

PHI901-a72en

Understanding and Complying with the Medicare/Medicaid Fraud and Abuse Laws and Rules



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Introduction



The Medicare fraud and abuse rules are complex and, in some cases, can be counterintuitive. This means that you might violate the rules without realizing that you did something illegal. Some practices that are perfectly legal for someone selling to a school or a manufacturing company are illegal when the customer is a health care provider whose services are paid for by Medicare or Medicaid. So you can't rely solely on your instincts or your notion of right and wrong. When dealing with situations in which Medicare fraud could take place, you must understand the rules if you're going to follow them consistently.

In this course, you'll learn both how to recognize Medicare fraud issues and where to go at Philips for help if you suspect anything is wrong or if you have any questions.

The Philips logo, consisting of the word "PHILIPS" in a bold, blue, sans-serif font, is centered within a white rectangular area that is framed by a light gray border.

Introduction

By putting the requirements of the industry codes and some other Philips Healthcare policies in one code, we have simplified our adherence to a number of requirements for our dealings with health care providers. Following the Code of Conduct helps us achieve compliance with the law, but that doesn't tell the entire story. You must also understand the law to be sure you're acting appropriately.

We want to stress to you the importance of this subject. A violation of the law could have detrimental effects not only on your business, but also your customers, you personally, as well as all of Philips. Violating the law or failing to follow the Code of Conduct and other Philips ethics standards could affect your continued employment at Philips.

Introduction

In addition to this training, we have established a number of helpful resources, including contacts in the Philips Legal Department, where you can go for questions; a worldwide ethics helpline (One Philips Ethics Line), where you can report violations and suspected violations; the Code of Conduct; and links to other documents and resources also found on the Philips Legal Department website. These appear at the bottom of every page of this training course—just click on the word "Resources."

It's your duty to know and abide by the Code of Conduct and other standards referred to in this training. You'll be reminded to retake the course at regular intervals. In addition, you may return to this site and retake all or part of this course—or print out individual pages—as many times as you like.

Accelerating our business is a key to profitable growth. However, acceleration requires navigation. This course will help you to successfully navigate in your business.

Yours truly,
Your Executive Team



Introduction

Two Philips Healthcare account managers, Lauren and Oscar, are meeting over lunch.

Lauren: Listen, Oscar, I really want to thank you for all your help getting started here. This is a whole new field for me, and it's been a learning experience.

Oscar: I'm learning a thing or two from you, too. I bet you could sell anything!

Lauren: *(laughing)* Well, I don't know about that. But I am very excited about a meeting I have lined up. It's with a very prominent doctor—everyone knows who he is, but everyone doesn't know he's a real fan of spa treatments.

Oscar: Okay...



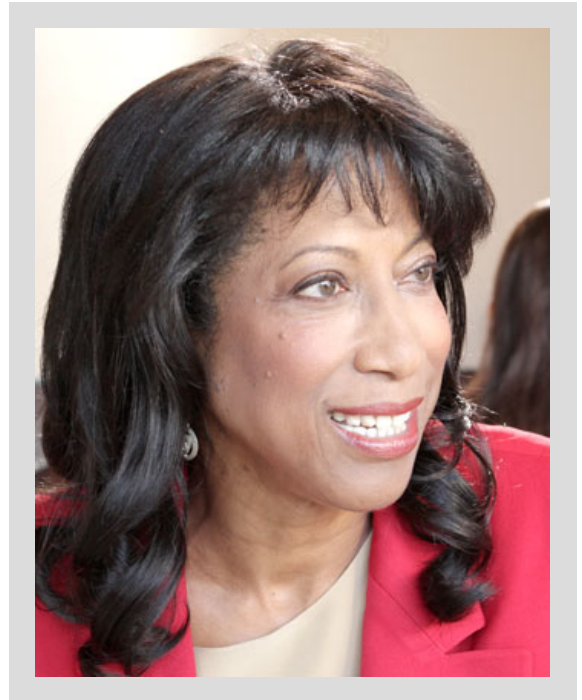
Introduction

Lauren: So to set the stage for a long-lasting—and profitable—relationship, I got him a gift certificate for the new spa downtown. Nice perk, huh? It's supposed to be fantastic!

Oscar: I'm sure it is, but you know you can't do that.

Lauren: Of course I can! Doctors don't always have time to really take care of themselves, so it's the perfect "nice to meet you" gift.

Oscar: Lauren, when it comes to our products, a lot more rules are involved.



Introduction

Lauren: I know, I know—safety is paramount! But I'm not making the products, I'm just selling them. And I can't let a few rules get in my way.

Oscar: You don't understand. Things are different in this industry, and—

Lauren: How different can it be? I've been selling for a long time, and if there's one thing I'm sure of, it's this: to get ahead, it's all about numbers, not how I get them.

Oscar: Think again. If you don't follow the rules, you're not going anywhere at this company. In fact, you could get us all into real trouble. And end up losing your job!



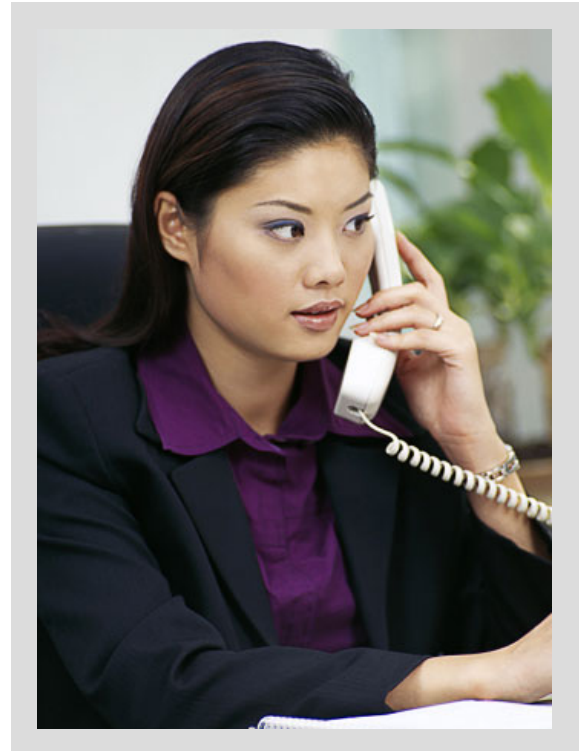
Introduction

Oscar's right. But the rules on gifts are just one thing you need to be aware of in our industry. There are also important rules about meals, training conferences, sales meetings, and reimbursement information, just to name a few. Violations of these rules can draw the attention of federal authorities. Gifts to health care providers are prohibited by law and the Philips Code.



Introduction

As you work through this course, you'll learn how to handle these situations and more. But keep in mind that this training can only help you spot issues related to the fraud and abuse laws and our Code of Conduct. It can't help you resolve all situations, because federal and state laws are complex and every situation is different. Whenever you have questions about this subject, be sure to contact your manager or the Philips Legal Department.



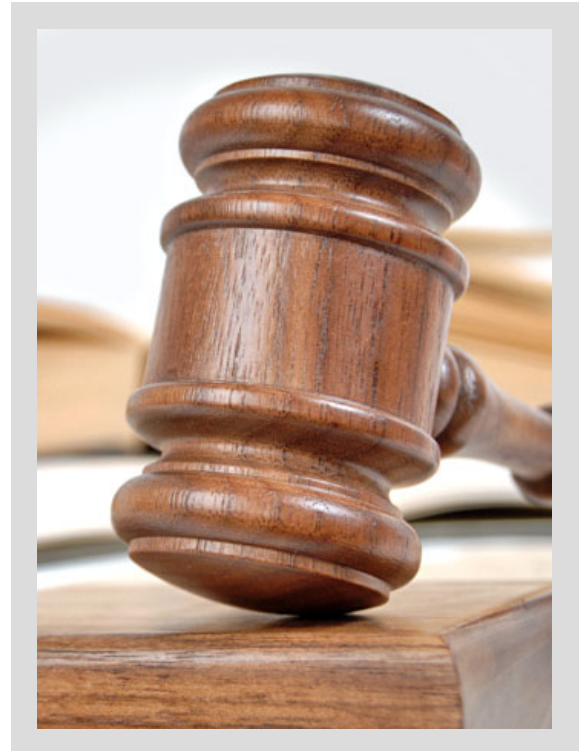
Federal Laws and Safe Harbors

Overview



In this lesson, you'll learn

- what the Anti-Kickback Statute is and how it affects Philips
- how the discount and personal services "safe harbors" can protect some practices
- what the False Claims Act is and how it affects Philips
- what are Transparency laws and how they work with the Code of Conduct
- how to handle free equipment and loaner equipment issues
- the importance of maintaining the separation of research and sales



Federal Laws and Safe Harbors

Overview

Bob is speaking on the phone with Jane, his sales manager.

Bob: Jane. It's Bob, returning your call.

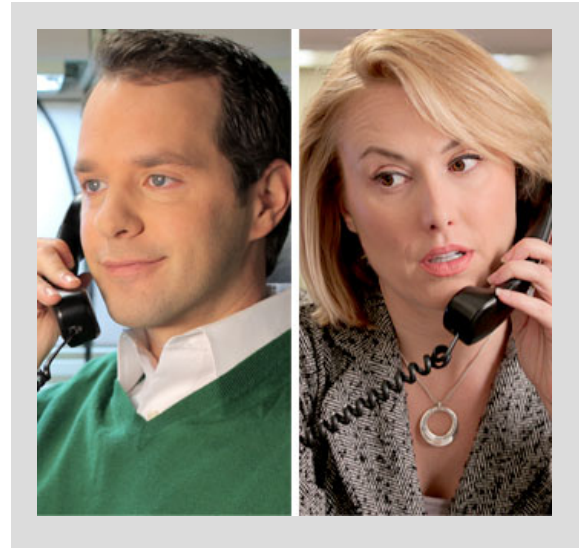
Jane: Hi Bob. I wanted to check in. The end of the quarter is getting pretty close and we're not going to make our numbers unless you've got some really good news I don't know about yet.

Bob: Tell me about it. This is the worst I've seen it in a while. But don't panic yet. I've got some ideas up my sleeve.

Jane: That's good. There's nothing like a face-to-face meeting to find out what folks need.

Bob: Oh...of course, but I'm not talking about meetings.

Jane: What are you talking about then?



Federal Laws and Safe Harbors

Overview

Bob: You know, showing my customers how much I appreciate them. I have some tickets that just might convince them to expand their orders to help us out so we can make our numbers.

Jane: Tickets to what?

Bob: I better not tell you. These are hard to get and pretty expensive.

Jane: You know, I don't want to hear about the "how." I just want to hear that we got the bigger order. Know what I mean?

Bob: Got it. Talk to you later.

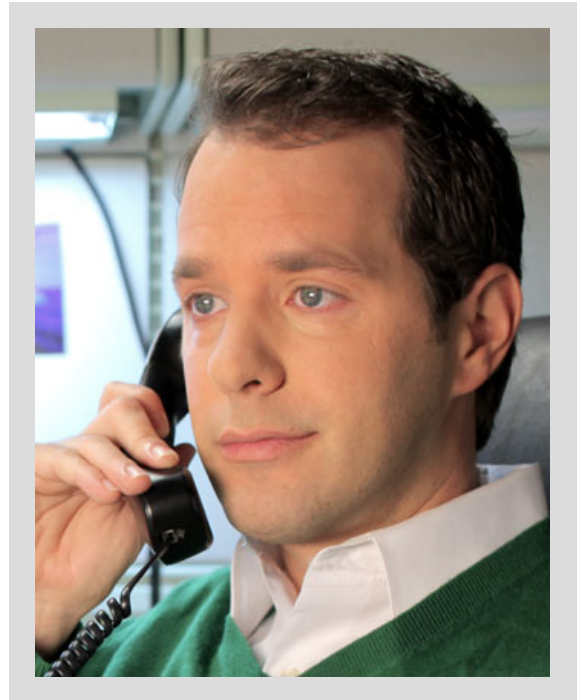


Federal Laws and Safe Harbors

The Anti-Kickback Statute

What do you think Bob's plan for making his numbers? Got to do what you got to do, right? Actually, no—not when it's a bad idea like this. In fact, the federal government likely would consider expensive tickets to be unnecessary and an illegal kickback, and both Bob and Jane could find themselves in serious trouble.

The **Anti-Kickback Statute** is a federal law that seeks to prevent financial considerations from interfering with medical and purchasing decisions. In general, this law applies when a company or individual offers incentives to encourage a health care provider, such as a doctor or hospital, to purchase its products.



Federal Laws and Safe Harbors

The Anti-Kickback Statute

The Anti-Kickback Statute imposes criminal, administrative, and civil penalties against persons or companies who offer, pay for, solicit, or receive anything of value, directly or indirectly, to induce either of the following:

- A referral—of a patient to a doctor or hospital—for a service paid for by federal health care programs
- The purchase, lease, or ordering—or arranging for the purchase, lease, or ordering—of goods or services that may be paid for by federal health care programs, such as the medical device products and personal emergency response systems sold by Philips



Federal Laws and Safe Harbors

The Anti-Kickback Statute

A kickback is any remuneration intended to induce a purchase, and could be money or anything else of value, such as a rebate, discount, gift, donation, free equipment or services, equipment loan, or credit arrangement. A kickback of any value is illegal. To deal with this complexity, our industry codes of ethics and the Code of Conduct prohibit even small gifts.



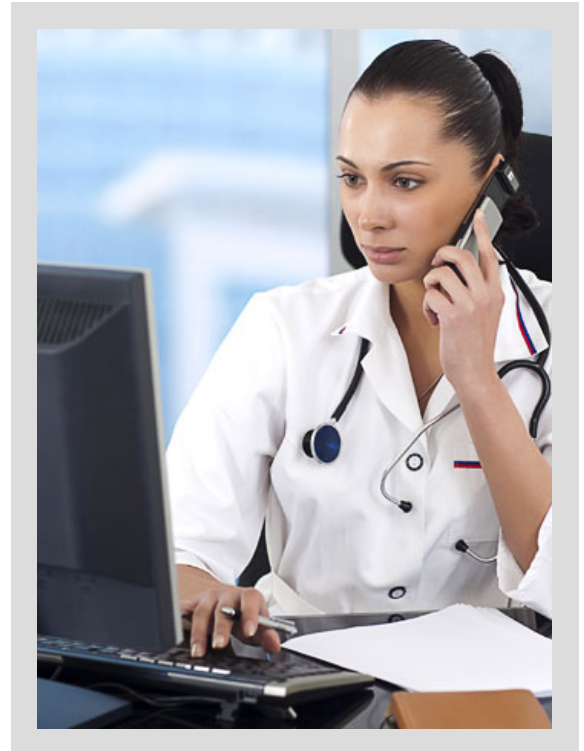
Federal Laws and Safe Harbors

The Anti-Kickback Statute

The Anti-Kickback Statute covers most federal health care programs, such as Medicare and Medicaid. You should also know that many states have their own anti-kickback laws that extend to all forms of health insurance as well as private paying patients.

The Anti-Kickback Statute applies to "individuals" and companies on both sides of an illegal kickback transaction—in other words, a manufacturer or the sales rep who offers an illegal kickback, as well as the hospital, physician, or anyone else who requests or receives the illegal kickback. "Individuals" can also encompass hospital purchasing officials, managed care executives, physician office staff, and others.

The bottom line is that companies and individual employees get into trouble when a kickback occurs. You can even go to jail if you offer or receive an illegal kickback or bribe.



Federal Laws and Safe Harbors

The Anti-Kickback Statute

Self-Check

Which of the following is true about the Anti-Kickback Statute?

Check all that apply.

- ☐ It prohibits medical device sellers from offering kickback payments to health care providers who buy their products.
- ☐ It covers anyone who refers Medicare and Medicaid patients in exchange for a kickback.
- ☐ It covers only those individuals or companies that offer illegal kickbacks.
- ☐ It prohibits anyone from purchasing or leasing goods or services that a federal health care program may pay for in exchange for a kickback.

Federal Laws and Safe Harbors

The Anti-Kickback Statute

A violation of the statute can occur even if a kickback doesn't result in an illegal referral or purchase. All that needs to happen is the offer of (or request for) anything of value with the intent of inducing a purchase or referral in return.



Top Ten

The Anti-Kickback Statute is one of the most significant fraud and abuse laws affecting the medical device industry.

The law seeks to prevent financial considerations from interfering with medical decision making, such as when medical device companies offer health care providers incentives to purchase or prescribe their products. It authorizes penalties against any entity that knowingly and willfully offers, pays, solicits, or receives anything of value to induce, or in return for, (1) referring, or arranging for referring, federal health care program patients, or (2) the purchase, lease, or ordering of (or the recommendation to purchase, lease, or order) goods, items, or services that may be paid for by such programs. A kickback can be a discount, free equipment, a gift, an equipment loan, a rebate, or even a special credit arrangement. A kickback is a bribe!

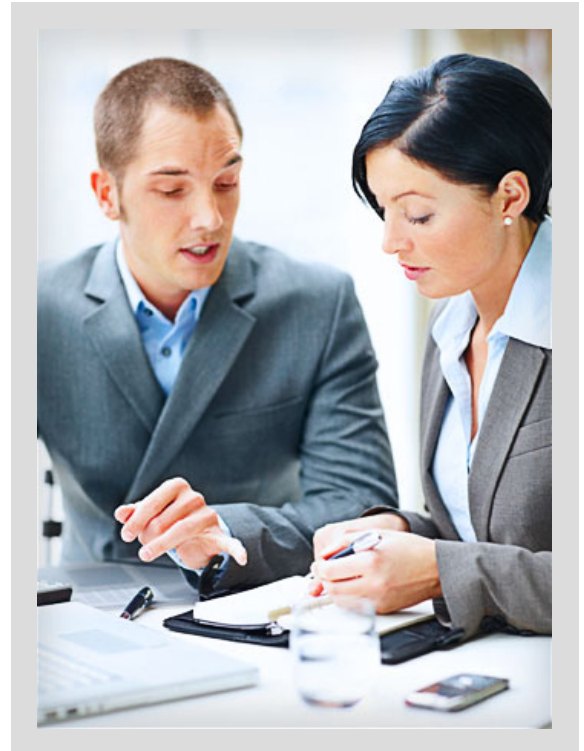
Federal Laws and Safe Harbors

The Anti-Kickback Statute

Because the Anti-Kickback Statute is so broad, the federal government has specified exemptions, called **safe harbors**, for business practices that it feels present little to no risk of fraud and abuse. If an arrangement satisfies all of the requirements of a particular safe harbor, it's immune from liability under the Anti-Kickback Statute.

Whenever possible, companies should try to structure relationships so they conform to a safe harbor, so you need to understand what the safe harbors are. If there's any question of whether a transaction falls within a safe harbor, you must consult the Philips Legal Department.

The safe harbors that are most relevant to our business are for **discounts** and **personal services arrangements**.



Federal Laws and Safe Harbors

The Anti-Kickback Statute

Discounts include price reductions, rebates, and credits. **Personal services** arrangements arise when medical device companies compensate health care providers, such as doctors or clinics, for providing certain services on their behalf—such as conducting clinical trials, providing consulting, advisory services, educational services, and performing research.



Consider This

We must be careful to structure relationships involving hospitals and physicians **and their employees** (or others in a position to order or purchase our products), so that they fit within a safe harbor whenever possible.

Federal Laws and Safe Harbors

Discount Safe Harbor

A discount means a reduction in the amount a seller charges a buyer. Discounts can include percentage discounts, rebates, tiered pricing, leased equipment, and services. The discount safe harbor in the Anti-Kickback Statute generally allows commercially reasonable discounts—as long as they are properly disclosed, consistently applied by the business, and reflected on official quotations and invoices. Other detailed requirements need to be met as well. Make sure you follow your business discount and authorization process.



Federal Laws and Safe Harbors

Discount Safe Harbor

Supplying goods or services for free, or at a reduced rate, in exchange for the purchase of other goods or services doesn't qualify as a discount **unless** the free or reduced-rate item and the purchased one are reimbursed using the **same** Medicare reimbursement methodology. So, offering products for free for use in research if the customer purchases products for clinical use does not fall under the discount safe harbor.

Above all, the manufacturer must list the discount on the invoice so that the buyer clearly sees the net price of all the products. Then the manufacturer must advise the buyer about its obligation to report discounted prices to the federal health care program. At Philips, our sales documentation should include this discount disclosure reminder. You should make sure that all discounts are clearly documented for the customer in the sales documentation.



Federal Laws and Safe Harbors

Discount Safe Harbor Self-Check

Global Medical Devices provides a discount to Memorial Hospital for device A in exchange for Memorial's purchase of device B. Both devices are used for patients of the hospital, and Medicare pays for both the same way. On the invoice, Global lists the discount prices for both device A and device B and informs Memorial that it has to report the discounts to the government.

Does this discount arrangement satisfy the safe harbor exemption?

- ☐ Probably
- ☐ Probably not

Federal Laws and Safe Harbors

Discount Safe Harbor

A **rebate** is considered a discount under the discount safe harbor as long as the rebate's terms are fixed and the seller discloses them to the buyer at the time of the sale. As with any other discount, the buyer may also be required to disclose the rebate in its reports to federal payors.



Did you know?

A rebate can count as a discount as long as the terms are disclosed at the time of sale. This is true even if the exact amount of the rebate is not known until it's paid.

Federal Laws and Safe Harbors

Discount Safe Harbor

If the buyer is a health care provider, the **seller** has to do the following:

- If the amount of the discount is known at the time of purchase, the seller must report the discount on the sales documentation and inform the buyer of its obligation to report it or,
- If the amount of the discount is not known at the time of purchase, the seller must report the discount program on the sales documentation, inform the buyer of its reporting obligation, and inform the buyer of the discount amount when it's known and identify the specific goods to which the discount applies.



Federal Laws and Safe Harbors

Personal Services Safe Harbor

The safe harbor for **personal services** applies in some situations in which a manufacturer like Philips contracts with a health care professional, a provider, or any party related to a customer to perform services. The safe harbor can protect manufacturers from anti-kickback liability if the following rules are observed:

- There's a written contract signed by both parties.
- The contract specifies the exact schedule and description of services.
- There is a legitimate business need for the services.
- The term is for at least one year.
- The payment amount is set in advance.
- The total payment to a health care provider is consistent with the fair market value for the services.
- The payment isn't based on the volume or value of any referrals or other business generated between the parties.

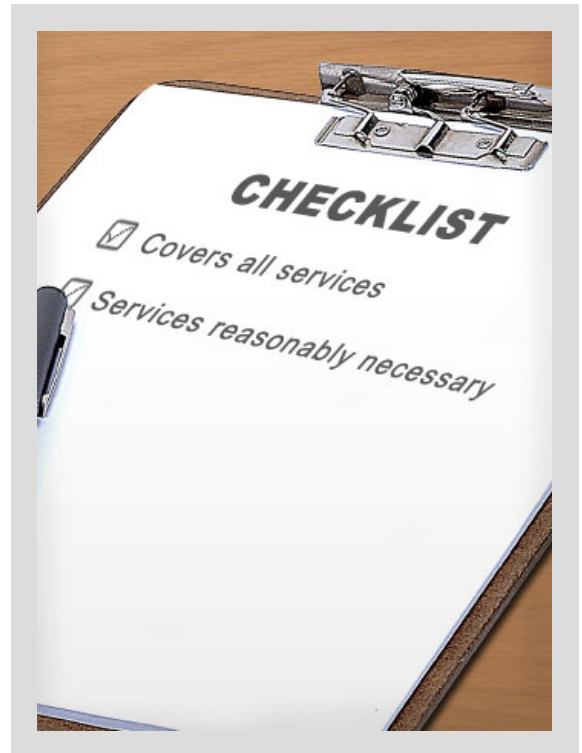


Federal Laws and Safe Harbors

Personal Services Safe Harbor

Finally, the following also must be observed:

- The agreement covers all services provided by the contractor.
- The aggregate services don't exceed what is reasonably necessary to accomplish a commercially reasonable purpose.



Federal Laws and Safe Harbors

Personal Services Safe Harbor

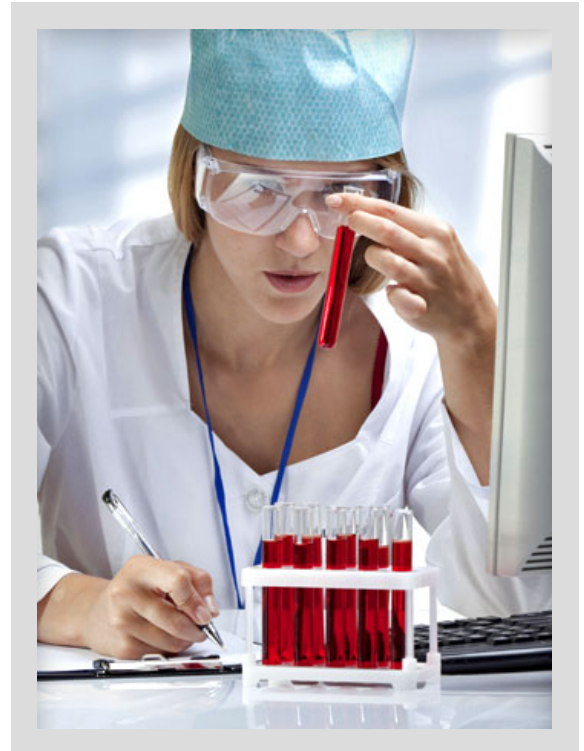
The personal services safe harbor can also apply to reference/demonstration site agreements and to participation by a customer in a Philips Healthcare advisory board.

Contracted clinical trials may also be structured under personal services agreements. These must be carefully structured to fit within the safe harbor, so consult the Philips Legal Department.

Sometimes we need to engage a hospital to assist us with R&D or product development activities. Since most hospitals are, or are likely to become, Philips customers, it's essential that all such agreements be carefully structured to satisfy the rules of the personal services safe harbor.

Philips Healthcare has a checklist to use in contracting with health care providers to make sure that all the requirements of this safe harbor are met. Click the "Resources" link for instructions and the checklist.

http://pwww.amec.intranet.philips.com/apps/l_dir/i1644801.nsf



Federal Laws and Safe Harbors

Personal Services Safe Harbor

Self-Check

ACME Medical Devices mails a letter to Dr. Daniels, offering to pay \$20 for every Medicare patient he refers to ACME. The doctor never opens the letter.

Did ACME violate the Anti-Kickback Statute?

☐ Probably

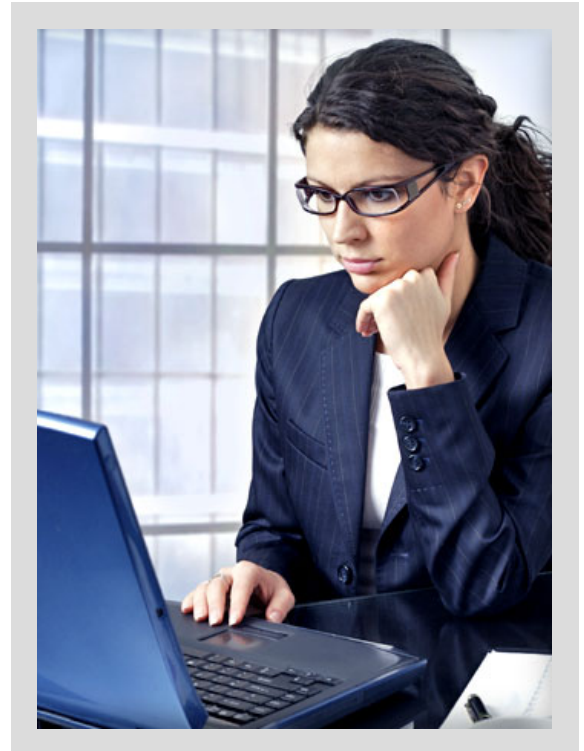
☐ Probably not

Federal Laws and Safe Harbors

The False Claims Act

The False Claims Act (FCA) is another key health care law that government authorities use to combat fraud in the medical device business. The act prohibits any person from knowingly making a false claim for payment to any federal program—in our case, programs that may pay for Philips products. It also makes it illegal to cause someone else to make a false claim.

Even though device manufacturers generally don't submit claims to federal health care programs, sales and marketing activities that violate the Anti-Kickback Statute may be viewed by government enforcement agencies as triggering a violation of the FCA.



Federal Laws and Safe Harbors

The False Claims Act

As an example, if a manufacturer participates in an illegal kickback scheme with a hospital, then any claims the hospital submits for reimbursement to Medicare or Medicaid might be false in the government's view.

The government takes the same position if it believes that the manufacturer has told the hospital to use a reimbursement code that's wrong. The government may try to hold the manufacturer liable for causing its customer to make a false claim.



Top Ten

The False Claims Act prohibits any person from knowingly making, or causing to be made, a false claim for payment to a federal program.

The act also makes it illegal to cause someone else to make a false claim. Device manufacturers generally don't submit claims directly to federal health care programs. But manufacturers can still violate the act if their marketing activities cause their customers to make a false claim.

Federal Laws and Safe Harbors

The False Claims Act Self-Check

Roberta is a sales manager at Medical Company. She offers to pay American Hospital's purchasing manager, Fred, \$10 for every pulse oximeter he buys. Fred buys 100 oximeters and accepts a check for \$1,000 made out to him personally from Roberta, and American Hospital submits a claim to Medicare for the purchase.

Who may be liable and how?

- ☐ Both Roberta and Fred under the FCA only.
- ☐ Roberta under the Anti-Kickback Statute only and Fred under the FCA only.
- ☐ Both Roberta and Fred under the Anti-Kickback Statute and the FCA.
- ☐ Roberta under the Anti-Kickback Statute only and Fred under the Anti-Kickback Statute and the FCA.

Federal Laws and Safe Harbors

The Sunshine Act and Other Transparency Laws

On March 23, 2010, the U.S. Congress enacted a health care reform law known as the Patient Protection and Affordable Care Act. It includes a provision commonly known as the **Sunshine Act** or **The Physician Payments Sunshine Law**. Under the act, generally, companies must record and disclose any payments they make to physicians and teaching hospitals that exceed \$10.

Federal Sunshine reporting is mandatory and must be absolutely accurate and complete the first time. Every employee who incurs expenses that are reportable by Philips must enter their expense information into the online reporting tools that have been set up to capture those expenses. This task is part of Philips' Global Transparency efforts in the health care industry.



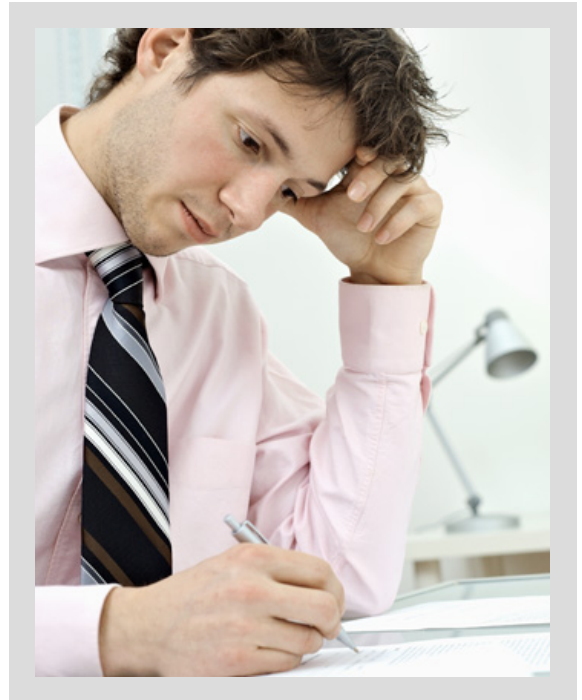
Federal Laws and Safe Harbors

The Sunshine Act and Other Transparency Laws

Philips Management must certify that the information being reported is fully responsive to Sunshine Act requirements before Philips can certify to the government that Philips is in compliance with the act.

There are civil and criminal penalties that can be imposed on Philips and its employees if they fail to fully and accurately report expenses. Not responding accurately and completely will invite further scrutiny from the federal government, as well as industry organizations and media outlets.

Compliance with the Philips Code of Conduct on Interactions with United States Health Care Providers is essential to make sure you do not record your own violations of law and the Philips Code.



Federal Laws and Safe Harbors

The Sunshine Act and Other Transparency Laws

Under the Code, you may conduct sales, promotional, and other business meetings with a health care provider to discuss Philips business (for example, product or service features, sales terms, or contracts). You should conduct these meetings in clinical, educational, conference, or meeting facilities, or in similar settings, and they should be near the health care provider's place of business.

You may pay for reasonable travel costs of health care providers when necessary (for example, to demonstrate non-portable equipment in the location closest to the customer site). **You may not pay these travel costs if the demo is taking place at a trade show, conference, or third-party seminar where the health care provider is an attendee or is participating in events unrelated to the Philips demo.**

You may provide occasional modest meals and refreshments, as part of the business meeting.



Did you know?

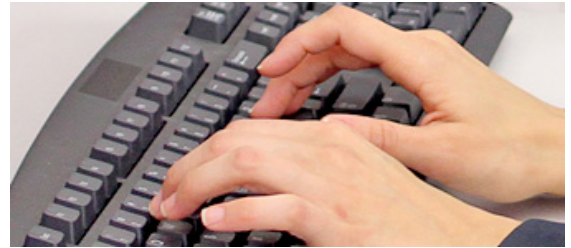
A Philips Healthcare representative must be present at all meals provided by Philips.

Philips may not pay for any meal for guests of a health care provider or for any other person who does not have a legitimate professional interest in the information being shared at the meeting. That means no meals for spouses or hospital staff with no direct interest in the business being discussed.

Federal Laws and Safe Harbors

The Sunshine Act and Other Transparency Laws

Meals may not be provided if the primary intention is the development or maintenance of goodwill or a general business relationship. Any meal provided to a health care provider must be incidental to the exchange of business information



Did you know?

Meals may not be provided if the primary intention is the development or maintenance of goodwill or a general business relationship. Any meal provided to a health care provider must be incidental to the exchange of business information

Federal Laws and Safe Harbors

The Sunshine Act and Other Transparency Laws

The governmental agencies will use the data that is publicly available from the various transparency laws to look for cases of improper influence or under reporting via benchmarking. Additionally, other non-governmental agencies (e.g., ProPublica) have scrutinized and will continue to scrutinize the publicly available data to look for irregularities and trends. So be sure to properly report any and all Transfers of Value to Covered Recipients.

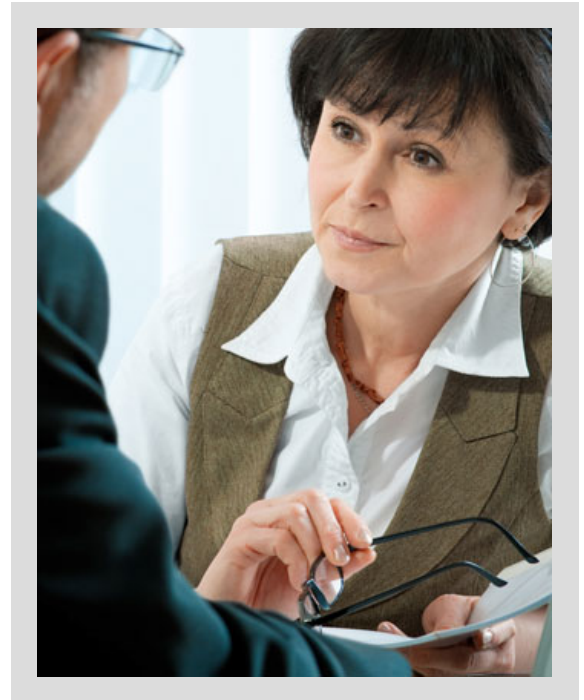


Federal Laws and Safe Harbors

Evaluation and Demonstration Products "Try and Buys" and Loaned Equipment

There are important rules that Philips must follow for evaluation and demonstration products. Evaluation or demo equipment may only be provided to health care providers under certain circumstances, such as the following:

Giving a health care provider the opportunity to evaluate a product before buying it. Under Medicaid Fraud and Abuse (MFA) regulations, an evaluation may last only for the period of time that it would reasonably take to determine how the product works in the environment. Philips policy recommends that the evaluation period be thirty (30) days or less when possible, and should not exceed sixty (60) days. "Try and Buys" are permissible as long as they meet these conditions. Philips cannot provide evaluation extensions to allow customers to use an evaluation product in an attempt to bridge a time gap between a customer order and Philips delivery.



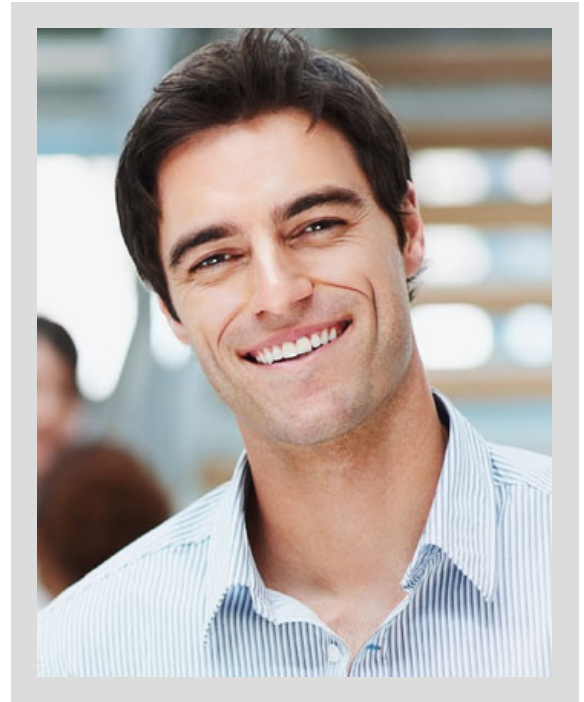
Federal Laws and Safe Harbors

Evaluation and Demonstration Products "Try and Buys" and Loaned Equipment

There are also cases where Philips may not provide demo/evaluation inventory at no charge. For example, a customer does not give Philips its normal lead time to deliver product to its site but still wants Philips to bridge the gap somehow.

This must be quoted as part of the deal, with a specific list cost and net cost. Otherwise, it must be treated as a rental with a monthly rate—rentals may not be provided at no cost.

It is acceptable to include a bridge equipment loaner in an original quote, but it must be priced in as part of the solution sold and net total discount. If not, the customer must pay for the rental separately.



Federal Laws and Safe Harbors

Evaluation and Demonstration Products "Try and Buys" and Loaned Equipment

Loaned equipment may or may not be evaluation or demo inventory. Regardless of where the equipment originates, there are very specific guidelines around equipment loans. Let's take a look at three acceptable examples of when loaner or demo equipment may be provided.



Customer 1

Philips sells equipment to a health care provider (HCP) and the equipment fails to meet mutually agreed to specifications. Philips policy allows Philips to provide the HCP with an equipment loan until replacement equipment can be installed as a Make Right.



Customer 2

A piece of equipment covered by product warranty or service warranty is not working. The equipment must be removed and sent back to the BU for repair. A loaned stock unit is shipped to replace the broken item as an interim measure.



Customer 3

Philips was given its normal lead time to deliver a product, but was unable to do so per the agreement. Philips provides a product from its inventory as a Make Right to bridge the gap until the new product can be delivered.

Federal Laws and Safe Harbors

Research Linked to Sales

At a recent AdvaMed convention in Boston, the U.S. Attorney General's Office indicated that research arrangements will be a large area of focus for compliance prosecution in the future.

In order to ensure that it is in compliance with regulations surrounding research arrangements, Philips must show each of the following on all of these arrangements:

- The research relationship is independent of the sale of equipment (unless being purchased solely for the research being performed and approved by the Philips lawyer supporting the research agreement).
- The HCP is performing genuine and bona fide research.
- The research arrangement consideration represents fair market value.



Did you know?

Any sale of a product made close in time to providing a research project to an HCP will be closely scrutinized for compliance by the U.S. Attorney General's Office.

Federal Laws and Safe Harbors

Research Linked to Sales

Furthermore, research arrangements must include well-defined milestones and deliverables in a written agreement.

Research must be evaluated and any resulting research agreements must be negotiated and managed by Philips Healthcare representatives who have **no** role in selling products or services to the health care providers who will receive or benefit from the research arrangement.

Salespeople need to route any requests to the BIU GM and inform customers that they cannot be otherwise involved due to compliance concerns that apply to both Philips and the customer.

There can be no linkage, implicit or explicit, between the research funding and the past, present, or future purchase of Philips Healthcare products or services (unless the products or services are being purchased for use in the research program being funded).



Federal Laws and Safe Harbors

Bottom Line

The federal Anti-Kickback Statute prohibits medical device companies from offering kickbacks to induce health care providers to buy their products. A kickback can be anything of value, including discounts, gifts, rebates, honoraria, continuing medical education grants, research grants, donations, free or loaned equipment, free services, or special credit arrangements.

Given the strict requirements of federal and state laws, practices that appear to have little risk of fraud or abuse might be considered violations. Safe harbors protect these legitimate practices if they meet the discount or personal services requirements.

The False Claims Act prohibits any person from knowingly making a false claim for payment to a federal program. The act also makes it illegal to cause someone else to make a false claim.



Training, Educational Conferences, and Sales Meetings

Overview



In this lesson, you'll learn

- that device companies should conduct training and education in settings that are clinical or educational and conducive to the exchange of such information
- how device manufacturers can support third-party educational conferences consistent with the Philips Code of Conduct
- how to conduct sales and promotional meetings that comply with the Philips Code of Conduct



Training, Educational Conferences, and Sales Meetings

Overview

Clay, a salesperson, is concluding a call with Dr. Roberts, a physician.

Clay: I'm glad you were able to make time for me today, Dr. Roberts.

Dr. Roberts: Not at all. It's good to get more info about your new therapy.

Clay: Well, we're very pleased with the trial results. And patients are responding well to how easy the product is to use. It's really a breakthrough.

Dr. Roberts: Actually, I had already heard good things about it from one of my colleagues.

Clay: Great!



Training, Educational Conferences, and Sales Meetings

Overview

Dr. Roberts: And I suppose you won't mind hearing that the word on this is much better than the new product offered by your leading competitor.

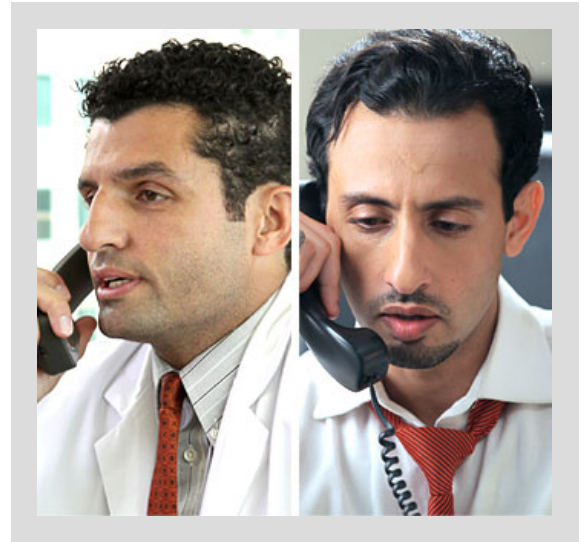
Clay: *(laughing)* No, that's not the sort of thing I have a hard time listening to at all.

Dr. Roberts: Didn't think so. But on the other hand, I'm flying to the Outer Banks for a training demonstration on their product at a clinic there.

Clay: The Outer Banks? Really?

Dr. Roberts: Good golf there, you know.

Clay: *(pause)* I see. Um...you know, we've got a hospital using our product in Palm Beach. What if I was to set an all-expense paid trip there for you to train on our product?



Training, Educational Conferences, and Sales Meetings

Philips Product Training and Education

Because Dr. Roberts is still deciding whether to buy Clay's product, his stay in Palm Beach could really turn out to be a sales meeting as much as a training session. In this situation, the Philips Code of Conduct could come into play.

The Code of Conduct sets standards for all kinds of interactions between manufacturers and health care providers, including health care professionals, hospitals, and other health care institutions.

The full text of the Philips Code of Conduct can be found by clicking on the "Resources" link at the bottom of this screen.

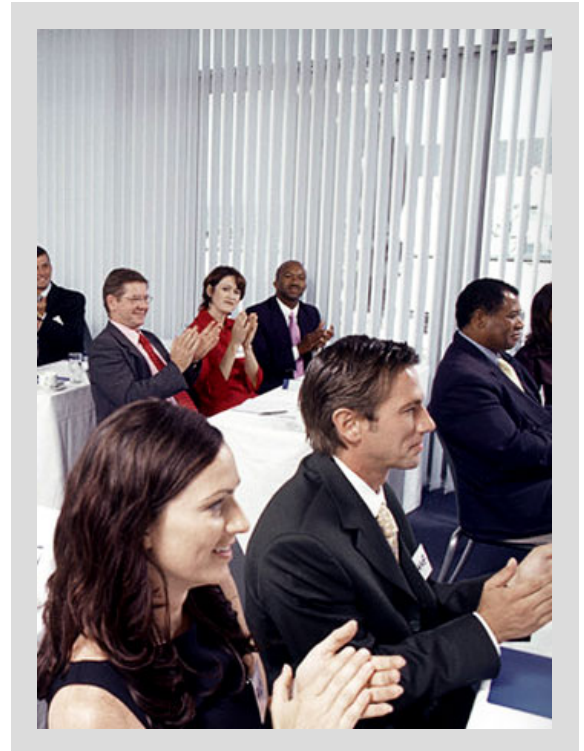


Training, Educational Conferences, and Sales Meetings

Philips Product Training and Education

Manufacturers should conduct programs and events in settings that are clinical or educational. Business-oriented hotels and other conference facilities are also appropriate. Inappropriate settings include luxury hotels and resorts.

Locations should be chosen that are conducive to training in the safe and effective use of Philips Healthcare products and services. They should require a minimum amount of travel for the participants and minimize the need for overnight stays. If a manufacturer covers any **modest** travel or accommodation expenses for a participant, then that participant must have a genuine need to be trained on the product. Training arrangements are almost always included in the sales or purchase agreement and clearly describe what we will and will not pay for.

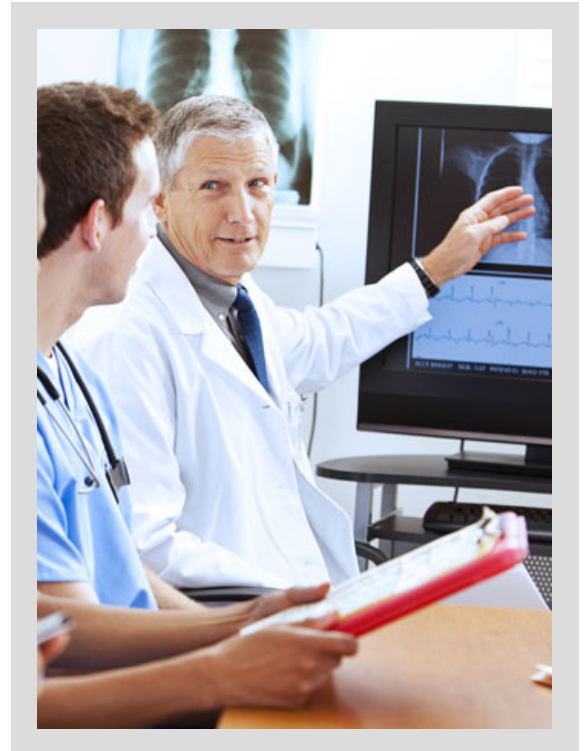


Training, Educational Conferences, and Sales Meetings

Philips Product Training and Education

Companies should conduct hands-on training on medical procedures at facilities designed for medical training, such as medical institutions or laboratories. Staff should be qualified and should be employed by, or under contract with, the company.

Training should occur at the customer's location or the closest site equipped for the training whenever possible. When that's not possible, it should be at a site that enables the company to provide the best quality training at modest and reasonable cost. The need for customer travel should be kept to a minimum.



Training, Educational Conferences, and Sales Meetings

Philips Product Training and Education

Hospitality, such as meals, refreshments, and receptions, should be secondary in time and focus to the training and education and must be modest. Functions shouldn't unnecessarily extend the length of the training program. Entertainment like sporting event tickets, theater tickets, or golf expenses should not be paid for, directly or indirectly. Also, hospitality should not be provided to those who won't use a company's product, such as spouses. Some states have their own laws for health care providers who are licensed in that state. Click on the "Resources" link for more information about interactions with health care providers in those states.



Top Ten

Product training and education conducted by device companies should take place in settings that are clinical or educational.

Such settings can include business-oriented hotels and conference facilities, if they're conducive to the training purpose of the meeting. Luxury resorts and other venues that emphasize style, comfort, and recreation, rather than business, are inappropriate. Meals and receptions should be modest and secondary in time and focus to training and education. And individuals who will not be receiving training or education, such as spouses, should not attend.

Training, Educational Conferences, and Sales Meetings

Philips Product Training and Education

Manufacturers may pay for reasonable travel and modest lodging costs for health care providers for training or education related to the safe and effective use of the manufacturer's products. When it's cheapest to train health care providers from multiple sites together at one central location, a device company may pay for reasonable travel, meals at the training facility, and lodging. Some states require that the training be specified in a sales agreement. Device companies should never pay customers for time and revenue lost during training.



Consider This

When all trainees are affiliated with one customer, the assumption is that it's more cost-effective to train at the customer's facility, unless it's impractical for some reason.

Training, Educational Conferences, and Sales Meetings

Sales and Promotional Meetings

Representatives of device manufacturers can meet with customers to discuss product features, contract negotiations, and sales terms. Generally, manufacturers may pay for only occasional modest meals for their customers during the course of such business meetings. And the meetings should typically occur at or near the customer's place of business. The Philips Code of Conduct sets specific standards for whether a meal is "modest."



Training, Educational Conferences, and Sales Meetings

Sales and Promotional Meetings

It's consistent with the Philips Code of Conduct, however, for manufacturers to pay for reasonable travel costs if it's necessary for a customer to tour a manufacturing plant or observe a demonstration of equipment that's not available near the customer. And remember, there must be a genuine need for the information to be shared.



Top Ten

Generally, manufacturers should only pay for occasional modest meals for their customers during the course of sales and promotional meetings.

Sales meetings between device manufacturers and their customers are a necessary part of doing business. It's okay for manufacturers to pay for some reasonable costs of those meetings, such as travel expenses for a customer who needs to tour a plant or observe a demonstration that requires equipment not available near the customer's place of business. Otherwise, meetings should occur at the customer's place of business, and the manufacturer should only pay for modest meals as defined in the Philips Code of Conduct.

Training, Educational Conferences, and Sales Meetings

Sales and Promotional Meetings

Self-Check

Surgeons at USA Hospital in Detroit want to observe image-guided surgery using equipment made by MediCo that can't easily be moved. A hospital in Chicago has the equipment and offers to demonstrate it. Which of the following probably would be an acceptable way to arrange a demonstration?

Check all that apply.

- ☐ MediCo pays for the surgeons to fly to Chicago and return in a single day.
- ☐ USA Hospital pays for the surgeons to fly to Chicago.
- ☐ The surgeons pay for their own plane tickets to fly to Chicago.
- ☐ MediCo pays for the surgeons to fly to Orlando, Florida, where a different hospital is willing to give a demonstration.

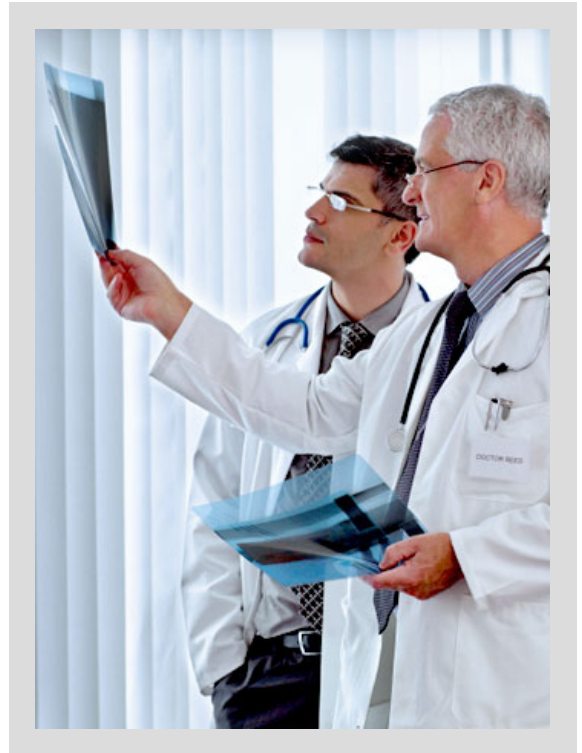
Training, Educational Conferences, and Sales Meetings

Supporting Third-Party Educational Conferences

Device manufacturers can support **third-party educational conferences**.

The conferences must be independent, educational, scientific, or policy-making events that promote scientific knowledge, medical advancement, and the delivery of effective health care. These typically include conferences sponsored by medical associations and accredited continuing medical education providers. Device companies may support such conferences in various ways, including educational grants **to the conference sponsor** to defray the cost of the education, support the provision of modest meals, or pay reasonable faculty expenses.

Device companies may also buy advertisements or rent booth or exhibition space under a separate commercial agreement.



Training, Educational Conferences, and Sales Meetings

Supporting Third-Party Educational Conferences

Device manufacturers may provide grants for third-party educational conferences to reduce the costs of educational activities at the conference or to support the attendance of health care providers in training. Payments may only be made to the conference sponsor, which would typically be a medical society or association, or to a training institution to subsidize the attendance of its residents and students. Payments to a sponsor who is also a health care provider or a customer of Philips should only be made for accredited CME programs and must be closely scrutinized for any relationships to past or future sales. Philips may provide modest meals or refreshments at receptions open to all conference attendees, although some states prohibit it. However, it is never permissible to provide entertainment or recreation.



Training, Educational Conferences, and Sales Meetings

Supporting Third-Party Educational Conferences

In every case, grants for conferences must meet several other standards:

- The gathering must be dedicated to promoting objective scientific and educational activities.
- The conference sponsor must select the attendees to invite or the health care providers in training to support financially.
- The sponsor must be engaged generally in the promotion of educational programs.
- The sponsor, not the manufacturer, should select program content, faculty, and educational methods and materials.
- The grant should not be based on the volume or value of past, present, or anticipated business with Philips.



Top Ten

The Philips Code of Conduct sets standards for the support of third-party educational conferences.

The guidelines state that conferences must be independent, educational, scientific, or devoted to policy making and must promote scientific knowledge, medical advancement, and the delivery of effective health care. Also, device companies may support such conferences through educational grants, by paying modest expenses, by buying advertisements, and by renting exhibition space. However, all of these are subject to further limitations described in the Code of Conduct. Monetary support for continuing medical education should not be a reward for past, present, or future sales.

Training, Educational Conferences, and Sales Meetings

Bottom Line

Philips-provided or Philips-sponsored product training and education should be conducted in settings that are clinical or educational or that emphasize business, not in venues that place an emphasis on style, entertainment, comfort, and recreation.

The codes provide guidelines for manufacturers that wish to support third-party educational conferences. For example, conferences must be independent, educational, scientific, or devoted to policy making.



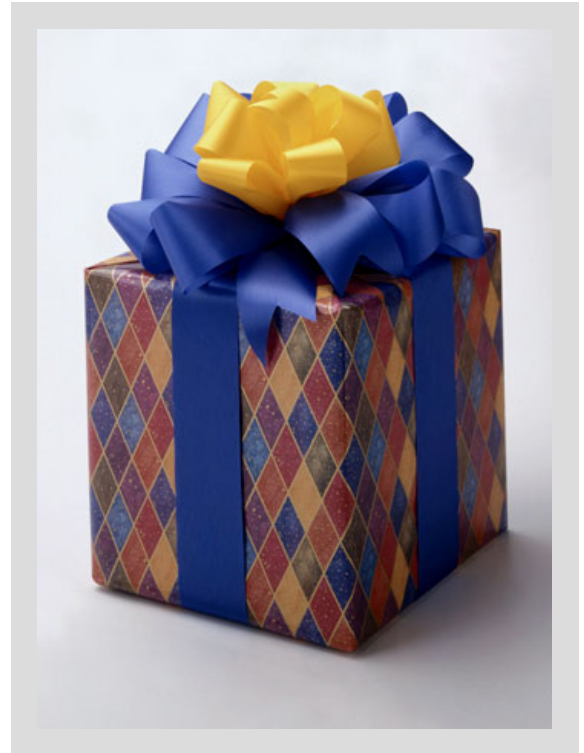
Consulting, Reimbursement, and Gifts

Overview



In this lesson, you'll learn

- how to avoid problems when using consultants
- that gifts are prohibited by the Philips Code of Conduct
- when it's appropriate to provide reimbursement and other economic information to customers
- when it's appropriate to provide grants and charitable donations
- the part you play in compliance and who you can contact for help



Consulting, Reimbursement, and Gifts

Overview

Marketing managers Andrea and Janis are on the speakerphone talking to Dr. Freel.

Andrea: Dr. Freel, we are delighted you're considering our consultation offer.

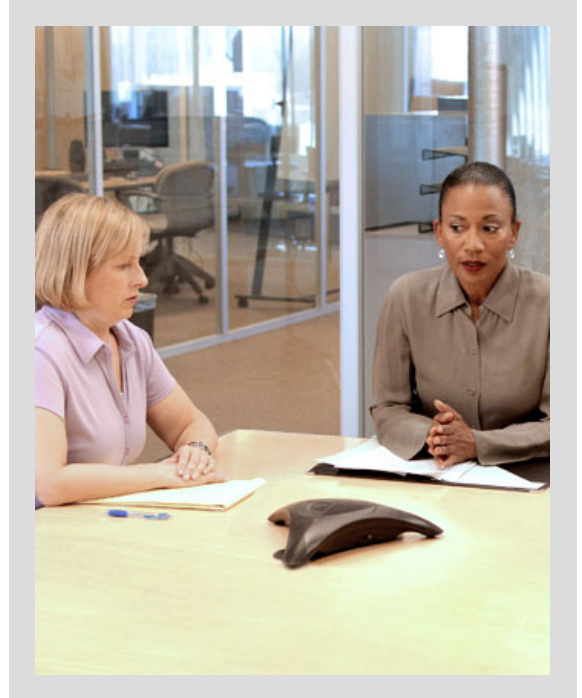
Dr. Freel: Well, I've had some terrific patient outcomes with your product. I'd love to help.

Janis: Did you receive the proposed agreement we e-mailed?

Dr. Freel: Yes, thank you. It looks good, but....

Andrea: But what?

Dr. Freel: I'm also doing my own research and preparing a grant proposal, and.... Well, I actually need to jump off this call in a minute to deal with that.



Consulting, Reimbursement, and Gifts

Overview

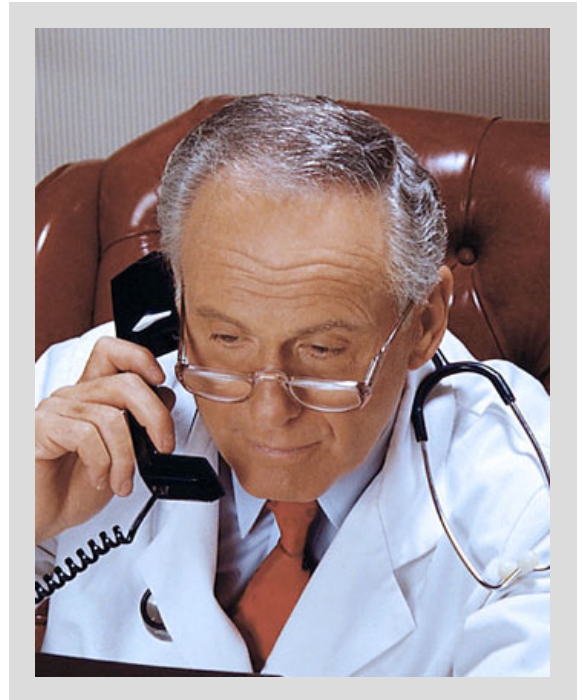
Janis: Um, all right. You can call us back when you have more time. Also, if you have any questions on the agreement, don't hesitate to ask.

Dr. Freel: Maybe I'm being too obtuse here. I would love to accept your consultation offer, but I need you to either back my grant or find me a grant.

Andrea: I'm not sure we're allowed.

Dr. Freel: Why not? It's all for a good cause, and frankly I doubt there are many doctors out there prescribing your device at the levels that my practice does.

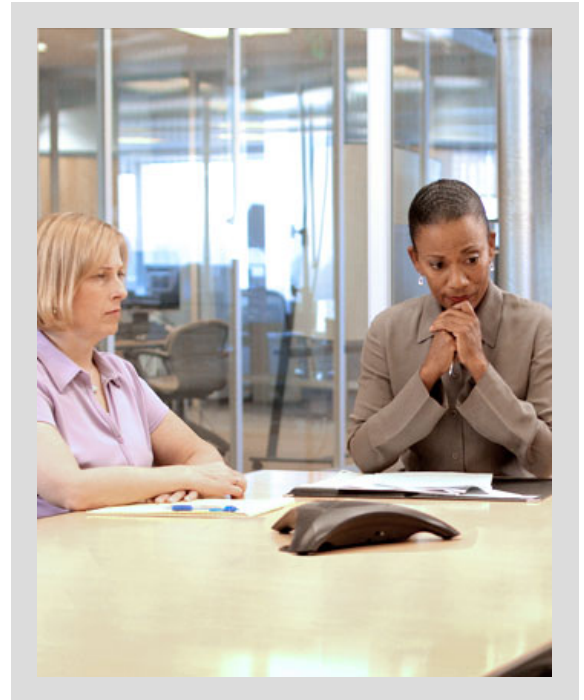
Janis: We're going to have to call you back.



Consulting, Reimbursement, and Gifts

Arrangements with Consultants

Manufacturers can improve the quality of medical technology by retaining health care providers as consultants who perform research, participate on advisory boards, make presentations at training seminars, and collaborate on product development. But federal laws regulate this area, and the Philips Code of Conduct guides business practices, too.



Consulting, Reimbursement, and Gifts

Arrangements with Consultants

The Code of Conduct describes eight standards manufacturers should follow when reimbursing consultants. Here are the first four:

- The parties involved should write and sign consulting contracts that list all the services the consultant will provide.
- Manufacturers should have a legitimate need for the consulting services.
- Manufacturers should choose consultants based on expertise and not on the amount of business they generate.
- Compensation should be based on fair market value for the service actually provided.

Click [here](#) to access the Fair Market Guidance Document.



Top Ten

The Philips Code of Conduct for Interactions with United States Health Care Providers and Professionals provides standards for Philips' dealings with the U.S. health care community.

The Code of Conduct is designed to ensure that Philips adheres to the Codes of Ethics established by the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging and Technology Alliance (MITA), which are national trade associations for device companies. Each has adopted guidelines for their members to provide ethical guidance regarding interactions between medical device manufacturers and health care professionals and institutions. The Philips Code blends the AdvaMed and MITA Codes to fit Philips' business.

Consulting, Reimbursement, and Gifts

Arrangements with Consultants

The last four standards are as follows:

- The company may pay for reasonable expenses incurred by consultants, such as travel, modest meals, and lodging.
- The venue and circumstances for meetings with consultants should be appropriate to the subject matter of the consultation and conducive to the exchange of information.
- Company-sponsored meals should be modest in value and subordinate to the business purpose of the meeting. The Philips Code of Conduct sets specific standards for whether a meal is "modest."
- Employees or agents with sales responsibility may provide input about the suitability of a proposed consultant, but they may not unduly influence the decision to engage a particular health care provider as a consultant.



Consulting, Reimbursement, and Gifts

Arrangements with Consultants

The eight standards aim to prevent manufacturers from paying physicians and other providers as a reward for purchasing products. The standards also help manufacturers retain only the minimum number of necessary consultants and pay them reasonably. These guidelines should also be applied consistently with the personal services safe harbor. Philips has implemented a [Health Care Provider \(HCP\) checklist](#) to help you follow these guidelines.



Top Ten

The Philips Code of Conduct provides a list of standards that manufacturers should follow when reimbursing consultants.

According to the list, both parties should sign a written consulting arrangement that lists all the services the consultant will provide. Compensation should be based on the fair market value of the services performed. Manufacturers should have a legitimate need for consulting services and shouldn't choose consultants based on the amount of business they generate. These and other standards on the list aim to focus research on improving medical products.

Consulting, Reimbursement, and Gifts

Arrangements with Consultants

Self-Check

Dr. Bob is a heart surgeon who earns \$300 an hour while performing surgery. ProductsCo wants to retain him to participate in a three-hour interactive discussion regarding the safety and effectiveness of certain surgical products.

How much should ProductsCo offer to pay Dr. Bob?

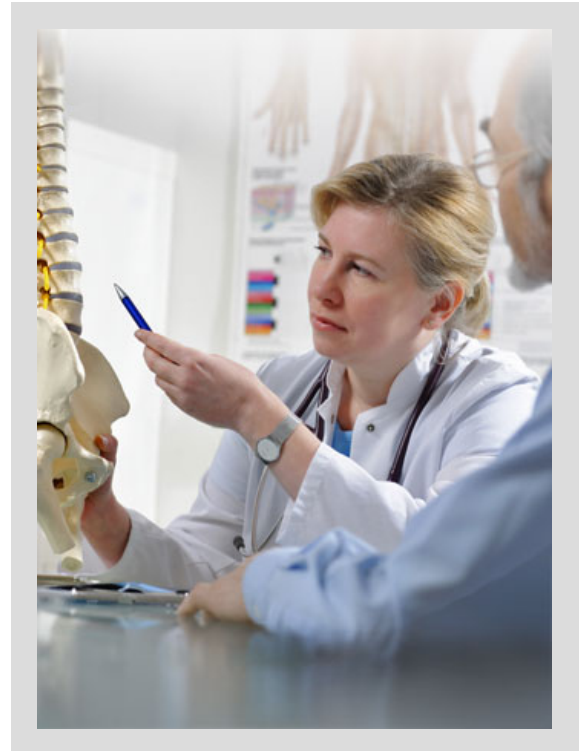
- ☐ \$300 per hour.
- ☐ Whatever amount the doctor and the company agree upon.
- ☐ Fair market value based on product safety and effectiveness consulting services.
- ☐ Nothing.

Consulting, Reimbursement, and Gifts

Gifts

Manufacturers may not give gifts in the form of cash or cash equivalents. Philips may not give any branded promotional item, regardless of value.

Philips employees also may not provide health care providers or their employees with 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 (for example, birth, death, graduation, or wedding).



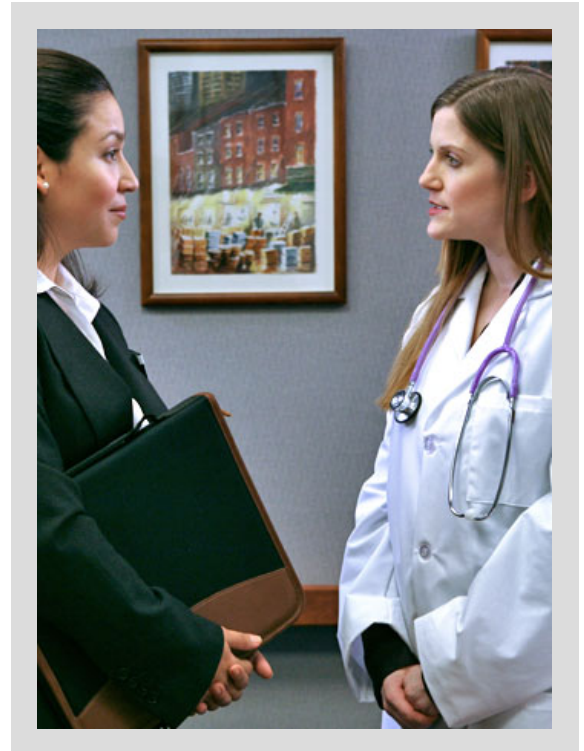
Consulting, Reimbursement, and Gifts

Providing Customers with Products for Evaluation

Manufacturers often loan or give samples of products to customers at no charge so that they can evaluate them and decide whether to purchase them. The Philips Code of Conduct permits such loans and samples, but because this practice can be abused for purposes unrelated to evaluation for purchase, the Code sets strict standards for them.

Here are some examples of abuse of evaluation products:

- A customer asks if we can loan them an "evaluation" ultrasound imaging system so they can double the number of studies they perform the next week.
- A customer is already using a particular Philips disposable product but wants additional "samples."
- A customer who is negotiating a purchase of one Philips system wants to "evaluate" a different Philips system for a year.



Consulting, Reimbursement, and Gifts

Providing Customers with Products for Evaluation

For any products provided for evaluation to a customer, the manufacturer must also provide the customer with a statement describing the no-charge status of the products. In the case of capital or multiple-use equipment, such as patient monitors and imaging systems, before the evaluation can begin, the customer must enter into a written agreement detailing the terms of the evaluation, including the length of the evaluation period, who will perform the evaluation, and the permissible frequency of use.

The number of samples of single-use products provided or the length of the evaluation period for multiple-use equipment must be no greater than reasonably necessary for a typical customer to decide whether the product meets their needs. Philips policy provides that the evaluation period should not exceed thirty (30) days when possible, and under no circumstances should it exceed sixty (60) days.



Consulting, Reimbursement, and Gifts

Reimbursement and Other Economic Information

It's generally okay for device manufacturers to provide their customers with accurate reimbursement and billing information relevant to their products. This can include coverage, coding, or billing information about Philips products and related procedures.



Consulting, Reimbursement, and Gifts

Reimbursement and Other Economic Information Self-Check

Shady Grove is a new hospital that decides to buy supplies from National Products.

It would be okay for National to supply Shady Grove with the correct codes the hospital would need when billing Medicare for the products.

☐ True

☐ False

Consulting, Reimbursement, and Gifts

Charitable Donations

Charitable donations further philanthropic values and should be a part of every corporate culture.

Philips is prohibited from giving donations to health care providers.

Manufacturers should also ensure that recipients are genuine charitable organizations and that payments qualify, and are appropriately classified, as charitable deductions for tax purposes.

To ensure that these requirements are met, all requests for charitable donations from Philips Healthcare must be submitted through the Charitable Donations Process. Click on the "Resources" link for more information about the process.



Top Ten

Manufacturers need to be careful when providing charitable donations.

The authorities may construe donations as an illegal inducement—i.e., a bribe—to obtain business. Manufacturers may be able to contribute to legitimate charitable organizations if they ensure that these donations are properly approved and recorded. The U.S. Government strongly recommends that manufacturers set up special programs for donations and insulate them from sales and marketing influence.

Consulting, Reimbursement, and Gifts

Your Compliance Obligations

As a Philips employee, please note the following:

- You must comply with applicable laws and the Philips Code of Conduct. We encourage you to raise questions and bring compliance matters to our attention.
- If you fail to abide by Philips' standards, you may be subject to discipline including, without limitation, suspension and termination of employment.
- You must do your part in helping Philips maintain the highest compliance standards.
- Acceleration of our business requires navigation—know your employee obligations.



Consulting, Reimbursement, and Gifts

Philips' Compliance Helpline and Contacts

Philips is committed to working with you and our customers to provide the best products and services under arrangements that comply with our Code of Conduct, industry ethical codes, and applicable laws.

If you have questions or believe a violation is about to occur or may have occurred, contact the Philips Legal Department or report it using the One Philips Ethics Line in those countries where the Ethics Line is available.



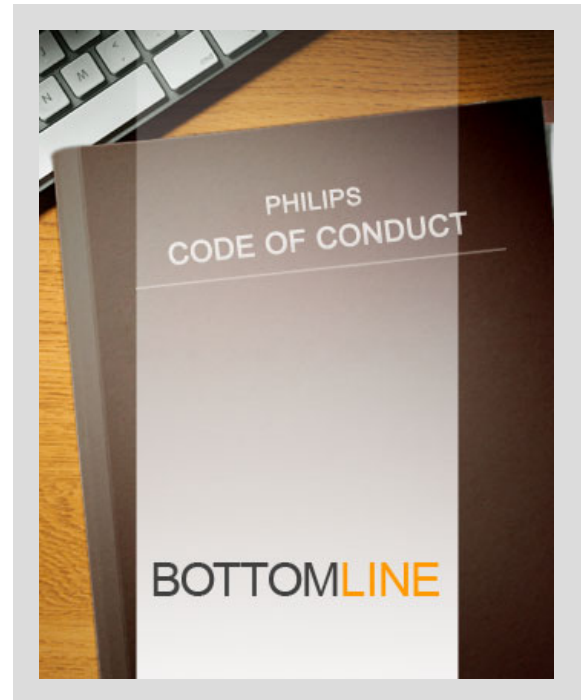
Consulting, Reimbursement, and Gifts

Bottom Line

To make certain that the use of consultants is appropriate and the focus is on improving health care, the Philips Code of Conduct provides a list of standards that manufacturers should follow when retaining consultants.

Gifts to health care providers are prohibited. Manufacturers should only make charitable contributions to genuine charitable organizations and should have a process for deciding on contributions independent of sales or marketing influence.

Manufacturers should make sure that any technical support or billing services they provide for customers are focused on the manufacturer's products and based on accurate information.



Knowledge Check

Questions

1. Generally, if an arrangement satisfies all the requirements of a safe harbor and is commercially reasonable, it may be

- ☐ a sham designed to generate referrals.
 - ☐ immune from liability under the Anti-Kickback Statute.
 - ☐ an illegal kickback arrangement.
 - ☐ probably not based on legitimate business reasons.
-

2. Philips gives a physician's office each of the following. Which is **least** likely to be treated as a kickback arrangement?

- ☐ A \$25,000 credit against future purchases of its new therapy paid up front in cash.
 - ☐ Proprietary software that allows the office to order from Philips's product website, which has no other use.
 - ☐ \$1,000 to attend a luncheon and hear about a new product.
 - ☐ Providing free billing services.
-

3. When conducting a sales or marketing meeting, it is permissible for Philips to pay for a customer's travel costs if the meeting is

- ☐ to finalize a sale with an existing customer.
 - ☐ meant to introduce the company's line of products to a new customer.
 - ☐ necessary for the customer to see a demonstration of equipment that is available at the closest location to the customer.
 - ☐ to allow the customer and the manufacturer to get acquainted at a modest business function.
-

4. Maria, a Philips sales representative, wants to give a gift to a long-time customer.

Which of the following gifts would not be in compliance with the Code of Conduct

Check all that apply.?

- ☐ Tickets to a Major League baseball game.
 - ☐ A decorative bowl worth \$250 that commemorates the 10th anniversary of business with Philips.
 - ☐ Flowers and candy.
 - ☐ Free equipment and services
-

Knowledge Check

Questions

5. Which of the following represents a likely violation of the Anti-Kickback Statute?

- ☐ Legitimate discount arrangements under the discount safe harbor through which Philips lowers the price of its products to make them more competitive.
 - ☐ Free equipment or services not included in a sales agreement.
 - ☐ Distribution of RC-approved on-label promotional materials.
 - ☐ Consulting agreements for which the payment is made at fair market value and is determined in advance.
-

6. Lauren meets with her supervisor to discuss offering a doctor a gift certificate to a spa. She asks him whether doing so might be in violation of company rules. Lauren's supervisor tells her not to worry and gives his approval to go ahead with the plan.

Should Lauren follow her supervisor's advice?

- ☐ Yes
 - ☐ No
-

7. Omar, a Philips sales representative, pays Dr. Rose \$10 every time she recommends a Philips device to a patient. Some of Dr. Rose's patients are on Medicare.

Who could be found guilty under the Anti-Kickback Statute?

- ☐ Omar
 - ☐ Philips
 - ☐ Dr. Rose
 - ☐ All of the above
-

8. Global Medical Products has just developed a new type of imaging device that it's ready to market. It's planning a two-day educational seminar and demonstration on new diagnostic techniques facilitated by the device.

It would most likely be appropriate for the company to invite and cover expenses for

- ☐ the CEOs of 200 hospitals to attend the seminar at a hotel.
 - ☐ radiologists from 200 hospitals to attend the seminar at a golf resort.
 - ☐ the CEOs of 200 hospitals to attend the seminar at a golf resort.
 - ☐ None of the above
-

Knowledge Check

Questions

9. State University hosts a conference on ethics in medicine for physicians and medical students in its metropolitan area. St. Mary's Medical Center is affiliated with the university and buys many Philips devices.

Would it be okay for Philips to consider approving State University's request for an educational grant to help subsidize the conference?

- ☐ Yes, if the grant is used to reduce costs, and if the conference is accredited, educational, and dedicated to promoting health care.
 - ☐ Yes, but only if Philips is allowed to choose the speakers and topics.
 - ☐ No, because St. Mary's is a major customer of Philips.
 - ☐ No, because St. Mary's isn't allowed to ask any device manufacturer to subsidize a conference.
-

10. Which of the following would be a legitimate reason for Philips to hire Dr. Narasimhan as a consultant?

- ☐ Last year, Dr. Narasimhan generated \$2.1 million in revenue for Philips through patient referrals.
 - ☐ This year, Philips has a bigger budget for consultants.
 - ☐ As an incentive, Philips offers consulting arrangements to all its best customers.
 - ☐ Philips is developing a new device, and Dr. Narasimhan can provide expert knowledge that no one else can provide.
-



TOPTEN

- **The Philips Code of Conduct for Interactions with United States Health Care Providers and Professionals provides standards for Philips' dealings with the U.S. health care community.**

The Code of Conduct is designed to ensure that Philips adheres to the Codes of Ethics established by the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging and Technology Alliance (MITA), which are national trade associations for device companies. Each has adopted guidelines for their members to provide ethical guidance regarding interactions between medical device manufacturers and health care professionals and institutions. The Philips Code blends the AdvaMed and MITA Codes to fit Philips' business.

- **The Anti-Kickback Statute is one of the most significant fraud and abuse laws affecting the medical device industry.**

The law seeks to prevent financial considerations from interfering with medical decision making, such as when medical device companies offer health care providers incentives to purchase or prescribe their products. It authorizes penalties against any entity that knowingly and willfully offers, pays, solicits, or receives anything of value to induce, or in return for, (1) referring, or arranging for referring, federal health care program patients, or (2) the purchase, lease, or ordering of (or the recommendation to purchase, lease, or order) goods, items, or services that may be paid for by such programs. A kickback can be a discount, free equipment, a gift, an equipment loan, a rebate, or even a special credit arrangement. A kickback is a bribe!

- **The False Claims Act prohibits any person from knowingly making, or causing to be made, a false claim for payment to a federal program.**

The act also makes it illegal to cause someone else to make a false claim. Device manufacturers generally don't submit claims directly to federal health care programs. But manufacturers can still violate the act if their marketing activities cause their customers to make a false claim.

- **Product training and education conducted by device companies should take place in settings that are clinical or educational.**

Such settings can include business-oriented hotels and conference facilities, if they're conducive to the training purpose of the meeting. Luxury resorts and other venues that emphasize style, comfort, and recreation, rather than business, are inappropriate. Meals and receptions should be modest and secondary in time and focus to training and education. And individuals who will not be receiving training or education, such as spouses, should not attend.

- **The Philips Code of Conduct sets standards for the support of third-party educational conferences.**

The guidelines state that conferences must be independent, educational, scientific, or devoted to policy making and must promote scientific knowledge, medical advancement, and the delivery of effective health care. Also, device companies may support such conferences through educational grants, by paying modest expenses, by buying advertisements, and by renting exhibition space. However, all of these are subject to further limitations described in the Code of Conduct. Monetary support for continuing medical education should not be a reward for past, present, or future sales.

- **Generally, manufacturers should only pay for occasional modest meals for their customers during the course of sales and promotional meetings.**

Sales meetings between device manufacturers and their customers are a necessary part of doing business. It's okay for manufacturers to pay for some reasonable costs of those meetings, such as travel expenses for a customer who needs to tour a plant or observe a demonstration that requires equipment not available near the customer's place of business. Otherwise, meetings should occur at the customer's place of business, and the manufacturer should only pay for modest meals as defined in the Philips Code of Conduct.

- **The Philips Code of Conduct provides a list of standards that manufacturers should follow when reimbursing consultants.**

According to the list, both parties should sign a written consulting arrangement that lists all the services the consultant will provide. Compensation should be based on the fair market value of the services performed. Manufacturers should have a legitimate need for consulting services and shouldn't choose consultants based on the amount of business they generate. These and other standards on the list aim to focus research on improving medical products.

- **The Philips Code prohibits gifts to health care providers.**

Branded promotional items, such as pens or mugs, are prohibited.

- **Device manufacturers can provide limited reimbursement assistance.**

Billing support may include accurate information regarding the manufacturer's products, such as identifying conditions for insurance coverage, appropriate coding or billing information for these products, and procedures that use the manufacturer's product. The value of this support should not be substantial.

- **Manufacturers need to be careful when providing charitable donations.**

The authorities may construe donations as an illegal inducement—i.e., a bribe—to obtain business. Manufacturers may be able to contribute to legitimate charitable organizations if they ensure that these donations are properly approved and recorded. The U.S. Government strongly recommends that manufacturers set up special programs for donations and insulate them from sales and marketing influence.



Q. What are AdvaMed and MITA?

- A. The Advanced Medical Technology Association (AdvaMed) and the Medical Imaging and Technology Alliance (MITA) are the largest medical technology trade associations in the United States. Both represent manufacturers of medical devices, diagnostic imaging products, and therapy systems, and both advocate legal, regulatory, and economic conditions favorable to medical technology companies. MITA also develops voluntary standards for certain classes of medical devices.

Q. What are the AdvaMed and MITA Codes of Ethics?

- A. They are sets of guidelines that help medical device manufacturers structure their sales and marketing to be consistent with ethical principles. While they are very similar, they have a few important differences reflecting the segments of the medical device industry that form their membership. They form the basis of the Philips Code of Conduct.

Q. What's the Anti-Kickback Statute?

- A. It's one of the most significant fraud and abuse laws affecting the medical device industry. It's intended to prevent financial considerations from interfering with medical decision making. Specifically, it authorizes penalties against any person or entity that knowingly and willfully offers, pays, solicits, or receives anything of value in return for (1) a referral, or arranging for a referral, of federal health care program patients, or (2) the purchase, lease, or ordering of (or the recommendation to purchase, lease, or order) goods, items, or services for which payment may be made by federal health care programs.

Q. What's considered a kickback?

- A. A kickback can be money or anything else of value, such as free equipment or services, rebates, discounts, gifts, or credit arrangements, offered in exchange for business. A kickback is a bribe.

Q. What's the FCA?

- A. The False Claims Act (FCA) is a federal law that prohibits any person from knowingly making a false claim for payment to any federal program. It also makes it illegal to cause someone else to make a false claim. It's one of the laws that authorities use to combat fraud in the medical device business.

Q. Since device manufacturers don't make claims to government programs, why should they worry about the FCA?

- A. If a manufacturer participates in an illegal kickback scheme, any claims it or its partner in the scheme submits might be false in the government's view. So the government can hold the manufacturer liable for causing its customer to make a false claim.

Q. Is it okay for manufacturers to provide modest meals and receptions at training and education programs?

- A. Yes, but such hospitality should take less time and receive less focus than the training and education. Also, attendees who won't use a company's product and don't participate in training, such as spouses, should not be invited. Philips has specific standards for what constitutes modest meals.

Q. Is it okay for manufacturers to pay for their customers' travel and lodging costs?

- A. Yes. When it's cheapest to train health care providers from multiple sites simultaneously at one central location, a manufacturer may pay for reasonable travel, group meals, and modest lodging. Manufacturers should never pay customers for time and revenue lost during training.

Q. What does the Philips Code say about consultants?

A. The Philips Code of Conduct describes eight standards manufacturers should follow when reimbursing consultants. The standards state that the parties involved should have written consulting agreements that list all the services the consultant will provide. The standards also state, among other things, that compensation should be based on fair market value, that manufacturers should have a legitimate need for consulting services, and that manufacturers shouldn't choose consultants based on the amount of business they generate.

Q. Is it okay for manufacturers to give gifts to health care providers?

A. No, gifts are strictly prohibited.