



# Philips Policy on Interactions with United States Healthcare Providers and Professionals

February 2021 (SRC)

Please Note: This Policy is revised from time to time. Always refer to the [Philips North America LLC Compliance Program](#) website for the most current version of this Policy

Dear Colleague:

We are Philips. We represent Philips in everything we do. Each of us reflects what we stand for as a company and as a global community committed to making the world a better place through meaningful innovation. Our reputation is a critical factor that distinguishes us in the marketplace. Compliance is a foundational building block of our reputation.

This “Philips Policy on Interactions with U.S. Health Care Providers and Professionals” builds upon the Philips General Business Principles (GBP). It builds upon our GBPs by adding specificity in a user-friendly way to the laws and rules applicable to dealing with U.S. Health Care Providers and Professionals when you are interacting with them in the United States or outside of the United States. It provides guidance on important business principles and ethical standards. It reflects our values. It exists to protect you, our customers, and our company. Read it carefully. Consider what this Policy means to you in your role. Each of us is expected to live by this Policy. Indeed, each of us must be a role model.

In the spirit of doing the right thing, if you are aware of any actions that may violate this Policy or put you, a colleague, a customer, or Philips at risk, speak up. We prohibit retaliation against anyone who makes a good faith report of known or suspected misconduct. See our “[whistleblower policy](#)”. We depend on you to let us know where we need to change or improve. If you ever have a question about The Policy on Interactions with US HCPs, the Philips General Business Principles, or their applicability to your role, ask! Ask your manager, ask a Philips lawyer or ask a GBP compliance officer, or use the Ethics Hot Line.

Compliance is a competitive advantage and ensures sustainable growth. Thank you for always acting with quality and integrity.

Kind Regards,

Frans van Houten



Vitor Rocha



#### Useful links

- [Philips North America LLC Compliance Program](#)
- [Philips General Business Principles](#)
- [Compliance officers](#)
- Philips Speak Up (Philips Ethics Line):
  - <http://philips.ethicspoint.com>

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# 1. Preamble: Goal and Scope

As part of its commitment to legal compliance, professionalism and ethics, Philips abides by a number of ethical codes established by medical device industry trade associations. For interactions with U.S.-licensed Health Care Providers, Philips has condensed various industry codes into a single Philips Policy on Interactions with United States Health Care Providers and Professionals. Wherever possible, the requirements have been put into the context of Philips' businesses to make it simpler for Philips employees and contractors to comply.

This Policy is part of the overall Philips Legal Compliance Program. The Philips Policy on Interactions with US HCPs supplements, and does not replace, the [General Business Principles](#) (GBPs), Philips Global Policy on Interactions with HCPs, related internal and external guidance, applicable laws and regulations such as the Physician Payment Sunshine Act (US Sunshine Law) which is part of the Affordable Care Act or any other part of the Philips Legal Compliance Program or any successor programs. The Philips Legal Compliance Office and all of its tools, such as the Philips Ethics Line, play a fundamental role in supporting and executing this Policy.

Philips is committed to compliance, monitoring, auditing and where necessary conducting investigations related to our compliance with the Philips Policy on Interactions with US HCPs. Philips requires its employees to comply with all applicable laws, regulations and codes and to foster an atmosphere of compliance within Philips. By doing so, we not only protect the company but also ourselves, our customers and our business partners.

## 1.1. To Whom Does this Policy Apply?

All Philips employees, agents and subcontractors, including, dealers, distributors, and resellers, who work for or on behalf of Philips are expected to comply with this Policy when dealing or interacting with U.S. HCPs who may be in a position to purchase, lease, use, provide or recommend the use of Medical Devices, services, or products. In addition, a Philips employee or agent may not encourage, facilitate or pay others to take actions that would violate this Policy.

## 1.2. Who are Health Care Providers and Professionals?

This Policy applies only to our interactions with U.S. Health Care Providers and Professional, even if that interaction occurs outside of the U.S. 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 Philips medical products, services or solutions in the U.S. Practically, this includes, among others:

- Clinicians, such as physicians, nurses, PhDs, technologists, pharmacists, medical staff such as dental hygienists or physician assistants, as well as clinicians in training.
- Hospitals, medical schools affiliated with hospitals, medical group practices, clinics, nursing homes, imaging centers, surgical centers, emergency medical services and home healthcare organizations, as well as nonmedical procurement personnel in these facilities who make or influence purchasing decisions.
- Medical device distributors and dealers, including Durable Medical Equipment ("DME") suppliers, who sell to Health Care Professionals or bill Medicare and Medicaid for their items and services.
- Health care-related trade associations which serve HCPs or have significant number of HCPs on its board, such as the American College of Radiology.
- Employees, administrators, officers and directors of Health Care Professionals are also considered Health Care Professionals, where involved in the decision to purchase or lease Philips services or products.

### 1.3. Definitions

- “FMV” means fair market value. See Guidance on Fair Market Value for Transactions with HCPs
- “HCP”, “Health Care Provider” or “Health Care Professional” means U.S. Health Care Provider or Health Care Professional. All have the meaning set forth in Section 1.2 above.
- “PSS” or “We” means Philips Products, Services and Solutions.
- “United States, or U.S.” includes all 50 U.S. states, all U.S. territories including Puerto Rico and the U.S. Federal District, Washington D.C.
- “Medical Devices” are devices or products regulated by a government agency such as the Food & Drug Administration (“FDA”), and include related services.

## 2. Compliance with the Policy

Philips has a multifaceted compliance program in place to support employee efforts to comply with this Policy. Additional policies and procedures for implementing the Philips Policy on Interactions with HCPs may be found on the [Philips North America LLC Compliance Program](#) and [Legal websites](#).

We encourage Philips employees to use the available resources, in particular the [Philips Ethics Line](#), to report actual or suspected violations of this Policy. Employee’s individual commitment is crucial to the success of this compliance program. Being a trusted partner helps Philips create the future of health care and helps everybody win.

If you have questions or need help determining if your situation may be in violation of this Policy, contact the Philips Compliance Program Administrator ([compliance.administrator@philips.com](mailto:compliance.administrator@philips.com)) to investigate alternatives. We are in this together. Getting this right is the only option.

In addition, many health care providers and suppliers have their own codes of conduct or ethics. It is recommended that when dealing with a HCP, Philips employees ask the HCP if he or she has his/her own code of conduct or similar policy document. If Philips employees are aware of such a code, they must not knowingly cause a health care provider or supplier to violate. For example, a Philips employee must not offer a meal to a nurse whose hospital prohibits its staff from accepting meals from vendors, even if it would otherwise be permitted under Philips’ policies.

### Q & A

#### Are any Philips employees excluded from this Policy?

No. The Philips Policy on Interactions with US HCPs applies to all employees who sell to, market to or interact with U.S. HCPs, no matter what line of business. This may also include distributors and agents who perform these activities on Philips’ behalf.

## 3. PSS Training and Education

Philips has a responsibility to demonstrate the safe and effective use of our products and Medical Technology to HCPs requiring such training. Philips may also provide education on disease state and our Medical Technology.

- All training programs, marketing materials and communications must be consistent with the FDA-cleared product labeling, where appropriate, of Philips’ products. In all cases, the training staff shall have the proper qualifications and expertise to conduct such training. Training staff may include qualified field sales employees who have the required technical expertise to perform the training.
- Training and education may be offered as a component of product sales, or as a service that we market and sell at commercially reasonable value, in conjunction with or separately from the sale or lease of other Philips PSS.

- Training may be offered without charge, but Legal needs to evaluate if it is appropriate to pay for travel or lodging of an HCP.
- Programs must be conducted in settings or an appropriate facility conducive to the exchange of scientific information.
- Philips may not compensate or reimburse HCPs for attending a third party education program or general education sessions. In some cases, programs may occur at centralized locations, and it may be permissible for Philips to reimburse HCPs for reasonable travel expense, relating to a Philips product training event.
- Philips may not host, fund or support the attendance of third parties (e.g. spouses or guests) that do not have a bona-fide professional interest in the program.

#### **Support in the Clinical Setting:**

Philips representatives may only enter the clinical setting to provide technical support on our Medical Technology, such as explaining our Medical Technology settings or technical control functions and making recommendations on the best use of our Medical Technology. Any guidance to an HCP provided by a Philips representative shall be consistent with the Medical Technology’s instructions for use and FDA labeling. Philips representatives may only enter and be present in the clinical setting at the request of and under the supervision of an HCP. Philips representative must be transparent that they are acting on behalf of Philips in a technical support capacity and MUST NOT interfere with an HCP’s independent clinical decision making. Philips representative must comply with applicable hospital or facility policies and requirements, including patient privacy and reasonable credentialing requirements to the extent such policies do not conflict with Philips policies and procedures or with law. Philips providing technical support for our Medical Technology should not eliminate an overhead or other expense that a Customer should otherwise incur while providing patient care during a procedure.

### **3.1 Products, Services and Solutions (“PSS”) Sponsored Training**

PSS training offered to our customers is routinely included in sales or other commercial agreements either as an additional line item for a price or specified as included in the price of equipment. Philips may also offer PSS training to customer free of charge when the training is not listed in a sales or other agreement, but in such cases, Legal must evaluate if it is appropriate to pay for travel or lodging. If the PSS training involves travel to a training center, it is important that the sales agreement clearly document what Philips will and will not pay. Any travel, transportation, lodging and meals Philips provides or pays for must be necessary, modest, and subordinate to the training.

Philips businesses and sales and service functions may have additional policies and procedures governing product training. Philips employees are responsible for knowing and following any such applicable policies and procedures for their business. If these policies and procedures conflict with the Philips Code of Conduct, follow the Code of Conduct.

### **3.2. Communicating for The Safe & Effective Use of Medical Technology**

HCPs may use a product for any use that they determine is in the best medical interests of their patients. This includes uses that are contained in the Medical Technology’s labeling or otherwise consistent with such labeling, but it could also include uses that are not approved or cleared (i.e. “off-label” uses). As recognized under U.S. law and by the FDA, off-label use of these Medical Technologies can be an important part of medical practice and may even constitute a medically recognized standard of care. Access to truthful and non-misleading information relating to Medical Technologies, including information on both on- and off-label uses, is critical to a Health Care Professional’s ability to exercise his or her medical judgment in the best interest of patients, to provide high-quality care, and to safely use available Medical Technology.

Industry appropriate communications of such information can include, among other activities:

- Proper dissemination of peer-reviewed scientific and medical journal articles, reference texts, and clinical practice guidelines;

- Presentations at educational and medical meetings regarding clinical trial results or research and development data for an investigational use (taking care that no claims are made regarding safety and effectiveness); and
- Discussions with consultants and Health Care Professionals to obtain advice or feedback relating to topics such as unmet patient needs, product research and development, and the like. The following principles recognize industry’s responsibility to communicate about medical and scientific information to assist in achieving positive patient outcomes and support of the public health: Company responses that contain information regarding unapproved or uncleared uses should be provided by authorized personnel; Company communications must be truthful and non-misleading; Information related to unapproved or uncleared uses should be identified as such.

## Q & A

**If we train a group of HCPs on the safe and effective use of portable equipment and/or software, is it appropriate to provide the “hands-on” training in a hotel or other meeting facility, other than a clinical facility?**

Yes, only if a training facility, medical institution, lab or other appropriate setting is not available and so long as the facility used is conducive to the training purpose.

### 3.3. Philips Organized Training and Education

Philips offers many educational programs for our customers, prospective customers and other Health Care Professionals. Unlike PSS training, these programs may not focus on instructing customers on our Medical Technology. Instead, they provide knowledge or training on skills that may be used more broadly in their job or profession and are sometimes not limited to the use of Philips PSS. Typically, Philips is involved in selecting the topics, content or instructors for these education programs and each participant is charged a commercially reasonable fee to attend. Examples of such programs are:

- Courses to familiarize HCPs with new imaging modalities or diagnostic, therapeutic or disease management methodologies
- Satellite programs at clinical or scientific symposia or conferences
- Hands-on technical skills training
- Preceptorships

## Q & A

**May I pay for a HCP’s travel to a Philips-provided or sponsored general educational program?**

No. It is appropriate for us to conduct a general educational program not limited to our products, but it is not the type of program for which Philips supported travel or lodging would be appropriate under our Code.

### 3.4. Joint Education and Marketing Events

It is permissible, in certain circumstances, to partner with HCPs to jointly conduct education and marketing programs. To do so, there must be a bona-fide legitimate need to engage in this activity. In addition:

- HCPs participating must be trained on the Philips guidelines and requirements at speaking engagements;
- The event must be balanced and promote both Philips and its Medical Technologies and the HCP, and the range of services offered for the diagnosis and treatment of the related medical condition;
- The HCP and Philips must make equitable contributions towards the program and costs;
- This arrangement must be documented in writing, outlining the purpose, roles, responsibilities, and contributions of each party, including costs.

Reach out to Legal in advance to make sure the event is structured properly.



### 3.5. Continuing Education Credits

For educational programs for which Philips offers continuing education credits, Philips shall follow the rules and standards of the accrediting body. It is important that all such programs be coordinated through a knowledgeable education coordinator, or similar role, within Philips to ensure that the program meets these standards. Such coordinators currently exist for a number of Philips businesses.

- Philips shall charge its customers and clients a commercially reasonable fee to attend such event or shall report the transfer of value (value of the course) consistent with applicable transparency reporting requirements. Such credits shall be provided infrequently and only with the appropriate intent.
- Light refreshments may be served at Philips educational programs.
- Philips may not pay for travel or lodging.
- If a program is provided free of charge or at a reduced price, Philips representatives cannot select individual attendees on the basis of their status as a Philips customer or prospective customer.
- Such programs must be made available to a broad segment of interested health care providers in the community.
- Philips sales teams shall not offer continuing education programs without involving the education coordinators.

#### Q & A

##### May a customer use funds from a Flexible Spending Account for training and educational purposes?

Yes, it may be appropriate to use a FSA for registration, travel, lodging and associated training and educational expenses. Payment from “Flex Accounts” must be clearly identified as a line item of commercially reasonable value in the sales agreement. It is the responsibility of the Philips employees making such arrangements to be sure the expenses are appropriately deducted from the flex account, and appropriately reported or disclosed to the customer.

## 4. Sponsorships, Grants, and Supporting Third-Party Educational Conferences

*Bona fide* independent, educational, scientific and policymaking conferences promote scientific knowledge, medical advancement and the delivery of effective health care. These conferences are typically sponsored by national, regional or specialty medical associations and by accredited continuing medical education providers. Philips may support accredited conferences in various ways:

### 4.1. Conference or Educational Grants

Philips may provide various grants to support a conference: (1) grants directly to a conference sponsor to offset the costs of a conference that is primarily dedicated to promoting objective scientific and educational activities and discourse; (2) educational grants directly to the sponsor or to a training institution to allow attendance at the conference by medical students, residents, fellows and other Health Care Providers in training, provided that the conference sponsor or the training institution—not Philips—selects the trainees who will attend; or (3) grants to the sponsor to support the provision of meals or refreshments or other general support for conference attendees.

- With limited exception, grants shall be paid only to organizations with a genuine educational function and may be used to reimburse only the expenses for bona fide educational activities that are **accredited**. On a very limited basis, support for non-accredited education events may be approved depending upon the business justification. Please contact your Compliance Officer for more information.
- The conference sponsor – not Philips – must control and be responsible for the selection of program content, faculty, educational methods and materials.

- Grants shall be consistent with any applicable standards established by the conference sponsor and, in some cases, shall meet the standards of an appropriately accredited or certified organization.
- In no case can a grant be related to any past, pending or future sale of a Philips PSS

Any Philips employee or agent who requests or arranges for a conference or educational grant shall obtain and submit supporting documentation that demonstrates the requirements in this Section have been met. The required documentation is described in greater detail in Documentation Requirements for Grants and Sponsorships to Support Scientific and Educational Conferences, which is available on the Philips North America LLC Compliance Program .

In accordance with the Contract Approval and Signing Authority Policy all grants must be approved by the authorized signer level. In addition, all grant requests must be approved by the Philips RS North America's Legal Department using the Grants and Sponsorship Review Form. Any such Grant may only be provided in accordance with the terms of the [Philips North America LLC Grants Policy](#).

Any approved grant must be memorialized in a written third party educational grant agreement with (and payments will be made only to) the conference organizer or accredited educational provider which will be reviewed by the Philips RS North America Legal Department, or designee, before being sent to the Third Party. The Grant and supporting materials should be sent to SRC.SalesEnablement@philips.com. For greater detail regarding the required process or documentation, review the [Philips North America LLC Grants Policy](#).

## Q & A

### What if the sponsor is a hospital and we do business with the hospital?

It may be appropriate to support a grant with a customer as long as the grant is not tied to any past, current or future sale of Philips PSS with that customer and such grants consistent with Philips Grants Policy. Contact the legal department or your Compliance Officer for guidance.

## 4.2. Conference Meals and Refreshments

- Philips may provide funding to the conference sponsor to support the provision of meals and refreshments to conference attendees.
- Philips itself may provide meals and refreshments for Health Care Professional attendees if such meals and refreshments are: (1) available to all Health Care Professional attendees; and (2) provided in a manner that is consistent with applicable standards established by the conference sponsor and the body accrediting the educational activity.
- Meals and refreshments shall be modest in value, subordinate in time and focus to the purpose of the conference and clearly separate from the continuing medical education portion of the conference.

## PRACTICAL TIP

On a case by case basis, support for non-accredited education events may be approved depending upon the business justification. Please contact your Compliance Officer for more information.

Philips has developed a Booth Rental Toolkit, available on the [Philips North America LLC Compliance Policies](#) website, for contracting for booth rentals at educational conferences, health fairs and other events sponsored by customers and other Health Care Providers. Booth Rentals are considered Sponsorships, see [Philips North America LLC Sponsorship Policy](#). Please work with SRC.SalesEnablement@philips.com for additional details.

## 4.3. Receptions

Receptions and similar events shall comply with the following:

- All sponsorships provided must be consistent with the [Philips North America LLC Sponsorship Policy](#), including the approval process and documentation requirements.

- If Philips uses tickets or invitations to control the total number of attendees at a reception, a significant percentage of such tickets or invitations must be available for distribution at the booth or online on a first-come, first-served basis.
- The venue must be consistent with guidance in this Policy.
- Food provided shall be modest in value. However, because per-person charges often include hall rental and other non-food and beverage expenses, applicable costs may require a per-person adjustment to include only direct food and beverage.
- Open bars are not permitted, if there is a bar at the event, a maximum (2) of two drink tickets may be provided to each HCP.
- Gifts (at place settings or otherwise) are not permitted.

#### 4.4. Sponsorships, Advertisements, Exhibits and, Booth Rentals

- Philips may purchase advertisements and lease booth space for its displays and exhibits at conferences, health fairs and other events sponsored by customers and other Health Care Providers. These activities are considered commercial transactions independent of any educational grant for the conference.
- Drawings, sweepstakes and similar situations which offer the opportunity for the targeted HCP to receive something of value from Philips are prohibited. Raffles organized by the Conference Sponsor to encourage overall booth viewership may be appropriate.

#### Q & A

##### **Is it appropriate to pay an exhibit fee for the privilege of displaying product information at an educational conference sponsored by a Health Care Provider?**

Yes, but only if the exhibit fee reflects the reasonable rental space valuation. Exhibit fees should be based on a fair market value basis and should reflect the fees that any other industry member would be charged. A [Booth Rental Toolkit](#) is available on our [Philips North America LLC Compliance Policies](#) webpage (Support Materials to the [Philips North America LLC Sponsorship Policy](#)).

## 5. Sales, Promotional and Other Business Meetings

Philips may conduct sales, promotional and other business meetings with Health Care Professionals to discuss, for example, PSS features, sales terms or contracts. These meetings must be conducted in settings conducive to the effective exchange of information. Whenever possible, these meetings shall take place at or close to the Health Care Professional's place of business.

#### **It is appropriate:**

- to pay for reasonable travel costs of Health Care Professionals, when necessary (e.g., demonstrations of non-portable equipment at a convenient customer site or Philips facility).
- to provide occasional modest meals and refreshments at such meetings.

#### **It is NOT appropriate:**

- to pay for the travel costs of Health Care Professionals to the location of professional conferences or trade shows, even if non-portable equipment will be demonstrated there, including new product introductions.
- to pay for meals, refreshments, travel or lodging of guests of HCPs or any other person who does not have a legitimate professional interest in the information being shared at the meeting.

## Q & A

**As a part of sales, promotional or business meeting, may I take the HCP golfing or to a professional sporting or other recreational activity that is conducive to the thorough exchange of information about Philips Healthcare's products and services, at our expense? What if the event/activity occurs after our business meeting?**

No. Even if these activities are conducive to the thorough exchange of information about Philips Healthcare's products and services, they are viewed as improper inducements by Philips and relevant governmental authorities. The answer is the same even if the event takes place following and apart from the meeting or exchange of information.

## 6. Consultants, Speakers, Faculty, Advisory Boards and Other Fee-For-Service Arrangements with Health Care Providers

Philips engages with Health Care Professionals to provide a wide range of valuable, bona fide consulting and other services for a fee through various types of arrangements, such as contracts for research, PSS development, development and/or transfer of intellectual property, speaking engagements, contracting for reference site visits, marketing, participation on advisory boards and presentations at Philips-provided or sponsored training. Philips must pay HCPs fair market value compensation for performing these services. Philips shall comply with all of the following standards in connection with any arrangements with Health Care Professionals:

- Consulting and other arrangements shall be entered into only when a legitimate need for the services is identified and documented (HCP Checklist) in advance and must not be intended as an unlawful inducement to obtain business from a HCP. A legitimate need arises when a company requires the services of an HCP to achieve a specific objective
- Selection of a HCP shall be made on the basis of the HCP's qualifications and expertise to meet the defined business need.
- Philips employees or agents with customer-facing roles may provide input about the suitability of a proposed consultant but may not control or unduly influence the decision to engage a particular HCP as a consultant or other service provider.
- Consulting and other agreements with HCPs to provide services to Philips must be written and describe all services, deliverables and compensation to be provided.
- When Philips contracts with a consultant to conduct clinical research or investigation services, there shall also be a written research protocol.
- Compensation paid to a consultant or service provider shall be consistent with fair market value in an arm's-length transaction for the services provided and shall not be based on the volume or value of the consultant's past, present or anticipated business with Philips.
- Philips may pay for documented, reasonable and actual expenses incurred that are necessary to carry out the consulting or other fee-for-service arrangement, such as reasonable costs for travel, modest meals and lodging, if such expenses are provided for in the written agreement.

## Q & A

### When is a HCP considered a “Consultant”? What types of arrangements with consultants are covered under this Section 6?

Any relationship between a Health Care Professional and Philips where services provided to us by the Health Care Professional are exchanged for remuneration constitutes a consulting arrangement and should comply with this section. Examples of consulting arrangements include agreements to provide education and training, speaking engagements, preceptorships, reference center, show site or center of excellence arrangements, participation on advisory boards or focus groups, medical technology development and research services arrangements (such as post-market research agreements, research and development agreements and clinical studies), and arrangements for the development and/or transfer of intellectual property. Educational and research grants are not considered consulting arrangements and are addressed elsewhere.

#### Practical Tip

Philips has incorporated a mandatory HealthCare Professional Checklist into the instructions for many of its consulting and professional service agreements to help document that these requirements have been met. If the agreement or tool that you are using does not include such a checklist, use the general checklist available on the Philips North America LLC Compliance Program website.

## Q & A

### What is the role of a Philips sales employee with regard to our engagement of a Health Care Professional as a Consultant?

The role of a sales employee should be limited to being a source of information to identify Health Care Professional who may have the qualifications and expertise to meet a previously identified legitimate need for services by Philips Healthcare. Sales employees should not attempt to influence the decision on engaging a particular Health Care Professional as a consultant.

## 6.1. Philip’s Employees Acting as Consultants, Speakers, Faculty, Advisory Boards and Other Fee-For-Service Arrangements

In the event that a Philips employee is requested by a Health Care Provider to be a consultant or speaker or to serve on an advisory board or other fee-for-service arrangement, such arrangement shall be documented in an appropriate written agreement between the parties with fair market value compensation provided to Philips, consistent with the agreement’s scope of work for such services. For completeness, the invitation itself must first be approved by the person to whom the prospective presenter reports.

#### Practical Tip

Fair market value shall be determined by using the Philips Guidance on Documenting Fair Market Value (FMV) for Agreements with U.S.- Based Health Care Providers found on the Philips North America LLC Compliance Program website. This document provides strict guidelines that focus on our financial relationship with Health Care Providers and a methodology to assess a range of permissible compensation for services.

## 6.2. Provisions on Payment of Royalties

Philips may consider entering into a royalty arrangement with a HCP only where the HCP is expected to make or has made a novel, significant or innovative contribution to, for example, the development of a PSS, technology, process or method. A significant contribution by an individual or group, if it is the basis for compensation, shall be

appropriately documented. The Philips Legal Function and Philips Intellectual Property and Standards should be involved early in the thought process to ensure Philips rules are applied appropriately. The calculation of royalty payments should be based on factors that preserve the objectivity of medical decision making and avoid the potential for improper influence. **To avoid the potential for improper influence**, the number of units purchased, used, or ordered by the HCP or members of the HCP’s practice should be excluded from the calculation of royalty payments.

## **Q & A**

**When a Health Care Provider seeks to trade in its existing equipment in connection with purchasing new Philips equipment, can the parties value the trade-in equipment above fair market value for determining the net price of the equipment?**

No. The valuation of used equipment is above its fair market value could be considered illegal remuneration under Medicare anti-kickback rules. There are sources of information available to you and Health Care Providers to help establish fair market value for used equipment, and you should turn to those sources and document that they used a credible source for the determination of fair market value.

## **7. Prohibition on Gifts, Entertainment, and Recreation**

Philips employees are strictly prohibited from offering, giving or receiving any gifts to or from U.S. Health Care Providers that personally benefit the HCP or his/her family members, office staff or friends (e.g., a Philips AED or Sonicare toothbrush or an iPad/iPod). Philips employees also may not provide HCPs or their employees gifts such as cookies, wine, flowers, chocolates, gift baskets, holiday gifts or cash or cash equivalents (such as gift cards), even for an important life event (e.g., birth, death, graduation or wedding). For more information, please refer to the [Philips North America Gifts, Meals and Entertainment Policy](#)

### **7.1. Branded Promotional Items (“Giveaways”)**

Philips may not give HCPs any type of branded promotional items, even if the item is of minimal value and related to the Health Care Professional’s work or for the benefit of patients. Examples of non-educational branded promotional items include umbrellas, pens, notepads, mugs, totes and other items that have the Philips name, logo or the name or logo of one of our PSS or any other Philips item.

### **7.2. Educational Items**

Educational items are permissible to give to HCPs, including medical textbooks or anatomical models used for educational purposes, genuine educational material supplied on “storage-only” media technology of negligible value, such as a CD-ROM, DVD or an appropriately sized thumb drive, or resident handbooks. These educational items may be branded.

### **7.3. Entertainment and Recreation**

Interactions of Philips employees and contractors with HCPs shall be professional in nature and shall facilitate the exchange of business, medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, Philips may not provide, arrange for or pay for any entertainment or recreational event or activity for any Health Care Provider. Such activities include, but are not limited to, theater, musical performances, dancing, sporting events, golf, skiing, hunting and leisure or vacation trips. Such venues for training and education events such as resorts, casinos, spas, or destinations typically considered vacation destination or peak season for such vacation destination are considered inappropriate venues.

A Philips employee may not accept any entertainment or recreational event or activity provided, arranged or paid for by a Health Care Provider.

## Q & A

**May I provide a gift such as flowers, gift baskets, meals, snacks, wine, or other refreshments to a Health Care Provider or a Health Care Provider's office or staff?**

No. These types of gifts and refreshments are not considered educational items or for the benefit of patients and are never permissible.

**May we raffle an item during a trade show, such as two round-trip airline tickets, that it could not otherwise give as a gift?**

No. Philips should not raffle or give away at a trade show an item that we could not otherwise give a Health Care Provider.

## 8. Modest Meals Associated with Business Interactions

- Philips may provide modest meals to HCPs as an occasional business courtesy under limited circumstances.
- Meals (including any meal, food or alcoholic beverage) provided by Philips to a HCP must be subordinate to a meeting involving the presentation or exchange of scientific, educational, training, PSS or other information that is directly related to Philips' business.
- Meals cannot be primarily intended for the development or maintenance of goodwill or a general business relationship. The presentation or exchange of information shall account for a significant part of the time spent for the meal.

It is not permissible to provide financial or other support such as food, beverages or gifts to support events such as "Professionals Week" or "Technicians Week" for nurses, sonographers or others, even though Philips supports the educational or scientific purpose of these events.

## Q & A

**An HCP called to reschedule the planned demo at her office, and has suggested meeting for lunch at the local ski resort because she will be there with their family. Can I accommodate this request?**

No. The meeting location must be conducive for a thoughtful exchange of information. A ski resort does not provide this environment and also gives the impression that recreational activity might be occurring.

### 8.1. Participants

- A Philips representative shall be present at all meals provided by Philips.
- Philips may not pay for any meal for guests of HCPs or for any other person who does not have a legitimate professional interest in the information being shared at the associated meeting.
- Philips may not provide meals for HCPs who do not participate in the meeting (e.g. food for an entire office, clinic or department if everyone does not attend the meeting).

### 8.2. Setting and Location

- Meals shall be held in a setting that is convenient and appropriate for the purpose of the associated meeting.
- If the meal cannot be conveniently provided at a Health Care Provider's office or a conference, training or demonstration facility, it shall be provided at a nearby restaurant or other location that is neither luxurious nor extravagant.

- The meal shall not be part of an entertainment or recreational event, nor shall the setting detract from the business purpose of the meal.

**Practical Tip**

“Moderate or modest” means middle-tier, in the sense that food and travel expenses are neither the most expensive nor the least expensive as measured against the local community standard, and limits have been set by Philips. When the term “modest” is used, you are always free to choose an even lower cost food, travel expense or hospitality option.

**8.3. Meals Must Be Modest**

Meals shall not overwhelm or distract from the business being conducted. They shall also be infrequent and modest in cost, judged by local standards. This guidance also applies when providing a meal to a U.S.HCP outside of the United States. The following schedule sets the current ceiling for the cost of meals, but even less expensive meals may be improper.

Type of Meal	Maximum cost/person *	Maximum cost/person * (Premium cities)
Dinner or Catered Meal	\$125	\$150
Lunch or Take-Out/ Bring-in	\$40	\$50
Annual Meal Limit, per external recipient, per calendar year**	\$1000	
*Including drinks, tax and tip ** The total annual meal spend per individual external recipient is limited to meals unrelated to a written service or consultant agreement. Premium Cities: New York City, Chicago, Boston, New Orleans, Las Vegas, Orlando, Miami, Seattle, Philadelphia, Washington D.C., Los Angeles, San Francisco, Orange and Santa Clara Counties in California		

The per-person cost of the meal shall be calculated by taking the total cost of the meal and dividing by the number of HCPs and Philips representatives present. For clarity, it is not permissible to split meals with colleagues who are not present at the meal; further, it is not permissible to split meals with other attendees to make the meal cost appear to meet the spend limits.

This schedule does not apply to meals provided outside of the U.S., but the same principles apply.

Lastly, Philips shall not give HCPs cash or cash equivalents (e.g. gift certificates or a credit card) to purchase a meal.

**Meals for government employees are subject to more stringent limitations.**

For more information, please refer to the [Philips North America Government Gifts and Entertainment Policy](#)

**Q & A**

**Is a general discussion to build good business relationships a “business presentation” such that it is appropriate to provide a business meal?**

No. Any meal, food or beverage (Meal) provided by Philips Healthcare to a Health Care Provider must be incidental to a presentation or exchange of scientific, educational, training, or product or other business information that is directly related to Philips business. The business discussion should account for most of the time spent during the meal. Development of general goodwill and business relationships should not be the primary purpose of a business meal, and a business meal should not be used for entertainment or recreational purposes.

**May I drop off a meal or refreshment at a Health Care Provider’s location for the provider and staff?**



No, a Philips Healthcare representative must be present at all meals provided by Philips. The meal may not be provided for those who do not participate in the information being shared at the associated meeting.

## 9. Discounts, Rebates, Free Goods, and Value-Added Services

Some marketing, sales and promotional programs may offer HCPs and our customers' discounts, rebates, or value added services in connection with the sale or leasing of Philips equipment. Philips has detailed guidance on how to comply with the applicable laws and regulations. This includes, among other things, careful and clear disclosure of discounts, rebates or any price reductions in contracts or on invoices. Please consult your Philips lawyer or Philips compliance officer to ensure proper analysis and discount disclosure documentation. For more information, please refer to the [Philips North America Discounts and Rebates Policy](#).

### 9.1. Consigned Products

Consigned Products are Medical Technologies that a company provides to an HCP for use in and storage at the HCPs patient care setting to which the Company retains title until the products is used. To provide Consigned Products, there must be a written agreement in place addressing the number and types of products to be consigned, how consigned product is to be billed and any customer segregation requirements of consigned products, and storage space rental terms (if applicable).The consigned product must be tracked, and periodic the inventory must be periodically reconciled between the number of consigned products used and the remaining consigned product left in inventory, the consigned product by Customer shall be billed appropriately; and expired consigned product shall be removed or returned.

## 10. Coverage, Reimbursement and Health Economics Information

Philips may provide general coverage, coding, reimbursement, and health economic information regarding our products that is accurate and objective. This includes coverage, coding and billing options, changes in coverage policies or reimbursement payment levels. Philips' Government relations, health economics and /or reimbursement staff also may collaborate with providers, patients and professional organizations to help shape government and commercial payor coverage decisions, guidelines, policies and reimbursement levels that would enable patients to access medically necessary services that utilize Philips products.

- Philips representatives may provide billing codes that are frequently used or associated with our products but we must not suggest or recommend how to code or bill for products or specific services delivered by an HCP. Reimbursement information should support the provision of medically necessary services and be fully consistent with health payer policies.
- Any reimbursement information must be derived from authoritative sources including Medicare websites, state or federal regulations, and private insurer websites. Those sources should be identified and providers should be directed to check those sources for the most up-to-date information.
- Philips must include appropriate disclaimers on any reimbursement information documents or websites making clear that such information does not guarantee to a HCP that any coding, coverage or reimbursement information will ensure coverage or payment at any specific amount for the Philips product or a related procedure.

- Philips must not provide customized coverage, reimbursement and health economics support specific to the individual Health Care Provider.
- Philips shall not interfere with an HCPs independent clinical decision making or provide coverage, reimbursement, and health economics support as an unlawful inducement. For example, it is not permissible to provide free services that eliminate an overhead or other expenses that an HCP would otherwise have incurred as part of its business operations. Philips shall not suggest mechanisms for billing for services that are not medically necessary, upcoding or for engaging fraudulent practices to achieve inappropriate payment.

### **Practical Tip**

In response to reimbursement- related questions or issues, Philips employees shall recommend that customers seek their own counsel and experts to guide them in any issues related to coverage, coding, payment and claims submission or direct customers to the market access and reimbursement group.

## **11. Collaborative and Independent Clinical Research**

Philips may engage in a variety of research opportunities. Collaborative research that is either Philips initiated or investigator initiated is defined as any external collaboration with a Healthcare Provider and or Health Care Organization that is non-commercial in nature, e.g., basic research, translational research, animal studies, data studies, non-clinical studies, equipment/product evaluations, usability studies; the common element is that the activity is not for selling a product or services. Philips shall comply with all of the following with respect collaborative research:

- All interactions with non-Philips collaborators must be authorized and provide value to Philips
- All non-commercial interactions with collaborators must be clearly and cleanly separate from any commercial dealings with that collaborator
- The proposed research must be legitimate, with well-defined milestones and deliverables contained in a written formal contract and approved by the legal department that at a minimum includes: a statement of the research or clinical objectives, identifies the principal investigator(s), handling of intellectual property, business rationale or relevance to the business, milestones tied to payments and deliverable timing, and a written fair market value assessment.
- All interactions with healthcare providers must meet compliance requirements of Philips and the countries of engagement, including documenting financial, regulatory and commercial (anti-bribery/anti-kickback) compliance
- Workflow and processes for initiating, managing and closing a non-commercial project with an external collaborator shall be pursued by using the ORION portal in Salesforce.com (Orion Salesforce)
- The Businesses/business organizations are responsible for adherence to this policy and initiating, managing, ensuring deliverables are received and closing projects, in a compliant manner.
- In addition, all Clinical Research must comply with the requirements out-lined in the Guidance for Non-Commercial Collaborations.

Alternatively, research that is independent of Philips may be supported through a Research Grant. Such grants must be approved by the relevant Grants Committee, and if in an amount over \$50,000, must be approved by the Market Grants Committee. Any such Grant may only be provided in accordance with the terms of the Philips North America Grant Policy. In addition, and independent research with or by an HCP:

- There must be a reasonable documented business rationale consistent with the Grant Plan for developing clinical information concerning Philips PSS, both pre-and-post-market. If approved, the Grant must be memorialized in a written third-party research grant agreement which will be reviewed by the Philips Legal Department, or designee, before being sent to the Third Party. The Grant and supporting materials will be stored by the relevant Compliance Officer at [compliance.administrator@philips.com](mailto:compliance.administrator@philips.com). For detailed information please review the Philips North America Grant Policy.
- Research participants must add unique independent scientific value with their participation.

## Q & A

### How are Clinical Study Agreements treated under our policy?

The arrangement should be governed by a written services agreement. The clinical program for which the services are being provided should fulfill a legitimate research purpose. A Clinical Study Agreement typically is entered into between Philips Healthcare and a Health Care Provider that is a facility, institution, or practice group, and fair market value compensation for the clinical research services is paid to that entity.

## 12. Charitable Donations

Philips may make donations for a charitable purpose, such as providing funds or equipment for indigent care, patient education or public education. Donations shall be made only to charitable organizations that are not themselves Health Care Providers. It is not appropriate to make a charitable donation for the purpose of inducing Health Care Providers to purchase, lease, recommend or use. Philips does not make donations to support Holiday parties or to support HCP capital improvements. Donations are currently provided through the [Philips Foundation](#) and the [North America Corporate Social Responsibility](#) function. Donations, especially to HCPs, should not be made outside of these two Philips groups without Legal approval.

## 13. Evaluation and Demonstration PSS

Philips may furnish products to customers without charge in reasonable quantities and/or for a reasonable amount of time to evaluate the appropriate use and functionality of the products, and for patient awareness, education, demonstration and training purposes.

- Philips shall provide HCPs with documentation and disclosure regarding the no-charge status of evaluation and demonstration PSS.
- The terms of an evaluation of the PSS shall be set in advance in writing and include frequency of use, who will evaluate the PSS, and length of the evaluation period.
- Capital or multiple-use equipment, such as patient monitors, imaging systems and software provided without transfer of title for evaluation purposes shall be furnished only for a limited period of time that is reasonable under the circumstances to allow an adequate evaluation for making a purchase decision. It is recommended that the evaluation period not exceed sixty (60) days when possible and under no circumstance shall it exceed ninety (90) days.
- Philips shall retain title to the PSS during the evaluation period and should have a process in place for promptly removing such PSS from the HCP's location at the conclusion of the evaluation period unless the HCP decides to purchase or lease the PSS and enters into an appropriate agreement with Philips.
- Demonstration PSS typically are not intended to be used in patient care and are usually identified accordingly by use of such designations as "Sample", "Not for Human Use" or other suitable designation on the PSS, packaging and / or documentation that accompanies the PSS.

- The number of single – use products provided at no charge shall not exceed the amount reasonably necessary for the adequate evaluation of the product under the circumstances.

#### Q & A

#### Is a demonstration or evaluation product that is provided at no charge to a Health Care Provider by Philips a gift?

Provided that Philips Healthcare comports with the requirements of the Code of Conduct, demonstration and evaluation products are not considered gifts.

#### Practical Tip

If you are not certain what “reasonably necessary for adequate evaluation” may mean in a given circumstance, contact [Compliance.Administrator@Philips.com](mailto:Compliance.Administrator@Philips.com) or Legal Department.

## 14. Interactions with Federal and State Government Employees

It is Philips policy to comply with U.S. federal and state laws and regulations governing interactions with federal employees and state employees. U.S. federal and state laws and regulations governing gifts, business meals, speaker’s fees, educational events, research grants, travel and lodging and similar items are generally more stringent than the provisions of this Philips Code of Conduct. Philips and its agents shall exercise extreme caution when dealing with any government entity and government employees, such as HCPs who work at federal, state or country hospitals/ facilities. The [Philips North America Government Gifts and Entertainment Policy](#) requires you to obtain approval prior to any interaction with a federal or state government employee where providing anything of value or payment of any kind is being contemplated.

## 15. Transparency Laws and Interactions with HCPs

Philips is obligated to report any and all transfers of value provided to Covered Recipients under Federal and some State Laws. Please refer to the [Transparency website](#) for the most up to date view of relevant laws and requirements. The US Transparency Policy spells out the specific details regarding US Covered Recipients and what is considered a transfer of value. Covered Recipient is a subset of Health Care Providers and may vary under federal or state laws. Examples of Covered Recipients are:

- For the Federal Law (The Sunshine Act or Open Payments System) Covered Recipients are physicians (including Doctors of Medicine (MDs), Doctors of Osteopathy (Dos), Optometrists (ODs), Podiatrists (DPMs), Dentists (DDS), and Chiropractors (DCs) and teaching hospitals).
- Massachusetts Law has a broader definition of a Covered Recipient and can simply be described as – “anyone in a position to decide which prescription drug or medical device is used” and can be an individual or a facility program.
- Vermont law, like Massachusetts, has a similarly broad definition. Transfers of value can be anything of value, outside of a commercial arrangement (sale) that is conferred to a Covered Recipient. These can be anything from a meal provided, to loaning equipment, to paying for research or clinical trials.
- Connecticut Law requires Philips to report transfers of value to Advanced Practice Registered Nurses (APRNs) from the state of Connecticut.

**Practical Tip**

For more information on obligations under the Federal and State laws visit the US Transparency website at <https://intranet.philips.com/Pages/US-Transparency.aspx>

For clarity, this website includes an up to date list of all applicable state laws. For example, Connecticut requires reporting of payments by manufacturers of covered devices to independently practicing advanced practice registered nurses (APRNs).