirements, including, without limitation, the Anti-Kickback Statute, False Claims Act, Stark Law, and any other federal health care program requirement.

To help facilitate and monitor compliance with these laws, Respironics has established a review and approval process for all Focus Arrangements which is set forth in this Policy and related procedures. All Focus Arrangements (as defined below) must be reviewed, approved, recorded and tracked in a centralized Arrangements tracking system in accordance with this Policy and associated procedures (*see (i) Focus Arrangements Review and Approval Procedure; and (ii) Centralized Arrangements Tracking System Procedure*). Additionally, all Promotional Functions related to Government Reimbursed Products and Services must comply with this Policy and associated procedures.

II. Scope

This Policy applies to Respironics, including both its business group and U.S. sales activities, and their officers, directors, and employees, and the Company’s consultants, contract workers, and temporary workers, who provide services to the Company, which relate to Government Reimbursed Products or Services (collectively “Company Representatives”). This Policy and its associated written Procedures and work instructions are independent from the Respironics Quality Management System, which is intended to ensure the quality of Respironics’ products in accordance with the requirements of 21 CFR 820, Quality System Regulations, and associated regulations and guidance.

III. Definitions

Arrangement: Every arrangement or transaction that:

- involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value, and
- is between Respironics, Inc. and
 - any actual or potential **source of health care business or referrals** to Respironics, or
 - any actual or potential **recipient of health care business or referrals** from Respironics.
 - The term “**source of health care business or referrals**” means 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 U.S. Federal health care program.

-
- The term “**recipient of health care business or referrals**” means any individual or entity (1) to whom Respironics refers an individual for the furnishing or arranging for the furnishing of any item or service, or (2) from whom Respironics 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 U.S. federal health care program.

Centralized Arrangements Tracking Systems (“CATS”) Sharepoint: The database that serves as the electronic repository for transactions, Focus Arrangements and supporting documentation entered into by the Company.

Respironics Code of Conduct (“COC”): Consists of three distinct policies: SimplyRight, Philips General Business Principles, and Code of Conduct on Interactions with Healthcare Professionals (collectively, “Code of Conduct”).

Respironics Compliance Officer (“CO”): Primarily responsible for overseeing and managing the Company’s Corporate Healthcare Compliance Program and related Corporate Integrity Agreement, and monitoring that the Company and its employees are complying with applicable regulatory, legal, and compliance requirements including internal policies and procedures, as well as external regulations and codes of conduct.

Covered Persons: Includes a) all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest of less than through public trading or in connection with the operation of employee incentive programs); b) officers, directors, and employees of Respironics; 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 Respironics excluding both vendors whose sole connection to Respironics is selling or otherwise providing medical supplies, equipment, services, or components to Respironics and customers whose sole connection to Respironics 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 agrees 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.

Focus Arrangements: Every Arrangement that is between Respironics and any actual source of health care business or referrals to Respironics and involves, directly or indirectly, the offering, payment, sale or provision of anything of value.

Government Reimbursed Products and Services: All Respironics products and services that are: (a) marketed or sold by Respironics in the U.S. (or pursuant to contracts with the U.S.) and (b) reimbursed in whole or in part under U.S. Federal health care programs.

Healthcare Laws: The Anti-Kickback Statute, False Claims Act, Stark Law, and any other U.S. federal health care program requirement applicable to the development, marketing, sale and promotion of Company's products and services.

Promotional Functions:

- the selling, detailing, marketing, advertising, or promoting of Government Reimbursed Products and Services; and
- the preparation or external dissemination of Promotional Materials or information about Government Reimbursed Products and Services, including those functions relating to Respironics' review and approval processes for Promotional Materials.

Promotional Materials: Any written, printed, or graphic material (whether in print or electronic form) containing information disseminated by or for Respironics that is intended to influence the potential prescription, purchase, or recommendation of any Government Reimbursed Products and Services.

IV. Policy

To ensure that all Focus Arrangements and Promotional Materials related thereto do not generate unlawful U. S. Federal health care program business in violation of the Healthcare Laws:

- All Focus Arrangements must be reviewed, approved, recorded and tracked in a centralized tracking system in accordance with this Policy and associated procedures (See (i) Focus Arrangements Review and Approval Procedure - RI-CPROC-002(a) and (ii) Centralized Arrangements Tracking System Procedure - RI-CPROC-002(b)); and
- All Promotional Functions related to Government Reimbursed Products and Services must comply with this Policy and associated procedures.

A. Requirements for the Review and Approval of Focus Arrangements

1. Each Focus Arrangement is required to undergo a thorough review and approval process to ensure that it does not violate the Healthcare Laws. This process is detailed in the *Focus Arrangements Review and Approval Procedure* (See RI-CPROC-002(a)) and includes:

-
- a. A legal review of each Focus Arrangement by counsel with expertise in the Anti-Kickback Statute,
 - b. Documented business need or business rationale for each Focus Arrangement, and
 - c. A financial review that includes, if applicable, determining and documenting the Fair Market Value (see Respironics, Inc. Code of Conduct).
2. All Focus Arrangements (except invoices) are required to be in a written document that reflects all of the terms of the Focus Arrangement, and must be signed by an authorized Company Representative on behalf of the Company, in accordance with the *Focus Arrangements Approval and Signing Authority Policy (See Policy No. RI-CP-006)*, and by all other parties to the Focus Arrangement.
 3. The fully signed written agreement for each Focus Arrangement must be stored in accordance with the *Centralized Arrangements Tracking System Procedure (See Pol No. RI-CPROC-002(b))*.

B. Requirements for the Legal Review and Approval of Promotional Materials

1. All Promotional Materials intended, prepared, or otherwise assembled for dissemination outside of Respironics must undergo a legal review and approval. Legal review may be performed by attorneys and paralegals with knowledge and training on the Anti-Kickback Statute, False Claims Act, and this Policy.
2. Company Representatives may not use or distribute externally Promotional Materials that are not approved by Legal.
3. Adding to, altering or modifying approved Promotional Materials, such as by highlighting, deleting, editing, or adding notes or other material, makes those materials unacceptable for use. Any changes to approved Promotional Materials or changes in the contextual use of Promotional Materials must be resubmitted for approval by Legal.
4. All Promotional Functions, including oral communications, relating to Focus Arrangements must be conducted in strict accordance with approved Promotional Materials.

C. Tracking Remuneration, Services and Usage

1. The Compliance Officer, or her/his designee(s), through the use of CATS SharePoint and other Company systems, will monitor and audit remuneration to and from parties to Focus Arrangements.
2. The Compliance Officer, or her/his designee, through the use of CATS SharePoint and other Company systems, will track service and activity logs to ensure that parties to the Focus Arrangements are performing the services required under the applicable Focus Arrangement (if applicable).

3. The Compliance Officer, or her/his designee(s), through the use of CATS SharePoint and other Company systems, will monitor the use of leased space, and sale of medical supplies, medical devices, equipment or other patient care items to ensure that such use or sale is consistent with the terms of the applicable Focus Arrangement(s) (if applicable).

D. Monitoring and Compliance Officer Review

1. The Compliance Officer or her/his designee(s), is responsible for monitoring compliance with this Policy and associated Procedures.
2. The Compliance Officer or her/his designee(s), must review the Centralized Arrangements Tracking System, internal review and approval process, and other Focus Arrangements procedures on at least an annual basis, and must provide a report on the results of such review to the Compliance Committee.

E. Violations of Policy and Procedure

1. If any individual discovers a violation of this Policy or any related procedure, or suspects any violation of any Healthcare Law, the individual shall disclose in accordance with the Respironics, Inc. Code of Conduct or will inform the Compliance Officer, and provide the Compliance Officer with all information known regarding the suspected violation.
2. The investigation of reports of suspected violations of the Healthcare Laws shall be conducted in accordance with the Code of Conduct and other applicable Company policies and procedures
3. The Compliance Officer will inform the Compliance Committee of potential violations or other investigations of suspected violations of this Policy and associated procedures.

F. Distribution and Training

1. The Compliance Officer or her/his designee(s), will communicate to all Covered Persons, through training and distribution of descriptive materials, the contents of this Policy and associated procedures.
2. The Compliance Officer, in conjunction with her/her designee(s), will review this Policy and associated procedures on an annual basis.

G. Document Storage and Maintenance

1. The Company must maintain Focus Arrangements documents for at least seven (7) years.

V. Appendices

Not Applicable

VI. References

1. Respironics, Inc. Code of Conduct
2. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
3. Focus Arrangements Review and Approval Procedure - RI-CPROC-002(a)
4. Centralized Arrangements Tracking Systems (CATS) SharePoint Procedure - RI-CPROC-002(b)
5. Focus Arrangements Approval and Signing Authority Policy -RI-CP-006

Referenced Documents:

Document Number	Document Description
RI-CPROC-002(a)	Focus Arrangements Review and Approval Procedure
RI-CPROC-002(b)	Centralized Arrangements Tracking Systems (CATS) SharePoint Procedure
RI-CP-006	Focus Arrangements Approval and Signing Authority Policy