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**PHILIPS RS NORTH AMERICA LLC**

**CONTRACTING WITH HEALTHCARE PROFESSIONALS OR PROVIDERS AND  
REFERRAL SOURCES POLICY**

**I. Purpose**

This document sets forth Philips RS North America LLC's (the "Company") policy for engaging United States ("U.S.") Healthcare Professionals or Providers ("HCPs"), Potential Referral Sources, Durable Medical Equipment (DMEs) Suppliers, and Healthcare Institutions (HCIs), Referral Recipients, and Non-Provider Referral Sources as advisors or Consultants. The 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. HCPs may also be retained to provide education to sales representatives at sales meetings, preceptorships, tutorials, and experience-based learning activities. The Company's retention of HCPs and Potential Referral Sources shall comport with the Office of Inspector General ("OIG") Compliance Program Guidance, the Company's Code of Conduct, and related Healthcare Compliance policies and procedures.

This policy also addresses situations in which referral sources or recipients or HCPs engage the Company to perform consulting services for the benefit of the HCP or Potential Referral Source.

**II. Scope**

This Policy applies to:

- The Company, including its business group, U.S. and U.S. territories' sales activities, and their officers, directors, and employees, and the 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 the Company pursuant to a consulting or fee-for-service agreement. This includes but is not limited to speaker agreements, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory boards, ad hoc advisory boards, research and research-related activities, authorship activities, and any other financial engagement or arrangements with HCPs and all events and expenses relating to such engagements or arrangements.

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**Consulting Engagement:** The Company's retention of Consultants for services related to or for the benefit of the Company and any other services requested by a department within the Company, such as speaker, speaker training programs, training and education services, product development activities, presentations, consultant task force meetings, advisory board, ad hoc advisory boards, research and research-related activities, authorship activities, feedback, product marketing assessment, clinical trial services, or any other financial engagement or arrangement with a DME Supplier, HCP or HCI and all events and expenses relating back to such engagements or arrangements.

**Contract:** A written legal agreement that documents the services the HCP or Potential Referral Source will provide to the Company (or the 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 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 Respironics' 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 and (f) reviewing and/or approving requests for grants or charitable contributions.

**Note:** Please review the [Focus Arrangements and Covered Functions Policy](#) for additional requirements related to Covered Functions.

**Covered Person:** includes: (a) all owners of the Company 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 the Company; 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 the Company excluding vendors whose sole connection with the Company is selling or otherwise providing medical supplies or equipment to the Company.

Notwithstanding the above, the term "Covered Persons" does not include (a) employees at Company's 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

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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 Company 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 Company during the calendar year.

**Covered Recipients:** Are a subset of U.S. Health Care Professionals or Providers or Potential Referral Sources. They may vary under federal or state laws. For Physician Open Payment reporting under CMS Covered Recipients include physicians, dentists, chiropractors, teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants, and certified nurse midwives.

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

- The fee the 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 the Company.
- The fee the Company and Referral Source agree upon to compensate the 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 the 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 of Health Care Business or Referrals meeting five (5) generally agreed-upon criteria: 1) Regularly sought out by their colleagues for opinions or advice; 2) Speak often at regional, national, and/or international conferences; 3) Have published articles in a major journal during the past two (2) years; 4) Early adopters of new and innovative treatments or procedures; and 5) Help establish protocols for patient care.

**Philips RS North America LLC Code of Conduct (“COC”):** Consists of three distinct policies: Simply Right, Philips General Business Principles, and Philips Policy on Interactions with Healthcare Providers and Professionals (collectively, “Code of Conduct”).

**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 federal health care program.

**U. S. Health Care Professional or Provider (“HCP”) or Potential Referral Source:** The term “HCP” 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:

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- Clinicians, such as physicians, nurses, PhDs, technologists, pharmacists and medical, staff such as respiratory technologists or physician assistants, as well as clinicians in training.
  - Health Care Institutions: 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 and have a significant number of HCPs or Potential Referral Sources on its board.
  - Employees, administrators, officers, and directors of HCPs are also considered HCPs, where involved in the decision to purchase or lease Company services, solutions or products.
  - Referral recipients or non-provider referral sources.

#### **IV. Policy**

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

- 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 an 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, services or solutions 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, and the Company Code 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 receive training on Company’s CIA requirements and Compliance Program. Written agreements for

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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.

When the Company is retained for consulting services, compensation received must be consistent with 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, services or solutions and other topics relevant to Company's business. This engagement type, as well as when an HCP or Referral Source engages the Company, should be designed to obtain bona fide services to address identified, legitimate business, scientific or medical needs of the 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, solution or service. 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.
- Compensation paid to a consultant shall be consistent with Fair Market Value in an arms' length transaction for services provided and shall not be based on the volume or value of the consultant's past, present, or anticipated business with the Company.
- Documentation of all Fair Market Value determination(s) for any Focus Arrangement, including the Fair Market Value amount or range and corresponding time period(s), the

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date(s) of completion of the Fair Market Valuation(s), and for new and renewed Focus Arrangements, the individuals or entities that determined the Fair Market Value amount or range, and the names the Covered Person(s) who received and/or were involved with the Fair Market Value determination(s).

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 criterion 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 the 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 -, the Company may reimburse Consultants for reasonable and actual expenses incurred that are necessary to carry

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out the consulting or other fee-for-service arrangement. All payments must be reasonable and represent FMV. The number of nights of lodging paid by the Company may not exceed the number necessary for services. The Company will not pay for any expenses incurred by a guest or anyone accompanying the Consultant. All expenses must be provided for in the written agreement.

#### **D. Review and Approval**

Transactions under this Policy shall be reviewed and approved in accordance with the Focus Arrangements and Covered Function Policy and related procedures.

#### **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 Arrangements and Covered Functions Policy and related procedures.

#### **F. Documentation and Tracking**

The Company is required to report payments or transfers of value made to U.S. HCPs and Potential Referral Sources that are classified as Covered Recipients pursuant to federal and state transparency requirements. Refer to the Philips RS North America LLC Code of Conduct and policies governing Transparency Reporting for more information.

All transactions under this Policy will be tracked and stored in accordance with the Focus Arrangements and Covered Functions Policy, the iCon Database Procedure and the Centralized Arrangements Tracking System (CATS) SharePoint Procedure.

#### **V. Appendices**

Not Applicable

#### **VI. References**

Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)  
Philips RS North America LLC Code of Conduct  
Philips Transparency Guide