Staying on the right side of the law! —
for Philips Healthcare employees and U.S. customers

Philips' Guide to Preventing Medicare Fraud and Abuse

FOR DUMMIES®

2nd Edition

Understand what constitutes fraud and abuse in your day-to-day business transactions

A Reference for the Rest of Us!®

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DEAR READER: This helpful guide is not a substitute for legal advice or a replacement for review of all applicable Philips policies. Whether you are a Philips employee or an employee of a health care provider, consult with your management and your legal department to make sure that specific actions comply with the applicable laws and guidelines. The information provided here is for general education and not intended to summarize complex and detailed legal requirements, but it is intended to help you understand the broad legal principles and underlying goals for compliance. Also, because the law and guidelines continue to change, you need to check with your legal or compliance department for the most up-to-date developments.

The material in this book is based on legal authorities, policies, and guidelines in effect as of May 2010. Since changes in regulations, ethical guidelines, and legal standards continue to evolve, make sure you get the most up-to-date guidance by checking with Philips' or your company's compliance officer or legal department.

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FOR DUMMIES®

2ND EDITION

Wiley Publishing, Inc.

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Introduction

The laws, rules, and regulations governing the business of health care are vast, complex, confusing, and — even on a good day — can really give you a headache. On the bright side, however, the information you find in this second edition of *Philips' Guide to Preventing Medicare Fraud and Abuse For Dummies* is sure to keep you on the right side of a very thin line that divides positive interactions between medical technology companies and U.S. health care providers from interactions that constitute Medicare fraud and abuse.

About This Book

Philips' Guide to Preventing Medicare Fraud and Abuse For Dummies, 2nd Edition, is part primer and part handbook. On a very basic level, you get acquainted with some important laws and ethical codes governing medical technology companies and health care providers, the significant financial and civil penalties you may incur when you break the rules, and — most important — how to go about transacting the sale or purchase of medical technology *without* getting yourself and your employer into a whole lot of legal trouble. In short, we show you how to use the substantial resources available to you through your employer, the government, and professional trade associations to engage in "squeaky clean" medical sales transactions.

Foolish Assumptions

In writing this book, we made some assumptions about you.

- You are already involved in selling or purchasing medical technology for which U.S. government health insurance programs, such as Medicare, Medicaid, and Tricare, are footing all or part of the bill.
- You may unknowingly be involved in a situation, now or in the future, in which a medical sales practice potentially violates one or more laws or ethical guidelines.

- You are a basically honest person working in a competitive industry who, while aggressively pursuing that great business deal, would like to avoid placing your employer in legal and financial jeopardy, keep yourself out of jail, and stave off professional catastrophe.

How This Book Is Organized

We divided this book into nine chapters, but you don't have to read the book straight through to make use of it — you can delve into any section at any time you'd like.

In Chapters 1, 2, and 3, we lay out for you the laws that you're expected to follow, the safeguards in place to ensure your success in complying with the laws, and the very significant penalties involved in breaking said laws. With this information, you're bound to feel empowered to recognize the possible legal conflicts that can arise during interactions between medical technology companies and health care providers and feel encouraged to seek appropriate assistance from your company to resolve those conflicts.

Chapters 4 through 7 describe medical sales practices and other interactions that typically occur between medical technology companies and U.S. health care providers, and we show you the "do's" and "don'ts" of structuring a Medicare-compliant interaction. Think of these chapters as a quick reference on how to recognize a practice that violates Medicare Fraud and Abuse Laws.

Lastly, no *For Dummies* book would be complete without the type of information contained in Chapters 8 and 9. The brief, "quickie" nuggets here give you easy references to compliance resources and sales strategies for your immediate use so that you can stay on the right side of the Medicare Fraud and Abuse Laws.

Icons Used in This Book

Every now and again you see little symbols in the left margin of the book. These *icons,* as they're known, draw your attention to certain points and concepts that are of particular importance and worth emphasizing.

This icon refers to important general concepts that are the foundation of the Medicare Fraud and Abuse Laws.

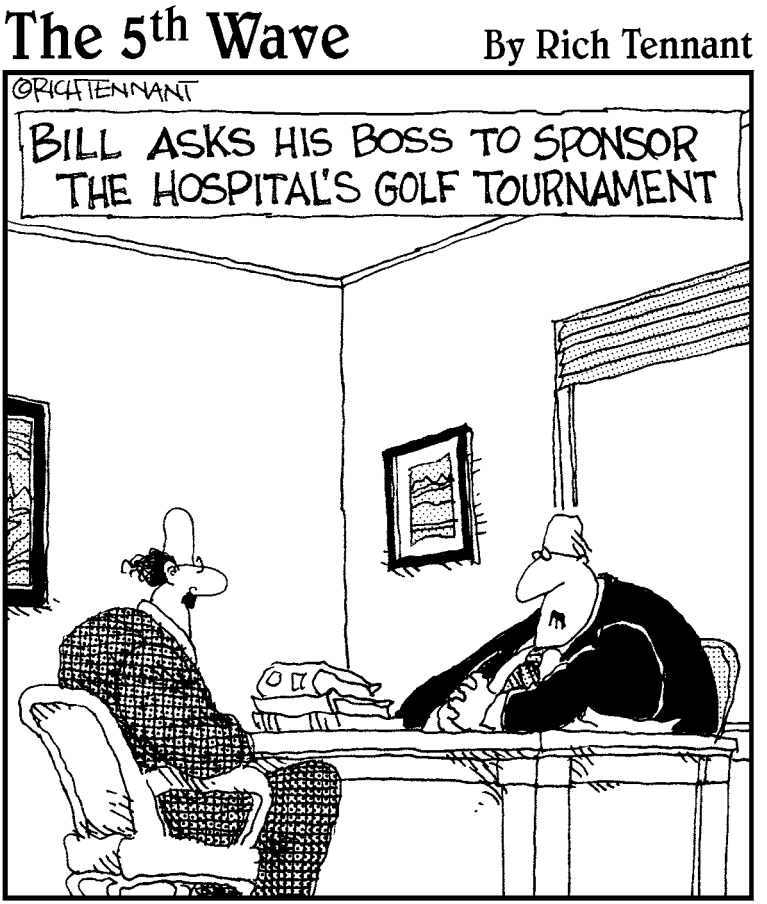
This icon precedes a suggestion for promoting Medicare compliance.

Take special note of the paragraph that follows this icon because the information therein details a situation that may land you in trouble with the law.

Where to Go from Here

You don't have to read this book from front to back, cover to cover, because there's no pop quiz at the end. But understanding the general principles of fraud and abuse as they apply to the health care industry and finding out how to recognize, report, and avoid violating the Medicare Fraud and Abuse Laws are all components of your professional responsibility. Let the Table of Contents guide you to the sections you need to read in order to avoid any gaps in your knowledge. You may go to any section in this book and read it independently of any other section to gain insight on a particular topic.

For rules on interactions with health care providers who are not located or licensed in the U.S.A., consult your local management team and local legal counsel.



"The short answer is 'NO', and the long answer is, 'Go home and read the For Dummies book on Medicare fraud."

Chapter 1

Getting the Basics of the Medicare Fraud and Abuse Laws

In This Chapter

- Becoming familiar with terminology, government programs, and agencies involved in medical sales practices
- Understanding Medicare's role in the relationship between medical technology companies and health care providers
- Getting the importance of "compliance" with Medicare Fraud and Abuse Laws

Whether you buy or sell medical technology, you're well aware of the many complicated rules and regulations that govern the health care industry. The health care provider and the medical technology company are both subject to multiple sets of legal and ethical standards, including federal and state laws, federal and state regulations, Medicare program rules, and trade association ethical guidelines.

You could give yourself an aneurysm trying to understand every law and regulation that applies to transactions between health care providers and medical technology companies. Fortunately, you don't have to understand every detail. But, you do need to understand — and understand well — the general concepts of fraud and abuse as they relate to interactions between a medical technology company like Philips and the health care providers who are their customers.

You, as an employee or an agent of your company, hospital, or medical practice, have an obligation to abide by any ethical guidelines adopted by your employer, as well as all federal and state laws and regulations pertaining to the purchase or sale of medical technology. In short, you need to recognize situations in which legal and ethical standards haven't been met and respond appropriately.

Talking the Talk: Understanding What Certain Terms Mean

Throughout this book, we use a few key terms and concepts that you need to know. You don't *have* to memorize them all (because you can always turn back to this section for clarification), but you definitely want to have a clear understanding of what these terms mean.

- **Ethical guidelines** refers to acceptable standards of behavior developed by certain trade and professional associations that relate to interactions between health care providers and medical technology companies.
- **Health care providers** refers to any person or organization that provides health care services, such as doctors and nurses and their technical, clinical, and administrative staff, hospitals, nursing homes, clinics, durable medical equipment dealers or distributors (DMEs), and any of their employees or agents.
- **Medicare** is used as shorthand to refer not only to Medicare per se, but also to any federal or state health insurance program, such as Medicaid, Tricare, and others.
- **Medicare Fraud and Abuse Law** is used as shorthand to refer to any federal or state law — like the anti-kickback laws, safe harbor regulations, and Stark laws — intended to protect against overcharging and overutilization and thus to protect the fiscal integrity of the health insurance programs. The **Federal Anti-Kickback Law** is covered under this term.

- **Medical sales** and **medical sales practices** refer to sales, marketing, promotional activities, and certain research and clinical activities within the medical technology industry.
- **Illegal remuneration** and **kickback** are used interchangeably to mean anything of value in the form of a discount, rebate, credit arrangement, free item or service, educational, research, or fellowship grant or support, or cash, used to improperly encourage or influence a business transaction involving Medicare patients or funds. Think *bribe*, *graft*, *payola*.
- **You** refers to Philips Healthcare and other medical technology companies, their agents, dealers, distributors, and employees, *and* to health care providers who are, have been, or could be Philips' customers.

Now you're armed and ready to read on.

Regulating Medicare: Whose Job Is It?

The Department of Health and Human Services (HHS) is the U.S. government's umbrella agency for Medicare and many federal health insurance programs. Congress empowers and funds HHS to administer the Medicare program and to make sure that the monies allocated to the Medicare Trust Fund, which collects and disburses Medicare funds, are utilized responsibly.

HHS is also the U.S. government's principal agency for protecting its citizens' health and providing essential services, such as health care and social services. The Office of Inspector General (OIG) operates under HHS's auspices as the "watchdog" agency to protect the Medicare Trust Fund from fraud, waste, and abuse. The OIG not only investigates suspected violations of the Medicare Fraud and Abuse Laws, but also works with the Department of Justice to prosecute other kinds of legal violations under the *False Claims Act* (see the section "Laws That Protect Medicare" later in this chapter) and to impose penalties on violators of the laws — including exclusion from participation in the Medicare program.

Federal health insurance programs: a primer

The federal government offers health insurance through a variety of major programs, and numerous smaller programs, such as the Public Health Service and the Indian Health Service.

Medicare is a federal program covering health care costs for citizens over the age of 65 and younger people who have been disabled. The program is divided into four parts:

- **Medicare Part A** pays for inpatient care in a hospital or rehab facility, care for patients with end stage renal disease, and for some limited home care services. Part A is funded through a payroll deduction tax on every working, tax-paying American, and from general tax revenues allocated by Congress.
- **Medicare Part B** pays for outpatient care such as durable medical equipment (for example, sleep therapy devices, home oxygen devices), and physicians' services such as doctors' visits, and is an optional program paid for by individuals who pay a monthly premium for the benefit. Congress also allocates funds to Part B from general tax revenues.
- **Medicare Part C** establishes Medicare Advantage *managed-care plans* that give individuals the option of possibly receiving a wider range of benefits than they get under traditional Medicare by enrolling in an HMO or a PPO plan.
- **Medicare Part D** is a limited prescription drug benefit.

Essentially, the *Medicare Trust Fund* is a bank account the federal government uses. The fund is divided into two parts:

- The Federal Hospital Insurance Trust Fund, which services only Medicare Part A
- The Federal Supplementary Medical Trust Fund, which services only Medicare Part B

Medicaid is a joint program between the federal government and the individual state governments and provides health insurance coverage for people with limited incomes and assets. Unlike Medicare, whose benefits are uniform across the country, Medicaid qualification and benefits vary from state to state. At the time of this writing, Medicaid usually covers inpatient and outpatient health care costs, custodial care, and medications.

Tricare is the health insurance program developed solely for the purpose of providing health care services and coverage to military personnel and their families.

Although it sounds like the OIG is just an enforcement agency, the OIG does in fact work with hospitals and medical technology companies to help all parties understand the law and structure business arrangements that meet the legal standards set by the Medicare Fraud and Abuse Laws. Interpreting and applying the Medicare Fraud and Abuse Laws is one of OIG's main functions. Having recognized that the *Federal Anti-Kickback Law* can be confusing and overly restrictive, the OIG publishes opinions advising whether particular business relationships violate the law. They also issue *safe harbor* regulations that protect certain relationships — such as sales that involve discounts or payments to consultants or administrative fees to Group Purchasing Organizations — from liability.

Why Medicare Cares about the Way You Do Business

Medicare and Medicaid spend tax dollars, lots of them, to pay health benefits for roughly 85 to 90 million Americans.

Because Medicare health care services are paid for with public funds, the government is obligated to make sure that every tax dollar is properly spent, and to protect the financial integrity of the Medicare Trust Fund, which is the repository for the money dedicated to paying for the Medicare program. One of the ways the government protects the Medicare Trust Fund is by monitoring business transactions between medical technology companies like Philips and the health care providers who buy its products.

The government is charged with making sure that you're not intentionally (or unintentionally) submitting or causing someone else to submit improper or inaccurate claims to Medicare by doing things such as:

- Overcharging for the cost of a medical device
- Charging for a medical device the patient either didn't receive or didn't need
- Paying or accepting a kickback in exchange for ordering or purchasing a medical device

Health care providers and medical technology companies regularly exchange money or other types of compensation with each other through a variety of different relationships. These relationships may include product sales, physician consulting arrangements, product training programs, research funding, educational grants, and charitable donations. The government is concerned that if not properly regulated, these relationships have the potential to involve kickbacks or the submission of improper claims to Medicare. The following is an example of a relationship that violates the Medicare Fraud and Abuse Laws:

> On a handshake over lunch, John, a sales rep from a major medical technology company, agrees to pay Dr. Smith $1,000 a month for the next two years if Dr. Smith agrees to provide "consulting services" for John's company. John never tells Dr. Smith what type of consulting services he is *supposed* to provide John's company for the $1,000, and Dr. Smith winds up sitting back and collecting the money for doing nothing except continuing to be John's loyal customer.

Kickbacks include any offer or payment of items or services with intrinsic value that are intended to improperly sway someone's decision in the sale or purchase of medical equipment. Wining and dining clients in expensive restaurants, offering clients trips or lucrative "make work" consultant contracts, and donating to charities associated with clients in an attempt to secure or increase their business are all examples of kickbacks and are strictly forbidden.

Laws That Protect Medicare

Medicare Fraud and Abuse Laws represent the U.S. federal and state governments' best efforts to protect the fiscal integrity of the Medicare program from fraudulent and abusive business practices. Medicare Fraud and Abuse Laws include the following laws and regulations:

- **The Health Care Fraud Act,** which makes submitting false or fraudulent information to a health care program a crime.
- **The Federal Civil False Claims Act,** which imposes significant monetary penalties for submitting or causing

someone else to submit false or fraudulent information to Medicare.

- **The Stark Law,** which prohibits a physician from self-referring Medicare and Medicaid patients for certain types of health care items and services.
- **The Federal Anti-Kickback Law,** which prohibits offering or paying or soliciting or accepting kickbacks in exchange for the purchase or sale of items or services that are reimbursable by a federal health care program.
- **The Civil Monetary Penalties Law,** which permits the OIG to assess substantial civil monetary penalties on any person or entity that violates the Federal Anti-Kickback Law, submits, or causes someone else to submit false or fraudulent information to a federal health care program.
- **The Office of Inspector General (OIG) Exclusion Authorities,** which permits the government to exclude individuals and entities from participating as Medicare providers, thus denying them access to Medicare reimbursement programs.

Although all these Medicare Fraud and Abuse Laws are relevant to both health care providers and medical technology companies, this book focuses on how the Federal Anti-Kickback Law affects interactions between health care providers and medical technology companies.

The Importance of Following a Medicare Compliance Program

The Medicare Fraud and Abuse Laws are complicated and sometimes confusing, and no one wants to become the target of an investigation by the OIG just because he or she didn't understand the laws.

Ignorance of the Medicare Fraud and Abuse Laws isn't a defense.

Philips, like most health care providers, offers its employees education and resources under its compliance program, which is geared toward helping you navigate through the

important information and rules you are expected to understand and follow.

Note: A compliance program may consist of classes, written policies and procedures, educational materials, fraud and abuse hotlines, and so on. A compliance program's goal is to teach you how to abide by the Medicare Fraud and Abuse Laws, as well as your own company policies, to protect sales reps, health care providers, and their respective companies from conducting improper or illegal business transactions.

The Philips confidential hotline (the "One Philips Ethics Line") can be reached by calling 800-218-1818 in the U.S. or Canada, 24x7.

Philips has chosen to implement a comprehensive compliance program for the following reasons:

- As a good corporate citizen, Philips wants to do its part to reduce waste, fraud, and abuse in the health care industry.
- Philips believes that compliance with federal and state laws, as well as ethical guidelines, translates into better patient care.
- Philips is committed to keeping its staff educated and successful while operating within the bounds of sound legal and ethical practices.

Becoming familiar with — and making your best effort to use — your company's compliance program is your best defense against the risk of receiving that unwelcome knock on the door from the OIG investigators.

This book is just one of the numerous compliance resources Philips has developed and made available to assist you in staying on the right side of the Federal Anti-Kickback Law.

See Chapter 3 for a more detailed view of how to use the compliance program to lessen the risk of violating the Federal Anti-Kickback Law.

Chapter 2

Working under Medicare's Fraud and Abuse Laws

In This Chapter

- Understanding the basics regarding medical sales under the Federal Anti-Kickback Law
- Realizing that the law has safe harbors
- Knowing the consequences of violating the Federal Anti-Kickback Law
- Getting help in complying with the law

Staying on the right side of the Medicare Fraud and Abuse Laws means first understanding what the laws say. Walking the straight and narrow isn't as easy as it should be because the laws don't always seem rational, they include many exceptions, and they change from time to time.

In this chapter, we explore the most important law governing the business relationship between a medical technology company and a health care provider, namely the *Federal Anti-Kickback Law*. We also provide you with a basic and general understanding of what the Federal Anti-Kickback Law does and doesn't allow you to do when transacting a sale of medical technology.

What the Federal Anti-Kickback Law Says

The Federal Anti-Kickback Law was enacted to curb the corrupting influence that money can have when it comes to health care decisions — including the sale and purchase of

medical technology. Because the federal government generally pays for some part of the medical equipment that health care providers use for Medicare patients, the government wants to be sure that it's getting what it pays for, and at a fair price. The Federal Anti-Kickback Law places restrictions on the relationship between a medical technology company and a health care provider.

In a nutshell, the Federal Anti-Kickback Law prohibits *illegal remuneration to induce a sale,* which means in plain English that the law:

- Prohibits a medical technology company from paying, or merely *offering to pay*, a health care provider to influence that person to buy, lease, order, recommend, or arrange for the purchase, lease, order, or recommendation of any item or service paid for by Medicare
- Prohibits a health care provider from soliciting, receiving, or *merely asking for a payment* in connection with the decision to buy, lease, order, or recommend items or services from medical technology companies

Remuneration or payment in the law's terms isn't limited to cash. Remuneration can mean almost anything of value, paid directly or indirectly, and may include

- Year-end rebates
- Volume discounts
- Paid consulting arrangements
- Free equipment
- Charitable donations
- Research funding
- An offer of gifts and meals
- Educational grants
- Training programs
- Evaluation and demonstration products (loaners)

If this list makes you a little nervous because you see that it includes many business practices common to the health care industry, relax. Your "nervousness" simply means that you're

on the road to understanding just how easy it can be to make a big mistake that can land you in some really hot water.

Even if a hospital merely requests a payment, or *kickback,* in exchange for entering into a deal in which Medicare funds are used, you may violate the Federal Anti-Kickback Law — regardless of whether the payment is ever made. And, if a medical technology company offers someone something of value with the intent of inducing him or her to buy, lease, or order an item or service covered by Medicare, the company may be guilty of a crime even if the person doesn't accept your offer.

Note: In addition to the Federal Anti-Kickback Law, be aware that many states have their own anti-kickback laws that are similar to the federal government's. However, state laws not only cover kickbacks related to Medicare business, but also to businesses covered by any type of health care insurance or program.

Complying with the Federal Anti-Kickback Law is important for *both* medical technology companies and health care providers because a violation of the law can subject both parties to criminal and civil penalties. Whether you are the party offering to pay or the one asking to be paid, you may well have the same legal exposure.

By following a few basic rules of behavior, you can go a long way in avoiding a violation of the Federal Anti-Kickback Law. When engaging in the sale or purchase of medical equipment,

- You cannot *offer* anything of value to "clinch the deal."
- You cannot *ask* for anything of value to "clinch the deal."

That's it. Simple, right? Ah, if only that were so. Alas, nothing is so simple in the health care industry. Okay, so here's where things get complicated and murky.

A *kickback* doesn't have to be in the form of cash. "Anything of value" can be a remarkably small item, such as a *fruit basket* or a *movie pass.* Throughout this book, you come across the following examples — all of which can be considered kickbacks if given or received with the hope of influencing someone's decision or "clinching the deal."

For a sales rep, *kickbacks* can be:

- Taking a health care provider out for an expensive meal
- Offering a client free theater or sporting event tickets
- Sending a health care provider a fruit basket or a bouquet of flowers (seriously!)
- Taking or sending a health care provider on a cruise
- Offering a health care provider discounts, rebates, and credit arrangements (What?! But isn't that a normal business practice?)

For a medical technology company, *kickbacks* can be:

- Entering into a consulting service agreement with a health care provider
- Paying a health care provider to attend a sales presentation
- Giving a charitable contribution to an organization directly or indirectly affiliated with a health care provider
- Providing a health care provider with a research or educational grant

If by now you're saying to yourself, "Omigosh! I took Ms. Smith from Hospital X out to lunch last week to discuss her need to purchase a new MRI for her institution, and now I'm facing one to five in a federal penitentiary," you may be overreacting a bit, but you're on the right track.

The matter of kickbacks is serious, and the federal government doesn't fool around. The government wants any relationship between a medical technology company and a health care provider to benefit patients — rather than being a product or service choice merely because of "remuneration."

The federal government does, however, recognize that common business practices, such as giving a good and loyal customer a discount, are important in all industries, including the medical technology and services industry. Therefore, the government has created some exceptions to the Federal Anti-Kickback Law to allow certain types of incentives and business relationships to continue. These provisions, called *safe harbors,* spell out the conditions and criteria that must

be met in order for a particular incentive or relationship to be protected.

Anti-Kickback Safe Harbors: Exceptions to the Law

In 1987, Congress realized that because the Federal Anti-Kickback Law was so broad that some, legitimate business practices — such as offering a hospital discounted prices when it increases the volume of its order — could result in honest members of the health care industry being in violation of the law. For this reason, both Congress and the U.S. Department of Health and Human Services (HHS) created "safe harbors" for various payment and business practices that, although potentially prohibited by law, would not be prosecuted.

The Office of Inspector General (OIG), under HHS's auspices, is the agency responsible for determining the legal standards of behavior in business relationships between health care providers and medical technology companies. In that vein, the OIG decides what qualifies for safe harbor status and enforces the federal government's fraud and abuse regulations to ensure that the law has not been violated.

To qualify for safe harbor protection, a business transaction or arrangement must meet stringent and very specific requirements. We examine safe harbor protection for specific business incentives in more detail later in the book.

In very general terms, the following *safe harbors* can be used to protect certain relationships between medical technology companies and health care providers:

- **Discounts.** Used to protect the offer and acceptance of various discounts including rebates, volume discounts, loaner equipment, some free goods, and value-added services. See Chapter 4 for more about discounts.
- **Personal services.** Used to protect consulting arrangements between medical technology companies and health care providers. Chapter 5 gives detailed information on how to qualify a consulting agreement for safe harbor protection.

No safe harbor exists for offering or receiving cash or lavish gifts before, during, or after a business negotiation between a health care provider and a medical technology company or its representatives.

Disclosure, or making something known, can set apart a discount that can qualify under a safe harbor from one that can't. More specifically, the government wants the terms of any discount, rebate, or credit between a medical technology company and a health care provider spelled out to the *nth* degree.

For example, in the case of a medical technology company that gives a discount to a health care provider, the company must properly report the discount it has given to the health care provider. The health care provider must in turn properly disclose the discount on any of the cost reports it submits to the government.

Likewise, in a consulting agreement between a medical technology company and a health care provider, the agreement must be in writing and fully describe the terms of the relationship including the services to be provided and the amount of compensation to be paid (see Chapter 5).

Penalties for Violating the Law

Violating the Federal Anti-Kickback Law is a felony and the punishment for doing so can include

- Up to five years in prison.
- Criminal fines up to $25,000.
- Administrative civil monetary penalties up to $50,000. In addition to anti-kickback penalties, the government has assessed millions of dollars in penalties against medical technology companies and health care providers under the government's civil monetary penalty authority.
- Exclusion from participation in federal health care programs. *Exclusion*, for a medical technology company, means that reimbursement for the company's products sold to any health care provider will not be paid by Medicare (or any other federal health care program). For a health care provider, exclusion means that the

health care provider can't receive payment for services to patients covered by Medicare (or any other federal health program).

Obviously, if you're caught on the wrong side of the Federal Anti-Kickback Law, in addition to whatever penalties the government might levy against you, your employer no doubt will want a word or two with you as well.

Ignorance of the Federal Anti-Kickback Law is no excuse. Violating the law has serious and unpleasant consequences.

Being able to prove that you have made every effort to comply with the law goes a long way in convincing the government not to levy the most severe penalties.

Getting Help with Following the Law

As with all things, honesty is your best policy.

In every situation, ask yourself: "Is my deal complying with the law?" Here's why:

- Both the government and your employer have zero tolerance for violating the Federal Anti-Kickback Law.
- The common business practices you use every day that are legal in other industries may not pass muster under the Federal Anti-Kickback Law.

If you don't know on your own whether your deal complies with the law — and chances are you don't have the legal background to answer this question on your own — you need to get some guidance.

Most employers in the health care industry offer help in the form of a *compliance program* regarding the Federal Anti-Kickback Law. Such programs may differ from company to company, but they usually include personnel within the company who can answer any questions you may have about the Federal Anti-Kickback Law relative to your sales practices (see Chapter 3 for more details about compliance programs).

These people may include, among others:

- Your supervisor
- Your company's legal department
- Your company's ethics hotline

Your company also may have written policies and procedures in place that relate to Medicare Fraud and Abuse Laws. Plus, the government provides resources, such as Web sites, to answer your questions. Here are two Web sites to check out:

- The Medicare Learning Network, `www.cms.hhs.gov/mlngeninfo`
- Compliance Guidance from the OIG, `oig.hhs.gov/fraud/fraudalerts.asp`

Chapter 3

The Nuts and Bolts of Compliance Programs

In This Chapter

- Understanding compliance programs in general and the Philips program in particular
- Adhering to ethical guidelines for the medical technology industry
- Following the simple rules of compliance

Although the Medicare Fraud and Abuse Laws can be confusing, compliance itself is simple. At some point, virtually every medical technology company and health care provider will engage in a transaction or enter into a mutual relationship that could trigger a question, issue, or investigation under the Federal Anti-Kickback Law.

This chapter describes a number of resources to help you negotiate the complexities of the Federal Anti-Kickback Law and, hopefully, avoid crossing the line into "kickback territory."

Adopting a Compliance Program

A *compliance program* is a set of internal company controls and procedures designed to minimize the possibility that the company's agents or employees will engage in fraudulent business practices, participate in a kickback scheme, or violate the Medicare Fraud and Abuse Laws in any other way.

The Office of Inspector General (OIG) strongly encourages not only medical technology companies to adopt a compliance program, but also every health care provider. To meet the

OIG's standards, a compliance program should incorporate the following seven key elements:

- A compliance officer or contact person to answer questions regarding the law or company policy
- Written policies and procedures designed to ensure the company is operating in accordance with the law
- Employee training and education of the company's policies and procedures
- Periodic auditing and monitoring of the company's operations
- A hotline or other method for employees to ask questions or report concerns
- A procedure for investigating reports and resolving problems
- Disciplinary standards for employees who violate company policy

Most health care–related companies, like Philips, have already adopted compliance programs since they're designed to keep themselves and their customers out of trouble with the law. If your company doesn't have a compliance program, it's in its best interest to develop one. The OIG provides help and guidance in building compliance programs. You can access the information on the Web at `http://oig.hhs.gov/fraud/complianceguidance.asp`.

Ask your employer to provide you with information about your company's compliance program and become familiar with its specific elements.

Working within the Philips Compliance Program

The Philips Healthcare compliance program is a multi-pronged plan designed to assist employees and customers with following both the letter and the spirit of the Medicare Fraud and Abuse Laws, including the Federal Anti-Kickback Law. The Philips compliance program was developed using the OIG's guidelines and includes

- Compliance officers and personnel.
- Written policies and procedures regarding appropriate marketing and sales practices and personal services arrangements with health care providers. The program is accessible to Philips employees on the company's intranet at the Healthcare Legal Department site.
- The adoption of the "Philips Healthcare Code of Conduct on Interactions with United States Healthcare Providers."
- Personnel, including your supervisor and the Philips legal department, devoted to assuring that you operate within the bounds of the law.
- Educational tools, such as Web-based training, live in-service training, and this *For Dummies* book.
- The One Philips Ethics Line, a hotline established for employees to answer questions about fraud and abuse, and to report suspected violations of legal or ethical behavior. The hotline can be accessed by phone at 800-218-1818.
- Disciplinary programs.

Philips employees are expected to conduct themselves and their interactions with health care providers in accordance with the Philips compliance program. Making the effort to understand and follow the compliance program will keep everyone — Philips' employees and health care provider customers — out of the government hot seat.

Adhering to Ethical Guidelines

Because the Federal Anti-Kickback Law is so broad in scope, a thin line exists between the legal exchange of an incentive or other compensation and the illegal payment of a kickback. The Medicare Fraud and Abuse Laws contain many gray areas, and no individual is expected or, frankly, encouraged to go it alone in deciding whether a particular practice or relationship is permissible under the law.

Always use the resources of your company's compliance program to help you understand how the Federal Anti-Kickback Law works — that's what the program's there for!

To help medical technology companies and health care providers understand how the Federal Anti-Kickback Law applies to common interactions and relationships between them, the Medical Imaging & Technology Alliance (MITA) and the Advanced Medical Technology Association (AdvaMed) developed their own "Codes of Ethics on Interactions with Health Care Professionals."

MITA's and AdvaMed's codes provide easy-to-follow rules of behavior designed to ensure the ethical and legal integrity of relationships between medical technology companies and health care providers. The codes can be accessed by going to `www.medicalimaging.org` and `www.AdvaMed.org`. If you are a Philips employee, Philips has combined these codes into its own Code of Conduct available on the Healthcare Legal Department intranet site.

These codes provide ethical guidelines for a number of common sales practices and business relationships between medical technology companies and health care providers. Topics covered by the codes include

- Customer training and education
- Third-party educational conferences
- Educational and research grants
- Sales and promotional meetings
- Consultant agreements
- Meals, entertainment, and recreation
- Personal and corporate gift giving
- Charitable donations to institutions
- Billing and other reimbursement information provided to health care providers
- Evaluation and demonstration products (loaners)

The American Medical Association (AMA) has also developed a set of policies governing gifts to physicians from the health care industry. The AMA guidelines served as a starting point for MITA's and AdvaMed's codes of ethics. AMA's guidelines are written specifically for physicians but can apply to any health care worker. You can access AMA's policies on ethics on its Web site, `www.ama-assn.org`. In addition, many hospitals have established their own similar policies.

Professional associations and trade groups

In the health care industry, professional associations and trade groups exist to advocate and lobby Congress and government agencies on their members' behalf, provide continuing education opportunities and forums, and offer guidance to their members on matters of professional conduct.

- Advanced Medical Technology Association (AdvaMed) is a trade association that represents manufacturers of medical devices, diagnostic products, and medical information systems.
- Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA) is a trade association that represents manufacturers of electrical products, including diagnostic imaging and therapy systems.
- American Medical Association (AMA) is a professional association of physicians dedicated to helping their members help patients by uniting physicians nationwide to work on the most important professional and public health issues.

Finally, there are certain state-specific restrictions and requirements with respect to interactions with health care providers. Specifically, California, Massachusetts, and Vermont have all enacted laws that limit the provision of certain items of value or activities that a medical technology company may give to an individual health care provider licensed in those states. If the state-specific guidelines are more restrictive than the MITA, AdvaMed or AMA policies, then the state-specific guidelines must be followed.

Working ethically, according to the "codes" and state laws

Neither medical technology companies nor health care providers are *required* to follow the MITA and AdvaMed codes of ethics. Philips decided to create its Code of Conduct to help its employees understand ethical business practices between Philips and its health care provider customers, which keeps everyone within the Medicare Fraud and Abuse Laws. The

Philips Code of Conduct also incorporates state-specific restrictions and requirements, where applicable. We go into great detail on this subject later in the book, but here's a brief synopsis of the key rules that apply to business transactions between medical technology companies and health care providers:

- Meals, refreshments, receptions, travel expenses, or lodging received by a health care provider and paid for by a medical technology company should
  - Be provided solely to support a bona fide educational product training, sales, promotional or business meeting when necessary.
  - Be occasional and modest in value.
  - Not be provided to a health care provider's family members or guests.
  - For meals/refreshments provided to MA-licensed health care providers, the meal must take place in the provider's office or in the hospital setting. All meals must be attended by a company representative and/or involve an informational presentation by a company representative.
  - Meals/refreshments cannot be provided to VT-licensed health care providers at no charge. However, companies may provide meals if the VT provider pays for the fair market value of the meals.
- Meetings between health care providers and medical technology companies, whether for educational, informational, training, or business purposes, should be held in a suitable location conducive to exchanging information. A Broadway theater, for example, does not qualify as an acceptable location for a meeting.
- A medical technology company giving gifts to a health care provider's staff or employees is acceptable only when:
  - The gift's value does not exceed $100.
  - The gift benefits patients or is educational in purpose. For example: a starter kit or educational brochures.

  - The gift isn't for the customer's personal, nonprofessional use. For example, golf bags, a bottle of wine, or flowers are all unacceptable gifts from a medical technology company to a health care provider.

- A medical technology company paying for entertainment, such as theater or sporting event tickets, spa treatments, golf outings, and the like, is never an acceptable practice and is to be avoided at all times.
- A medical technology company making a charitable donation is only acceptable when:
  - The charity is a bona fide not-for-profit organization and is separate from and not under the control of a health care provider engaged in a business relationship with the donor medical technology company.
  - The donation is used primarily to benefit patients or the public and not for operating expenses or equipment purchased by the health care provider.
  - The donation has been approved in accordance with the company's policies and procedures.
- A medical technology company awarding research funding to a health care provider is acceptable only when:
  - The health care provider submits a legitimate, written research proposal to the company.
  - The health care provider's research proposal is reviewed and approved by a research review committee that operates independently of the company's sales and marketing department.
- A medical technology company making an educational grant is acceptable only when:
  - The recipient is a training institution or independent conference sponsor — never an individual health care provider.
  - The recipient training institution offers continuing education credits for the funded program.
  - The training institution or conference sponsor is free to select the faculty, content, and attendees for the conference.

  - The grant isn't used to pay for health care providers' attendance other than faculty or health care providers in training, such as residents and fellows.
  - The grant is approved in accordance with the company's policies and procedures, independent of the company's sales and marketing department.

- A medical technology company paying a health care provider for performing consulting or similar services is acceptable only when:
  - A written contract exists between the company and the provider specifying the services to be performed and payments to be made.
  - The written contract between the parties was approved by the medical technology company's legal department, or at minimum, conforms to the legal department's established contract requirements.
  - The health care provider's services must legitimately be needed by the medical technology company.
  - Neither the selection of the consultant nor his compensation is linked to the volume or value of business generated by the consultant.
  - The consultant health care provider is compensated at the fair market value for services rendered.
  - Selection of consultant must be based on qualifications and expertise to meet a defined need.
  - Selection should not be controlled or unduly influenced by sales personnel.
  - Exhibit fees at conferences are subject to these standards.
- A medical technology company discounting its products is acceptable only when:
  - The price quotation and invoice to the customer disclose the value of any discount, or if applicable, the existence of a rebate program.
  - The medical technology company informs the customer in writing that it should retain any information pertaining to the discount and must make that information available to the government if requested to produce it.

- The contract of sale is written on forms that include the medical technology company's standard terms and conditions, or on another form approved by the company's legal department.
- Any subsequent rebate payment cross references the original invoice.

Every business practice has nuances and potential pitfalls. Checking with your supervisor before completing a transaction is the best way to stay out of trouble.

Reporting a violation of the Medicare Fraud and Abuse Laws

You may find a time in your career when you observe or are asked to participate in some activity or conduct that you feel may be fraudulent, illegal, or unethical, or that gives the appearance of impropriety. Should this occur, bring the issue immediately and directly to your supervisor or the Philips legal department. Other avenues available to Philips employees include the One Philips Ethics Line by phone at 800-218-1818.

Don't keep questionable conduct to yourself. Always report any suspected violation of the Federal Anti-Kickback Law to your supervisor or the One Philips Ethics Line.

Failure to report a breach of legal or ethical standards, even if you decline participation in the activity, can lead to monetary fines, penalties, and jail time. You could also get fired.

Chapter 4

Protecting Discounts and Rebates

In This Chapter

- Understanding the discount safe harbor
- Paying rebates to health care providers
- Offering tiered pricing
- Providing loaner equipment
- Giving rebates to group purchasing organizations

It's just plain common sense and good business practice to provide people with incentives to buy a product, right? Well, even though that statement is true, in the health care industry, discounts, rebates, and other incentives that promote products and induce purchases by health care providers can easily run afoul of the law — which is why Congress added a discount "safe harbor" to the Federal Anti-Kickback Law (refer to Chapter 2) to protect certain legitimate sales practices.

Simply stated, the key to operating within the safe harbor protection is *disclosure.* In other words, if a manufacturer or seller accurately *discloses* a price reduction to a buyer — a hospital, for example — and if the hospital then *discloses* or passes along the price reduction to Medicare, you have a discount or rebate that complies with the law. Because Medicare naturally wants to benefit from any price reduction extended to its insured by a medical technology company, your job — as a sales rep — is to remind the customer that it must keep Medicare informed of any discounts/rebates. After all, Medicare cannot benefit from a sales incentive it knows nothing about.

The Federal Anti-Kickback Law identifies the kinds of sales incentives that can be given to health care providers without violating the law, as long as the incentives fall within the protections of a safe harbor. In other words, health care providers *can* get a break on the products they buy, but any "break" must abide by strict guidelines.

In this chapter, we show you how a medical technology company can give health care providers sales incentives (such as discounts, rebates, tiered pricing, loaner equipment) and give rebates to Group Purchasing Organizations (GPOs), and still comply with the Federal Anti-Kickback Law.

Sales Incentives = Discounts

One term the government uses to describe a sales incentive is "discount." A *discount* is any reduction in the price of a product or service. Discounts can take many forms, including

- **A direct reduction in price taken at the time of sale.** For example, the list price of a product is $100, but you give the customer a 20 percent discount so that the customer pays only $80 at the time of purchase.
- **A rebate in which part of the purchase price is returned after payment.** For example, the customer pays $100 for a product, but two weeks later receives a check for $20, actually resulting in a 20 percent discount to the customer.
- **The offer of tiered pricing.** For example, the customer pays $100 each for the first 10 products purchased, $90 each for the next 10 products, and $80 each for all products purchased after that.
- **The use of demo and evaluation (loaner) equipment at no charge or at a much reduced charge.** For example, before purchasing a piece of equipment costing $500,000, you give the customer the opportunity to test the equipment at no charge for a period of one month.
- **A fee paid to a GPO.** For example, a medical technology company agrees to pay a GPO a 3 percent fee on any purchases of the medical technology company's products that are made by the health care provider members of the GPO.

Giving the Buyer a Break Upfront: Discounts

Discounts can be protected if they meet a safe harbor "standard of disclosure" under the Federal Anti-Kickback Law and its regulations. The discount safe harbor presents detailed requirements on how to disclose and report discounts. Examples of these requirements include the following:

- Under the discount safe harbor, discounts given at the time of purchase are allowed so long as the medical technology company gives the health care provider an invoice, statement, or other document reporting the discount and notifying the health care provider of its obligation to report the discount to Medicare (see Figure 4-1).
- The discount must be based on purchases of the same product or service within a single fiscal year.
- The health care provider must either claim the benefit of the discount in the fiscal year in which it was earned or the following year in a Medicare cost report, if applicable.
- The health care provider must retain records reflecting the discount information and must be able to furnish this documentation to the government upon request.
- Providing either a discount on a product or a product free of charge to induce a health care provider to buy a different product from the medical technology company may be protected if Medicare pays for both the discounted product and the product that is purchased at full price under the same reimbursement method.

Records and Disclosure. Health care providers are reminded that if the purchase of goods or services hereunder includes a discount, such as a price reduction or a loan of goods at reduced cost, they must fully and accurately report such discount on cost reports or other applicable claims for payment submitted under any Federal health care program, including but not limited to Medicare and Medicaid, as required by Federal law (see 42 U.S.C. 1320a–7b(b)(3) and 42 CFR 1001.952[h]).

Figure 4-1: Sample notice language for invoices, agreements, and so on.

The same reimbursement method could be based on a DRG (Diagnosis Related Group) or an APC (Ambulatory Payment Classification), or other Medicare payment methods, including the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule under Medicare Part B and the Physicians' Fee Schedule under Medicare Part B.

- **DRGs (Diagnosis Related Groups)** are clusters, or "groups," of related diagnoses established by Medicare for hospitalized patients. Patients are classified into DRGs based on their underlying diagnoses and the procedures performed while they are hospitalized. Medicare uses DRGs as the basis for a fixed payment to the hospital for patients' care. DRG payments typically cover hospital operating costs, with capital costs made in a separate payment to the hospital. The DRG payment is the same each time regardless of how long the patient actually stays in the hospital or how many resources are used in his or her care. Hospitals were previously paid based on the cost of each service or item used in a patient's care and still report their costs or charges to Medicare, making accurate disclosure important.
- **APC (Ambulatory Payment Classification).** An APC, like a DRG, is a payment system for Medicare patients, except that it is used for the outpatient setting. Most products and supplies used in the outpatient setting are paid under the fixed APC payment amount, but in some cases, new products can be paid on a temporary basis using the method based on their costs.
- **Medicare Part B.** Under the DMEPOS Fee Schedule, Medicare Part B applies to Medicare payments for durable medical equipment, such as continuous positive airway pressure (CPAP) and home oxygen equipment, prosthetics and orthotics, parental and enteral nutrition, and surgical dressings. The

> Physicians' Fee Schedule applies to payments made to physicians and other health care providers who provide services to Medicare beneficiaries. Such services may include diagnostic tests such as sleep studies or polysommography.

Say that a surgical tape manufacturer gives a hospital a free box of bandages for every two rolls of tape purchased. Because Medicare pays for bandages and surgical tape as part of the fixed, lump sum payment it makes to the hospital under the DRG or APC systems, this discount could be protected by the discount safe harbor — as long as the net prices of both the bandages and tape are disclosed to the hospital on the invoice or quote so that they can be reported to Medicare in the hospital's cost reports.

Offering the hospital free bandages if they agree to buy an MRI machine, however, may not qualify as a *discount* that can be protected under the safe harbor. Bandages are single-use, disposable items that are paid for through the DRGs for operating costs, whereas major medical equipment such as MRI machines is a capital expenditure that is reimbursed under a different reimbursement method.

Say that you are running a "buy ten, get two free" promotion on purchases of CPAPs. As long as the invoice for the twelve CPAPs reflects the total net price of the products — either that the products were purchased at the regular price and two were free, or that twelve products were purchased at a discounted price — then the discount could be protected under the safe harbor.

A "prebate" or "signing bonus" paid in order to obtain a contract is not a discount and would not be covered by the discount safe harbor. This type of payment — made before any purchase, and therefore not attributable to any identified purchase of products — is prohibited.

DRGs: One price fits all!

Medicare established DRGs (Diagnosis Related Groups) as a means of reining in ever-increasing costs for inpatient hospital care. Rather than paying hospitals for the costs of each product and service provided, such as blood tests, x-rays, implants, and medications — payment for the entire inpatient stay is now based on a prospectively fixed payment amount determined from the patient's diagnoses and the procedures performed. Hospitals report their charges/costs and Medicare updates DRG weights and payments every year, so accurate reporting of net charges or costs keeps the DRG weights and payments up to date.

Giving Buyers (Some of) Their Money Back: Rebates

A *rebate* is money returned to a health care provider after a product or service has been purchased rather than being discounted from the price at the time of purchase. For example, a medical technology company would be offering a rebate if it agreed that within four weeks of purchasing the company's cardiac imaging software package, the health care provider would receive a check for $500. Similar to the rules described in the preceding section on discounts at the time of purchase, rebates are fine as long as:

- The terms of the rebate are fixed at the time of sale.
- At the time of sale, the medical technology company gives the health care provider an invoice, statement, or other document explaining the terms of the rebate and notifying the health care provider of its obligation to report the rebate to Medicare.
- The health care provider retains the rebate information and, if requested, provides information to Medicare regarding the rebate.
- The medical technology company informs the health care provider of the exact amount of the rebate, once it is earned, and identifies the products to which the rebate applies.

- The rebate is earned based on purchases of that same product or service within a single fiscal year.
- The health care provider must claim the benefit of the rebate in the fiscal year in which it was earned or the following year.
- If the health care provider submits cost reports to Medicare, the health care provider must fully and accurately report the rebate in the applicable Medicare cost report.
- The health care provider must, upon request, provide the government with documentation regarding the rebate.

A key rebate regulatory requirement is as follows: When the value of a rebate isn't known at the time of sale, the medical technology company first discloses the existence of the rebate program. Then, when the amount of the rebate becomes known, the medical technology company provides the health care provider with documentation of the calculation of the rebate, identifying the specific goods purchased to which the rebate applies.

What this means simply is that when purchases of different products trigger a rebate, the medical technology company needs to allocate the rebate across the products purchased and make it clear what the net value of each of the products is.

Tiered Pricing: One Price (Doesn't) Fit All

Tiered or *volume* pricing is a price reduction offered at the time of sale that increases incrementally as the number of products purchased incrementally increases. Simply stated — the more you buy, the less you pay. For example, if a hospital buys between 1 and 10 boxes of surgical screws, its cost is $20 per box. If the hospital buys more than 10 boxes, it pays $15 per box. ***Note:*** This type of discount would need to meet the discount safe harbor requirements as described earlier in the "Giving the Buyer a Break Upfront: Discounts" section of this chapter.

Loaner Equipment: Try It, You'll Like It!

You wouldn't buy a car without test-driving it first. Well, many health care providers feel the same about buying high-priced medical equipment. They want to test-drive it before they buy. For example, before buying a $275,000 gamma camera, a hospital may ask a medical technology company if it can use the equipment at no charge for a few weeks so that its radiologists can try the camera to see whether they like the way it handles and the images it produces. This testing period during which a medical technology company permits a health care provider to use a piece of medical equipment at no charge or at a significantly reduced charge — referred to as an "evaluation or demonstration product," "loan," or "consignment" — may be permissible under the Federal Anti-Kickback Law if the arrangement meets certain requirements. The health care provider using the loaner equipment must enter into a written agreement with the medical technology company that has been pre-approved by its legal department.

The evaluation or loan agreement must comply with the following applicable standards:

- A written agreement with the hospital or doctor specifying the term of the loan (one month, two months, three months) must exist. The written agreement must contain the discount disclosure statement (refer to Figure 4-1).
- The term is only as long as is necessary to give the health care provider a meaningful trial period (and not just free use for an indefinite period of time).
- If any supplies are being sold along with the loaned equipment, the medical technology company issues an invoice for the supplies bearing the discount disclosure statement.
- Depending on the nature of the loan, the loan agreement contains a notice that the health care provider may not be able to bill Medicare or other payers for loaner equipment or procedures performed using loaner equipment, and the provider should check the payer's rules first.

- The medical technology company explains, as necessary, any purchase and pricing options.
- The agreement calls for products to be recovered promptly at the end of the loaner period unless the health care provider opts to purchase the equipment, in which case you must convert the loan to a sales arrangement.
- Health care providers are also interested in trying out newly released consumable products (for example, single use or disposable products), such as masks for sleep therapy devices, before committing to buy larger quantities of them. You may provide limited quantities of sample consumable products to health care providers to help them evaluate the use and functionality of the products and what to order. The samples should be used in patient care, and you should inform the health care providers that they may not charge Medicare or any third party payor for the patient's use of the samples.
- Vermont law allows companies to provide reasonable quantities of evaluation products to VT health care providers, but evaluation periods cannot exceed 90 days in length.

Group Purchasing Organizations (GPOs): Strength in Numbers

In addition to the discount safe harbor, the Federal Anti-Kickback Law provides a safe harbor for fees paid by a medical technology company to a GPO, or Group Purchasing Organization. A GPO is an organization that pools the purchasing power of health care providers giving a medical technology company the potential for higher volume purchases which, in return, enables the medical technology company to offer GPO members reduced prices on its products.

Regulatory requirements governing the GPO and its contract with medical technology companies do exist. The health care provider members of the GPO cannot be owned by the GPO nor can they be subsidiaries of the same parent company as the GPO. Novation and Premier are examples of GPOs whose members are primarily hospitals.

Any fees paid by a medical technology company to a GPO are permissible under the Federal Anti-Kickback Law so long as:

- The GPO maintains a written agreement with each of its health care provider members.
- The agreement specifies the amount each medical technology company or other vendor will pay in fees to the GPO based on purchases of that company's products or services by the GPO members. The agreement can simply state that the GPO fee is 3 percent or less of purchases, or if the fee is greater than 3 percent of the purchases, the agreement needs to state the specific amount of the fee.
- The GPO discloses in writing to its members at least annually (and to the government upon request) the amount of fees the GPO received from each medical technology company or other vendor.
- The GPO cannot own any of its members and cannot be owned by a company that owns any of its members.

You can violate the law by merely *offering* or *asking for* a discount or rebate that does not comply with the safe harbor! Even if the buyer doesn't accept the discount or rebate, you can wind up in a messy situation just by *proposing* it. Both buyer and seller can be penalized for this violation of the law, so be sure to offer only those sales incentives — including discounts and rebates — that meet the standards described in this chapter.

Disclose discounts, rebates, and credits in accordance with the law.

Chapter 5

Paying Experts for Product Development, Medical Presentations, and Other Services

In This Chapter

- Drafting the consulting agreement
- Finding the right consultant
- Holding meetings with your consultant

Many health care providers serve as consultants to companies like Philips, providing valuable research, participating in advisory boards, making presentations at company-sponsored education and training, and assisting in product development training. But be careful, because paying a health care provider consultant (referred to in this chapter as a "consultant"), if not done correctly, may be viewed by the government as a *kickback* (an illegal monetary incentive to induce the purchase of a product or service) to that health care provider. Kickbacks — beyond any reasonable doubt — will get Philips, its salespeople, and the health care provider in a lot of hot water. The good news is that the Federal Anti-Kickback Law (refer to Chapter 2) creates *safe harbors* that allow Philips to pay consultants, so long as a written agreement that meets certain standards exists.

In this chapter, we tell you about the federal rules that protect conforming consulting arrangements between Philips and heath care providers. We also mention state law requirements, when they exist.

The Consulting Agreement

To make sure that a consulting arrangement complies with the law, and won't get you or Philips in trouble, your best offense is a good defense. A *good defense* is a sound agreement that conforms to the requirements established by the government regarding consultants. These requirements are contained in a specific safe harbor (refer to Chapter 2) under the Anti-Kickback Law covering "personal services contracts." To ensure that your consulting arrangement is protected, the arrangement must comply with the following guidelines:

- The arrangement must be in writing and signed by both a company representative and the consultant.
- The agreement must be for a term of at least one year.
- The agreement must describe all of the services that the consultant will provide during the term covered by the contract.
- If the services will be provided on a part-time or periodic basis, the agreement must detail the schedule for when the consultant will perform the services required by the contract, and the precise length and exact charge for the services.
- The total amount the consultant will be paid over the term of the contract must be fixed in advance.
- The amount paid to the consultant must be consistent with fair market value in an arm's length transaction. This means that you pay the consultant who happens to be a customer the same amount you'd pay a consultant you wanted to hire who wasn't in a position to purchase your products.
- The amount paid to the consultant cannot be linked to the volume or the value of referrals, orders, or purchases the consultant makes of the company's product. Neither

can the amount paid be linked to purchases by the consultant's hospital that may be influenced or induced in any way by the consultant.

- The agreement cannot require the consultant to do anything that would violate federal or state laws. For example, the agreement could not require that the consultant pay $200 to each physician that listens to the consultant make a presentation on the company's products (since that would violate the Federal Anti-Kickback Law).

If a contract doesn't meet every one of the requirements in the preceding list, the government will look at the contract much more carefully. That's why you need to be sure that the services the consultant provides are necessary and that the payment isn't more than you would pay for those same services to someone who isn't a customer.

Consulting agreements with health care providers are fine so long as they comply with the law. As a Philips employee, do not enter into a consulting agreement with a health care provider without first seeking advice from the Philips legal department. The legal department has drafted a checklist and agreements that meet the safe harbor standards and must be used in any consulting arrangement between Philips and a health care provider.

The safe harbor for personal services applies to many different arrangements including, for example, research, physician product evaluation, clinical trial agreements, and customer participation in the medical advisory board of a medical technology company — such as Philips.

Note: It's a good idea to have the consultant document the actual services rendered, before paying for them.

Hiring a Consultant

You can hire only as many consultants as you need to accomplish a legitimate business purpose.

For example, if five physicians can provide the necessary feedback on a new product, don't hire ten just to get the other five familiar with the product.

Legitimate business purpose?

Here's an example of what constitutes a legit business purpose for hiring a consultant and what doesn't.

Will fly: A leading radiologist is hired to review and compare the convenience and usefulness of features of an MRI machine and to compare these new features to those of competitive products.

Won't fly: A leading radiologist — who happens to be buying a new MRI machine — is hired to review the features of a product the medical technology company is discontinuing. This review isn't legit because the company is getting rid of the product so a "review of the features" is totally useless. It's just an excuse to pay the radiologist a kickback.

Base your selection of a consultant only on the consultant's qualifications and ability/expertise to address the legitimate business purpose outlined in the agreement. In other words, don't hire a pediatrician to evaluate the features of an MRI machine.

Do not, in any way, link your selection of a consultant to the volume or value of business generated by the consultant or the consultant's affiliates, business partners, and so on. If you hire the consultant for research services, you must have a written *research agreement* (see Chapter 7 for information about research grants and more).

You may place a consultant under a retainer with services to be provided on an as-needed basis as long as all of the requirements are met (see the section on "The Consulting Agreement," earlier in the chapter).

If the project for which you hire a consultant is cancelled early (for whatever reason), review the agreement to determine what you owe the consultant for any services the consultant actually provided prior to termination or cancellation of the project.

Meetings with the Consultant

After you ensure that your consulting contract with a health care provider complies with the personal services safe harbor, you need to make sure that you're familiar with the

ethical guidelines that dictate how you should handle meetings with consultants.

- A legitimate business purpose exists to justify the meeting.
- The location of the meeting is appropriate and conducive to the exchange of information. That is, the meeting is being held in a clinical, educational, or conference type of setting — *not* in a nightclub, spa, resort, or at a sporting event.
- You cannot pay or offer to pay for the consultant's guest or spouse.
- Meals, lodging, and travel offered in connection with the meeting are modest in cost. In addition, these meals, lodging, and travel are "subordinate in time and focus to the business part or your meeting." That is, they do not distract participants from the purpose of the meeting (meaning, again, they are not held in a nightclub).

  Note: Meals provided to MA-licensed health care providers during a consulting meeting must take place in the provider's office or in a hospital setting (including a restaurant located in a hospital), and must be attended by a company representative.

  Companies may provide meals and refreshments to VT-licensed consultants only as part of the compensation for the fair market value of services provided.

  You may not give a consultant theater tickets, tickets to sporting events, golf outings, fishing trips, or other forms of entertainment. Taking a consultant to a modest lunch to discuss product development, on the other hand, is allowed (although there are more stringent requirements for MA- and VT-licensed providers). For more on business courtesies such as travel and meals, see Chapter 6.
- The meeting has to have a genuine business purpose, and "tone." A meeting held at a sailing regatta, for example, would not have a "business" tone and would be considered an "improper" inducement. As a general rule, if something *feels* improper, it probably *is* improper. Another test in interactions with health care providers that is sometimes reasonable is: how would I feel if my activities were reported on the front page of my home town newspaper?

The same rules that apply to meeting with a consultant also apply to meetings the consultant attends with others on behalf of a medical technology company.

Chapter 6

Business Courtesies and Product Training Events

In This Chapter

- Giving gifts as a sales incentive
- Paying for travel, meals, and lodging
- Taking clients out for a meal

Establishing and building professional relationships, including sales relations between medical technology companies and health care providers, can include the exchange of certain business courtesies such as meals, travel, lodging, and receptions. In today's world, these business courtesies must be modest and related to the exchange of business information. When considering business courtesies as a means of establishing good relations — and sales — think *"modest." Modest* gifts. *Modest* dinners. *Modest* travel, *modest* accommodations. . . .

In this chapter, we discuss how business courtesies can be provided as a means of developing relationships between medical technology companies and health care providers while still adhering to the legal and ethical standards governing medical sales practices.

Giving Gifts

With very limited exceptions, medical technology companies should not *give* and health care providers should not *receive* gifts. The exchange of gifts could violate the Federal

Anti-Kickback Law because it could sway (or *appear* to sway) a health care provider's professional judgment or purchasing decisions.

Taking a health care provider out to an expensive dinner may be tempting, but doing so could lead to trouble for both of you, even if you don't submit the bill to your company for reimbursement.

Just as medical technology companies have the AdvaMed and MITA Codes of Ethics, physicians are subject to ethical guidelines on gifts developed by the American Medical Association (AMA). The general theme of these guidelines is that gifts must primarily benefit patients, have an educational function, and be *modest*.

- Acceptable gifts must have a value in the general range of less than $100.
- The only types of gifts that are appropriate are those with a genuine educational purpose or benefit to patients and that are modest and given occasionally.
- Gifts made with any strings attached are not acceptable.
- Gifts tied to a physician's prescribing practices are not acceptable.

The AdvaMed and MITA codes echo the AMA's limitations on gift giving. For example, a medical textbook or an anatomic model costing $100 or less is an acceptable gift for a physician, because each one serves a genuine medical-education purpose, and benefits patients. Keep in mind, however, that repeated gifts of $100 textbooks and anatomic models given to the same doctor could violate the guidelines, as could multiple gifts of the same $100 textbook to multiple members of a hospital-materials management group or members of a clinical department. Also keep in mind that gifts given to a health care provider's staff, such as the office manager, materials manager, or receptionist, are treated as if they are given directly to the health care provider. Some health care providers may also have rules about gifts. Follow their rules if they are stricter.

Giving medical textbooks is an excellent way of establishing and maintaining good client relations while also serving the greater good of helping doctors take better care of their patients. Giving a laptop computer to a cooperative purchasing manager, on the other hand, breaks every ethical rule on gift giving and could get you in trouble very quickly. Here are some additional considerations:

- You cannot escape these rules by making a personal gift.
- Do not give gifts, no matter how small, to government-owned entities or their personnel.
- If the customer has a gift policy with a different limit than the values shown here, the lower or more restrictive of the two is applicable.

Gifts of small fruit baskets, flowers, cookies, gift cards, and wine are prohibited. Food and alcoholic beverages as gifts are always prohibited under all circumstances.

Holidays, such as Christmas or New Year's Day, are not considered exceptions. You may not give gifts on these occasions either.

These gift-giving rules apply whether the recipient is a consultant to your company or a health care provider who is a company customer.

Offering Meals — Dining with the Docs

The term *business courtesy* is used to describe providing a health care provider with meals, including refreshments and receptions. Other traditional forms of business courtesy, such as entertainment, most gifts, and recreational activities, are prohibited by the MITA and AdvaMed Codes of Ethics, so we don't need to go into them here.

Meals can only be offered by a medical technology company if they are part of a business or sales meeting, presentation, training, or educational program. A good meal to cement a business relationship doesn't count! The meals must be

- Modest
- Provided at the health care provider's office or at the training or demonstration center, or if that is not convenient, at a nearby restaurant appropriate for a business discussion
- Attended by a company representative — no dropping off lunch at the physician's office for her hungry staff

Meals can only be offered to participants in the meeting or training, not to spouses, children, and other guests of the health care provider who just happen to be in the neighborhood. The best way to prevent this from happening is to state in the invitation that Philips and AdvaMed guidelines prohibit hospitality being offered to guests. What should you do if the spouse or guest just shows up? You can take the health care provider aside and politely ask him or her to pay for the guest/spouse dinner; or if you are reimbursing the provider for expenses, you can deduct the cost of the dinner from reimbursed expenses.

Meals provided to MA-licensed providers cannot take place at a restaurant, unless it is a restaurant inside a hospital. Meals cannot be provided to VT-licensed providers unless they pay fair market value for the meals.

So, with the exceptions for MA- and VT-licensed providers, a sales rep can bring in pizza for a product demonstration to a physician's office, but not for the receptionist or other office staff not participating in the demonstration. The sales rep can't take a good customer out to lunch to show her appreciation for his business, but she can if she's discussing the features of her company's latest product and it's not feasible to meet in the customer's office.

Modest means moderate in price for the locality and not overwhelming or distracting. Philips has strict guidelines on how to determine whether a meal is modest, and you should check the "Philips Healthcare Code of Conduct for Interactions with U.S. Health Care Providers."

Hosting Product Training Events

Medical technology companies are required by law to ensure that the medical technologies they sell are safe and effective. They do so by making medical product training available to the health care providers who purchase and use the technologies.

Because these types of training programs often last more than one day and take place at specific, central locations, health care providers are often required to travel out of town. *Business courtesies,* such as plane tickets, meals, and lodging (discussed in the preceding section), may be given in connection with these product training sessions — which can include travel to company facilities to take a look at nonportable equipment (see the section, "Visiting the Office and/or Company Facilities" later in the chapter).

When medical technology companies like Philips sponsor such events, the programs must meet several compliance requirements before extending associated business courtesies to the physician or health-care-provider attendee. These requirements state that

- Programs and events must be conducted in a clinical, educational, or conference setting such as a company facility, a business hotel, or a conference center.
- Programs requiring "hands on" training in medical procedures must be held at training facilities, medical institutions, laboratories, or other appropriate venues, including company facilities.
- The training staff must have proper qualifications, education, experience, and expertise to conduct the training.

If the planned training program meets these qualifications, you may provide health-care-provider attendees with business courtesies in the form of modest plane tickets, lodging, and meals in connection with the program.

Any payments for travel, lodging, and other expenses associated with product training programs for MA-licensed providers must be described in a written purchase agreement for the product. Similarly, the commitment to provide such payments for VT-licensed providers — and the amounts or

categories of such payment — must be described in a written agreement between the VT-licensed provider and the medical technology company.

Tying In Business Courtesies at Training Events

All meals and business courtesies, receptions and meals conducted in conjunction with a medical products training program or conference, must be modest in value, open to all attendees, and "subordinate in time and focus to the educational training purpose of the meeting."

For example, a lunch at the training facility between the morning and afternoon program would be a reasonable form of hospitality. On the other hand, holding a three-day medical-product training session at a well-known golf resort with an award-winning wine list, at which attendees may spend more time on the links than in the lecture sessions, would be inappropriate.

You are not permitted to pay the tab for a health care provider's guest or any other person who lacks a legitimate professional interest in the information being shared at the training session. If a doctor wants to bring a spouse, the doctor has to foot the bill unless the spouse is also a health care provider legitimately attending the session. You can, however, pay for a nurse or an interpreter whose presence is required to assist the health care provider while attending the program.

The meals are to be modest in value and subordinate in time and focus to the training and professional purposes of the program.

Let Us Not Entertain You

Entertainment may not be used as a sales incentive. "Entertainment" in this context means leisure, recreational, or similar activities such as a sporting event, theater performance, or fishing outing. You cannot, for example, take a potential client to the Super Bowl to "discuss medical products."

Entertainment as a sales incentive is not permitted regardless of whether the cost is paid out of the salesperson's pocket or with company funds.

A good sales rep follows the motto "when in doubt, find out." When unsure about the legality of an activity being considered to induce a client to purchase a product, contact the Philips legal department or a compliance officer.

Doing Lunch: Sales Meetings with Health Care Providers

Sales reps often meet with health care providers to pitch their products and negotiate sales terms and contracts. Where possible, these meetings should be conducted at the place of the health care provider's business. Is it permissible to take the doctor who is considering the purchase of an MRI machine to lunch? Yes, if the meal is

- Modest in value
- "Subordinate in time and focus to the business discussions" about the product and the doctor's needs — that it won't distract the doctor from discussing the clinical, technological, and medical features of the product at hand
- Conducive to the exchange of ideas about the product
- Provided when both a health care provider and a Philips representative are present

For MA-licensed providers, lunch cannot take place in a restaurant (unless it is a hospital restaurant). No lunch for VT-licensed providers, unless they pay their own way.

"Subordinate in time and focus to the business discussions" means that discussing the product, its features, the physician's need for the product, and so on is the main focus of the lunch, not discussing your favorite pro basketball team while enjoying a gourmet meal. So, bring 'em to lunch in the hospital coffee shop or cafeteria, or buy a group of doctors a platter of sandwiches, potato salad, and a pot of coffee for a lunch-time product presentation.

Even though a particular activity may seem *conducive to the exchange of ideas* about products and services, the location may be "improper." For example, golf outings, vineyard tours, and Broadway theater productions are not appropriate venues in which to discuss medical products.

Visiting the Office and/or Company Facilities

If the health care provider needs a tour of the Philips offices or plant for a demonstration of nonportable equipment, you may provide reasonable travel costs. But remember: no guests or spouses, unless they have a legitimate professional reason for attending.

As is the case with other allowable forms of travel, such as that for medical conferences or training sessions, the "modest" rule also applies when bringing doctors and health care providers to company facilities. Travel costs, including plane tickets, meals, and lodging, must be modest.

A written agreement may be required for visits by MA- and VT-licensed health care providers. Be sure to check with the legal department before arranging for such visits.

Chapter 7

Dealing with Requests for Grants and Donations

In This Chapter

- Funding medical and scientific research
- Giving educational grants
- Making charitable donations

Support for independent medical research and education is widely encouraged by the health care industry and also by the federal government. This kind of scientific and philanthropic activity is an honorable tradition and a necessary part of technological innovation.

Any attempt to use the promise of research funds, educational grants, or charitable donations to influence a health care provider's decision-making, however, isn't honorable or legal. If medical technology companies want to be philanthropic to advance medical science, they must do so in a manner that's consistent with the Federal Anti-Kickback Law (refer to Chapter 2). The ethical guidelines issued by MITA and AdvaMed (which Philips has voluntarily adopted) are designed to help medical technology companies assess how they can make philanthropic grants and donations in a way that complies with the law.

You can find out more about the MITA and AdvaMed's Codes of Ethics in Chapter 3 and by navigating to "Code of Ethics" from the Home pages of their respective Web sites at `www.medicalimaging.org` and `www.advamed.org`. Philips' Code of Conduct is based on the AdvaMed and MITA Codes and can be found on the Philips Healthcare Legal Department intranet site.

In this chapter, we discuss the ethical guidelines that medical technology companies and health care providers need to consider when making or accepting research grants, educational grants, or charitable donations.

Funding Research

Health care providers commonly ask sales reps to fund their medical research projects, which are primarily funded through *research grants* and *research and development agreements.*

- A *research grant* is a donation that's used for general academic research, which will be published but won't benefit the company that makes the donation. The company that makes the grant typically doesn't expect the research to lead to specific improvements in the manufacturing of its own medical devices or to new uses of its existing devices, but rather to generally advance science and clinical knowledge in, for example, disease states of general interest to the grantor. The ethical guidelines recommend that medical device manufacturers refrain from giving research grants to health care providers.
- A *research and development agreement* provides funding for the limited purpose of attaining specific research goals, objectives, and milestones, and generating information that is then used to develop and improve products of the medical technology company that made the funding available. In other words, a health care provider holds a consulting agreement for the provider to conduct research that hopefully will advance the medical technology company's products or their use. Any compensation paid to the health care provider — who functions as a consultant — is based on reasonable costs of the project. Refer to Chapter 5 for additional information on the requirements for consulting agreements with health care providers.

Funding a health care provider's research project is certainly not illegal, but such funding may be questioned by the government if you don't take care to ensure that no improper conditions are attached to the money. For example, you buy my

products and I'll give you research money. In order to reduce the risk that research funding may be mistaken as something else (specifically, a kickback), research funding by a medical technology company must be structured to satisfy the standards of the *personal services safe harbor* to the Federal Anti-Kickback Law and its ethical guidelines.

To comply with the Federal Anti-Kickback Law, the Agreement must

- Explain the nature of the research services that will be provided to the medical technology company over the course of the agreement.
- Set forth the term of the contract, which must be at least one year.
- Divulge the total amount of compensation that will be paid to the health care provider over the course of the agreement. The compensation
  - Must be set at a fair market value for the services to be provided.
  - May not be linked to the volume or value of products the health-care-provider consultant buys or the amount of Medicare business the health care provider generates for the medical technology company.
- Only involve the provision of services that are reasonably necessary to accomplish a commercially reasonable business purpose (such as conducting research on patient outcomes in connection with a new product in order to determine long-term effectiveness).

The Agreement must not require the health care provider to engage in any activities that violate any federal or state law.

The ethical guidelines similarly recommend that

- Any research a health care provider wants to fund or that a medical technology company agrees to fund must be *legitimate* (conducted in such a way and on a subject that would be regarded as valid by the medical community as a whole) with well-defined milestones and goals clearly described in a written agreement.

- Any awarding of research funds must be handled by someone who is *not* part of the medical technology company's sales department. Sales reps can accept requests for research funding from health care providers as long as you refer those requests to an independent department for review through an established application process.
- Research funding should not be based on or in any way tied to past, present, or future purchases of products or services by the health care provider. A researcher can be given funding to buy a medical technology company's products if the products need to be used as part of the research project.

As far as research funding goes, your role as sales rep is limited to that of messenger, giving health care providers information about the company's research funding program and passing a research funding application on to the appropriate department for review. If you, as a sales rep, need more information in this area, please contact your legal department.

Giving Educational Grants

According to ethical guidelines, medical technology companies can make educational grants if the grants are given to educational, scientific, or policymaking conferences that promote scientific knowledge, medical advancement, or the delivery of effective health care. Conferences that fit the bill are typically sponsored by third-party national, regional, or specialty organizations, or accredited continuing medical education providers including medical schools and universities.

We do not support educational conferences, sponsored by an individual or entities that are medical technology companies or health care providers — unless the health care provider is properly accredited to sponsor continuing medical education and meets the accreditation rules for such events.

Who gets the grant money?

Educational grants made by a medical technology manufacturer should go

- Directly to the conference sponsor to help defray the general costs of the conference.
- Directly to a conference sponsor for *reasonable* honoraria, travel, lodging, and meals for health care providers who are faculty members participating in the educational conference.
- To the training institution or conference sponsor for the purpose of helping doctors-in-training and other health care or medical students to attend. The grant money can be used to cover the costs of travel, lodging, and meals for those selected to attend the conference. However, grant money to attend a conference is not to be given directly to a health care professional in training or any other health care provider.

Educational grants should not be given or received directly by any health care provider to pay for that health care provider's costs associated with attending an educational conference.

Here are some examples of activities that would not be appropriate for a grant of any kind, research or educational:

- Travel, lodging, time, or other costs of health care professionals or office staff attending educational conferences
- Underwriting the operating costs of physician practices or other direct purchases of our products, including but not limited to the costs of:
  - Patient education materials developed and distributed by physician practices to their patients
  - Social events for staff (for example, holiday parties, staff dinners, and so on)
  - Medical or office equipment

What conditions must a conference provider meet?

In order for a medical technology company to give an educational grant to a conference provider, the conference provider must meet the following conditions:

- The conference must be primarily dedicated to promoting objective scientific and educational activities and discourse.
- If the purpose of the educational grant is to sponsor the attendance of a resident, fellow, or other health care provider in training at an educational conference, the training institution or conference provider selects the recipient — not the medical technology company.
- The grant money must be used to support only genuine educational activities and associated meals or receptions, but not such "entertainment-related" activities as physician karaoke night.
- The conference provider must select program content, faculty, educational methods, and materials — not the medical technology company. A medical technology company may, however, suggest potential faculty members that the conference sponsor is free to accept or reject.

Can I pay for exhibit space at an educational conference?

Medical technology companies can purchase advertisements and lease booth space for company displays at educational conferences if they have a legitimate marketing need for them and they pay a reasonable rate. The fees must be reasonable, particularly if the sponsor is related to a health care provider.

Supporting a conference: Rules for conference sponsors

Professional organizations, such as medical schools and academic health centers, sponsoring conferences that receive support from medical technology companies are encouraged to abide by the "Standards for Commercial Support" adopted by the Accreditation Council for Continuing Medical Education (ACCME). You can read more about these standards by navigating to "ACCME Standards For Commercial Support" under "Popular Downloads" at the ACCME Web site, `www.accme.org/`.

Making Charitable Donations

Medical technology companies can make donations for certain charitable purposes that directly benefit patients or the public — such as providing funds for the care of patients who would not otherwise get care, patient education, and sponsoring an event from which the proceeds go to such a charitable purpose. Philips can make donations only to charitable organizations independent from a health care provider.

Although many hospitals are charitable organizations, hospitals are also customers, so you as a Philips sales rep are not to make donations to them. However, hospitals frequently have foundations with independent directors, who select and provide funding for hospital projects. Donations to these independent foundations for the purposes discussed are okay if approved by the Donations Committee in accordance with established procedures, but donations that will be used for capital improvements to the hospital or its operating budget are not. You can find the link to the Donations Committee on the Legal Department Web site.

Examples of sponsored events to which a medical technology company can donate money include fund raising events, *if* the proceeds from these events will benefit a charitable organization. Remember, however, that the charitable organization must be independent from a health care provider — particularly if that health care provider has a business relationship with the medical technology company.

In rare instances, Philips may make personal donations to an individual engaged in a genuine charitable mission for support of that mission. If, for example, a medical technology company wants to provide medical devices to a doctor who is volunteering in a disaster-relief effort, the donations would be okay even though the volunteers are not working for a charitable organization.

Philips has established an approval process for reviewing all requests for donations submitted by charitable organizations.

Medical technology companies and their employees should never make a donation if even one purpose violates the following ethical guidelines, which state that a donation:

- *Must* be charitable in nature, such as providing support for indigent care and patient health-education activities, and be paid to a bona fide charity independent of a health care provider.
- *Must not* be made as an inducement to purchase, lease, recommend, or use the medical technology company's products or services.
- *Must not* be linked to past, present, or future purchases, leases, or referrals of the medical technology company's products.

A medical technology company is responsible for ensuring that any donations it makes are to charitable, not-for-profit 501(c) (3) organizations that are independent of the health care providers who buy the company's products. These companies should also ensure that the purpose of the donation is a legitimate, charitable one. To find out more about tax-exempt, charitable organizations and the rules and regulations governing them, visit the Internal Revenue Service Web site at `www.irs.gov/charities/charitable/index.html`.

Philips sales reps *cannot* commit to making any research or educational grants or charitable donations to health care providers.

Chapter 8

Ten Very Smart Sales Practices

In This Chapter

- Conducting business in the bounds of the Medicare Fraud and Abuse Laws

Every smart and knowledgeable sales rep knows that it pays to adhere to legitimate sales practices in selling medical device products. The Medicare Fraud and Abuse Laws can be complicated so here are ten simple tips designed to help you operate in compliance with the laws.

Read this book. It's packed with useful information, giving you the do's and don'ts of interacting with health care providers. It's user friendly and, heck, even has a cartoon.

Share this book with customers. Smart sales reps will take this book on sales calls and even give it to customers and other health care providers to help them understand why the sales rep can't offer certain sales incentives (such as a free golf bag) or engage in certain activities (like taking a physician to a football game). So, the next time a client asks "Can't Philips throw in a trip to Bermuda if I buy that MRI machine from you?" the answer is "Sorry, no can do. But here's a complimentary copy of *Philips' Guide to Preventing Medicare Fraud and Abuse For Dummies* that explains why we're both better off without a trip to Bermuda."

Get to know the Federal Anti-Kickback Law and its safe harbors. Get familiar with the Federal Anti-Kickback Law and the safe harbor regulations (refer to Chapter 2). After you digest everything you can about this, discuss your questions with a member of the Philips compliance or legal departments.

Follow Philips policies and procedures. In striving to operate in compliance with the laws and rules governing medical device sales, Philips developed its own set of sales policies and procedures. Let these company-approved policies and procedures guide your dealings with customers and other health care providers. In an effort to assure the highest level of compliance with the law, Philips has set standards for interactions between its sales reps and customers. As a sales rep, be sure to familiarize yourself with these policies and procedures. You can find a link to the Philips Healthcare Code of Conduct for Interactions with U.S. Health Care Providers on the Philips Healthcare Legal Department Web site.

Use only company-approved agreements. When entering into agreements with health care providers, whether it be a sales agreement, consulting agreement, or other arrangement, use only forms created or approved by Philips' legal or compliance departments. The language of Philips' forms has been tailored by the legal department to ensure that your business is transacted without running afoul of the law.

Let the Philips Donation Policy guide the selection of charitable donations. Health care providers who ask you for a grant or donation must understand that sales reps are not authorized to make such a decision. Instead, you can give health care providers the appropriate Web site. As a sales rep, you cannot agree to fund such a request without formal approval under the Philips Healthcare Donation Policy. You can find the link to the Donations Committee in the Philips Healthcare Legal Department Web site.

Make "modest" your motto. When offering meals or other hospitality to health care providers, the K.I.S.S. rule applies: Keep It Simple, Sales rep. Okaaay, how's this instead: If the food is of such a high caliber that the customer comments on it, you've probably exceeded the bounds of modesty. A quick sandwich and a soft drink are fine. Filet mignon washed down by a lively Cabernet isn't. Be sure to use your good, solid judgment, and to always err on the less expensive side. Remember, food and beverage must be secondary to the main purpose of your meeting. Don't forget the gift rules in the new Philips Code of Conduct for Interactions with Health Care Providers in the USA. Gifts to health care providers are being increasingly restricted by drug and medical device codes of ethics, state laws, and hospital and institutional rules.

Entertain family, friends, and neighbors — not health care providers. When you want to see that new Broadway revival of *Oklahoma!,* take your spouse, not the radiologist from North General Hospital. And those nine holes at that four-star golf resort? Same scenario. An appropriate guest is a neighbor, not the head of purchasing at the VA hospital. Get the picture?

Send flowers, wine, and food baskets — not! Gifts such as these are unacceptable. If you get the urge to send flowers, think spouse — not hospital purchasing department.

When in doubt, find out. Ask questions. In fact, contact a supervisor or your legal department with any questions or concerns you have about handling a particular situation. Philips wants its sales reps to thrive in the complex world of medical sales and encourages you to use all of its resources. In addition, Philips provides its employees a toll-free, 24-hour hotline (800-218-1818 for the U.S. and Canada, 24x7) to which Philips employees can report concerns.

Chapter 9

Ten Really Great Compliance Resources

In This Chapter

- Taking a look at Philips compliance resources and more

You've heard the expression that "a little bit of knowledge is a dangerous thing." That's why Philips has compiled this list of resources to help you gather lots of knowledge about the legal and regulatory world in which you operate.

This book. *Philips' Guide to Preventing Medicare Fraud and Abuse For Dummies,* 2nd Edition, is an invaluable compliance resource. Read it, use it, and keep it close by. Share the wealth of information with your colleagues, customers, and suppliers.

Your supervisor. Your supervisor should be trained to help you adhere to legal sales and purchasing practices. So, go to your supervisor with your questions about compliance. Even if your supervisor can't answer your inquiry, he or she should know who you can contact to get your answer.

Philips online compliance training course. Philips offers a variety of online training courses, including one on avoiding Medicare fraud. All Philips sales and service personnel should take the course at least once every two years. The courses are extremely informative, and you can take them at home at your convenience. If you are a Philips employee and have not been invited to take the course (and you think you should), send an e-mail to `legal.questionsaboutethics@philips.com` with the Subject line "Please sign me up" or call the legal department. You will receive an invitation by e-mail.

Philips written policies and procedures. Philips' employees are expected to be familiar with the policies and procedures

applicable to their jobs and to stay current with any policy changes. In particular, Philips has a Code of Conduct that incorporates the AdvaMed and MITA Codes of Ethics.

Philips Compliance Hotline. Philips' employees should call the hotline to report ethics complaints or violations. The number in the U.S. and Canada is 800-218-1818 and is available 24x7. Direct questions concerning compliance with ethical rules to the compliance officer or the legal department.

AdvaMed Code of Ethics on interactions with health care professionals. Philips is a member of several trade organizations including the Advanced Medical Technology Association (AdvaMed). The AdvaMed Code of Ethics addresses business interactions between you and your customers. No one expects you to memorize the AdvaMed code, especially since you can read the code in its entirety by navigating to "Code of Ethics" from the Home page of the AdvaMed Web site at `www.advamed.org`.

The MITA Code of Ethics on interactions with health care professionals. The Medical Imaging & Technology Alliance, a division of the National Electrical Manufacturers Association (NEMA), is a trade association for medical imaging equipment firms, including diagnostic imaging therapy systems. MITA also has a Code of Ethics that addresses business interactions between medical technology companies and customers. For a closer look at MITA's code, go to "Code of Ethics" from their Home page at `www.medicalimaging.org`.

The AMA Policy Opinion E-8.061: Gifts to Physicians from Industry. The American Medical Association (AMA) provides guidance to physicians on ethical issues related to accepting gifts from drug or medical device manufacturers. Get to know the standards for doctors to help you and them stay on the right side of the law. You can access AMA policies online on its Web site, `www.ama-assn.org`.

Published OIG reports of anti-kickback violators. Want some chilling, real-life examples of Medicare fraud and abuse? The Office of Inspector General (OIG) provides actual accounts of fraudulent activity and the enforcement action it has taken on its Web site, `http://oig.hhs.gov/fraud.asp`.

Help from the Centers for Medicare & Medicaid Services (CMS). CMS is a terrific place to gather all sorts of general information on the Medicare program and its rules. The site provides links to many other valuable compliance resources, so visit it early and often at `www.cms.hhs.gov/mlnGenInfo/`.

Note the ways to stay in compliance — 24x7!

Keep on the right side of the Medicare

Fraud and Abuse Laws

Ever wonder about unwittingly violating the Medicare Fraud and Abuse Laws or other ethical codes simply because you don't even know the basics? Take heart! This book attempts to ease your concerns by explaining the basics of the Federal Anti-Kickback Law, how the law applies to everyday interactions between medical device companies and health care providers, and the resources available to help you stay on the compliance path. By developing a basic understanding of the law and remembering a few key do's and don'ts, you can operate in compliance with the law and help your company or hospital stay on top of Medicare fraud and abuse requirements.

Discover how to:

- *Avoid costly penalties by complying with the law*
- *Engage in "squeaky clean" medical technology sales transactions*
- *Recognize when medical device companies and health care providers need to work together to comply*
- *Seek assistance from your company's compliance and legal experts to ensure compliance*

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